Law Reform Commission of Canada
Commission de réforme du droit du Canada

PROTECTION OF LIFE

biomedical experimentation involving human subjects

Working Paper 61

Canada

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BIOMEDICAL EXPERIMENTATION INVOLVING HUMAN SUBJECTS

1989

Notice

This Working Paper presents the views of the Commission at this time. The Commission's final views will be presented in its Report to the Minister of Justice and Parliament, when the Commission has taken into account comments received in the meantime from the public.

The Commission would be grateful, therefore, if all comments could be sent in writing to:

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Table of Contents

Introduction

Progress in the pharmacological, medical and biological sciences, of necessity, involves experimentation on human subjects. The effectiveness of medications, investigative procedures and treatments must at some point be tested on human beings. Although tests conducted on laboratory animals, especially those most closely related to humans, are indispensable, they are not sufficient to identify with certainty the possible effects and consequences of certain treatments. We have only to recall the tragic history of thalidomide, which was tested successfully on monkeys.

Pharmacology was, for a long time, an empirical science. Although the effects of opium, digitalis and quinine have been known for several centuries, how these substances act did not really become known until recently. Only when science could analyze and measure how these substances acted could it move beyond mere observation to make scientific predictions. This development was furthered by such other factors as the growth since the nineteenth century of the chemical industry, the synthesis of increasingly complex substances, improvements in scientific testing, and the development of highly precise statistical techniques.

Medicine and biology underwent similar development. Only comparatively recently in human history has medicine turned from observation to experimentation. Medical knowledge was long based exclusively on the accumulated observations of various pathologies. Although clinical observation remains important today, medical science now also attempts to recreate a situation experimentally, thereby allowing direct observation, monitored and repeated at will.

The history of medicine shows that there has always been a need for experimentation on human beings. For example,[1] in 1721 the surgeon Charles Maitland inoculated Newgate prisoners, who had been condemned to death, with smallpox. They were then promised unconditional release by the King in return for their participation in the experiment. Again, in 1796, Edward Jenner, who was also studying smallpox, inoculated an eight-year-old boy with pus from a diseased cow. About 1830, in Germany, a series of experiments on human subjects was carried out in an attempt to discover a cure for cholera. Closer to our own time, in 1905 Fletcher used inmates of a mental institution for his experiments on beriberi.

Scientists have also been known to use themselves as experimental subjects. Hunter and Reed inoculated themselves with gonorrhoea and yellow fever respectively, and in 1892 Marc Von Pettenhofer deliberately injected himself with the cholera bacillus. In 1910 Pierre Curie wore a radioactive bandage for several days merely to

1. N. Howard-Jones, "Expérimentation humaine et déontologie : une interprétation historique" (1982) 4 *Cahiers de bioéthique 39*; and M.H. Pappworth, *Human Guinea Pigs: Experimentation on Man* (London: Routledge & Kegan, 1967).

demonstrate that radium could cause burns. Lastly, in 1939, Werner Forsmann introduced a catheter into the right ventricle of his own heart to show the effectiveness of a procedure he was trying to develop.

Nowadays, most of these experiments would be ethically and legally unacceptable. Nevertheless, there have also been clear cases of abuse in recent times. The experiments conducted by Nazi doctors on prisoners of war and civilians during the Second World War are too well known to review here. More recently, an article by Beecher in the *New England Journal of Medicine* in 1966 described a score of contemporary experiments on humans which in his view were morally unacceptable.[2] Some U.S. examples which received extensive media coverage include: the deliberate infection of mentally retarded children at Willowbrook Hospital in Texas with a hepatitis virus; the infection of three hundred black men in Tuskegee, Alabama, with syphilis. They were used as a control group and left without treatment;[3] the injection of cancerous cells into elderly men at the Jewish Chronic Diseases Hospital, New York, without their consent; and ketone-metabolism experiments on the heads of foetuses kept alive by perfusion.

No country in the world, including Canada, can claim to be free of such abuses. For example, it was recently learned that in Montreal during the 1950s and 1960s, LSD and other hallucinogenic drugs were administered, at the instigation of the CIA, to psychiatric patients at the Allan Memorial Institute in Montreal for the purpose of investigating brain-washing techniques. Subsequently civil suits were launched and a report was submitted to the Department of Justice in 1986.[4]

Does this mean, however, that because of this potential for abuse, all experimentation on humans should be banned? We feel it would be naïve to take such a view. A ban on all human experimentation would condemn society to the scientific *status quo*. The pursuit of scientific knowledge remains a valid objective. Moreover, every time a new product, after completion of all other testing, is administered to someone, there is, in a broad sense, "experimentation." Most countries, including our own, that strictly regulate the marketing of medications and drugs also require testing on human beings before allowing commercial distribution. An unconditional ban would in fact be impossible to monitor and would probably result in increased clandestine testing, which is even more dangerous.

Once the need for human experimentation is acknowledged, the problem is to clearly define a policy that reflects this consensus and can provide a basis for regulation. The difficulty lies in the search for effective controls and the development of legal and ethical standards that reflect what our society considers morally acceptable.

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2. H.K. Beecher, "Ethics and Clinical Research" (1966) 274 *New Eng. J. of Med.* 1354.

3. U.S. Department of Health, Education and Welfare, *Final Report of the Tuskegee Syphilis Study, Ad Hoc Advisory Panel* (Washington: Public Health Services, 1973).

4. *Opinion of George Cooper, Q.C., Regarding Canadian Government Funding of the Allan Memorial Institute in the 1950's and 1960's* (Ottawa: Supply and Services Canada, 1986).

The Belmont Report of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research in the United States, identifies three basic principles that should act as guidelines for all regulation concerning experimentation.[5]

The first is *respect for the dignity and autonomy of human beings*. The Law Reform Commission of Canada has already considered this principle in other documents in the Protection of Life series.[6] We will not review those findings here. Suffice it to say that the legally recognized principle of the dignity of the human being prohibits degrading or humiliating experiments or tests. By virtue of their personal autonomy, legally competent persons are absolutely free to make decisions concerning their own bodies, and in particular to agree to participate in an experiment. Respect for this autonomy presupposes free, informed consent and protective measures for those whose decision-making ability is affected by age or mental capacity. There can be no question of permitting experimentation on human beings without their consent or that of a person whom the law has empowered to give consent.

Second, is the ethical principle of *beneficence*. It is not enough to require the free and informed consent of the subject of an experiment; this simply shows respect for that person's autonomy. It is also necessary to protect the subject from danger or harm which might result from participation in an experiment. This principle can be expressed in two ways. First, an experiment is to be condemned if it is clear that it may cause the subject a degree of harm which is unacceptable in the circumstances. This relates directly to an important concept of balance between expected benefits and risks incurred. We will return to this below. Second, the investigator must take all necessary measures to reduce any harmful effects that an experiment might have on a subject.

The third principle is that of *justice*, which requires that the risks and benefits of experimentation be fairly distributed among various social groups. This principle is particularly important, for example, in testing medications and in selecting control groups or subjects for single- or double-blind experiments. The Commission fully supports these three principles and considers them basic to the reforms it proposes.

In an analysis of experimentation on human subjects, it is of crucial importance to use precise scientific terminology. Accordingly, it seems essential to define the terms that we will be using in this paper.

In the broadest sense, experimentation is the attempt to increase human knowledge through the systematic use of experiments. It is thus a technique, a process that makes it possible to verify certain facts by creating conditions favourable for their realization.

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5. National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, *The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research* (Bethesda, Md.: the Commission, 1979) at 4-10.

6. See Law Reform Commission of Canada [hereinafter LRC], *Sanctity of Life or Quality of Life*, Study Paper by Edward W.Keyserlingk (Ottawa: Supply and Services, 1979); *Consent to Medical Care*, Study Paper by Margaret A. Somerville (Ottawa: Supply and Services, 1979); *Crimes Against the Foetus*, Working Paper 58 (Ottawa: LRC, 1989).

While the aims of experimentation may vary, in medical matters they fall into two main classes: research, and treatment or therapy.[7]

Research is a scientific activity directed to the advancement and systematization of knowledge. Its objective is an overall increase in the sum of knowledge on a given subject. It seeks to benefit society as a whole, in the sense that it is society that will benefit from developments in scientific knowledge. One example is current research on the immune suppressant cyclosporin, which has substantially reduced the risk of rejection of transplanted organs. In another area, space research has led to the development of new medical and surgical equipment.

A rigorous, well-conceived methodology is essential in research. It should be set out in a protocol indicating the various steps to follow in testing the working hypothesis. The role of the researcher or scientist is to adhere strictly to this protocol and to remain neutral with respect to the results obtained. In other words, the researcher's loyalty is to the experiment itself. Therefore, where the goal of an experiment involving human subjects is to prove or disprove a hypothesis, the main concern is not the immediate welfare of the subject but the scientific success of the project.

Treatment or therapy is the opposite of research in the following three ways. First, its aim is to cure an individual's illness or disease and it can only be measured in terms of the patient's interests. Second, it is administered on the basis of individual needs not according to a predetermined protocol. Finally, and perhaps most important, the therapist's role is quite different from the researcher's; the objective being not to increase scientific knowledge but to cure the patient or relieve suffering. The therapist's loyalty is to the patient and a fiduciary relationship is implicitly established as an integral part of the process. For example, a physician would be betraying his therapeutic role were he to place the making of scientific observations above the interests of his patient.

Thus, biomedical experimentation is conducted on human subjects either for scientific research (for example, to check the side effects of a particular medication), or for therapeutic reasons (for example, administering a new medication to terminally-ill patients in hopes of relieving their suffering or achieving a cure), in which case we could call it therapeutic experimentation or — more correctly, in our opinion — innovative therapy.

It is not always easy to draw a clear line between "research" and "treatment." A treatment may lead to a major scientific discovery; conversely, scientific research may have a therapeutic effect on the human subject of an experiment. Finally, research may be undertaken solely to evaluate a therapy. In this case, it will be described as what may seem to be a contradiction in terms: *experimental treatment*. By this we mean a treatment in the true sense of the word, an act performed for the direct and immediate

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7. With respect to medical treatment in the strict sense, the Commission has already made specific proposals for legislative reform. See LRC, *Recodifying Criminal Law — Revised and Enlarged Edition*, Report 31 (Ottawa: LRC, 1987) recommendations 6(6) and 7(3).

benefit of the recipient, but not yet fully proved in scientific terms. This uncertainty about results encourages law and ethics to prescribe additional precautions concerning administration, particularly regarding the disclosure of risks. This concept is sometimes called *innovative therapy* or *new therapy*. Most medical procedures could doubtless be considered experimental therapies when they are first introduced. Thus, kidney transplants were an experimental therapy twenty years ago, but are clearly no longer experimental today.

Scientific research is sometimes divided into pure research and therapeutic research; the latter term has almost become a part of everyday language. *Therapeutic research* is research that it is hoped will yield certain therapeutic benefits for the subject. However, for the purposes of this paper, we should point out that this term can be misleading. It is true that "research" and "therapy" are sometimes aspects of a single procedure, as when the goal of the procedure is the discovery of a therapy, or when the experiment may have a beneficial effect on the subject. For obvious reasons, however, these terms may not be associated in this way in legal contexts. As we will see, the rules governing research and treatment are not the same. For example, the conditions determining whether consent is valid vary according to whether the experimentation is part of a research program or is connected with the administration of a therapy. The same is true regarding the limits of the obligation to disclose the risks involved. In this perspective, to describe an act as *therapeutic research* is inaccurate and dangerous. It is inaccurate because the word "therapeutic" is then understood in a broad, derivative sense i.e., the research may lead to treatment, but its *primary goal* is the advancement of knowledge, not the cure or relief of the experimental subject. Dangerous because the investigator's primary role is as a researcher and not as a therapist. Using the two words together may give a false impression of the real situation and lead the subject to consent to an experiment in the mistaken belief that it will be of immediate personal benefit. Thus, it is possible that the more stringent requirements respecting consent and disclosure of risks may not be complied with.

The ambiguity of this expression has often been pointed out. The Belmont Commission[8] and the Medical Research Council of Canada,[9] among others, have banished it from their vocabulary and in our opinion we should do likewise. In itself, the expression can be used to describe a real situation but in legal contexts it is highly ambiguous. In order to be precise and to avoid confusion, we shall therefore use the term *experimentation* in only one sense, that of non-therapeutic biomedical experimentation.

The three aims of this paper are as follows: the first is to provide a clear survey of the current state of the law on this issue. It will become apparent that on the provincial, national and international levels there is a large body of law dealing with experimentation. The underlying philosophy and the policies that express it are not

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8. *Supra*, note 5 at 2-4.

9. Medical Research Council of Canada, *Guidelines on Research Involving Human Subjects* (Ottawa: Supply and Services Canada, 1987) at 9.

necessarily the same in each instance. This makes it necessary to choose among various prospects for the future.

Second, we will attempt to review the problems raised by experimentation and take a closer look at aspects that, although perhaps less known, are every bit as important — for example, experimentation on foetuses, children and prisoners.

Finally, it is clear that the field of biomedical experimentation is currently in a state of rapid development and change, as attested by the recent revision of the Medical Research Council's acceptable standards in this area.[10] We will attempt to set out an approach to the issue, in particular with regard to whether the current state of the law is satisfactory or whether it calls for legislative or some other type of reform.

10. *Ibid.*

CHAPTER ONE

The Current State of the Law

Biomedical experimentation on human subjects raises many complex legal problems that transcend, so to speak, traditional legal categories. For example, infringement of the rules subjects the researcher not only to criminal sanctions (prosecution for assault, for example) but also civil sanctions (damages for harm caused), administrative sanctions (withdrawal of research funds by the funding organization) or disciplinary sanctions (suspension from the researcher's professional association).

Such rules reflect fundamental principles embodied in national and international law by such instruments as legislation and codes of ethics. It is in this very broad context, then, that our analysis should be considered: we will begin with international law, move on to Canadian federal and provincial law, and end with a brief comparison with the law of certain foreign countries.

I. International Law

There are a number of international legal instruments regulating experimentation on human subjects. Chronologically, the Nuremberg Code[11] led the way in 1947. At the end of World War II, the world was shocked and horrified to learn of the experiments conducted by Nazi doctors, who were brought before an international war crimes tribunal at Nuremberg. Their trial resulted in the document known as the Nuremberg Code, which sets out ten conditions for the legality of experimentation on human subjects. These conditions are as follows:

> (1) The voluntary consent of the human subject is absolutely essential.
>
> This means that the person involved should have legal capacity to give consent; should be so situated as to be able to exercise free power of choice, without the intervention of any element of force, fraud, deceit, duress, over-reaching, or other ulterior form of constraint or coercion; and should have sufficient knowledge and comprehension of the elements of the subject matter involved as to enable him to make an understanding and enlightened decision. This latter element requires that before the acceptance of an affirmative decision by the experimental subject there should be made known to him the nature, duration, and purpose of the experiment; the method and means by which it is to be conducted; all

11. The text of the Nuremberg Code is printed in *Trials of War Criminals Before the Nuremberg Military Tribunals Under Control Council Law* No. 10, vol. II (Washington: U.S. Government Printing Office, 1949) at 181-82.

inconveniences and hazards reasonably to be expected; and the effects upon his health or person which may possibly come from his participation in the experiment.

The duty and responsibility for ascertaining the quality of the consent rests upon each individual who initiates, directs or engages in the experiment. It is a personal duty and responsibility which may not be delegated to another with impunity.

(2) The experiment should be such as to yield fruitful results for the good of society, unprocurable by other methods or means of study, and not random and unnecessary in nature.

(3) The experiment should be so designed and based on the results of animal experimentation and a knowledge of the natural history of the disease or other problem under study that the anticipated results will justify the performance of the experiment.

(4) The experiment should be so conducted as to avoid all unnecessary physical and mental suffering and injury.

(5) No experiment should be conducted where there is an *a priori* reason to believe that death or disabling injury will occur; except, perhaps, in those experiments where the experimental physicians also serve as subjects.

(6) The degree of risk to be taken should never exceed that determined by the humanitarian importance of the problem to be solved by the experiment.

(7) Proper preparations should be made and adequate facilities provided to protect the experimental subject against even remote possibilities of injury, disability, or death.

(8) The experiment should be conducted only by scientifically qualified persons. The highest degree of skill and care should be required through all stages of the experiment of those who conduct or engage in the experiment.

(9) During the course of the experiment the human subject should be at liberty to bring the experiment to an end if he has reached the physical or mental state where continuation of the experiment seems to him to be impossible.

(10) During the course of the experiment the scientist in charge must be prepared to terminate the experiment at any stage, if he has probably (*sic*) cause to believe, in the exercise of the good faith, superior skill and careful judgement required of him that a continuation of the experiment is likely to result in injury, disability or death to the experimental subject.

These provisions prescribe a set of criteria aimed at protecting the integrity of the person. Generally accepted by the medical community of the time, these criteria were used to judge the conduct of Nazi doctors. The document recognizes, at least implicitly, the legitimacy and legality of experimentation on human subjects, provided certain basic conditions are met. It was later criticized, mainly for two reasons. First, it did not distinguish between different types of experimentation, giving the impression that they must all be acceptable. Second, because section 1 made the subject's legal capacity a requirement, it seemed to ban all experimentation on persons without such capacity, such as children or the mentally ill, and to exclude consent by a legal representative in such cases.

The Geneva Declaration,[12] drawn up in 1948 by the World Medical Association and amended in 1968, does not deal specifically with experimentation but forcefully

12. The Geneva Declaration is reprinted in "Medical Ethics Declarations" (1984) 31:3 *World Medical Journal*.

restates the ethical principles of medicine and repeats the famous Hippocratic oath, thereby reaffirming that a doctor's first duty is to his patient.

The Helsinki Declaration,[13] adopted in 1964 by the World Medical Association, is of considerable importance. Revised in Tokyo in 1975 and again in Venice in 1983, it is probably the most comprehensive international statement on the issue that we have at present. It is here, that for the first time a distinction is made between therapeutic and non-therapeutic experimentation. The Tokyo revision of 1975 largely eliminated differences in regulation of these two types of activity: neither the interests of science nor the desire for successful completion of research should be allowed to prevail over the health or life of the experimental subject. We should point out that, unlike the Nuremberg Code, article I-11 of the Declaration allows experimentation on incompetent persons under certain conditions:

> I – 11. In case of legal incompetence, informed consent should be obtained from the legal guardian in accordance with national legislation. Where physical or mental incapacity makes it impossible to obtain informed consent, or when the subject is a minor, permission from the responsible relative replaces that of the subject in accordance with national legislation.

Finally, it is interesting to note a significant difference between the first draft and the version that was adopted. The original draft formally banned experimentation on prisoners on the grounds that, since they were in a state of detention, they lacked the freedom to make such an important decision; this does not appear in the final text.

The Declaration, which is too long to reproduce in full here, is divided into three parts. The first part sets out basic principles, the second deals with clinical research, and the third with non-therapeutic medical research.

In Manila in 1981, the World Health Organization and Council for International Organizations adopted the *Proposed International Guideline for Biomedical Research Involving Human Subjects*.[14] As its preamble clearly states, this text does not merely repeat the principles set out in the Helsinki Declaration, but makes concrete suggestions for applying them, especially in developing countries. More particularly, these guidelines set out rules governing how to obtain informed consent from experimental subjects.

Two major United Nations texts should also be considered. The first is a report published in 1976 by the World Health Organization at the UN's request.[15] The second

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13. The full text of the Helsinki Declaration appears in "Medical Ethics Declarations" (1984) 31:4 *World Medical Journal*.

14. The "Proposed International Guidelines for Biomedical Research Involving Human Subjects," also known as the Declaration of Manila, are reprinted in Z. Bankowski and N. Howard-Jones (eds.), *Human Experimentation and Medical Ethics, XVth CIOMS Round Table Conference* (Geneva: CIOMS, 1982) at 409-423.

15. WHO, *Health Aspects of Human Rights with Special Reference to Developments in Biology and Medicine* (Geneva: World Health Organization, 1976).

is article 7 of the *International Covenant on Civil and Political Rights*,[16] adopted by the General Assembly on December 16, 1966 and ratified by Canada. It reads as follows:

> 7. 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.

Finally, we might also mention in a more specific context, the four Geneva Conventions on the protection of prisoners of war, adopted on August 12, 1949[17] and amended by two protocols in 1977.[18]

With regard to Europe, we should mention the second directive of the Council of the European Economic Community, dated May 20, 1975.[19] Article 3 of the *European Convention on Human Rights*[20] offers protection similar to that provided by article 7 of the *International Covenant on Civil and Political Rights*.

A few remarks are in order concerning these international documents. First, there are problems with enforcement. The rules they set out are tenuous, unaccompanied by any real controls or traditional legal sanctions. Second, these general statements are ambiguous with respect both to the principles themselves and to their practical application, a feature not limited to international documents. Third, since the Nuremberg Code all such documents have condemned the kind of experimentation revealed in the abuses of World War II, and seek to promote the humanitarian notion that the interests of society cannot justify every act and that unrestricted human experimentation cannot be allowed solely on the basis of general social utility. For experimentation to be legitimate, it must be accompanied by safeguards to ensure respect for the person. Finally, these documents without exception clearly highlight the potential conflict between the role of investigator and therapist. They thereby demonstrate the need to clearly separate these roles in the interest of the subject.

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16. (1976) 999 U.N.T.S. 172.

17. (1) Geneva Convention relating to the Treatment of Prisoners of War. (2) Geneva Convention relating to the Protection of Civilian Persons in Time of War. (3) Geneva Convention for the Amelioration of the Condition of the Wounded and Sick and Armed Forces in the Field. (4) Geneva Convention for the Amelioration of the Condition of Wounded, Sick and Shipwrecked Members of Armed Forces on Sea. See Edmund Jan Osmaczyk, *ibid.* at 293 and Henry W. Degenhardt, *Treaties and Alliances of the World*, 3d ed. (Detroit: Gale Research Company, 1983) at 1-2.

18. (1) Protocol I relating to the Protection of Victims of International Armed Conflicts. (2) Protocol II relating to the Protection of Victims of Non-international Armed Conflicts. See Degenhardt, *ibid.* at 2-3.

19. JOCE, 9 May 1975, at 13-22.

20. Also known as Convention for the Protection of Human Rights and Fundamental Freedoms (1955) 213 U.N.T.S. 222.

II. Canadian Law

In Canada, there are two categories of document dealing with regulating experimentation. The first is federal and provincial legislation and regulations. Most often, these contain general provisions declaring certain types of conduct illegal, in this case certain types of experimentation. Sometimes they contain provisions dealing specifically with experimentation. The second category consists of documents, codes of ethics and reports, which, while not necessarily enforceable, strongly urge researchers experimenting on human subjects to observe certain standards of conduct.

A. Federal and Provincial Legislation

The *Canadian Charter of Rights and Freedoms*[21] naturally has pride of place. Two of its provisions express standards which in effect make certain kinds of experimentation illegal. The first is found in section 7:

> **7.** Everyone has the right to life, liberty and security of the person and the right not to be deprived thereof except in accordance with the principles of fundamental justice.

Any experimental activity which endangers one of the protected values is therefore illegal. The second provision is found in section 12:

> **12.** Everyone has the right not to be subjected to any cruel and unusual treatment or punishment.

According to current case law, "treatment" may be broadly construed rather than being limited to therapy. As the Commission has already written with regard to behaviour-alteration techniques,[22] this provision appears sufficiently broad in scope to protect the experimental subject.

In this discussion of general provisions, we should also mention the current provisions of the *Criminal Code*[23] dealing with the protection of the human person. Most of these have already been studied by the Commission and it would be redundant to review them here. The traditional offences against the person (assault, homicide, and so on) make it possible to penalize those causing harm to a subject who has not given valid consent to an experiment.

With respect to medications, citizens are given general protection by the *Food and Drugs Act*[24] and more specific protection by the regulations made under the Act. These regulations control the introduction of new medications onto the market, and although they do not specifically refer to experimentation as such, a number of them implicitly

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21. Part I of the *Constitution Act, 1982*, being Schedule B of the *Canadian Act 1982*(U.K.), 1982, c. 11.

22. LRC, *Behaviour Alteration and the Criminal Law*, Working Paper 43 (Ottawa: LRC 1985).

23. R.S.C. 1985, c. C-46.

24. R.S.C. 1985, c. F-27.

touch on this area by providing general protection. Thus, the *Food and Drug Regulations*[25] set out the precise conditions under which a manufacturer may distribute a new medication to "qualified investigators" for clinical testing. These conditions provide a basic level of protection for experimental subjects who agree to have new chemical substances tested on them. The regulations also stipulate that researchers must strictly monitor the use of medications, indicate any serious incidents resulting from their administration, and submit a detailed report. Only closer study than is possible here would enable us to say whether this Act and its related regulations adequately protect the public against the risks surrounding the introduction of new medications.

In the area of provincial legislation, Quebec is of particular interest because it has taken the initiative of giving concrete legislative expression to certain principles. First, section 1 of the *Charter of Human Rights and Freedoms*[26] provides that every human being has a right to life and to personal security, inviolability and freedom. Section 4 recognizes the right of every person to the safeguard of his dignity, and section 5 his right to the respect of his private life. Section 5 may prove to be of real use in research involving the social sciences. These provisions form a backdrop to the more detailed regulation provided by the *Civil Code*. Articles 18 and following in the chapter entitled "Of the Enjoyment of Civil Rights" were added to the *Civil Code* in 1971 in response to the practical difficulties to which the first heart transplants gave rise. These provisions are based on the principle, set out in article 19, that the human person is inviolable and that no one may cause harm to a person without his consent or without being authorized by law to do so. For the purposes of our study, article 20 is of particular interest. It reads as follows:

> **20.** 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.

Bill 20, *An Act to add the reformed law of persons, successions and property to the Civil Code of Québec*,[27] assented to on April 15, 1987 but not yet in force, amends these provisions slightly while on the whole retaining the same approach and the same basic philosophy. The new text of articles 18, 19 and 20 reads as follows:

> **18.** A person of full age may alienate part of his body *inter vivos* or undergo an experiment, provided the risk assumed is not disproportionate to the anticipated benefit.
>
> The person having parental authority, the tutor or the curator may, subject to the same condition and with the permission of the court, give consent to an alienation or experiment

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25. C.R.C., c.870, s. C.08.005.

26. R.S.Q., c. 12.

27. S.Q. 1987, c. 18.

which concerns a minor or a person of full age who is unable to give consent. However, the refusal of a minor fourteen years of age precludes any alienation or experiment.

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

The court shall also obtain the opinion of the person concerned unless that is impossible, and shall respect his refusal except for a grave reason.

20. Before ruling on an application for permission, the court shall satisfy itself that the alienation of part of the body, medical care or experiment is in the interest of the person concerned and is advisable in the circumstances; it shall also satisfy itself that the risk involved in these acts is not disproportionate to the anticipated benefit or that they are beneficial to the person despite their major and permanent effects.

As we can see, Quebec law stipulates that, for experimentation to be legal, two basic conditions must be met: the subject's consent must be obtained and the risk incurred must be proportionate to the benefit anticipated. According to Quebec civil law, which is like the common law in this respect, there must not only be consent but it must also be free and informed. Provided these conditions are met, Quebec law recognizes the legality of non-therapeutic biomedical experimentation and codifies the basic rules governing it. It goes even further by regulating cases where the experimental subject is a minor. The provision cited above provides that where the minor is "capable of discernment"[28] his consent must be obtained as well as that of the person having parental authority and a judge of the Superior Court. Protection of the minor's interests is also reinforced by the provision that the risk incurred must not be a *serious* risk to the minor's health. The test is thus far more stringent than it is for a subject of legal age, for whom the law merely requires a reasonable risk/benefit ratio (thereby letting it be understood that the risk may be serious or high where the benefit is substantial), whereas for the minor it prohibits experimentation involving serious risks, regardless of how substantial the possible benefits are.

Still in the area of provincial private law, we should mention the well-known decision in *Halushka* v. *University of Saskatchewan*.[29] In that case a student had been approached to test an experimental anaesthetic. The doctor told him that the experiment involved the introduction of a catheter under general anaesthetic. However, he concealed two major facts: the product was new and had not been fully tested, and the catheter was to be introduced right up into the student's heart. In the course of the experiment the student suffered a heart attack that resulted in serious bodily and material harm. The court held that the University of Saskatchewan was liable, on the grounds that the subject's consent had not been properly obtained, since a significant part of the risk inherent in the experiment had been concealed from him.

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28. For an interpretation of this concept, see the recent decision in *Cayouette* v. *Mathieu*, [1987] R.J.Q. 2230 (S.C.).

29. (1965) 53 D.L.R. (2d) 436 (Sask. C.A.).

B. Ethical Documents

Only texts of a general nature will be considered here, although for the sake of completeness we should mention the many codes of professional conduct for professional associations and groups involved in experimentation on human subjects (Canadian Medical Association, provincial colleges of physicians and surgeons, and so on). Every Canadian university and every research centre worthy of the name has also adopted rules or codes of ethics that govern their researchers who are engaged in experimentation on human subjects.

First, there is the 1977 report of the Canada Council, entitled *Ethics*.[30] It was prepared by an *ad hoc* committee responsible for developing ethical guidelines to be followed by universities seeking grants from the Canada Council for research involving experimentation on human subjects. The report is not limited to the medical and biological sciences, but includes the humanities and social sciences as well as research involving foreign cultures, countries and ethnic groups. Special emphasis is placed on obtaining free and informed consent, the confidentiality of the information obtained, the information to be provided by the researcher, risk assessment, and methods involving deception.

The second document is a report entitled *Ethics in Human Experimentation*, published in 1978 by the Medical Research Council of Canada.[31] It is the result of painstaking work and contains a remarkable summary of a whole series of legal and ethical issues connected with experimentation. Starting from a very broad definition of research, and not wanting to make any distinction between physically and mentally intrusive techniques (questionnaires, behaviour analyses), the Council reached the conclusion that, once general parameters have been defined, ethical matters should be left to the supervision of the institutions performing the research. After reviewing the traditional rules governing risk and informed consent, the Council also dealt with the legitimacy of experimentation on special groups of subjects.

The Medical Research Council of Canada further reviewed this issue and in November 1987 published *Guidelines on Research Involving Human Subjects*.[32] The Council is opposed to direct legislative intervention for two reasons. The first has to do with the difficulty of establishing uniform rules due to the division of legislative powers in Canada. Second, the Council considers that self-regulation by codes of ethics in research is sufficient. The report substantially reaffirms its previous recommendations, although with some variation, and takes a firmer position on some new forms of experimentation involving children. Finally, in Part Two the Council considers the role

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30. The Canada Council, *Ethics — Report of the Consultative Group on Ethics* (Ottawa: Supply and Services Canada, 1977).

31. Medical Research Council of Canada, *Ethics in Human Experimentation*, Report 6 (Ottawa: Supply and Services Canada, 1978).

32. *Supra*, note 9.

that a research ethics committee should play: its activities should not be limited to pre-project control but should extend to the monitoring of project development and progress.

III. Foreign Law

Since it is clearly impossible to discuss all legal developments relating to human experimentation in every country, we have had to choose among them. Of the two countries selected, one was chosen because of the type of regulatory model it has adopted (the United States will be our example here), and the other because its approach provides solutions fundamentally different from those with which we are familiar (the French model).

A. The United States

The proximity of the United States, its leading role in biomedical research in the West, and its constant scientific exchanges with Canada would alone be sufficient to justify a separate analysis of the rules in force in that country. For our purposes, however, it is the historical background of regulation in this area that is of most interest. Our survey will explain how the United States moved from an almost total absence of controls, based on the promotion of scientific progress, to the establishment of strict rules and mechanisms.

The first guidelines, inspired by the Nuremberg Code, were published in the United States in 1953 by the Center of National Institutes of Health.[33] This organization for the promotion of clinical research implemented a decentralized method for evaluating and reviewing research programs throughout the United States, using a system known as "peer review." Between 1958 and 1962, Senator Kefauver led an investigation into the pharmaceutical industry which turned up a number of serious problems. On the basis of the Senate committee's findings, Congress intervened to strengthen the supervisory and intervention powers of the Food and Drug Administration (FDA). This administrative agency, with broad regulatory powers, is responsible for monitoring the legality and quality of pharmaceutical, medical and cosmetic products.

In 1966, the Livingston Report[34] on biomedical experimentation sharply criticized certain practices and denounced the tendency of many researchers experimenting on humans to expose their subjects to unacceptable risks in the interests of science.

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33. For a general survey of the historical development of regulation in the United States, see *inter alia* C. McCarthy, "Le développement de la politique américaine de protection du sujet humain en recherches biomédicales et comportementales" (1982) 4 *Cahiers de bioéthique* 121; and J. Katz, ed., *Experimentation with Human Beings* (New York: Russell Sage Foundation, 1972).

34. R.B. Livingston, *Memorandum to Director, N.I.H., Progress Report on Survey of Moral and Ethical Aspects of Clinical Investigations,* presented 4 November 1964, cited by McCarthy, *ibid.* at 137.

Between 1965 and 1971, the National Advisory Health Council and the Surgeon General adopted a series of general policy regulations emphasizing the respect due to human experimental subjects, regulations which researchers would have to observe if they wished to receive research funds or public grants. In 1971, the federal Department of Health, Education and Welfare (DHEW) published its own policy statement on the subject.[35] One year later, however, a public scandal erupted over the facts that came to light in the Tuskegee case.[36] It was learned that, in connection with a study of syphilis, some 300 American black men in Alabama had been inoculated with the syphilis virus without their consent. A number of them died as a result of this experiment because the doctors involved did not see fit to give them antibiotics that had proved to be effective. A Senate subcommittee chaired by Senator Kennedy found that a critical review of all relevant standards was of the utmost urgency. This was how the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, also known as the Belmont Commission,[37] came to be set up.

This Commission sat from 1976 to 1978 and accomplished a considerable amount of work.[38] Composed of eleven members, six of whom were laypersons, it published a series of studies and reports dealing with research on foetuses, prisoners, children and the mentally deficient, and with psychosurgery, disclosure of information, the operation of review committees, the ethical rules governing the administration of health care and, finally, the consequences of recent biomedical discoveries.[39]

According to the *National Research Act*,[40] DHEW was to implement the Commission's recommendations within six months of their publication. DHEW had no difficulty, during the 1970s, making regulations concerning the foetus, but declined to follow the Commission's recommendations concerning prisoners and stated that it lacked the authority to make regulations in the area of psychosurgery. On the whole, however, the regulations, which have been amended several times since then, follow most of the Commission's recommendations.[41] They constitute a coherent and complex code governing experimentation and research on human subjects.[42]

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35. U.S. Department of Health, Education and Welfare, *The Institutional Guide to DHEW Policy on Protection of Human Subjects* (Washington: N.I.H., 1971) cited by McCarthy, *supra*, note 33 at 138.

36. *Supra*, note 3.

37. The Commission was created pursuant to ss. 201-205 of the *National Research Act*, 42 USCS § 2891-1.

38. See M. Yesley, "La tâche accomplie par la Commission pour la protection des sujets humains" (1982) 4 *Cahiers de bioéthique* 195.

39. For a list of the publications of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (Belmont Commission), see the selective bibliography at the end of this paper.

40. 42 U.S.C.S., § 2891-I.

41. For a list of publications of the Commission relating to these recommendations, see the selective bibliography at the end of this paper.

42. "Protection of Human Subjects: Policies and Procedures," 38 *Federal Register*. 31738 (1973).
"Protection of Human Subjects," *39 Federal Register*. 18914 (1974).
"Protection of Human Subjects: technical amendments," 40 *Federal Register*. 11854 (1975).

B. France

The attitude of French law to experimentation deserves special mention because it developed in an original way. France is one of the few countries which until very recently did not recognize the legality of non-therapeutic experimentation on healthy subjects.[43]

Prior to 1941, there were no provisions in France governing the testing of medicines. Comprehensive regulation of the whole field was achieved by the Order of September 23, 1967,[44] the Decree of November 21, 1972,[45] and the Decree of December 16, 1975.[46] These provisions deal with the conditions under which new medications may be introduced onto the market, the precautions to be followed in clinical testing, and the form and content of protocols. Furthermore, the Law of July 11, 1975[47] regulates medical and biological research laboratories. Finally, article 601 of the *Code de la santé publique*,[48] amended by the Order of September 23, 1967, gives the minister responsible certain powers to determine who may be authorized to test new products.

The situation with regard to biomedical experiments is more complex. French law starts from the principle that the relationship between doctor and patient is contractual in nature. There must therefore be informed consent, lawful cause and object, and the capacity to enter into contractual relations. According to case law and literature, experimentation is permissible only where it is therapeutic, providing the subject with a reasonable expectation that his condition will thereby be improved. French case law also requires that there be a reasonable risk/benefit ratio. In this connection, articles 18

"Protection of Human Subjects: fetuses, pregnant women and In Vitro Fertilization," 40 *Federal Register*. 33526 (1975).

"Protection of Human Subjects: research involving prisoners," *42 Federal Register*. 3076-91 (1977).

"Protection of Human Subjects: Informed Consent: Standards for Institutional Review Boards for Clinical Investigations, and Clinical Investigations which may be reviewed through expedited review procedure," 46 *Federal Register* 8942 (1981).

"Public Health Service Human Research Subjects," *46 Federal Register* (1981).

"Protection of Human Subjects," 45 Code of Federal Regulations, Office for Protection from Research Risk, March 8, 1983.

American Psychological Association, Committee for the Protection of Human Participants in Research, *Ethical Principles in the Conduct of Research with Human Participants* (Washington, D.C.: The Association, 1983).

43. For a critical analysis and summary of the French position, see A. Fagot-Largeault, *L'Homme bio-éthique : pour une déontologie de la recherche sur le vivant* (Paris: Maloine, 1985).

44. J.O., 28 September 1967. This Order specifies the conditions relating to the introduction of new medications onto the market and requires ministerial authorization.

45. J.O., 30 November 1972. Decree No. 72-1062 specifies the conditions for the application of section L.601 of the *Code de la santé publique* relating to medications.

46. J.O., 11 January 1976. This Decree defines the formalities applicable to clinical expertise of medications and reiterates the European Economic Community Directive of 20 May 1975, *supra*, note 19.

47. J.O., 13 July 1975; rectif. J.O., 22 August 1975.

48. *Codes de la santé publique, de la famille et de l'aide sociale* (Paris: Dalloz, 1988).

and 19 of the 1979 *Code de déontologie médicale*[49] give a good indication of the current state of the law:

> [TRANSLATION]
> Art. 18 — In the course of their investigations and acts or when prescribing treatment, doctors should refrain from exposing patients to unjustified risks.
>
> Art 19 — The use of a new treatment on a patient is to be contemplated only after sufficient biological study, under strict supervision, and only where the therapy can be of direct use to the person.

Thus, "pure" or non-therapeutic experimentation was long considered to be illegal, as the case law had found it to be. However, most French commentators opposed the rigidity of this position on the grounds that in effect it paralyzed scientific development. They also argued that some non-therapeutic biomedical experiments on human subjects were nevertheless being performed in France. Accordingly, they wanted the legislature to take a clear position in favour of non-therapeutic biomedical experimentation, provided that it be so regulated as to ensure that subjects have effective protection.[50]

On October 9, 1984, France's National Consultative Ethics Committee, an organization bringing together doctors, researchers, jurists and others from a number of disciplines, published an opinion entitled *Problèmes éthiques posés par les essais de nouveaux traitements chez l'homme*.[51] It analysed the various stages in the testing of new treatments, discussed the ethical issues raised by these experiments, and provided clear and interesting recommendations on the subject. The National Ethics Committee is not a legislative body, however, and its recommendations and opinions do not have force of law. They nevertheless carry considerable weight, given the Committee's considerable moral authority over French researchers and scientists.

In 1988, the French Conseil d'État published a major document entitled *De l'éthique au droit*.[52] This report is one of the few complete analyses of the full range of problems raised by legalized encroachments on bodily integrity. It deals directly with biomedical experimentation and makes a series of recommendations, the most important of which follow. First, it suggests clearing up the ambiguity in current French law by recognizing the legality of non-therapeutic biomedical experimentation on human subjects. For such experimentation to be valid, however, free and informed consent would have to be obtained, and a positive risk/benefit ratio established. The experiment should not involve any remuneration and should be carried out only on the approval of an ethics committee.

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49. J.O., 30 June 1979.

50. See D. Schwartz *et al.*, *Problèmes éthiques posés par les essais de nouveaux traitements chez l'homme : réflexions et propositions*, in Comité national d'éthique *Rapport 1984* (Paris: La Documentation Française, 1985) and *Recherche médicale, santé et société*, Colloque du XX[e] anniversaire de l'INSERM (Paris, 1984).

51. Comité national d'éthique, *Problèmes éthiques posés par les essais de nouveaux traitements chez l'homme* in *Comité national d'éthique* Rapport 1984, supra, *note 52 at 35* (Paris, 1984).

56. LRC, *Criteria for the Determination of Death*, [Report 15] (Ottawa: Supply and Services Canada, 1981).

Second, the Conseil d'État took a clear position on the subject of foetal and embryo research. It formally banned certain types of experimentation (cloning, ectogenesis, and so on), prohibited the creation of embryos solely for research purposes, and made approval of the protocol by the National Ethics Committee and the consent of both parents necessary. Finally, the Conseil decided on a limit of fourteen days for *in vitro* embryo research and advocated the destruction of frozen embryos after five years. The use of tissues from dead foetuses was not prohibited, but was made subject to severe restrictions: it may be carried out only for diagnostic or therapeutic, never for commercial or industrial, purposes. Furthermore, only those embryos or foetuses that have not attained viability and that have already been determined to be dead may be used. The report of the French Conseil d'État is definitely, along with the Benda Report[53] from the Federal Republic of Germany, among the most considered treatments of the subject.

Finally, on December 13, 1988 the National Assembly and the Senate of France passed a law entitled *Loi relative à la protection des personnes qui se prêtent à des recherches biomédicales*.[54] It defines the conditions under which experimentation is legal, provides the necessary amendments to existing legislation, the *Code de la santé publique* in particular, and sets out the applicable administrative and penal sanctions.

First, the statute distinguishes between biomedical research from which direct therapeutic benefit is expected and other kinds of research. This distinction was made necessary because French law traditionally distinguished only between experimentation on healthy volunteer subjects (what we are here calling non-therapeutic experimentation) and experimentation on the sick (what we are calling experimental therapy).

A person of legal age capable of consent may participate in non-therapeutic experimentation under certain conditions. The same is true for minors and those of legal age under guardianship, provided that the experiment involves no serious foreseeable risk to their health, that it be useful to those in the same age-group or those who have the same disease or suffer the same mental deficiency, and that it cannot otherwise be carried out. The family council or the judge having jurisdiction in tutorship matters must also be involved. On the other hand, persons deprived of freedom may not be solicited for research that is not likely to result in substantial and direct benefit to their health.

In general, experimentation is considered to be legal where five main conditions are met. First, the research must be genuinely scientific in nature, which also means that experimentation on animals has to have been adequate to ensure that the subject is not exposed to unnecessary risks. The law provides that the risk must not be disproportionate to the expected benefit. Second, the protocol must have the prior approval of a regional research ethics committee. Third, the subject's free and informed consent must be obtained in writing and the subject must remain free to withdraw his

53. *Fécondation in vitro, analyse du génome et thérapie génétique*. (Rapport Benda) (Paris: La Documentation française, 1987).

54. J.O., 20 December 1988.

consent at any stage of the experiment. Fourth, true to the principle it has always upheld, French law requires that participation in an experiment must always be gratuitous: the subject may be compensated for expenses incurred, but within very strict limits, so as to prevent the emergence of "professional human guinea pigs." Finally, after some discussion, the principle of automatic compensation in case of harm to the subject was rejected; instead, the person responsible for the protocol must take out insurance to compensate the subject in case of accident.

It is still too early to judge this law, for two reasons. First, it has not yet given rise to the practical applications that alone will make it possible to measure the efficacy of the system. Second, it sets out only the basic principles, leaving the details to regulatory decrees which have not been issued to date and in all likelihood will not be for several months. However that may be, the law of December 20, 1988 has settled the question of the legality of non-therapeutic experimentation in France.

To wind up our discussion of French law, we should mention a recent case about which much has been written. A doctor from Amiens performed experiments on brain dead people kept alive artificially. That raised an outcry, particularly on the part of families whose authorization had apparently not been obtained. The National Ethics Committee issued an opinion condemning the practice.[55] Were such experimentation to be performed in Canada, under the various provincial laws governing such matters the researcher would have to obtain the authorization of the spouse, the family or next of kin in order to be able to make use of the corpse unless the subject himself, while he was alive, had given his body to science and thus consented to his corpse being used for experimental purposes. The Law Reform Commission, in its Report *Criteria for the Determination of Death*,[56] made specific recommendations concerning the determination of brain death, which were specifically intended to remove all ambiguity surrounding the distinction between an act performed on a living person and one performed on a corpse.

Experimentation on human subjects is regulated to some extent in other countries, in particular Great Britain, Australia, Sweden, Germany, Switzerland and Spain. In recent years, the development of new medical technologies involving artificial fertilization (*in vitro* fertilization, embryo transfer and freezing) has led some countries, including Great Britain (the Warnock Report[57]) and Australia (the Waller Report[58]), to address more squarely the difficulties arising from scientific research on human embryos, as the Ontario Law Reform Commission has recently done.[59]

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55. *Avis sur l'expérimentation médicale et scientifique sur des sujets en état de mort cérébrale*, 1988.

56. LRC, *Criteria for the Determination of Death*, [Report 15] (Ottawa: Supply and Services Canada, 1981).

57. *Report of the Committee of Inquiry into Human Fertilization and Embryology* (Warnock Report) (London: HMSO, 1984).

58. *Report on the Disposition of Embryos Produced by In Vitro Fertilization* (Waller Report) (Melbourne: Government Printer, 1984).

59. Ontario Law Reform Commission, Report on Human Artificial Reproduction and Related Matters (Toronto: the Commission, 1985).

However, there are significant differences in the ways in which different societies deal with such problems. Some countries, the United States for example, have clearly opted for a regulatory model that applies to all research subsidized by public bodies. Although research sponsored by private foundations or organizations is governed by rules laid down by the sponsors, on the whole the standards prescribed by public authorities seem to be observed as well. Most other countries have only piecemeal regulation. Testing of medications is usually regulated, and occasionally, as in Australia, certain specific types of research as well, but in general biomedical research rarely is. The most common form of regulation is internal regulations issued by the various funding organizations. Statute law, both civil and criminal, only serves to prevent the most flagrant abuses, and is usually not primarily intended to provide a complete code regulating experimentation. It may thus be observed that, on the one hand, except for basic principles, the law usually prefers to rely on the ethical standards defined by the scientific community itself. On the other hand, given past abuses and the increasing complexity of scientific research, the public in general and jurists in particular have been demanding more and more active legislative and regulatory intervention.

We should also mention a Dutch draft bill that contains some interesting provisions. In general, it stipulates the usual conditions for the validity of non-therapeutic biomedical experimentation (consent, proportionate risk). However, authorization to go ahead with experimentation would depend on the decision of a multidisciplinary central commission of 13 members (articles 3 and 15 to 25). Moreover, subsection 6(2) of the bill is of interest in that it sets out the minimum information that the investigator has to provide to the subject. The investigator has to disclose the nature, purpose and duration of the experiment; possible risks to the subject's health; the dangers that interruption of the experiment could entail; possible annoyances or inconveniences; and the fact that the central commission has approved the project. Finally, articles 8 and 9 set up a system of no-fault damage and compensation insurance for the subjects' benefit in case the experiment were to cause them any harm.

CHAPTER TWO

Conditions for Experimentation on Human Subjects

As we pointed out at the beginning of this study, some may object in principle to the legalization of any form of experimentation on human subjects, whether for purposes of pure research or for therapeutic reasons. Religious, philosophical, ethical and social arguments may be advanced to support such a position, the logical outcome of which would be an express legislative ban on grounds of public policy and the introduction of a specific offence criminalizing acts that are experimental or not exclusively therapeutic.

Our consideration of the question here starts from the opposite assumption. We recognize that the objectives of non-therapeutic biomedical experimentation are legitimate and socially and humanly acceptable when their purpose is to improve methods of diagnosis and treatment or to increase our knowledge of the sources and etiologies of diseases in human beings. To place a total ban on human experimentation would not only be unrealistic; it would go against the interests of humanity.

However, this recognition in principle is not enough. History records many acts, initially undertaken with the best intentions in the world and for perfectly legitimate purposes, that led to unacceptable results. A valid end does not in itself legitimize all means of attaining it. In experimentation the stakes are high, since the autonomy, health and sometimes even the life of the human subject may be at risk.

In our opinion the problem does not lie in the *legitimacy* of experimentation as such, but in its *legality*. Once we make the basic assumption that human experimentation is useful and desirable, the next step is to ask ourselves, keeping in mind all the social values and constraints imposed by the legal system, under what conditions it can be considered to be legal. Legalizing experimentation requires that we establish the legal conditions for its validity and also that we provide legal mechanisms for ensuring that these conditions are fully met in practice.

There remains a possible misunderstanding that should be cleared up. We have situated this analysis in the context of medical law: in other words, we are considering only the legal system as it concerns experimentation connected with medical science. Non-medical experimentation (in the social sciences, for example) may or may not be ethically acceptable, legitimate or legal. That is an issue we do not intend to address here. Moreover, we are not dealing with experiments that only appear to be medical in nature, such as those conducted by the Nazis during the Second World War. For example, one experiment sought to reproduce high-altitude conditions in a bomber by

placing a prisoner in a decompression chamber so that the subject's "reactions" to a rarefied atmosphere could be studied.[60] Although just as unacceptable, the experiment that involved inflicting phosphorous burns so that a medication that might heal them could be tested, was nevertheless medical in nature.[61]

It is clear that, whatever the legal system or country, there is something of a consensus regarding the general conditions for the legality of experimentation on human subjects: first, the subject must have consented to the procedure; second, there must be an acceptable ratio between the risk to which the experimental subject may be exposed and the benefit that may reasonably be expected from it.

RECOMMENDATION

1. (1) Non-therapeutic biomedical experimentation should be considered legal and permissible under the criminal law where:

(a) the subject's free and informed consent has been properly obtained; and

(b) there is an acceptable ratio between the risks incurred by the subject and the benefits expected to result from the experiment.

I. Consent

Before considering the first condition, we must carefully distinguish the notion of consent from that of capacity: consent is an expression of the will, whereas capacity is the ability accorded by the law to express one's will. In this sense, consent is to be ranked above capacity, because a person considered incompetent (a minor, for example) could have sufficient intelligence and discernment to give valid consent. Nevertheless, those declared "incompetent" by the law belong, in general, to groups that, because of age or mental capacity, are deemed to be incapable of giving valid consent. For consent to be valid, the law requires that there be consent, that it be free and that it be informed.

A. Consent as a Condition

In both criminal and civil terms, the experimental subject's consent is indispensible if an experiment is to be legal. Any breach of the subject's bodily integrity not authorized by the subject will be punished, since it amounts to criminal assault. The Commission's proposed new Criminal Code maintains this position.[62]

60. Centre d'études Laennec, *L'expérimentation humaine en médecine* (Paris: P. Lethielleux, 1952) at 175-77.

61. *Ibid.* at 193-94.

62. *Supra*, note 7 at 61-63.

Certain experiments performed some years ago in the United States appear morally and legally unacceptable in this respect. Katz[63] reports a number of very troubling instances. In a Jewish hospital in Brooklyn, a physician doing cancer research injected senile, chronically ill old men with cancer cells without their consent. In a hospital in Willowbrook, mentally handicapped children were deliberately infected, without anyone's consent, with a hepatitis virus. Finally, as we have already mentioned, in Tuskegee, Alabama, 300 black men were inoculated with syphilis and left without treatment, although effective antibiotics existed.[64] Such acts are ethically unacceptable and justify recourse to civil, administrative or disciplinary remedies.

In this respect, the rules for biomedical experimentation are similar to those for medical treatment — with one important difference, however. In treatment, emergency or necessity can justify dispensing with the patient's consent. A doctor with an unconscious patient is not required to wait until the patient regains consciousness before beginning treatment. In experimentation, on the other hand, such exceptions cannot be allowed; for example, non-therapeutic experimentation cannot be permitted on a patient who is unconscious and therefore unable to express his will.

It is not enough that consent to biomedical experimentation be given at the beginning of an experiment: it must continue in effect throughout the entire duration of the experiment, and this has two important practical consequences. The first is that an experiment cannot continue on the basis of initial consent when conditions have changed or procedures have been modified; the researcher is then under a legal obligation to obtain the subject's consent to the new experimental conditions. The second is that, notwithstanding the initial consent, the subject must always be completely free to withdraw from the experiment.

Consent may be expressed in a number of ways. The criminal law requires no special formalities, as long as consent can be satisfactorily proved. Consent to an experiment may thus, like consent to treatment, be express or implied. In experimentation, however, since the investigator's potential liability is greater (because the act is not performed for the individual's direct benefit, which might be sufficient for consent to be presumed), it is customary to require it in writing. Production of written consent by the researcher is not proof of the intrinsic validity of the consent, but creates a presumption that it was properly obtained.

B. Free Consent

The courts have often had difficulty defining what free consent is in such everyday matters as the circumstances surrounding the execution of a contract. When it comes to applying this notion to a field as complex as medical law and experimentation, the issue becomes even more difficult.

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63. *Supra*, note 33.

64. *Supra*, note 3.

Ideally and in the abstract, free consent is what is given by an individual who has correctly perceived the facts on which his decision is based, who has not been the victim of any kind of deception, and who, finally, has reached his decision without being subjected to any physical, moral, intellectual or circumstantial pressure or duress. In everyday life, on the other hand, completely free consent is more a myth than a reality, since many factors are likely to have a deciding influence on the will. It must therefore be admitted that, practically speaking, there are various degrees of freedom of consent. The law should intervene only when the degree of constraint on that freedom is unacceptable in comparison with what is at stake; and in medical matters what is at stake is bodily integrity, a value far outweighing mere economic interests. Accordingly, absolute freedom of consent should be considered an ideal to be achieved, a goal to be approximated as closely as possible.

1. Error

An error is a belief contrary to reality that derives from an incorrect appreciation of the facts by an experimental subject. To avoid its occurring, the investigator has a duty not only to fully inform the subject, but also to make sure that the subject understands what he has been told and to clear up possible misunderstandings. An error on a material fact (the nature of the experiment, methodology, probable results and, of course, risks) makes it impossible, from a legal standpoint, to view consent as having been validly given.

2. Deception and Non-Disclosure

Deception and non-disclosure raise complex problems. In principle, there should be no exceptions to the duty to be honest in human relationships. When, in addition, the relationship is medical or quasi-medical in nature and therefore, in effect, a fiduciary relationship, this requirement should be enforced with special rigour. The relationship between the doctor or researcher and the experimental subject should be based on complete confidence. A subject who relinquishes some of his bodily integrity without personally receiving any direct therapeutic benefit does so because he trusts the person who is going to breach that integrity. Accordingly, as a general rule, all deception, non-disclosure or falsification in connection with the experiment, its aims, methods and attendant risks is to be condemned. Disclosure of aims, methods and risks must be frank and complete.

Concealment raises special problems, however, when it is necessary in order to successfully carry out an experiment. To give a well-known example, one might wish to test the actual effect of a medication by excluding from the test results the psychological or psychosomatic impact on the subject of the fact that a substance is being tested which he believes to be of therapeutic value and in which he has placed a lot of hope (the placebo effect). This is done by selecting two groups of people on whom the medication might be effective. One group is given the medication and the other is given an inert substance (placebo), so that their effects may be compared. The experiment may be conducted in several different ways. Both groups may be informed of the method being employed, in which case there is really no deception. Conversely,

the procedure may be completely concealed from both groups. Finally, the doctor who prescribes the medication or the substance may or may not be informed (single- or double-blind experiment).

The deception in all such cases is not for the deliberate purpose of harming the individual and, objectively speaking, the purpose of the experiment remains morally valid since it is being carried out for the purpose of better determining the effects of a medication. The question remains, however, whether the pursuit of a legitimate end in itself justifies the use of apparently unlawful means.

Many factors have to be considered. The first is that in some cases deception is in fact indispensable if scientifically meaningful results are to be obtained. It is true, as the Medical Research Council of Canada is not alone in pointing out, that many experiments that currently use these sorts of methods could be carried out differently, without the need for resorting to lying.[65] In some cases, however, no other method will work.

Second, even in cases where the risks associated with an experiment are not high, concealment may have a negative or even harmful effect on the subject. For example, it has been observed that some people who have been deceived about the purpose of an experiment or the methods used experience a negative reaction leading to problems and sometimes even to psychological disorders. An example is the subject who thought he was participating in a learning experiment, when what was actually being measured without his knowledge was his degree of sadism or propensity to inflict pain. Moreover, where a medication is being tested, the very legitimacy of the experiment may be called into question. The following is an example. A group of heart patients is divided into two groups and the real medication is administered over a one-year period to one group while a placebo is given to the other; both groups are led to believe that they are being given real medication. A death rate two or three times higher is subsequently discovered in the second group. It is not difficult to imagine the legal and moral problems that this would raise. To deceive a patient in this way may dissuade him from seeking treatment elsewhere and thereby have direct consequences on his life or health.

Generally, then, one should start from the principle that all acts of deception are to be avoided. When deception is justified in the name of the validity and importance of the research and because no other procedure is possible in the circumstances, precautions should be taken to eliminate or diminish its harmful consequences. The Canada Council[66] has made the following recommendations:

> (1) that deception never be permitted when there is any risk of harm to the subject or when debriefing is not possible;
>
> (2) that if deception is claimed to be indispensable to the methodology, the researcher be required to show that no other methodolgy would suffice and evidence be shown that significant scientific advance could result from the research, before the deception is considered justifiable;

65. *Supra*, note 9 at 26.

66. *Supra*, note 30 at 9.

(3) that if deception is to be used, the researcher be able to show that nothing has been withheld from the subject which might, if divulged, have caused him to refuse to participate;

(4) that when deception is employed, debriefing take place as soon as possible.

In addition, the Medical Research Council of Canada has reaffirmed the position it took in 1978 and has made it even more detailed.[67] Deception is permissible under certain conditions: there must be no other means of achieving the research goal; the research must not involve any risk for the subject; no information may be withheld which, if made known, would cause the subject to refuse to participate in the experiment; the research must be of significant scientific value; and, finally, it must be possible to debrief the subjects and inform them of the reasons why deception was necessary once the research has been completed. The Commission agrees with the standards proposed by the Medical Research Council of Canada.

RECOMMENDATION

1. (2) Experimentation should be considered legal, even where the subject has been deceived, where:

(a) there are no other means of achieving the research goal;

(b) the experimentation involves no risk to the subject;

(c) no information is withheld which could cause the subject to refuse to participate;

(d) the research is of major scientific value; and

(e) it is possible to debrief the subjects and inform them why deception was necessary once the research has been completed.

3. Duress

Duress in any form undermines the voluntary nature of consent: although it does not do away with the external manifestations of the subject's agreement, the consent is really only apparent. It is given to avoid a greater evil, to escape from a situation perceived as being even more harmful. Duress can take the form of physical violence, as when subjects are forced to participate in an experiment. This is of course completely unacceptable and amounts to criminal assault.

Duress may also take more subtle forms, such as conduct that has a conscious or unconscious influence on the individual's will. It should not be forgotten that in medical matters the relationship between doctor and patient or investigator and subject is often a relationship of authority (no pejorative connotation intended). The latter is in a state of dependence with respect to the former. A researcher enjoys a certain prestige and has overall credibility in the subject's eyes. If, in addition, the experiment has a therapeutic component, the researcher's influence on the subject may be considerable.

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67. *Supra*, note 9 at 26-27.

For example, the subject may believe, rightly or wrongly, that his refusal to participate will be taken badly and might have serious consequences for his future relationship with his doctor or the researcher.

It is not easy to measure the impact of this type of constraint for the purpose of deciding whether it is legally acceptable. Human decision-making is the result of complex psychological processes, leading some to say that people are never completely free but rather always predetermined. The problem presents itself differently in law, particularly in criminal law.

First, the purpose of the criminal law is to punish with as much rigour as possible unlawfully exercised duress where it has a decisive impact on the subject's consent. Clearly, such punishment can take place only after the fact. In each case, it is up to the courts to decide whether consent was truly free. The *Criminal Code* provisions protecting the bodily integrity of the person are probably sufficient to ensure the effectiveness of this first type of intervention. Because this whole matter is largely a question of how facts are interpreted, it would be presumptuous to think that the legislature could, within the terms of the current *Criminal Code* or a possible future code, regulate in more detail and with greater precision an acceptable threshold of what constitutes free consent. It appears to us that the recognition — even implicit, as at present — that consent obtained by force or through the exercise of an unacceptable degree of duress is of no legal effect and cannot be used as a valid defence against an assault charge, is in principle sufficient.

Second, the criminal law can go further. It can seek to reflect certain social concerns and in the name of public policy completely ban all experimentation on some groups because it regards them as particularly susceptible to duress. For example, we might first think of the dying. A person about to die is in a particularly vulnerable situation because of the distress and resignation that generally accompany the prospect of impending death. Would there not be a temptation, even if unwitting, to approach such people rather than the non-terminally ill when testing a new product or medication, presenting it as their "last chance"? If the experiment has no therapeutic value, can it really be argued that it is legitimate to proceed and that the consent given is sufficient? On the other hand, if the experiment is of potential therapeutic benefit, however uncertain, is it not natural to have someone whose chances of survival are in any event almost non-existent take advantage of it?

There is a similar problem with prisoners. Some argue that prisoners are in a constant state of duress and that therefore their consent can only be apparent. This position is reflected in the laws of most countries that prohibit experiments on prison populations. Others take a diametrically opposed position and argue that the restrictions to which prisoners are subject do not constitute a valid reason to automatically exclude this entire segment of the population. They point out that each case should be assessed on its own merits, that it is best to refrain from generalizing, and that prisoners may find participation in an experiment to be a worthwhile experience that gives them the feeling that they are doing something socially positive, thus helping in their rehabilitation.

The second type of legal intervention differs from the first in that it is essentially preventive and does not merely punish abuses. By forbidding researchers access to certain population groups, it seeks to eliminate any possibility of abuse. We will return to this subject further on.

C. Informed Consent

The third condition is that consent must be informed. A great deal has been written about the concept of informed consent in recent years, especially because of the rules regarding medical treatment laid down by the Supreme Court.

Consent is the agreement of a human mind to a certain state of affairs. For there to be consent, this agreement must be in relation to an object that is specific and well-defined. These attributes can only come from two sources — the subject's own sensory perceptions and information provided by others. In the context of experimentation, the researcher or physician has the legal duty to brief the subject or patient and to provide him with all the factual information he needs to come to a decision.

Canadian case law, both criminal and civil, provides valuable information on the concept and limits of informed consent and the duty to inform. Among decisions dealing more specifically with the expression of consent in regard to medical treatment, *Hopp* v. *Lepp*[68] and *Reibl* v. *Hughes*[69] have made a major contribution to the question and have to some extent even changed positive law on the subject. The Supreme Court decisions seem to have substituted the test of the reasonable patient for the former test of the reasonable doctor. These two common law concepts differ from each other on both the theoretical and the practical level. The first requires only that a doctor disclose to his patient what another doctor would have disclosed in similar circumstances. The second test is more demanding, since it requires that the doctor disclose to his patient what an average patient in the same situation could expect to have been told.[70]

Without embarking on a detailed analysis of this case law, which has frequently been commented on, we think it useful to quote an important passage from the decision in *Hopp* v. *Lepp*, written by then Chief Justice Laskin:

> In summary, the decided cases appear to indicate that, in obtaining the consent of a patient for the performance upon him of a surgical operation, a surgeon, generally, should answer any specific questions posed by the patient as to the risks involved and should, without being questioned, disclose to him the nature of the proposed operation, its gravity, any material risks and any special or unusual risks attendant upon the performance of the operation.[71]

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68. [1980] 2 S.C.R. 192.

69. [1980] 2 S.C.R. 880.

70. See M.A. Somerville, "Structuring the Issues in Informed Consent" (1981) 26 *McGill L.J.* 740.

71. *Supra*, note 69 at 210.

Halushka v. *University of Saskatchewan*[72] states the traditional position of the law on the issue of non-therapeutic biomedical experimentation. On the question of the duty to inform, the Saskatchewan Court of Appeal held that where experimentation was involved the duty was at least as great, if not greater, than in a case involving ordinary treatment:

> In my opinion, the duty imposed upon those engaged in medical research ... to those who offer themselves as subjects for experimentation, as the respondent did here, is at least as great as, if not greater than, the duty owed by the ordinary physician or surgeon to his patient. There can be no exceptions to the ordinary requirements of disclosure in the case of research as there may well be in ordinary medical practice. The researcher does not have to balance the probable effect of lack of treatment against the risk involved in the treatment itself.[73]

A similar problem came before the Alberta Court of Appeal in *Cryderman* v. *Ringrose*[74] and *Zimmer* v. *Ringrose*.[75] These cases, however, concerned a new method of sterilization. One might therefore question whether in these instances real "treatment" was involved. Be that as it may, in both cases the courts assumed that real treatment was involved, even though it was experimental or innovative in nature. In addition, the principle expressed in *Halushka* was recently applied by the Quebec Superior Court in *Weiss* v. *Solomon*.[76] The Court found that in the case of purely experimental research, for consent to be valid the investigator was obliged to disclose all known risks, however unlikely they were to materialize.

Given current case law and the standard of conduct set out in the two Supreme Court decisions cited above, we find that the duty to inform is even stronger in the case of experimentation than in the case of treatment. In effect, the duty to inform no longer depends on there being a balance between the risk that the subject may run and the *personal benefit* he may anticipate from it, since by definition no benefit of the kind is expected. Accordingly, there must be full, frank and complete disclosure not only of the purpose of the experiment but also of any risks, the methodology to be used, and possible effects.

For the information to be considered complete, it is also necessary for the subject to have understood and assimilated the information provided. In our opinion, mere disclosure of information by the researcher is not sufficient. The researcher must ensure that the subject both understands this information and is capable of assessing it critically before making his decision.

It may be asked whether the criminal law should, as a matter of principle, make express provision for and define the content of the duty to inform. We consider this inadvisable for two reasons. The first is that the Supreme Court of Canada has in its

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72. *Supra*, note 29.

73. *Ibid.* at 443-44.

74. (1978) 89 D.L.R. (3d) 32.

75. (1981) 28 A.R. (2d) 69.

76. [1989] R.J.Q. 731 (S.C.).

decisions laid down certain rules that make legislative intervention less necessary.[77] The second is that, as the Supreme Court has pointed out, the application of these rules to particular situations leaves a great deal of leeway for the assessment of individual facts. Rules that are too general are unlikely to be of much help. It will be up to the civil law and the criminal law to apply these general principles to particular cases.

In Report 31, *Recodifying Criminal Law*,[78] the Commission, to eliminate the ambiguity to which section 45 of the current *Criminal Code* may give rise, proposed the adoption of a specific provision on medical treatment and medical research. The provision would extend current law, which is silent on the subject of consent, and provide an exception to crimes against bodily integrity for treatment administered in the following circumstances:

> [...] with the patient's informed consent for therapeutic purposes, or for purposes of medical research, involving risk of harm not disproportionate to the expected benefits.[79]

The proposed reform thus makes free and informed consent an essential test of the legality of experimentation.[80] It also requires that there be an acceptable ratio between risks run and benefits expected: this is the second condition, which we will now examine in somewhat more detail.

II. The Risk/Benefit Ratio

The second condition for the legality of experimentation is that there be an acceptable ratio between the risks incurred by an experimental subject and the benefits he may expect to derive from the experiment. This "proportionality principle" requires some explanation, but it should first be said that the ratio can never be truly mathematical and therefore never strictly objective. The assessment of risk, like that of benefit, requires a value judgment based on particular data. This process involves a subjective element which it is impossible to exclude. Moreover, evaluation of what constitutes an "acceptable" ratio is itself subject to variation depending on time and place, factors relating to the usefulness of the experimentation, and the subject's personality.[81]

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77. *Hopp* v. *Lepp*, *supra*, note 68; *Reibl* v. *Hughes*, *supra*, note 69.

78. *Supra*, note 7.

79. *Ibid.*, recommendation 7(3)(a) at 62.

80. This is in accordance with Recommendation 5, Report 28, *Some Aspects of Medical Treatment and Criminal Law* (Ottawa: LRC, 1986) at 16. However, the Commission may perhaps wish to re-examine the various aspects of free and informed consent at some future date.

81. For another analysis of this subject, see R. J. Levine, *Ethics and Regulation of Clinical Research*, 2nd ed., Baltimore and Munich: Urban & Schwarzenberg, 1986 at 37-65. Professor Levine argues that risk and benefit are not parallel constructions and that the effect of such constructions leads to confusion. Instead, he parallels risk of harm and probability of benefit, and suggests a test of "balance of harms and benefits" with regard to magnitude, expected duration and probability of occurrence.

A. The Concept of "Benefit"

The very concept of "benefit" warrants more detailed analysis. 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. Thus, in *Halushka*[82] the expected "benefit" was a demonstration of the merits of a new surgical anaesthetic.

On the other hand, as we saw at the beginning of this paper, some experiments, while they further the general advancement of science, can also be of therapeutic value to the individual. This is the case where a new medication is tried on a patient whose condition has been untreatable by traditional therapies. When assessing the risk/benefit ratio, it is necessary to keep in mind that "benefit" refers sometimes to a general social benefit and sometimes to an experimental subject's individual benefit.

B. The Concept of "Risk"

Second, what is meant by the term "risk"? In the interest of the better protection of human rights, the term should be given the broadest possible legal content. Thus, risks should include not only risks relating to life and physical health but also those affecting mental health. As most ethical codes recognize, they should also include mere social inconveniences. For example, the possibility that the subject might be exposed to social ostracism following an experiment should be considered a risk.

To begin with, it is difficult if not impossible to fully objectify risks. In any experiment, as in any medical act, some of the risk can be evaluated on the basis of past experience. Sometimes the frequency of its occurrence can be more accurately estimated through the use of particular statistical techniques. However, this is not possible in every case and assessment may remain within the realm of pure conjecture. In that case, the analysis of probabilities must be reasonable. Moreover, in addition to the statistical or general risk, the investigator must take account of the individual risk. The risks that members of a group may run as individuals are not the same for each. For instance, one subject may be in better physical condition; another may suffer from heart disease that would make the experience even more dangerous for him.

In this case, and also as a general rule, the researcher has a duty not to hesitate to eliminate unnecessary risks. He must therefore refuse to use as subjects individuals whose physical condition would substantially increase the danger of an experiment. Moreover, in the performance of an experiment any risk that is not strictly related to carrying out the protocol should be eliminated.

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82. *Supra*, note 29.

The risk should be then assessed on the basis of two factors: its objective seriousness on the one hand and the probability of its occurring on the other. It is the combination of these factors that makes it possible to determine whether or not a risk is "acceptable." The objective seriousness of the risk is a measure of its consequences were it to come about. Thus, a risk would be considered serious if the possible consequence is serious. If there is a chance that the experiment could lead to the subject's death or cause him permanent psychological or physical harm, a researcher would assess the risk as being serious, regardless of the probability of its occurring. If, on the other hand, the experiment might result in a mere temporary inconvenience, the risk would not be considered serious. This would be the case where people are asked to submit to a routine medical examination for statistical purposes.

Next, risk should be assessed in relation to the probability of its occurring. This is generally what is meant by low-risk or high-risk research. The probability that the risk, as already defined, will in fact occur is then assessed.

It is the combination of the two factors that serves to determine whether or not an undertaking is acceptable. Thus, an experiment involving a serious risk (death or permanent injury) is unacceptable even where the probability that it will materialize is low: the risk, even if it is highly unlikely to occur, is objectively too serious to allow the experiment to take place. On the other hand, a significant probability that the risk will materialize is not necessarily an obstacle if the risk is only an inconvenience presenting no real danger. For example, an experiment using a new medication the only side effect of which is to dilate the pupils for a few minutes would be allowed, but not one that risks causing permanent blindness.

Establishing whether the risk is indeed proportionate therefore involves analysis on two levels. The risk must be acceptable in terms of its seriousness and the probability of its occurring; it must also be acceptable in terms of the benefit expected from the experiment.

Thus, an experiment is neither legally nor morally acceptable where the risk, especially if serious, outweighs the benefit. Moreover, it is clearly unacceptable to subject a human being to any risk whatever where an experiment has no real scientific value. It is necessary to review the goals of an experiment before it takes place. On the other hand, even where the goal is worthwhile and the possible benefit to science great, experimentation on a human being is not legitimate where it may result in death or cause serious or permanent psychological or physical harm. In other words, everything must be done to protect the life and integrity of the human subject, even at the expense of increase in knowledge. Here again, some major subjective elements come into play. In general, it is the person conducting the experiment who assesses the risks. The obvious danger in this is that the risks could be underestimated, even if unintentionally and unwittingly. However, the ethics committees that review applications for research grants are usually composed of independent people, which to some extent militates against the possibility of this happening.

With respect to current law, section 45 of the *Criminal Code*, which stipulates that the act performed must be "for the benefit of that person," seems at first glance to call into question the very legality of non-therapeutic biomedical experimentation. Moreover, section 45 mentions only "surgical operation," which on the face of it seems to be very restrictive. Case law has always interpreted this expression broadly, however, having it include all acts of a medical nature.[83]

This provision, which also stipulates that it must be reasonable to perform the operation, having regard to all the circumstances of the case, appears sufficient to make criminal sanctions available in the case of an experiment with an unacceptable risk/benefit ratio. The same idea, differently expressed, appears in article 20 of the Quebec *Civil Code*, which provides that the risk assumed must not be "disproportionate" to the benefit anticipated. However, in the opinion of the Commission, the existing ambiguity should be removed. That is why in its proposed provision[84] it suggests the express inclusion of this recently enacted condition that the risks run be proportionate to the benefits expected from the research.

In short, the Commission is of the opinion that medical experimentation should be permitted, provided that certain conditions relating to consent and risks are met.

RECOMMENDATION

2. The *Criminal Code* should be amended by the addition of a provision which excludes from offences against bodily integrity those cases of non-therapeutic biomedical experimentation in which free and informed consent is properly obtained and the risks incurred are not disproportionate to expected benefits.

This was the Commission's position in Report 31, recommendation 7(3)(a), referred to above. However, the word "treatment" in this draft of the provision could lead to confusion. Our intention was to give the term a broad meaning, one that would include both essentially therapeutic acts and purely scientific research; but the word "treatment" seems really to apply only to acts performed for exclusively therapeutic purposes. In the interests of clarity, it would therefore be appropriate to amend Report 31, recommendation 7(3)(a).

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83. See LRC, *Medical Treatment and Criminal Law* [Working Paper 26] (Ottawa: Supply and Services Canada, 1980) at 54-61.

84. *Supra*, note 7, recommendation 7(3)(a) at 62.

RECOMMENDATION

3. Clause 7(3)(a) of the Commission's Report 31, *Recodifying Criminal Law, Revised and Enlarged Edition*, should be amended to read as follows:

7(3) Exceptions.

(a) Medical Procedure. Clauses 7(2)(a) and 7(2)(b) do not apply to medical procedures performed with the subject's free and informed consent, for therapeutic purposes or for the purposes of scientific experimentation, where the risks involved are not disproportionate to the expected benefits.

CHAPTER THREE

Special Cases

The general conditions examined above in connection with the legality of experimentation apply where the experimental subject is capable of giving free and informed consent. In this respect some categories of subjects pose special ethical and legal problems. First, the nature of the consent given by a prisoner should be examined. Second, the use of children also raises questions. Where a child has not yet reached legal age or lacks the necessary discernment, should the parents or guardian be allowed to consent on his behalf to his participation in an experiment? Third, the same problem arises in the case of persons with a mental deficiency that makes it impossible for them to understand the consequences of their acts. Finally, there is the question of experimentation on human embryos and foetuses which, obviously, cannot consent to anything. May someone consent on their behalf? Is consent necessary? Is the impossibility of obtaining consent a sufficient reason to ban all experimentation in the name of public policy?

I. Prisoners

In the last few years a great deal has been written about experimentation on prisoners, and in the United States the topic has been the subject of lively legal and ethical debate. The major relevant international documents, the Nuremberg Code and the Helsinki Declaration, do not expressly prohibit the use of prison populations in scientific and medical research.[85] Furthermore, a comparison between the first draft and the version finally adopted at Helsinki in 1964 shows that the total ban on the use of prisoners found in the initial draft was deliberately omitted from the final version. On the other hand, the resolution passed by the United Nations General Assembly on December 18, 1982[86] clearly appears to prohibit it, as does a resolution of the Council of Europe.[87]

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85. See pages 7-9.

86. Resolution 37-194 (111th plenary session), December 18, 1982."The Principles of Medical Ethics relevant to the role of health personnel, particularly physicians, in the protection of prisoners against torture and other cruel, inhuman, or degrading treatment" appear in (1983) 37:3 *WHO CHRONICLE* at 91-92.

87. Resolution 73-5, February 12, 1987.

A number of studies, including those conducted by the Belmont Commission of which we spoke above, have shown that experimentation on prisoners is a phenomenon almost exclusively confined to the United States.[88] European countries, including France[89] and the Federal Republic of Germany,[90] expressly prohibit this practice. England and most other countries, although they do not prohibit it, do not engage in it. In Canada, it appears to be prohibited in federal and provincial institutions. For instance, section 21 of the *Regulation respecting Houses of Detention*[91] made under the *Act respecting Probation and Houses of Detention*[92] reads as follows:

> **21.** An imprisoned person may not be subjected to medical and scientific experiments that may be detrimental to his mental or physical integrity.[93]

Experimentation on prisoners in the United States really began during World War II with the pharmacological testing of treatments for infectious diseases that might be contracted by members of the armed forces. Various abuses came to light during the 1950s and 1960s and were strongly denounced. In some states the practice was completely banned. In its recommendations the Belmont Commission took a position somewhere between permissiveness and total prohibition. It considered that an unconditional ban on experimentation involving prisoners was inappropriate, but that certain precautions should be taken to ensure that consent would be freely given. Based on these recommendations, DHEW issued regulations which are even more restrictive than those proposed by the Belmont Commission.[94]

In the course of its investigations, the Belmont Commission made a number of interesting observations. First, contrary to what might be expected, almost all of the more recent experiments on prisoners involved the testing of medications or new cosmetic products that involved little risk. Next, payments to prisoners for their participation were always very small, making it doubtful whether economic incentives played much of a role in obtaining their consent. Finally, the Commission noted that in most cases the same experiments could have been conducted as rigorously and successfully using subjects from the general population.

Why are prisoners so attractive to researchers? The answer is simple. Prisoners are a captive population leading a routine existence. Their lifestyle greatly facilitates the administration of research protocols and the collection of data, especially where the research is related to new medications and pharmaceutical products.

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88. See National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, *Research Involving Prisoners* (Washington, D.C.: Department of Health, Education & Welfare, 1976).

89. *Code de procédure pénale*, art. D380(3) and Law of 20 December 1988, art. 209.3.

90. Medicines Act, August 24, 1976. Bundesgesetzblatt 1, 2445.

91. R.R.Q. 1981, c. P-26, r.1 art. 21.

92. R.S.Q. 1977, c. P-26.

93. For federal regulations, see: *Penitentiary Service Regulations*, C.R.C., c. 1251.

94. See National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, *supra*, note 88.

Both advocates and adversaries of the legalization of research using prisoners advance substantial arguments in support of their positions. The main argument of those who oppose legalization is as follows: in experimentation (where the subject derives no personal benefit), it is absolutely essential that consent be freely given. The fact that the prisoner is in a prison environment means that there are several reasons why he is unable to give free consent. He is more susceptible to undue influence; his motive for participating is often not disinterested, but rather related to his hopes for improving his lot (breaking the monotony, earning money or privileges, making a good impression on authorities, obtaining early release, having his sentence reduced or being granted parole). His being deprived of freedom makes his consent suspect and, given the possibilities for abuse, justifies an outright ban.

Proponents of the opposite view argue that an outright ban on the use of prisoners is discriminatory and unfair. They note that, in general, prisoners are highly motivated and that performing a socially useful, altruistic act that gives them a sense of self-worth is often an expression of their desire to make amends. They also argue that, while participation in an experiment should never be linked to a reduced sentence or parole, the desire to break the monotony of prison life or to improve one's lot is perfectly legitimate. Finally, one can only speak of coercion where there really is a threat. To offer a prisoner a tempting reward for his participation is not to threaten but merely to encourage, and does not in any way undermine his freedom to choose.

Nevertheless, no one would seriously dispute that the voluntary nature of a prisoner's consent must be considered more critically than in the case of a person having the exercise of his freedom. It must also be admitted that, except for research on the condition of prisoners themselves, prison populations tend to be used more out of convenience than out of scientific necessity. The same type of research can be conducted in the same manner on subjects who are not imprisoned, even though with more difficulty.

The mere existence of additional difficulties is not, in our opinion, a sufficient reason for legalizing experimentation on prisoners. We believe that the danger of abuse is too great. The fact that prisoners, unlike children or the mentally ill, do not constitute a distinct biomedical group, and that there will always be uncertainty about how free their consent is, whatever precautions may be taken, in our opinion also justifies a formal ban on the use of prisoners as experimental subjects and thus the maintenance of the status quo. Faced with this dilemma, the Commission believes it is necessary to consider the issue further before taking a position either in favour of a total ban or of acceptance under some conditions of experimentation on prisoners in Canadian prisons. We are also very interested in hearing from concerned parties and the public.

II. Children

The legal and ethical problems surrounding the use of children in experiments are not restricted to the case of children; they also arise with the other classes of persons incapable of giving valid consent. Those with a mental deficiency that deprives them of their capacity to give consent are in the same position as young children whose intellectual faculties, understanding and decision-making abilities are not yet sufficiently developed.

Experiments involving children continue to be highly controversial. The legal profession is sharply divided on the issue.[95] There is agreement on only one point: experimentation of a therapeutic nature, that is to say which offers a reasonable hope of benefiting the child (such as the testing of a new medication in the treatment of leukemia) is legitimate and legal under ordinary conditions because its ultimate aim is to provide an individual benefit. Where the controversy arises is with respect to non-therapeutic experimentation.

Before we consider the arguments in support of each position, a few remarks are in order. First, everyone agrees that experimentation on children should be prohibited where adults capable of giving consent could be used just as well. Second, it is clear that from a scientific standpoint some experiments can be performed only on children. This is true for most research on childhood diseases (such as infantile leukemia, cystic fibrosis, chorea) and on certain congenital deformities. The issue must be faced squarely: an outright ban on any research involving children would limit the growth of scientific knowledge concerning these diseases and disorders and thereby adversely affect the development of cures and remedies, so the stakes are considerable.

Everyone agrees that a child is more vulnerable than an adult because it is impossible for him to weigh all the factors that should guide him in making a decision. The same holds true for an adult whose mental faculties are impaired. Whatever solution is chosen, in a society such as ours the law must, because of the possibilities for abuse, provide enhanced protection for its most vulnerable members.

This issue was the subject of a controversy between two American theologians, Ramsey[96] and McCormick.[97] Ramsey opposed any type of non-therapeutic experimentation involving children. He considered children incapable of adhering to the objectives pursued by the researcher. He felt it would be immoral to allow consent by a representative (parent or guardian), since non-therapeutic experimentation could not be of direct benefit to the child. The preservation of the health and enhancement of

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95. See the first report of the Medical Research Council of Canada, *supra*, note 9.

96. P. Ramsey, *The Patient as Person: Explorations in Medical Ethics*, (New Haven: Yale University Press, 1970); "The Enforcement of Morals: Non Therapeutic Research on Children" (1976) 6:4 *Hast. Cent. Rep.* 21; "Children as Research Subjects: A Reply" (1977) 7:2 *Hast. Cent. Rep.* 40.

97. R.A. McCormick, "Proxy Consent in the Experimentation Situation" (1974) 18 *Perspectives in Biology and Medicine* 2; "Experimentation in Children: Sharing in Sociality" (1976) 6:6 *Hast. Cent. Rep.* 41.

the well-being of a child were the only objectives to which a third party could consent on that child's behalf. Since non-therapeutic experimentation serves neither of these purposes, it should be totally prohibited.

McCormick and others[98] replied to this reasoning with two arguments. First, they advanced the notion of social utility. To ban all research involving children would be to condemn other children, since advances in the treatment of childhood diseases would no longer be possible. Second, although consent remains an important and even vital element, it should not necessarily be the one and only factor. Essentially, consent is given to indicate acceptance of the risks inherent in an experiment; the risk factor should thus be the major focus in any debate on the subject. In the name of what principle, it could then be asked, should there be a ban on an experiment of major scientific value and which involves no risk for the child? For those who support the second position, the legality of experimentation on children must therefore be determined primarily in terms of the risk involved in the experiment. Consent in the form of parental permission should continue to be required. However, if the risks involved in an experiment are humanly acceptable, the impossibility of obtaining the subject's own consent should not to be used to justify an absolute ban.

Most of the national and international documents dealing with ethical issues favour the second position. For instance, the Venice amendments to the Helsinki Declaration allow experimentation involving children. Where a child is able to consent, his consent must be obtained, in addition to that of his parents of course. In the United States, the Belmont Commission found non-therapeutic experimentation on children to be legitimate provided that certain conditions were fully met: the experiment cannot be properly performed on any other groups; consent of children over seven has to be obtained; the risk has to be minimal and assessed by an independent ethics committee; and the research has to be of major scientific importance.[99]

Article 20 of the Quebec *Civil Code* expresses an uncommon position. It distinguishes between a minor "capable of discernment" and one who is not. It forbids any experimentation on a child in the second category. However, it does allow experimentation involving children in the first category, on two conditions: first, there must be consent from a person having parental authority, and there must be authorization by a Superior Court judge; and, second, the experiment must not constitute a "serious risk" to the child's health. According to article 20, in the case of a person of legal age the risk must not be "disproportionate to the benefit anticipated." In the case of a minor, there can be no question of an acceptable ratio. Any experiment presenting a *serious* risk is prohibited, even if the risk/benefit ratio is otherwise acceptable.

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98. See B. Freedman, "A Moral Theory of Consent" (1975) 5:4 *Hast. Cent. Rep.* 32; H.K. Beecher, *Research and the Individual: Human Studies* (Boston: Little, Brown, 1970) at 63.

99. National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, *Research Involving Children: Report and Recommendations* (Bethesda, Md.: The Commission, 1977).

This position is considerably relaxed under article 18 of Bill 20,[100] which allows, in principle, experiments on minors under fourteen years of age with the permission of the court and the consent of the person having parental authority. However, the new provisions stipulate that the risk may not be disproportionate to the anticipated benefit and that the refusal of a minor who has reached fourteen years of age precludes experimentation.

In 1978, the first report of the Medical Research Council of Canada[101] included both a majority and a minority position. A majority of the working group was of the opinion that research on children was legitimate, provided that substituted consent was obtained and that the risk/benefit ratio was acceptable. The minority, on the other hand, advocated a total ban on non-therapeutic experimentation on the grounds that when the parent or guardian consents on a child's behalf they are acting as "fiduciaries" and must therefore act in the child's exclusive interest. They should therefore have no authority to consent to an act that is not in his interest. In its second report, the Council reaffirmed the majority position and recognized the legitimacy of experimentation involving children, adding however that the child has to be properly consulted and his opinion taken into account.[102]

In Canada, as elsewhere, there is a tendency to reject a total ban on non-therapeutic experimentation involving children. We believe that this is a reasonable position and that a complete ban is not called for. We also believe that the ethical and legal guarantees proposed in some of the above-mentioned models are highly desirable.

RECOMMENDATION

4. The Commission recommends that the legality of non-therapeutic biomedical experimentation involving children should be recognized in a general federal statute on experimentation, provided that all the following conditions are met:

(a) the research is of major scientific importance and it is not possible to properly conduct it using adult subjects capable of giving consent;

(b) the research is in close, direct relation to infantile diseases or pathologies;

(c) the experiment does not involve any serious risks for the child;

(d) the consent of a person having parental authority and of an independent third party (a judge, an ombudsman or the child's lawyer) is obtained; and

(e) where possible, the consent of the child should be obtained. Moreover, whatever the child's age, his refusal should always be respected.

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100. *Supra*, note 26.

101. *Supra*, note 9.

102. *Supra*, note 9 at 29-30.

III. Those with Mental Disorders

Experimentation on persons with a mental disorder or illness raises problems similar in some respects to those raised by experimentation on prisoners and in other respects to those raised by experimentation on children. In effect, such persons are often not free, and the observations we made in connection with prisoners therefore apply to them. But regardless of whether or not they are confined, their situation resembles that of children in that they are in theory incapable of giving valid consent.

It is therefore not surprising that issues affecting those with mental disorders and children are frequently discussed together, since the principles that apply to the one generally apply to the other.

First, for the same reasons that experimentation on prisoners has been banned, experimentation on confined, mentally disordered people should be banned where the choice of subjects is based solely on grounds of ease of observation and analysis of results.

It should also be pointed out that the mentally disordered do not form as well-defined a group as, for instance, children. It is a very heterogeneous group and includes people who are institutionalized as well as those who are not. If the term mental disorder is taken in a broad sense, the category also includes those in a state of irreversible coma. Finally, mental disorder and mental illness may be temporary or permanent, and can vary greatly in severity, to the extent that one affected person may be absolutely incapable of understanding an experiment and giving his consent, whereas another may have this capability.

Article 11 of the Helsinki Declaration permits experimentation on a mentally disordered person, but requires that person's representative to give consent in accordance with national legislation. The 1977 Hawaii Declaration[103] of the World Psychiatric Association states that only those experiments that contribute to the growth of psychiatric knowledge are permissible. On the other hand, the Council of Europe's Committee of Ministers has taken the opposite position: it wants to see non-therapeutic experimentation on persons with mental disorders banned.[104]

The Belmont Commission in the United States has published a number of recommendations on the subject.[105] They reveal the difficulty the Commission had arriving at a firm position. There were two reasons for this. First, there are no solid, detailed guiding principles in positive law. Second, this kind of experimentation gives

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103. The full text of the Declaration appears in D. Clarence and D. Blomquist "From the Oath of Hippocrates to the Declaration of Hawaï" (1977) 4 *Ethics in Science and Medicine* 139.

104. Rec. No. R-83 (1983).

105. National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, *Research Involving Those Institutionalized as Mentally Infirm: Report and Recommendations* (Bethesda, Md.: The Commission, 1978).

rise to conflicts and ethical difficulties. The Commission finally decided in favour of legalizing experimental research on the mentally disordered, mainly because a complete ban would very probably amount to hindering progress in the fight against mental illnesses and disorders and would destroy the prospects for improving the lot of this segment of the population. The Commission nevertheless rightly observed that historically the most flagrant abuses have been of the mentally disordered and that strong protective mechanisms were in order. In this regard, experimentation should be subject to two basic conditions. First, only minimal risk is acceptable. Second, the subject's approval should be obtained if at all possible, while that of his legal representative should be necessary in all cases. To all intents and purposes, the rules would in fact be the same as those governing research on children.[106]

In France, on the contrary, it appears that all experimentation on mental incompetents of legal age is prohibited on grounds of public policy. A recent case, in which a doctor experimented on persons in a state of brain death, gave rise to a major controversy. The National Ethics Committee, condemned the practice outright on the following grounds.[107] First, it is unethical to subject a sick person to tests not connected with the treatment of his illness. Second, it is impossible to obtain valid consent and, in the Committee's opinion, it would even be illegal to accept the consent of next of kin to legitimize an experiment. In its report mentioned above, the Conseil d'État was in favour of a total ban on non-therapeutic experimentation on the mentally incompetent.[108]

The Medical Research Council of Canada has never taken a clear position on the issue.[109] It points out the need to distinguish legal incapacity from incapacity to consent to a medical act. Just because a person is under guardianship should not mean he should automatically be deprived of the right to express his opinion regarding a medical act, if at the time he possesses the necessary capacity and understanding. Like the French National Ethics Committee, the Council, in view of the *Canadian Charter of Rights and Freedoms*, questions the legality of consent by another in these cases. Can the right to integrity be, in effect, subject to waiver by a third party? The Council seems prepared to acknowledge only research involving no risks, but its position remains unclear.

It is possible to interpret article 20 of the Quebec *Civil Code* as completely excluding the mentally disabled from the class of persons on whom experiments may be performed. In fact, by analogy with minors, it could be argued that experimentation

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106. See G. Schaefer, "Limited Guardianship: Additional Protection for Mentally Disabled Research Subjects Used in Biomedical and Behavioral Research" (1980-81) 16 *The Forum* 796; B. Barber, *Informed Consent in Medical Therapy and Research* (New Jersey: Rutgers University Press, 1980) at 177 ff.

107 Comité national d'éthique, *Avis sur les expérimentations sur des malades en état végétatif chronique*, February 24, 1986.

108. *Supra*, note 52 at 30.

109. *Supra*, note 9 at 30-32.

should be prohibited where a mentally disabled person lacks sufficient discernment, but should be permitted where this is not the case.

In this regard, the provisions of Bill 20 give rise to a problem of interpretation. Article 18 allows experimentation with the permission of the court and the tutor or curator, provided that the risk assumed is not disproportionate to the anticipated benefit. However, article 20 stipulates that the court ruling on the application for permission shall satisfy itself that the experiment is "in the interest of the person concerned," which would limit the scope of article 18 in the case of non-therapeutic experimentation.

With respect to ethical principles, the legal problem is therefore complex. An absolute ban on experimentation involving the mentally deficient can be objected to on the same grounds that we discussed in connection with children: it precludes certain kinds of desirable progress in the treatment of mental illnesses. On the other hand, and again as in the case of children, permitting experimentation with no restrictions requires disregarding the basic condition that consent be obtained, at least where the handicap is such as to deprive the subject of all discernment. As the Cameron affair at McGill University's Allan Memorial Institute[110] clearly shows, abuses are possible and, because the mentally deficient form a more heterogeneous group, they are probably even more vulnerable than children. If law and ethics are to allow experimentation on the mentally deficient, strict requirements must therefore be laid down.

In the Commission's opinion, non-therapeutic biomedical experimentation should be allowed on persons with a mental deficiency, but it should be surrounded with ethical and legal guarantees.

RECOMMENDATION

5. The legality of non-therapeutic biomedical experimentation on mentally deficient persons should be recognized, in a general federal statute on experimentation provided that the following conditions are met:

(a) the research is of major scientific importance and it is not possible to properly conduct it using adult subjects capable of giving consent;

(b) the research is in close, direct relation to the subject's mental illness or deficiency;

(c) the research does not involve any serious risks for the subject;

(d) the consent of the incompetent person's representative and of an independent third party (a judge, an ombudsman or the incompetent person's lawyer) is obtained; and

(e) where possible, the incompetent person's consent is to be obtained, and his refusal is always to be respected.

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110. *Supra*, note 4.

IV. Embryos and Foetuses

The ethical and legal issues raised by research on embryos and foetuses are extremely complex, and as likely as not to provoke highly emotional responses because they are linked to the controversy surrounding abortion and each person's own position on the subject. Moreover, experimentation on embryos and foetuses touches on a very difficult philosophical, theological and ethical problem: the beginning of human life.[111] At what moment in the development of the product of conception are we dealing with a human being or a human person? What value should society place on embryonic and foetal life?

The Law Reform Commission, in Working Paper 58, *Crimes Against the Foetus*,[112] defined the term foetus as "the product of a union in the womb of human sperm cells and egg cells at all stages of its life prior to becoming a person"[113]: the term does not therefore include embryos fertilized *ex utero*. This is the meaning the word will have here.

Historically, experimentation began on the foetus. According to a special report of the Belmont Commission, it has taken four main directions.[114] First, research on the physiology and development of foetal tissue, hence on the growth of the foetus. Second, research relating to the diagnosis and detection of foetal diseases and congenital deformities. Third, some research has been done on foetal therapy and pharmacology, in particular on the possible effects of certain medications. This type of research, it should be said, is mainly retrospective and based on observation of aborted foetuses. It is this type of research that led to the discovery that the German measles vaccine could penetrate the placental barrier in women and have a teratological effect on the foetus, which was not the case with monkeys. Finally, there is research on foetuses that are not viable outside the womb, to determine whether they can be saved by somehow reproducing the uterine environment. This research has sometimes been described in layman's terms as the creation of an "artificial womb." As well, recent developments in France and the United States include experiments using the thymus glands of dead foetuses to produce a growth hormone, and those using foetal tissue to research the etiology of cancer.

Directly connected with the problem of experimentation on foetuses is the use of tissues from dead foetuses for the treatment of some diseases. Some current research offers hope that the implantation in the brain of certain foetal tissues or substances could have curative properties in the case of, for instance, Alzheimer's disease and

111. M. Rivet, "Le droit à la vie ou l'hominisation du XXI[e] siècle: l'éthique et le droit répondant à la science," in D. Turp and G.A. Beaudoin, eds., *Perspectives canadiennes et européennes des droits de la personne* (Cowansville, Que.: Yvon Blais, 1986) at 445.

112. *Supra*, note 6.

113. *Supra*, note 6 at 52.

114. National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, *Research on the Fetus: Report and Recommendations* (Bethesda, Md.: The Commission, 1975).

Parkinson's disease. It should be noted in this connection that in principle these bodily substances are taken only from dead foetuses and that in strictly legal terms the taking of tissue from corpses is already regulated. From an ethical standpoint, however, there are those who object to the practice for a number of reasons. First, there is the connection with abortion, around which, as we know, there is nothing resembling a social consensus. Second, some fear that society will come to close its eyes to the production of foetuses solely for tissues and substances. The problem is complex and will not be dealt with here since it is, strictly speaking, outside the bounds of biomedical experimentation.

In addition to the above, research is also being done on *in vitro* fertilization techniques using embryos a few days old. Not every embryo formed as a result of *in vitro* fertilization is necessarily reimplanted. The ethical and legal problems posed by surplus embryos are complex. May they be frozen? Destroyed? Experimented on? The situation of the embryo is in fact different from that of the foetus. It should be remembered that at a few days old the embryo consists of just a few undifferentiated cells. Although it possesses life, it is not viable and, because of the total absence of even a primitive nervous system, it cannot feel any pain. Embryo research is also of real interest, making possible a better understanding of the very process of the creation and development of human life. It has important consequences for embryo conservation and freezing techniques as well as for the development of artificial reproductive technologies. Finally, with regard to genetic research, it makes possible the hope that one day ways will be found to repair the errors of nature and to correct genetic deficiencies in as yet unborn infants. This set of problems has given rise to a number of studies.[115]

A. Foreign Legislation

A brief comparative survey shows that most countries look unfavourably on non-therapeutic experimentation on embryos and foetuses. Some American states[116] ban it completely, even though federal regulations allow it under certain conditions.[117]

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115. For Britain, see *inter alia, Report of the Committee of Inquiry into Human Fertilization and Embryology, supra*, note 57.

For the Federal Republic of Germany, see the report of the Benda Commission, *supra*, note 53.

For Australia, see the *Report on the Disposition of Embryos Produced by In Vitro Fertilization, supra*, note 58; *Report of the Special Committee Appointed by the Queensland Government Inquiry into the Laws Relating to Artificial Insemination, In Vitro Fertilization and Other Matters*, 1984; *South Australia Report on Artificial Insemination and Related Matters*, 1984.

For France, see *Sciences de la vie: de l'éthique au droit, supra*, note 52.

For Canada, Ontario Law Reform Commission, *Report on Human Artificial Reproduction and Related Matters, supra*, note 59, vol. II, Recommendation 31 at 281; Medical Research Council of Canada, *supra*, note 9 at 32-35; Barreau du Québec, *Les enjeux éthiques et juridiques des nouvelles technologies de reproduction* (Montreal, 1988).

116. For example, Minnesota: Min. Stat. Ann. 145-422(1) New Mexico: N. Mex. Stat. Ann. ss. 24-9-A-1; Louisiana: Rev. Stat. Lsa., Civil Code – Ancillaries, § 9 : 122.

117. Code of Federal Regulations, Title 45, Part 46 (1975), revised 1983.

In France, apparently only therapeutic experimentation in line with research on the birth and development of normal foetuses is allowed. In 1986 the National Ethics Committee[118] proposed a three-year moratorium on some categories of research, the goal of which is to develop genetic diagnosis procedures before implantation. This moratorium is not legally binding but has undoubted moral force because of the Committee's prestige.

The report of the Conseil d'État also deals with the question at length. In line with an international consensus on the issue, it clearly forbids certain types of research (modification of genomes, cloning, ectogenesis, parthenogenesis). It prohibits removal or production of embryos solely for research purposes and subjects experimentation to stringent basic requirements: consent of both parents, authorization by the National Ethics Committee and absolute ban beyond a fourteen-day limit.[119] The Law of 20 December 1988 is silent on the matter.

The Council of Europe is currently contemplating the adoption of a set of regulatory provisions dealing with the issue as a whole.[120] It is likely that within a few years the various European countries will agree on a common policy and thereby avoid unduly large differences among their respective scientific communities. In 1987, Denmark banned all forms of experimentation on embryos and foetuses until the relevant public body has drawn up clear standards.[121] In England, the Warnock Report[122] contains a series of proposals concerning experimentation on embryos in the context of new reproductive technologies.

In Canada, the Ontario Law Reform Commission has studied the problem and made certain recommendations.[123] It is of the opinion that research on fertilized ova should be allowed under certain strict conditions. These are: prior approval of the research protocol by the relevant authorities, examination of the protocol by an independent ethics committee and that experimentation be limited to a fourteen-day period.

The Medical Research Council of Canada considers that an absolute ban on embryo and foetal research is unjustifiable and that it should be allowed under certain conditions. It sets a limit between the 14th and 17th days of development, beyond

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118. Comité national d'éthique, opinion of December 16, 1986.

119. *Supra*, note 54 at 89.

120. Recommendation 1046 (1986) concerning the use of human embryos and foetuses for diagnostic, therapeutic, scientific, industrial and commercial purposes, 18th session, September 24, 1986.

121. See the bill entitled [TRANSLATION] "An Act to Set up an Ethics Committee and to Regulate Certain Aspects of Biomedical Research," Bill No. 76, May 22, 1987.

122. *Supra*, note 57. See also *Report on Human Fertilization and Embryology: A Framework for Legislation* (London: HMSO, 1987).

123. *Supra*, note 59.

which experimentation on embryos may not be carried out, and recommends a ban on the production of embryos solely for purposes of scientific research.[124]

Australia has often been a pioneer in the area of new reproductive technologies. It is therefore not surprising that several reports have been drawn up that together constitute a code of ethics for Australian researchers.[125] The State of Victoria was the first to pass legislation dealing specifically with new reproductive technologies, legislation that contains a number of provisions concerning experimentation.[126] Again embryo and foetal research is allowed, provided that stringent conditions are met.

B. General Principles Governing Experimentation on Embryos and Foetuses

The Commission is of the opinion that any policy in the area of non-therapeutic biomedical experimentation should have to comply with certain fundamental principles. The first is respect for all forms of human life, whatever its stage of development. The rules governing experimentation should therefore also reflect respect for the sanctity of human life from its beginnings.

Second, the law should never treat embryos and foetuses as mere objects. Accordingly, their commercialization or the commercialization of research on them should be strictly prohibited, although this prohibition should clearly not extend to the use of embryonic or foetal tissue for therapeutic purposes.

Third, it seems clearly unethical to allow the creation of embryos solely for experimental purposes. In other words, only surplus embryos conceived in connection with an *in vitro* fertilization program and not reimplanted should be used in experiments rather than simply be destroyed. We will return to this question below.

Fourth, the Commission is of the opinion that, with respect to experimentation on foetuses, research policy should be clearly dissociated from abortion policy. A woman's right to have an abortion and her decision to do so does not necessarily mean that science may freely dispose of the aborted foetus. Consequently, the prospect of abortion should not affect the criteria determining the admissibility and legitimacy of research. However, if an experiment has been found to be ethically acceptable for foetuses in general, it seems legitmate to prefer to conduct it on a foetus to be aborted rather than on one intended to be brought to term, since this would decrease the risks even further.

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124. *Supra*, note 9 at 33-35.

125. *Supra*, note 115.

126. *Infertility (Medical Procedures) Act*, 1984, No. 10163.

Fifth, the Commission considers it important that permissible types of research be strictly defined. Like many others, the Commission is of the opinion that some experiments should by their very nature be considered unethical and contrary to public policy.

It is important to establish controls for monitoring embryo and foetal research. Within the broad framework established by legislation, there should be provision for ensuring that research is ethical before it is undertaken. It is also necessary to ensure that it remains ethical during the period of experimentation and, once the experimentation has been completed, to ascertain the ethical value of the lessons to be learned for the future. The Commission is of the opinion that peer review is absolutely indispensable, as being the only way of properly evaluating the scientific aspects of a protocol and ensuring that it is ethical. It is also of the opinion that the ethics committees that presently approve research would do well both to include members from other disciplines (ethicists and jurists) and to play a wider role. In effect, in most cases these committees now do nothing more than accept or reject protocols. Once they approve an experiment because they consider it ethical, they have no authority to monitor it.

Finally, there is the question of the consent of parents to do research on their embryos or foetuses. The issue is even more sensitive when the foetus is in the womb, but the problem remains the same.

With respect to the question of consent, one thing is clear from the outset: no experiments should be allowed on a foetus *in utero* without the mother's free and informed consent. But is it useful, necessary or even desirable to obtain the father's consent as well? Three positions are possible. According to the first, the mother's consent should be sufficient, since she is in the best possible position to make an informed decision, and requiring the father's consent could be perceived as an undue restriction on the woman's rights over her own body.

The second position is to the opposite effect: non-therapeutic experimentation is purely elective and the child to be born is also the father's child. Requiring his consent is considered as providing additional protection.

Finally, there are some who, arguing that it is sometimes difficult if not impossible to identify the father, consider that where he is known, the mother's consent should still suffice unless he objects to the experiment.

Upon consideration, the Commission is of the opinion that the consent of both parents should be necessary. It seems important, on the one hand, to underline the fact that a child has two parents and hence to grant the father the right of refusal and, on the other hand, to respect his moral, religious or personal reasons for withholding consent. We would also extend this rule to experimentation on embryos since the underlying reasoning applies in that case as well.

RECOMMENDATION

6. Non-therapeutic biomedical experimentation on embryos and foetuses should be recognized, in a general federal statute on experimentation, provided that all the following conditions are met:

(a) the experimentation has received the prior approval of a multidisciplinary ethics committee responsible for ensuring that the research is ethical and scientifically genuine and having direct authority to monitor and control it;

(b) the embryo or foetal research is carried out in centres or hospitals recognized by the appropriate public authorities; and

(c) the consent of both parents of the embryo or foetus has been obtained.

C. The Differences between the Embryo and the Foetus

From a biological standpoint, there are differences between an embryo and a foetus. It is known that, in the current state of science, the embryo cannot continue to develop outside the womb beyond a certain period of time. On the other hand, the development of the foetus is a slow process ending in the birth of a person: at a certain point, the foetus is endowed with nervous perception; at another, the foetus is viable even if expelled from its mother's body. For this reason, it seems to us essential to distinguish between these two stages in the development of the product of conception, each of which gives rise to different scientific, ethical and legal questions despite their undeniable common denominator: the existence of a potential human being.

1. Experimentation on Embryos

As we mentioned above, embryo research (we are speaking here of embryos fertilized *ex utero*: see the definition of the foetus given above) is currently being carried out on embryos produced by *in vitro* fertilization as a solution to the problem of sterility and which end up not being reimplanted. What might come to mind here is, of course, the deliberate creation of embryos solely for purposes of scientific research, something that will be that much easier when science discovers how to freeze oocytes. Researchers with frozen sperm and oocyte banks at their disposal will in theory no longer have to rely on the therapeutic process of *in vitro* fertilization for a supply of embryos. However, for the time being most jurists and ethicists look askance at the production of embryos for purely experimental purposes. They consider it to be in conflict with the respect due to human life even in a primitive state. The situation is not the same with respect to surplus embryos. There are three possibilities for embryos that are not reimplanted in the woman who provided the oocyte required for their creation: they could be destroyed, donated to another sterile couple or, before being destroyed, be used for research. The Commission is of the view that, if circumstances do not permit donation, experimentation to advance knowledge seems to be preferable to outright destruction.

RECOMMENDATION

7. (1) The creation of embryos solely for purposes of scientific research should be prohibited and punished as a criminal offence.

The fate of the embryo that has been used for experimental purposes poses another problem. As we will see further on, the current international consensus is that the period during which research may be carried out should be limited (to fourteen days, generally speaking). Furthermore, the Commission agrees with the unanimous opinion of medical and legal authorities that embryos that have already been used for experimental purposes should not be reimplanted in a woman. The risk that such experimentation would leave traces is indeed too great.

RECOMMENDATION

7. (2) The re-implantation of embryos that have been used for experimental purposes should be prohibited and subject to criminal penalty.

Let us now return to the main problems raised by embryo research. The first question is to determine how standards relating to embryo experimentation should be defined by law. The view of the Commission is that not all types of research on embryos should be permitted. Moreover, the scientific community itself disapproves of certain types of research, and in this it has the support of ethicists and of all the governmental and quasi-governmental reports on the subject. Among these types of research are cloning, ectogenesis, parthenogenesis, and the crossing of human and animal gametes. The Commission shares this point of view and considers that certain types of research on embryos should be prohibited and criminally punished. A description and a complete list of them should be drawn up in consultation with the scientific community.

RECOMMENDATION

7. (3) Certain types of experimentation on embryos, in particular cloning, ectogenesis, parthenogenesis, and the crossing of human and animal gametes, should be prohibited by criminal law; a complete list of types of experiment should be drawn up after consultation with scientific authorities.

The second question involves determining until what point *in vitro* research on embryos is ethically acceptable. Currently there is some international consensus that a limit of fourteen (sometimes seventeen) days should be imposed. In scientific terms the figure is, of course, arbitrary, but a number of reasons can be put forward to justify it. To begin with, after fourteen days of cellular development the embryo *ex utero* cannot be reimplanted. Furthermore, it is at this point that it becomes known if the embryo is

going to twin. Finally, it is towards the fourteenth or even the seventeenth day that the neural tube, that is to say the central nervous system, begins to develop.

While we are aware that this fourteen-day limit is arbitrary the Commission nevertheless considers that, given the current state of knowledge, it is appropriate to agree to a standard that enjoys broad international support, if only to ensure that research done in Canada will be as respected as that done in the rest of the world.

RECOMMENDATION

8. (1) Experimentation on embryos should be prohibited after the fourteenth day of embryonic development.

Like sperm, the human embryo may be frozen. Medical science has already produced living children from embryos that had been frozen. However, freezing raises certain problems. First, science does not yet really know what the effects of prolonged freezing are. Second, if freezing extends over a long period of time, the very principle of generations may be disrupted: think of the prospect — science fiction for the time being, but already theoretically possible — of the reimplantation some fifty years hence of an embryo created in 1989. Such difficulties have prompted most countries to impose time limits on freezing. Given the current state of knowledge, these limits are of course completely arbitrary. However, a figure of five years seems to meet with more or less general approval. The Commission agrees with this position.

RECOMMENDATION

8. (2) The freezing of embryos should be allowed, but it should not be prolonged for more than five years.

Gametes and human embryos cannot be considered to be simple cells or simple tissues. The first are the virtual sources of new human life; the second already have life. Furthermore, the development of new reproductive technologies gives rise to a host of problems concerning control of sperm and embryo banks, their management and accessibility, and the ethical and legal responsibilities connected with them. Canadian authorities have long been aware of these problems. Indeed, as early as 1981 an advisory committee submitted to the Minister of National Health and Welfare a report on the storage and use of human sperm.[127] The report contained a series of recommendations, some of which are now out of date but others of which are still relevant. The Commission is of the opinion that new recommendations concerning not

127. *Report of the Advisory Committee on the Storage and Utilization of Human Sperm to the Minister of National Health and Welfare* (Ottawa: Health and Welfare Canada, 1981).

only sperm banks but embryo banks as well should be drawn up, so as to establish clear and precise standards, and guard against the drawbacks and dangers of uncontrolled expansion and commercialization of such banks.

RECOMMENDATION

8. (3) Standards should be developed for the creation, expansion and management of sperm and embryo banks.

2. Experimentation on Foetuses

Non-therapeutic biomedical experimentation on foetuses also raises sensitive questions. Some criteria are the same as for experimentation on embryos (authorization by an ethics committee, prior approval of the team or centre, the impossibility of obtaining the same results by experimentation on animals or adults, consent of both parents). But the foetus also poses a special problem that should be dealt with in somewhat more detail.

Experimentation on the foetus may take place either inside or outside the mother's womb. In *ex utero* experimentation, a new factor comes into play: either the foetus is dead or doomed because nonviable, or else it is viable. In the case of an already dead foetus, experiments are presently limited to the taking of foetal tissue. As we have seen, the law requires various kinds of authorization. If on the other hand the foetus is viable, from both a legal and ethical standpoint it must be treated as a human being with all the rights of a person.

In effect, a foetus that has proceeded completely and permanently from its mother's body becomes a "person" as defined in the Law Reform Commission's proposed new Criminal Code. In this connection, the reader is referred to Working Paper 58, *Crimes Against the Foetus*.[128] Therefore the conditions set out above in the case of experimentation involving children apply.

Unlike the embryo, which is to be destroyed in any event, a foetus inside the womb raises the question of whether the risks are proportionate to the expected benefits. As we have seen, in the case of competent adults the law requires that there be no serious risk to life or health. Naturally, this requirement should continue to apply to the mother whose body is subjected, even indirectly, to an experiment that primarily concerns the foetus. That said, the Commission considers that when it is impossible for experimental subjects themselves to give consent, they should be provided with additional protection. For children and the incompetent, the Commission recommended that experimentation be allowed where it did not involve serious risk. Since the whole life, integrity and health of the unborn child can be compromised by experimentation

128. *Supra*, note 6 at 51.

on the foetus, the Commission considers acceptable only those experiments involving no risk or only minimal risk, this being defined as a risk normally associated with pregnancy.

RECOMMENDATION

9. The only experiments on the foetus that should be considered acceptable are those involving no risk or only minimal risk, this being defined as a risk normally associated with pregnancy.

CHAPTER FOUR

Conclusions

This paper reflects the complexity of the questions raised by non-therapeutic biomedical experimentation involving human subjects, and shows that a strictly legal analysis cannot hope to resolve them. A multidisciplinary approach involving law, ethics and medical science is required. However, it is for the law, in the form of legislation, regulations and judgments, to set the limits of what is socially acceptable in this area. This is a public responsibility that the state may not evade. Despite the integrity and keen professional sense of Canadian researchers, human experimentation cannot be viewed as a purely medical question in which the law has no role to play.

It is possible to contemplate, and some in fact advocate, the law intervening only where the limits of what is permissible have been overstepped. It would be sufficient to include in the Commission's proposed new Criminal Code a provision decriminalizing what would otherwise constitute a crime against the person. As we have already mentioned, the Commission has recommended adoption of the following provisions:[129]

7(2) Assault by Harming. Everyone commits a crime who harms another person:

(a) purposely;

(b) recklessly; or

(c) through negligence.

7(3)(a) Medical Treatment. Clauses 7(2)(a) and 7(2)(b) do not apply to the administration of treatment with the patient's informed consent for therapeutic purposes, or for purposes of medical research, involving risk of harm not disproportionate to the expected benefits.

However, as we have also explained, to clear up any possible ambiguity the last paragraph should be changed to read as follows:

(a) Medical Procedure. Clauses 7(2)(a) and 7(2)(b) do not apply to medical procedures performed with the subject's free and informed consent, for therapeutic purposes or for the purposes of scientific experimentation, where the risks involved are not disproportionate to the expected benefits.

These provisions nevertheless remain very general. Although they protect the individual against the most glaring abuses (for example, against experiments that involve a serious risk to life or health, or against tests conducted on a person without his free and informed consent), they by no means define the legal framework governing

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129. *Supra*, note 7, recommendation 7(3) at 62.

experimentation, the types of subjects that may be used, or the special conditions that should be imposed to protect certain categories of vulnerable subjects.

Of course it could be maintained that this is not within the role of criminal law, which is to protect the fundamental values of society. Its purpose is simply to foster a climate of social harmony that favours the development of the full potential of all citizens, and to correct and punish unacceptable abuses. Its role is not to regulate the public's conduct down to the last detail, nor to regulate an entire sector of lawful activity such as medical research and experimentation. It would thus be unrealistic to suppose that the *Criminal Code* could contain such detailed regulation as that enacted by the United States, for example, in the *Code of Federal Regulations for the Protection of Human Subjects*.[130]

In other words, the *Criminal Code* should continue, through the provisions that define offences against the person, to protect such basic values as integrity of the person, the right to self-determination, and the requirement that consent to an experiment be free and informed. However, its role is not to define the composition of ethics committees or the conditions under which research on children or embryos may be conducted. In the Commission's opinion, there is therefore no need to add detailed experimentation regulations to the *Code*. The provision proposed above appears to be sufficient to provide a general framework, which is all the criminal law is expected to do.

But does this mean that federal legislation should stop there? Some maintain that the law has no place in this area, at least not yet; that it should leave the task of developing rules to medical ethics; that it is only when these ethical rules have taken concrete form and there is consensus that it will be possible to give them legislative form. These issues, it is argued, and not without reason, are controversial. They say that to provide statutory regulation now could adversely affect research freedom, that Canadian researchers are responsible people and that the law can and should have confidence in them.

The Commission does not share this way of looking at things. First of all, legislative intervention does not mean that society mistrusts its researchers or that it wishes to stop scientific development. To legislate means something else entirely. Where the integrity of the person can legally be endangered, it seems important that limits and rules be clearly defined. It is up to the law to protect basic values, and it cannot and must not leave this role to ethics. Moreover, and contrary to what one might think, there are many researchers nowadays who would like to have a clear idea of what may legally be done and what should be prohibited. There are also many who consider that the rules and the parameters within which they are to work should be defined so as to indicate what limits are to be observed.

It should also be borne in mind that the protection of rights and of the bodily and psychological integrity of some classes of subjects (foetuses, children, the mentally

130. *Supra*, note 117.

incompetent, prisoners) is guaranteed by the Canadian Constitution and the *Charter of Rights and Freedoms*. In the Commission's opinion, it is not necessarily desirable to wait for an accident or a manifest abuse and then have the courts, in a decision like that in *Morgentaler*,[131] indicate to Parliament what it should have done. The fact that there could be discrimination is also very important. In a country like Canada, it seems to us essential that there be consistency of thought and action on an issue of such importance. To take a hypothetical example, it would seem to us highly unfortunate were there to be a great deal of experimentation on foetuses or the mentally deficient in one province while a neighbouring province banned it.

Finally, as this paper will have made clear, two very important facts emerge from a consideration of the international situation. First, especially for the past few years, there has been a considerable effort to establish standards for experimentation involving human subjects. Second, many countries have either already passed legislation dealing with all or part of this issue or else have begun the process that will lead to legislation: examples are Great Britain, the Netherlands, Spain, France, the Federal Republic of Germany, Australia, the United States, Switzerland, and the Scandinavian countries, Denmark in particular.

The Commission therefore considers that, in addition to the general provisions on the subject included in its proposed new Criminal Code, Parliament should enact general legislation on non-therapeutic biomedical experimentation that would also prescribe penalties.

Moreover, some kinds of experimentation on embryos are so reprehensible as to seem to us to warrant criminal penalties. Thus, the criminal law should punish such experiments as the production of embryos for research purposes, reimplantation of embryos that have been used for experimental purposes, cloning, ectogenesis, parthenogenesis, and the crossing of human and animal gametes.

131. *R.* v. *Morgentaler*, [1988] 1 S.C.R. 30.

CHAPTER FIVE

Summary of Recommendations

1. (1) Non-therapeutic biomedical experimentation should be considered legal and permissible under the criminal law where:

(a) the subject's free and informed consent has been properly obtained; and

(b) there is an acceptable ratio between the risks incurred by the subject and the benefits expected to result from the experiment.

(2) Experimentation should be considered legal, even where the subject has been deceived, where:

(a) there are no other means of achieving the research goal;

(b) the experimentation involves no risk to the subject;

(c) no information is withheld which could cause the subject to refuse to participate;

(d) the research is of major scientific value; and

(e) it is possible to debrief the subjects and inform them why deception was necessary once the research has been completed.

2. The *Criminal Code* should be amended by the addition of a provision which excludes from offences against bodily integrity those cases of non-therapeutic biomedical experimentation in which free and informed consent is properly obtained and the risks incurred are not disproportionate to expected benefits.

3. Clause 7(3)(a) of the Commission's Report 31, *Recodifying Criminal Law, Revised and Enlarged Edition*, should be amended to read as follows:

7(3) Exceptions.

(a) Medical Procedure. Clauses 7(2)(a) and 7(2)(b) do not apply to medical procedures performed with the subject's free and informed consent, for therapeutic purposes or for the purposes of scientific experimentation, where the risks involved are not disproportionate to the expected benefits.

4. The Commission recommends that the legality of non-therapeutic biomedical experimentation involving children should be recognized in a general

federal statute on experimentation provided that all the following conditions are met:

(a) the research is of major scientific importance and it is not possible to properly conduct it using adult subjects capable of giving consent;

(b) the research is in close, direct relation to infantile diseases or pathologies;

(c) the experiment does not involve any serious risks for the child;

(d) the consent of a person having parental authority and of an independent third party (a judge, an ombudsman or the child's lawyer) is obtained; and

(e) where possible, the consent of the child should be obtained. Moreover, whatever the child's age, his refusal should always be respected.

5. The legality of non-therapeutic biomedical experimentation on mentally deficient persons should be recognized, in a general federal statute on experimentation, provided that the following conditions are met:

(a) the research is of major scientific importance and it is not possible to properly conduct it using adult subjects capable of giving consent;

(b) the research is in close, direct relation to the subject's mental illness or deficiency;

(c) the research does not involve any serious risks for the subject;

(d) the consent of the incompetent person's representative and of an independent third party (a judge, an ombudsman or the incompetent person's lawyer) is obtained; and

(e) where possible, the incompetent person's consent is to be obtained, and his refusal is always to be respected.

6. Non-therapeutic biomedical experimentation on embryos and foetuses should be recognized, in a general federal statute on experimentation, provided that all the following conditions are met:

(a) the experimentation has received the prior approval of a multidisciplinary ethics committee responsible for ensuring that the research is ethical and scientifically genuine and having direct authority to monitor and control it;

(b) the embryo or foetal research is carried out in centres or hospitals recognized by the appropriate public authorities; and

(c) the consent of both parents of the embryo or foetus has been obtained.

7. (1) The creation of embryos solely for purposes of scientific research should be prohibited and punished as a criminal offence.

(2) The re-implantation of embryos that have been used for experimental purposes should be prohibited and subject to criminal penalty.

(3) Certain types of experimentation on embryos, in particular cloning, ectogenesis, parthenogenesis, and the crossing of human and animal gametes,

should be prohibited by criminal law; a complete list of types of experiment should be drawn up after consultation with scientific authorities.

8. (1) Experimentation on embryos should be prohibited after the fourteenth day of embryonic development.

(2) The freezing of embryos should be allowed, but that it should not be prolonged for more than five years.

(3) Standards should be developed for the creation, expansion and management of sperm and embryo banks.

9. The only experiments on the foetus that should be considered acceptable are those involving no risk or only minimal risk, this being defined as a risk normally associated with pregnancy.

DISSENT RESPECTING EXPERIMENTATION ON HUMAN EMBRYOS

Joseph Maingot, Q.C., Commissioner

Whether human life is formed in the womb or in a petri dish through the technique of *in vitro* fertilization, to intentionally cause the death of an embryonic human life remains unacceptable. The technologically aided production of human embryos cannot be faulted where they are used to induce pregnancy. However, consistent with the dissent in Working Paper 58,[1] the production of more human embryos than will actually be introduced into the uterus for the treatment of infertility is, in my view, unacceptable. To create surplus embryos which may simply be discarded, or experimented upon and then discarded, constitutes disregard for human life.

The majority states that any policy in this area should be based on respect for certain fundamental principles. One is respect for all forms of human life whatever its stage of development. It goes on to say that rules of experimentation should reflect the sacred character of human life from its beginning. This respect, however, is not manifested by permitting the production of surplus human embryos nor by their use for experimentation and their eventual destruction.

1. LRC, *Crimes Against the Foetus* [Working Paper 58] (Ottawa: LRC, 1989).

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