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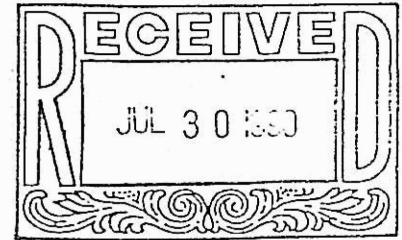
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July 26, 1990



Mr. Ron Shulman
Thomas R. Berger
Barrister & Solicitor
Suite 300 - 171 Water Street
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Dear Mr. Shulman:

On the basis of the factum in the case of:

LINDA MACDONALD V. HER MAJESTY THE QUEEN

with which you have provided me, and on the basis of my experience as a medical ethicist, I am able to respond to your request for an opinion anent the ethical acceptability of the procedures performed on Linda MacDonald by Dr. E. Cameron as follows:

1. Fact of research/experimentation

I am of the opinion that from the perspective of medical ethics, the procedures to which Dr. Cameron subjected Linda MacDonald were experimental in nature even by the standards of the 1950's and 1960's. I say this because the procedures were acknowledged to be non-standard procedures with essentially undefined parameters, where the purpose of engaging in the procedures was inter alia to gather data and to refine the parameters themselves.¹ According to the usual understanding of the term, this constitutes research or experimentation. This understanding of the terms was current even at the time that Dr. Cameron was working in this area, and was so

¹ See Application by Dr. MacDonald, Tab 14. See also the evaluation by Dr. Lowy [Tab 11, at 5]:

There can be no doubt that ... Cameron's extreme experimental treatments were misguided (emphasis added) ... The treatments in question are primarily the following:

1. "Depatterning".
2. Powerful psychoactive disinhibiting drugs...
3. "Psychic Driving" ...

the evidence by Dr. Termansen, (Tab 12 at 152); the evidence of Dr. Doyle, (Tab 15, at 3); the affidavit of Dr. Joseph, (Tab 16, at 1); the affidavit of Dr. Weinstein (Tab 21, at 14); the affidavit of Dr. Salzman (Tab 22, at 1); the affidavit of Dr. Lifton (Tab 23, at 3 ff.); the general affidavit of Dr. Rothman (Tab 25).

widespread that it found reflection even on the international scene. This is attested to by the fact that the Public Health Council of the Netherlands defined human experimentation in 1955 as any "intervention in the psychic and/or somatic integrity of man which exceeds in nature or extent those in common practice. ["Report on Human Experimentation," Public Health Council of the Netherlands (Minister of Social Affairs and Health)]. Not that Dr. Cameron would necessarily have had access to, or even have been aware of, this particular document. However, as I said, this document reflects what was current opinion all over the world at this time about what constitutes experimentation.

However, even aside from any question of whether Dr. Cameron was aware of this definition, or should have been aware of it, or whether it reflected generally accepted medical understanding of the matter, in my opinion there is good evidence to show that Dr. Cameron himself saw his procedures as experimental in nature. At Tab 14, there is a copy of an application by Dr. Cameron entitled "Application for Grant", dated in the year 1957. I have lectured and taught at several North American Universities since 1968 both in the US and Canada (among others, the University of California, Irvine; the University of Victoria and the University of British Columbia) and have sat on Review Committees and Advisory Committees. On the basis of this I can say that Applications for Grants are not made to engage in a procedure which is well-established or accepted. They are made only in the context of research or experimentation. The procedures outlined in this application by Dr. Cameron therefore can be classified as experimental even according to his own understanding of the term. Otherwise he would not have made an application for a grant to defray the expenses involved in conducting them. They would have been funded by otherwise appropriate methods of defraying the costs incurred in the course of therapy. The procedures referred to in this application appear to be essentially those involved in the treatment of Linda MacDonald.

Of course it could be said that when Dr. E. Cameron applied these procedures to Linda MacDonald they were not longer experimental. However, the testimony of Dr. Lowy, Dr. Lifton, Dr. Rothman, et al. leads me to believe that this was not the case.² I must defer to their judgement.

2. Therapeutic v. Non-Therapeutic Experimentation

Medical ethics draws, and has always drawn, a distinction between therapeutic and non-therapeutic experimentation. While the distinction has not always been stated very clearly, it was certainly well established by the early 1960's. Therapeutic experimentation is the engaging in experimental or research procedures, regimens or undertakings that are intended to benefit the patient and where there is good evidence that these procedures,

² See note 1, supra.

regimens or undertakings will benefit the patient to a degree that is greater than the standard accepted approach. Anything else is, and has been, considered non-therapeutic experimentation. That understanding was in existence at the time that Dr. Cameron worked at Allen Memorial.

I can only conclude from the evidence that Linda MacDonald was being subjected to non-therapeutic experimentation in the traditional and by then well-established sense of the term.

However, even if it should be argued that the experimentation was therapeutic, the fact remains that proper informed consent should have been had from the patient. Alternatively, if the patient was not competent to give it, it should have been had from another appropriate proxy decision-maker. This is well established by the Codes of Ethics that were then in existence, both nationally and internationally.

3. Codes of Ethics

(a) national

The Code of Ethics of the Canadian Medical Association of 1945, and its reformulation of 1956 and 1961 (which, I believe, covers the time-frame in question) attest to the fact that it was a standard of medical ethics that patients should give informed consent to medical or other procedures. While this standard was frequently honoured more in the breach than in the observance, and while the precise nature which such informed consent should take had not as yet been spelled out in legal terms, as it was later in Reibl v. Hughes and Hopp v. Lepp, the fact remains that it was part of the then Codes.

Furthermore, it was clear even at that time that the distinction between therapy and experimentation or research ought never to be blurred, and that in any case informed consent was absolutely essential. I see the decision in Halushka not as introducing something new, but as a Canadian reflection of what had been part of internationally accepted medical ethics since at least the 1930's.

The Code of Ethics of the Canadian Medical Association of 1945 also states (at 26) that "For the honourable physician the first consideration will always be the welfare of the patient" and that there is an obligation "to give his patients ... the best treatment possible in the circumstances." (Idem.) It seems to me that the letter of Dr. Lowy and the letters of the other physicians indicate very clearly that Dr. Cameron's treatment was not the best that was available at the time. Consequently, it seems to me, he was in breach of this clause of the CMA Code by which, as a physician practising in Canada, he was bound.

The Code of 1956 (reaffirmed in 1961) also states that: (at 27)

When the propriety of performing an operation or of adopting a course of treatment may entail considerable risk to the life, activities or capacities of the patient [consultation with colleagues] has to be considered, and particularly when the condition which it is sought to relieve by this treatment is in itself not dangerous to life.

It is my impression that this was not followed in the present case.

Furthermore, the Code of Ethics of the Canadian Medical Association of 1922 already contained a duty to report to the Committee on Ethics of the Local Medical Society any difference of opinion in fundamental matters such as this. (Code of 1922, at 9.) Again, it is my impression that this did not happen in the case of Linda MacDonald. One might reasonably conclude from this that those physicians who were involved in the experiments, were of the opinion that they were inappropriate, and did not report it, were in contravention of this requirement.

(b) international

As several witnesses have pointed out, experimental, heroic and otherwise unusual procedures were seen to be ethically quite special since before the turn of the century. Closer to our time, the matter was restated formally by the Judicial Council of the American Medical Association in 1946, when it set up three requirements that an experiment on human subjects would have to meet, whether it was therapeutic or not:

1. voluntary consent of the person on whom the experiment was to be performed;
2. the dangers inherent in or associated with the experiment would have to have been investigated previously by animal experimentation; and
3. the experiment would have to be performed under proper medical protection of the subject and with proper management.

To the best of my understanding, and based on the data available to me, these conditions were not met in the case at issue. There was no voluntary consent to the particular enterprise in question; the dangers had not been investigated in animal models; and the management contravened the condition of proper medical management and protection. While the second condition may have been irrelevant in light of the psychiatric nature of the case, the first and third requirement were of the essence. In this regard, it seems to me that Dr. Termansen's statement that (Tab 7, at 2)

Dr. Cameron and his associates had not conducted such a follow-up study of the effects of "depatterning" procedures...

can only be interpreted as lack of proper scientific and medical management even for that time.

Of course I am especially concerned about lack of appropriate consent, since that was a sine qua non of acceptable experimentation highlighted in the Nuremberg Code of 1947. That Code was not the introduction de novo of something with which the medical community had been unfamiliar heretofore, but rather was seen as the expression of a position on ethics that had become standard by that time. The Code reads, inter alia, as follows:

Rule 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, overreaching, 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 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 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.

In my opinion, these conditions were violated in the case of Linda MacDonald. The same Code also forbids, at rule 5, any experiment where there is a prior reason to believe that the subject will sustain death or disabling injury. Given Dr. Cameron's experiences with other subjects prior to enrolling Linda MacDonald, I believe that rule 5 was contravened as well.

Furthermore, rule 10 states that:

During the course of the experiment the scientist in charge must be prepared to terminate the experiment at any stage, if he has probable 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.

In my opinion, this rule was also violated in this case.

Finally, anent the duties recognized by the Nuremberg Code as binding upon physicians, Rule 9 states that:

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.

In light of the data available to me, it would seem to me that this stage had been reached by Linda MacDonald (and, incidentally, most other subjects of Dr. Cameron's experiments) quite early on without this Rule being followed. Consequently it seems to me that therefor there was a breach of internationally recognized medical ethics in this regard as well.

It might be objected that in 1949, the General Assembly of the world Medical Association adopted a Code of Ethics in which it stated that

A doctor shall not in any circumstances do, authorize to be done or condone anything that would weaken the physical or mental resistance of a human being, except for the prevention and treatment of disease.

Consequently, so it might be argued, the treatment that Linda MacDonald received would have been allowed by this clause. However, in my estimation this clause was not intended to apply to, nor did it license, experimental procedures. Consequently, so far as I can see, Dr. Cameron's treatment of Linda MacDonald would not have been saved by this clause.

It should also be noted that the Code of Ethics of the Canadian Medical Association of 1956 includes the Declaration of Geneva³ (Geneva, 1948) which includes the vow that the physician:


... will not use my medical knowledge contrary to the laws of humanity.

This inclusion of the Declaration is reaffirmed in 1961 and 1963. It would seem to me that thereby Canadian physicians were bound not to act contrary to the ethical standards enunciated at Nuremberg: standards, the breach of which was characterized as "crimes against humanity."

I hope that this answers the question that you asked me to consider.

Sincerely yours,

CANADIAN MEDICAL ASSOCIATION


Eike-Henner W. Kluge, P.h.D.
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³ Code of Ethics of the Canadian Medical Association, 1956, at 16.