LEGAL ASPECTS OF MEDICAL EXPERIMENTATION

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Medical experimentation on human beings is hardly ever mentioned by Danish legal writers, even in books specifically dealing with the legal responsibilities of doctors.[1] The reasons for this are probably twofold: first, Danish lawyers know next to nothing about medical research and, secondly, because of what happened in Germany during and after the second world war they are inclined to close their eyes and ears to any signs or rumours of Danish doctors following in the footsteps of the medical scientists of Nazi Germany.

In fact, however, a great deal of medical experimentation on human beings is going on in Denmark (as in all other Western countries), and lawyers, too, will sooner or later have to face realities. The present author will attempt to do just that by throwing some light on the legal aspects of medical experimentation according to Danish law.

1. WHAT IS MEDICAL EXPERIMENTATION?

Medical experimentation comprises three distinctly different phenomena.

(1) First, there is the experimental step taken by a doctor in the treatment of a patient in his care, when tried and well-known remedies are seen to be of no avail. This kind of experiment is characterized by its purpose, which is to serve the interests of the patient in one way or another, whether it be by curing him of an illness, by preventing further deterioration of his health, or by alleviating his sufferings.

(2) Secondly, there is the experiment performed by a medical scientist on sick or on healthy persons with the purpose of furthering medical science or, in other words, gathering information of one kind or another which ultimately may be of use in the treatment, diagnosis or prevention of human sickness.

(3) Thirdly, intermediate between these two kinds of experiments there is the controlled clinical experiment which is carried out on patients with

[1] See Ellinor Jacobsen, *Lægers strafferetlige ansvar*, Copenhagen 1958; Bengt V. Tidemand-Petersson, *Lægeansvar*, Copenhagen 1960.

the aim of furthering medical science and which at the same time serves the interests of the patients. An experiment with two different modes of medical treatment of women with diagnosed cancer of the breast provides an example.[2]

2. THE CONTROLLED CLINICAL EXPERIMENT

While the simple (uncontrolled) experiment as part of a course of medical treatment is nothing but an instance of the application of the age-old practical method of trial and error, the controlled clinical experiment represents the application of the refined scientific methods which medical science nowadays employs. Put very succinctly, the controlled clinical experiment can be described as a systematic collecting of project-related clinical data the nature and number of which, because of a controlled variation, make possible a final conclusive numerical analysis.[3] A typical example of this sort of experimentation is pharmacological research. But the principles implied in this kind of research are also put to use in testing different non-pharmacological kinds of treatment, e.g. surgical or radiological therapy, diagnostic procedures, such as manual or radiological examination, or prophylactic measures, such as vaccination.

A controlled clinical experiment is generally carried out in the following way. In order to obtain information, e.g. about the clinical effects of a certain substance, a group of persons is exposed to the action of the substance in question (this group may be termed the "treatment group"). Simultaneously another group of persons (the "control group") is exposed to the action of another substance, which is known to have no pharmacological effects (this substance is generally termed a "placebo" or a "blind" preparation) or, where necessary in order not to harm the persons in this group, the best of the medical preparations hitherto used. In order to eliminate as far as possible all other differences between the two groups than those caused by the substance the clinical effects of which are being studied, the two groups must be relatively large and the persons taking part in the experiment must be selected at random (so-called "randomization"). In order to eliminate distortions due to prejudice or bias on the part of the persons taking part in the experiment and/or on the part of the

[2] For a discussion of the specific ethical problems involved in random allocation of different kinds of medical treatment in a Danish medical experiment of this kind, see Charles Fried, *Medical Experimentation, Personal Integrity and Social Policy*, New York 1974.

[3] Cf. Povl Riis, "Den kontrollerede kliniske undersøgelse", in Jørgen Pedersen and Bent Havsteen, *Lægevidenskabelig forskning*, Copenhagen 1973.

persons conducting the experiment, it is often thought necessary that during the experiment neither the former nor the latter should know which group is the treatment group and which is the control group. The experiment is in this case characterized as "double blind".

This basic methodological idea can be varied in many ways. Sometimes randomization is impossible because the purpose of the experiment requires that members of the two groups shall belong to different populations. Typically they are sick and healthy people, respectively. The study may concern anomalous immunological reactions in persons suffering from a certain disease. In that case the scientist has to try to eliminate differences due to external causes by a one-by-one matching of the persons in the two groups. Where this proves impossible, one may use the same persons in the two groups for the experiment and for the control purpose. Then each person taking part in the experiment is successively exposed to different influences while all other conditions of the experiment are unchanged. In yet other cases (and ideally always in cases where the control group receives a "placebo" treatment) it may be necessary to have not two but three groups taking part in the experiment, viz. a group which is exposed to the action of the substance under examination, a second group which receives "placebo" treatment, and a third group which is not treated at all. However, none of these or similar variations in experimental design changes anything in the basic methodological idea of the controlled clinical experiment.

3. MEDICAL EXPERIMENTATION IN AN HISTORICAL PERSPECTIVE

While the use of the practical method of trial and error (combined with intelligent observation of the effects of isolated experimental steps as part of medical treatment) is probably as old as the medical profession itself, the controlled clinical experiment and its methodology is of comparatively recent date. Its principles are copied from methods successfully employed for several centuries in physics and the natural sciences in general. According to some sources, controlled clinical experimentation was first carried out in the middle of the 18th century by James Lind (1716–94). Lind demonstrated that patients suffering from scurvy (scorbutus) could be cured by the juice of citrous fruits, but not by water or oil.[4] Since then there has been a steady increase in the use of this scientific method in medical

[4] See Clarence Blomquist, *Medicinsk etik*, Stockholm 1971.

science. A notorious example is the medical experiments made in Europe during the 19th century involving inoculations with venereal diseases. Many of these experiments were performed, without the subjects' knowledge, on patients being treated for other diseases.[5] Experimentation of this sort would undoubtedly today be considered criminal in most parts of the world, certainly in Scandinavia. Even more ill-famed are the medical experiments performed on inmates of German concentration camps during the second world war, which in the Nuremberg trials led to severe punishments for "crime against humanity". In these experiments the scientists deliberately infected the inmates with various bacteria and viruses, *inter alia* malaria, epidemic jaundice and spotted fever (typhus).[6] These notorious experiments, in contrast to the ordinary and far more common medical experiments which have attracted no notice as such outside the medical world, were of no benefit to the persons on whom they were performed. On the contrary, the subjects were exposed to grave, sometimes even deadly risks and they had not knowingly consented to be used as objects of experimentation.

Since the second world war the controlled medical experiment has been put to a steadily increasing use throughout the world, especially as an all-important tool of pharmacological research. In the United States of America, medical experimentation has occasionally caused public scandal. Most notorious is the Jewish Chronic Disease Hospital Case. Three doctors at the Jewish Chronic Disease Hospital in Brooklyn, New York City, undertook, with the approval of the director of medicine, a study of immunological reactions by injecting "live cancer cells" subcutaneously into 22 chronically ill and debilitated patients without their consent (though apparently without any danger whatsoever to the patients of inducing cancer).[7] Disciplinary measures were later on taken against two of the doctors on account of these actions. Incidentally, one of the two doctors was shortly afterwards elected vice-president of the American Association for Cancer Research and subsequently became president of that association.

In the Scandinavian countries there has as yet been no such public scandal. The reason for this is not that there is no medical experimentation taking place here. Medical experimentation seems to be going on in all the Scandinavian countries, although no official statistics on the extent of such experimentation are available. However, the reaction against the German

[5] See Jay Katz, *Experimentation with Human Beings*, New York 1972, pp. 284 ff.

[6] See *Trials of War Criminals before the Nuremberg Military Tribunals*, vols. I and II, "The Medical Case", Washington D.C., 1948, also Katz, *op. cit.*, pp. 292 ff.

[7] See Katz, *op. cit.*, pp. 10 ff.

medical experimentation during the second world war was stronger here than in the United States. Possibly for this reason Scandinavian medical scientists have been more wary about the type of medical experiments they conduct. For a layman it is hard to imagine that Scandinavian doctors would undertake an experiment like the one at the Jewish Chronic Disease Hospital reported above.

4. MEDICAL TREATMENT AND MEDICAL EXPERIMENTATION COMPARED

The relationship between a doctor and his patient is viewed by both as a relation between a person wanting help (the patient) and another person offering help (the doctor). This is reflected in the fact that when payment passes between the parties, it is the patient that pays the doctor for his services. From the point of view of the individual it is the other way round when medical experimentation in its purest form, the controlled clinical experiment which does not purport to benefit the subjects of the experiment, is concerned. Here the subjects of the experiment are helping the medical scientist in his investigations, as is reflected by the fact that it is the subjects of the experiment (e.g. students and nurses) who are paid, when payment is offered. This basic difference between medical treatment and medical experimentation, which is of crucial legal importance, is sometimes veiled by the assertion that the medical experiment is part of a quest for knowledge in order to alleviate the sufferings of humanity. This is all very well as an explanation of the fact that payment is not always offered to subjects of medical experiments. It may even be of some importance as an argument for a public compensation scheme for injuries to subjects of medical experimentation and as an argument why doctors should not pay compensation themselves. But it would be a dangerous illusion for a medical scientist to believe that on account of this he can carry out experiments without consent from the subjects of his experiments. There is an especially apparent risk of a social conflict when, as is often the case, the medical scientist is at the same time acting as a physician treating the subject of his experiment as his patient (or when the subjects of his experiments are at the same time being treated as patients by other doctors at the institution where he is performing his medical research).

In a larger perspective, medical treatment and controlled medical experimentation are two closely related but nevertheless distinctly different activities, which have an equal claim to social approval as being of public utility. However, they may be judged differently from a legal point of view because of their differing character.

5. SOURCES OF LAW

5.1. *Danish Law*

Considering the fact that medical experimentation on human beings is nowadays quite common in Denmark, it is slightly disturbing to realize that, while medical experimentation on animals is strictly regulated by statute law (Act no. 93 of April 31, 1953, on the use of animals in biological experimentation and the cure of diseases), there are no general legal rules expressly dealing with experimentation on human beings.

The Act no. 197 of May 14, 1970, concerning the medical profession is based upon an earlier statute of 1935. Though it is not expressly so stated, the 1970 Act is obviously intended only to regulate professional medical treatment (not medical experimentation).

The taking of human tissue from living human beings as well as from corpses is regulated in the Act of June 9, 1967, on the use of human tissue, with later amendments. Sec. 1 (1) expressly states that (with certain minor exceptions, enumerated in sec. 9) human tissue may be taken from living human beings for purposes of medical treatment only. Medical treatment within the meaning of this act presumably encompasses transplantation experiments which purport (among other things) to benefit the receiver(s) of the transplanted tissue. The 1967 Act, which will be discussed in some detail below, consequently applies to subjects of this kind of experimentation as far as donors are concerned.

The Act no. 327 of June 26, 1975, concerning medicinal drugs seems to take it for granted that all registered drugs used as human medicines have gone through a trial procedure encompassing clinical experimentation on human beings, but it does not regulate the use of drugs for experimental purposes. The statutory powers conferred on administrative agencies by this act are, however, so wide that they may in time lead to administrative regulations on clinical testing similar to those issued by the American Federal Food and Drug Administration.[8] At the present time (August 1975), however, no administrative regulation of clinical testing is in force.

Besides the above-mentioned statutes, there are two acts which are of some relevance when dealing with the legal aspects of medical experimentation, namely the Act no. 137 of April 26, 1968, on insurance against industrial accidents, with later amendments, and the Act no. 234 of June 7, 1962, concerning compensation for injuries caused by vaccination; the

[8] See William J. Curran, "Governmental regulation of the use of human subjects in medical research. The approach of two federal agencies", in Paul A. Freund, *Experimentation with Human Subjects*, London 1972.

last-mentioned statute has been amended by an Act no. 606 of December 20, 1972.

Though, superficially, clinical experiments have little to do with compensation for industrial accidents, the compensation insurance authority ruled in 1970 that the Act of 1968 applied to persons who had knowingly consented to take part in clinical testing of new medicinal drugs and that they were entitled to compensation for injuries due to the clinical experiment in which they had been taking part. Later on, in a decision of 1972, the authority ruled that the 1968 Act did not apply to sick persons who, without their consent, were unwittingly taking part in a controlled clinical experiment with a new medicinal drug, whether as a member of the "treatment group" or of the "control group".[9]

The Act concerning compensation for injuries due to vaccination states that persons injured by certain kinds of vaccination have a right to compensation from the state. In administrative practice, compensation has also been paid to persons who have been injured by medical treatment involving donation of blood or other kinds of transplantation of human tissue.

Danish law in the field of torts has nothing to show as far as medical experimentation is concerned. Case law concerning medical malpractice is of little interest in this connection as far as controlled medical experimentation is concerned, because of the different purposes of medical treatment and medical experimentation. However, a tort claim might be considered where medical experimentation also purports to serve the interests of the subjects of the experiment.

In Danish legal writing prior to the introduction of the Act of 1967 concerning the use of human tissue, it has been questioned whether a person can lawfully consent to a dangerous but unnecessary operation.[1]

Because of this paucity of Danish sources of law which have a direct bearing upon medical experimentation, one has to a great extent to fall back on very general principles derived from other sources of law, such as the Criminal Code or court decisions within the field of the law of torts.

5.2. *International Law*

The summing-up in the Medical Case of the Nuremberg Trials puts forth certain basic principles (now generally known as the Nuremberg Code) which "must be observed in medical experimentation in order to satisfy moral, ethical and legal concepts". The Code should be viewed as an

[9] Direktoratet for ulykkesforsikringen j.nr. 3-161/70.

[1] See Henry Ussing, *Retsstridighed*, Copenhagen 1949; see also Jørgen Trolle, "Lægeansvaret", in *U.f.R.* 1959 B, pp. 10 f.

abstract of testimonies of expert witnesses during the trial concerning the legitimacy of medical experimentation on human beings. By their inclusion in the summing-up, which forms part of the judgment in the Medical Case, they have, however, become part of international law.

Art. 7 of the International Covenant on Civil and Political Rights, adopted by the General Assembly of the United Nations, 1966, contains the following statement:

> 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.

On the other hand, art. 3 of the European Convention on Human Rights only states that

> No one shall be subjected to torture or to inhuman or degrading treatment or punishment.

As yet the European Court of Human Rights has had no occasion to decide whether art. 3 also covers medical experimentation on human beings (without their free consent).

5.3. *Ethical Codes*

Since the Nuremberg Trials the medical world has constantly been battling with the ethical problems involved in medical experimentation on human beings. As a result of this, national and international medical associations have agreed upon ethical codes setting forth principles upon which medical experimentation on human beings ought to be based. The most important of these ethical codes is the World Medical Association Declaration of Helsinki, 1964, containing what is termed "recommendations as a guide to each doctor in clinical research"; these recommendations do not relieve "doctors ... from criminal, civil and ethical responsibilities under the laws of their own countries".

6. LEGAL PRINCIPLES CONCERNING MEDICAL EXPERIMENTATION

In Western democratic countries, the basic ethical and legal principles concerning medical experimentation may be expected to be the same in all essentials, albeit with differences regarding the details. These common basic principles could be indicated by keywords, such as benefit, risk and

consent. Unnecessary experimentation on human beings, i.e. experimentation serving no useful purpose or purposes that could equally well be served in other ways, e.g. by animal experiments or laboratory work, is not only unethical but also illegal when the subject of the experiment is thereby exposed to risks of physical or mental harm. In cases where the subject may possibly benefit from the experiment, these risks have to be weighed against the benefit; and the result of that comparison should again be weighed against the prognosis the subject would have had if he had not taken part in the experiment. Where there is no possible benefit to the subject of the experiment, such risks may sometimes, though not very often, be weighed against the immediate benefit to other subjects of the experiment. According to sec. 1 (4) of the Act on the use of human tissue, the doctor is not, however, allowed to take tissue if the donor will thereby be exposed to an appreciable risk of serious injury. In other cases where there is no immediate benefit to be expected for the subject of the experiment or other persons and the legitimacy of the experiment therefore depends solely upon the benefits which the public at large may expect to receive from medical research, even a small risk may make the experiment socially unacceptable. However, in such cases the lawfulness of the experiment will as a rule probably depend, in legal practice, on whether the subject of the experiment was truthfully informed of the nature of the experiment and of any risks involved, and whether he freely consented to take part in the experiment. A free, informed consent on the part of the subject of the experiment is a mandatory requirement not only in the last-mentioned cases but also when other persons, but not the subject himself, may benefit from the experiment. The demand for an informed consent may be disregarded when the subject himself benefits from the experiment, e.g. when he is a sick person taking part in an experiment relevant to his own illness, and it is deemed to be in his own interest not to be informed of this. I have in mind cases where the patient does not know that he is suffering from a serious illness and the information necessary in order to obtain a consent may reasonably be expected to cause harmful psychological effects.

As a matter of course, legitimate medical experiments must be performed with due care and terminated at once if the subject withdraws his consent (which he is free to do at any time) or when a continuation of the experiment is likely to result in injury, disability or death to the subject of the experiment. In the medical world a declaration made by a subject that the experimenter will be relieved from liability for injuries resulting from a medical experiment is considered unethical and such a declaration would probably be set aside by any court of law.

There are legal problems attached to the question what constitutes a valid consent of the subject to the experiment, and these problems may be solved differently in different countries. According to the Helsinki Declaration, "consent should as a rule be obtained in writing". The Danish Act on the use of human tissue has in sec. 1 (2) a similar prescription that the act of consent has to be in writing. Except for cases covered by this act, there is no statutory requirement that the consent should be in writing. The consent must be given freely, which implies that the subject must have legal capacity. According to sec. 1 (2) of the Act on the use of human tissue, the subject must have reached the age of 20, at which time a person comes of age in Danish law. Some exceptions are made pertaining to instances where the taking of tissue is to the immediate benefit of someone else. A case when a 16-year-old donor gives tissue to his twin brother provides an example. In such a case both the donor and his guardian must give their consent. With regard to medical experimentation concerning persons under 20 years of age, which is not covered by this act, it seems doubtful whether Danish courts would accept as legitimate medical experiments which are not to the benefit of the subject of the experiment, even when performed with the child's own consent and that of his guardian or parents, if the subject of the experiment is thereby exposed to any risk whatsoever. In this respect there seems to be a difference between Danish law and some state laws in the United States of America. For instance, in the so-called Willowbrook case, mentally retarded children were, apparently without legal consequences for the experimenter, infected with hepatitis as part of a medical experiment with the consent of their parents.[2]

The consent of the subject of the experiment must be obtained "without the intervention of any element of force, fraud, deceit, duress, overreaching, or other ulterior form of constraint or coercion".[3] This condition is of especial importance when, as is often the case, the subject of an experiment is in the professional care of a doctor who is doing medical research. The consent should be considered void when it is given by the patient because he believes, wrongly or rightly, that he will be denied further medical treatment if he refuses to take part in the experiment. It is difficult to give an answer to the question whether prisoners can lawfully give their consent to be subjects of medical experimentation. It is probable that, in most European countries, medical experimentation on prisoners is considered unethical. However, the practice of using prisoners as human

[2] See Jay Katz, *Experimentation with Human Beings*, New York 1972, p. 633, pp. 1007 ff., Henry K. Beecher, *Research and the Individual, Human Studies*, Boston 1970, pp. 122 ff.

[3] Cf. *Trials of War Criminals before the Nuremberg Military Tribunals*, vols. I and II, "The Medical Case", Washington D.C., 1948.

guinea pigs in medical experimentation seems to be quite common in the United States of America.[4] The situation is particularly delicate when the prisoner is serving a sentence for an indeterminate period of time, since the prisoner then may easily act under the impression that the time of his release will depend upon his willingness to cooperate in a piece of medical research which is sponsored by the prison authorities. There is a general objection to the use of prisoners as subjects of medical experiments, namely that prisoners are as a rule underpaid and emotionally and intellectually undernourished and so only too ready to accept offers of money in return for participation. In my opinion, prisoners should not be considered eligible as subjects of medical experimentation. Since there is no express rule in Danish law to that effect, however, the validity of a prisoner's consent to take part in a medical experiment will depend upon the individual circumstances of the case.

According to Danish law the person performing the experiment would, in the case of a violation of these basic principles, have committed a criminal or civil wrong entailing responsibility. The subject of the experiment may claim damages for injuries from the experiment provided that he is able to prove a causal relationship. As mentioned under 5.1 above, he may in some cases have the right to claim compensation even where there has been no fault on the part of the experimenter.

7. NEED FOR STATUTORY REGULATION OF MEDICAL EXPERIMENTATION DISCUSSED

As pointed out earlier, it seems somewhat incongruous to regulate by statute experimentation on animals, when the legislators are doing next to nothing with regard to experimentation on human beings. However, there is a special reason why we should have statutory regulations of experimentation on animals. Without them there would be little or no protection of animals against suffering and harm from experimentation. On the other hand, it has always been one of the basic purposes of our law to protect human beings against suffering and harm caused by other persons. Therefore, the law, as it stands today, offers human beings some protection against medical experimentation regardless of the existence of any specific statutory regulation.

Nevertheless, there may still be a need for statutory regulation of medical experimentation on human beings. The act regulating experimentation

[4] See Jessica Mitford, *The American Prison Business*, London 1974.

on animals, for instance, limits the use of animals for purposes of experimentation to certain approved institutions, makes the keeping of case records with a prescribed content mandatory and establishes a board which has to look into the conduct of animal experimentation and review all case records of experimentation on animals. Similar statutory rules concerning experimentation on human beings might possibly have a favourable effect on the way in which such experiments are conducted and would at the same time make it easier for subjects of medical experiments to prove a causal relationship between a medical experiment and injuries caused by the experiment.

On another point, too, statutory regulation is to be recommended. Along the lines of the Danish Act concerning compensation for injuries due to vaccination, "reasonable probability", as opposed to a probability amounting almost to a certainty, should be sufficient evidence of causal relationship. In a case of medical experimentation which is of no benefit to the subjects of the experiment, it might be argued that the statute should establish a presumption for a causal relationship, at least in those cases where the experiment is performed on subjects considered healthy at the start of the experiment.

Apart from these matters there seems to be no urgent need for statutory regulation of medical experimentation on human beings. As a matter of public policy, however, it might be advisable to pass legislation restating the already acknowledged basic legal principles concerning medical experimentation.