PROTECTION OF PERSONS IN MEDICAL RESEARCH: THE NETHERLANDS

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1 Introduction

On 19 March 1998, the Utrecht University Hospital (*Academisch Ziekenhuis Utrecht*) announced that in 1996 an international experiment with an anti-coagulation drug had been halted after the death of seventeen patients. In the experiment, 1,316 patients participated, 665 of whom received aspirin to reduce the risk of a new stroke. The other 651 patients received the anti-coagulation drug which aimed at preventing coagulation in the brain. Of the latter group, 53 patients had serious hemorrages and seventeen died. In the aspirin group six patients had similar complications and one died. The research team supposes that the anti-coagulation drug has diluted the blood too much, so it could leak away through damaged vascular walls. The experiment had been examined and approved by the medical ethical commissions of all 58 participating hospitals. After the first experiment was stopped, a new experiment with an adapted anti-coagulation drug was started, again after the approval of the 58 hospitals concerned. So far, only 135 patients – out of 4,500 needed – have agreed to participate.[1]

This case, described in medical journals,[2] exemplifies the dangers of medical research on human beings. Strokes are at present one of the major causes of death in the Western world and medical research as to the possible therapies is indeed indicated. But such research in itself has dangers, witness the case mentioned above.

Dangers such as those involved in medical experiments raise the question whether or not such experiments should be subject to regulation, either by the legislature or by way of self-regulation. The Netherlands, after the example fo the United States (National Research Act 1974), has recently opted for the former. This paper will examine the 1998 Act on Medical-Scientific Research with Human Beings (*Wet medisch-wetenschappelijk onderzoek met mensen*) in some detail.

1. NRC Handelsblad 19 March 1998, p. 1; Volkskrant 19 March 1998, p. 1.
2. J. Gorter, Annals of Neurology 1997.

It may be self-evident to most readers, but it is perhaps good to set out the main arguments in favour of medical experiments with human beings. First of all, the state of art would probably never proceed if medical doctors would not once in a while have experimented with their patients. Secondly, it has often been observed that Academic Hospitals, where experiments often take place, attact a better quality doctors and therefore provide a higher quality care. Thirdly, patients may themselves profit from experiments, when traditional therapies have failed.

In the latter case, the interests of patient and doctor will coincide. But in the other cases, this is not necessarily so. Research may be done while the patient will not really profit from it or is unaware of its potential dangers. It has therefore become generally accepted that medical experiments are only permissible under strict conditions. Although such conditions may be set out by case-law or self-regulation, the major way of doing so seems to be legislation. In this report I shall set out how the Dutch legislature has reacted to the problems raised above. I shall start with a brief description of the Act and how it came about, as well as its constitutional implications (Nr. 2). I shall then analyse some notions which the new Act uses (Nr. 3). Two requirements for medical-scientific research are the approval of the research project (Nr. 4) and informed consent (Nr. 5).

A point of discussion has been the measure of liability and compulsory insurance (Nr. 6). Medical experiments are now often international, which raises the question whether regulation should also be international (Nr. 7). Finally, I shall draw some conclusions (Nr. 8).

2 Legislation and constitutionality

In the Netherlands, medical research on human beings is now regulated by a specific act: the *Wet medisch-wetenschappelijk onderzoek met mensen* (Act on Medical-Scientific Research on Human Beings) of 26 February 1998.[3] The enactment has taken some time, which is not unusual with regard to legislation in medical affairs in the Netherlands – nor with regard to legislation in general.[4] The original bill on medical experiments was

3. Staatsblad 1998, Nr. 161.

4. The new Dutch Civil Code (1992) took fortyfive years of draftsmanship and still is not fully ready yet.

introduced in 1990. It had been preceded by a draft bill in 1988.[5] Parliament then was very critical of the proposals with regard to non/therapeutical experiments. During the parliamentary debates, in particular the question whether or not the proposed bill was in conformity with the European Convention on Human Rights and the New York Convention on Human and Political Rights was seriously challenged. This resulted in the establishment of a government commission chaired by Meijers. Within a year, the Meijers commission reported to the government. Its major suggestions were taken over by the government: the Act's title was changed and other substantive changes were brought about.

The Netherlands is one of the few countries in the world where Judicial Review has not been enshrined in the Constitution. As is the case in the United Kingdom, it is thought that Parliament is a sufficient watchdog of the Constitution. Not only should Parliament watch over a bill's compatibility with the Constitution, legislation may not be at variance with international treaties either. But the latter check may also be carried out by the courts. Two such international treaties are the United Nations Covenant on Human and Political Rights and the European Convention on Human Rightsand Political Freedoms. The Dutch courts are competent to review the compatibility of Dutch legislation and these international instruments, which of course include a bill of rights. This leads to the paradoxical situation that although Dutch courts are not allowed to review the compatibility of legislation with the Dutch Constitution, they are allowed to review the compatibility of the said legislation with the bills of rights enshrined in the two Conventions.

3 Definition of medical-scientific research

Many therapies are of an experimental nature. If treatment with medication A does not have the required results, or undesired side-effects, another medication may be opted for. To this extent, each patient is someone upon whom an experiment is conducted. This in itself does not necessitate legislative intervention. What does necessitate this? The Dutch Act distinguishes between therapeutical medical research, from which the individual participant may benefit, and non-therapeutic research which is unlikely to benefit the individual participant.

5. See Lucas Bergkamp, Medical Experiments with Human Beings in the Netherlands, in: E.H. Hondius, G.J.W. Steenhoff (Eds.), Netherlands Reports to the Thirteenth International Congress of Comparative Law, The Hague 1990, p. 445-456.

Another classification bears on whether or not the research requires innovative intervention or accepted medical intervention. The latter kind of research may be invasive or non-invasive.[6]

4 Approval of research projects

Under Articles 2 and 3 of the new Act, experiments must meet certain requirements. They must also be subjected to an ethics commission.

An important body under the new Act is the 13-member Central commission for medical-scientific research (*Centrale commissie*). The central commission will be charged with hearing appeals against negative decisions of the ethics commissions and with hearing in first instance demands for medical experiments on incapacitated patients and as to experiments for which there is as yet little expertise in the Netherlands.

5 Informed consent

In accordance with the general prinicple of informed consent, which is found in Article 7:450 Civil Code, Article 6 of the new Act requires the participant's written consent. There are specific requirements in case of minors and of incapacitated majors. The person who conducts the experiment shall inform the participant of the aim, the character and the lengthe of the experiment, the risks involved, the risks of walking out, and the objections against the experiment. The participant shall have sufficient time to grasp the meaning of the information given.

One of the most controversial parts of the new Act has to do with experiments upon incompetent persons. Ever since the nazi experiments in concentration camps and the subsequent Nuremberg trial, these have suffered a very bad reputation. It is only in recent years that experiments are once again looked upon in a more favourable way.

6. As to these distinctions see H.D.C. Roscam Abbing, Medical Research Involving Incapacitated Persons; What Are the Standards?, European Journal of Health Law 1994, p. 147-160.

6 Liability and Insurance

In the original bill the government had proposed a strict liability of scientists who conduct medical experiments and an an obligation to take out third-party liability insurance. Insurance companies protested that they would not cover such risks. The final text therefore lays down an obligation to take out a first-party insurance, with the patient being experimented upon in the position of insuree (Article 7).[7] This model resembles the Nordic patient insurance schemes, which in Scandinavia and Finland cover all medical acts, not just scientific experiments.

The new provisions have been criticised by commentators.

7 International Aspects

The medical experiment with treatment against strokes and which cost 17 patients their lives, was not a purely Dutch experiment. Foreign hospitals were also involved. This raises the question to what extent medical experiments should be the object of national or international regulation. This question was discussed in the Netherlands prior to the enactment of the new 1998 Act. It has been argued that the new Act does not completely conform to the Good Clinical Practice directives.[8] On the other hand, there does not seem any conflict between the Dutch Act and the European Convention for the protection of human rights and dignity of the human being with regard to the application of biology and medecine.[9]

8 Conclusions

The new Dutch Act on Medical-Scientific Experiments strikes a balance between sometimes conflicting interests between those who have an interest in medical experiments: patients, scientists, commercial interests, etc. The Act is not very far removed from present-day practice in the Netherlands. The growing scale of medical experiments makes it necessary to consider the

7. N. Frenk, Medische experimenten: van risicoaansprakelijkheid naar directe schadeverzekering, Aansprakelijkheid % Verzekering 1997, p. 9-10.
8. F.C.B. van Wijmen, De Wet medisch-wetenschappelijk onderzoek met mensen, Tijdschrift voor Gezondheidsrecht 1998, p. 58, 71.
9. Van Wijmen, o.c., at p. 72-73.

gradual enactment of international regulation of medical experiments. The Dutch Act may serve as – a – model for such international regulation.

Legislation is like a TV-set: every now and then, it should be dumped and a new product should be adopted. This American idea is very alien to Dutch legal culture, which still sees legislation as something permanent, *aere perennior*, to speak with Horace. But it is now more and more accepted that legislation does need regular overhauls. This is especially the case where 'experimental' legislation like the current Act is involved. The Act therefore foresees a regular evaluation: within four years and then every five years.

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