Belgian Advisory Committee on Bioethics

Opinion no. 14 of 10 December 2001 concerning
" the ethical rules with regard to persons suffering from dementia"

Request for an opinion of 15 July 1998,
from Mr Marcel Colla, Minister of Public Health and Pensions

Summary of the question

1. Does a seriously disturbed psychological situation such as Alzheimer disease, justify special protective measures being taken?
2. Only persons who can give free, autonomous and informed consent may participate in non-therapeutic experimentations. Hence, patients with a serious form of Alzheimer's disease cannot participate. One would, however, be able to derogate from this principle under very strict conditions, provided that the experimentation would represent a minimal risk and burden for the patient. This also means that the experimentation or the specific measures concerned, would be stopped as soon as the patient refuses his participation. I would appreciate your opinion in this respect.

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FIRST PART: SUMMARY AND RECOMMENDATIONS

The members of the Committee were of the opinion that the two questions put by minister M. Colla, although different, often refer to the same ethical problems. They have therefore decided to answer the two questions with just one opinion. For the purposes of clarity, they summarise the essential elements of the opinion together, as well as the resulting suggestions and recommendations. In the second part of the opinion, the proposed recommendations are explained.

Chapter I. Introduction

Section 1

In the introduction, a definition is first given of the diseases to which this recommendation relates: dementias as irreversible degenerative disorders of the brain in a previously healthy person.

Section 2

2.1. The Committee then presents an analysis of the major ethical problems linked to dementia. The Committee unanimously agrees that, with regard to persons suffering from dementia, we should display real solidarity, and in this regard proposes many measures to represent the person in the case of incapacity. With certain points, however, the opinions of the members of the Committee diverge depending on the ethical drifts associated with them. The Committee will give a concise explanation of the drifts which, depending on the case, relate to human dignity with autonomy, with relational exchange or with a transcendent dimension.

2.2. In practice the most difficult ethical problem with persons suffering from dementia is the gradual loss of their autonomy, being their competence to consent to their proposed treatments and measures. This question is again being focused on with the current draft law on the rights of the patient. The Committee accordingly concentrates specifically on the forms of substitution for consent: prior consent and the appointment of a trusted representative.

The members of the Committee are of the opinion that one must examine the various objectives that can be striven for with prior consent, and consequently also the different functions the trusted representative is considered to fulfil. It can be the case, for example, that someone giving prior consent does not per se want the same "trusted representative" to be responsible for requesting the termination of life in his place at a certain stage of his illness, and to ensure his comfort in the course of the illness.

a) If the prior consent concerns medical operations at the end of the life and with a possible request for the termination of life, it is absolutely necessary for the trusted representative to have been appointed by the person in question. The Committee also again refers to the insuperable differences of opinion between its members as regards the ethical legitimacy of consent when this involves the termination of life. As regards this point we refer to the opinion no. 9 of 22 February 1999.

b) The question concerning the quality of life of a person suffering from dementia who gradually loses his capacity to consent, forms another problem. In the spirit of the current draft law on the rights of the patient, in particular chapter III, the members of the Committee are of the opinion that innovative work is required in this area. We must indeed ensure on the one hand to take account to the extent possible of the decision capacity of which the patient

still disposes, and on the other hand only act in his place to the extent to which his incapacity to decide increases. The situation is currently vague, and one puts one's trust in the "natural guardians" of the person suffering from dementia: his family, the doctor or even the management of the home where he/she is staying. The members of the Committee consider it appropriate that the parties involved draw up prior consent and, when they are still capable of this, be able to change the person appointed and if necessary take any decisions in their place. With the purpose of preventing any confusion, they propose calling this person "the representative of the person suffering from dementia"[1]. (NB: The draft law of Minister M. Aelvoet uses the term "representative of the person"). The Committee is also of the opinion that one must legally regulate the statute of the "representative of the person". The justice of the peace would appoint the "representative" chosen by the person suffering from dementia if consent has been given in this respect. If not, and here the Committee goes further than the draft law on the rights of the patient, the justice of the peace would have to intervene and ex-officio appoint a "representative of the person": the justice of the peace would be defined according to a procedure to be determined by the legislator. The representative would assist the person suffering from dementia when taking decisions, or if appropriate take the decisions in his place, and this for the purposes of his optimal comfort and quality of life while respecting his previous choices. The question of whether the representative can decide if the person suffering from dementia can be subjected to medical experimentations is of a more specific nature and will be discussed in the chapter in which the problems arise.

c) The management of the property of the person suffering from dementia forms yet another problem. The law of 18 July 1991 regulates this subject and allows the justice of the peace to appoint a "provisional administrator" who is financially neutral. The wording of the law and administrative procedure make clear that the administrator is not responsible for ensuring the provision of care or the quality of life of the patient, and that he indeed usually does not have the competence required in this respect. He may therefore not be confused with the "trusted representative", nor with the "representative of the person" as mentioned above.

After the clarification of the general ethical issues, the advice then discusses the two questions of minister M. Colla in two separate chapters.

Chapter II. Special protective measures required with dementia

The advice discusses the following subjects in detail:

- The quality of life of the person suffering from dementia, home care and placement **(point 1).**
-Therapeutic persistence, the stoppage of the treatment, the request for the termination of life **(point 2).**
-Certain questions with respect to the cost of the treatment **(point 3).**
- Consent to the provision of care. How can the ability of persons suffering from dementia to give consent be conceived in a wider sense? **(point 4.1);** the current legal solutions for the incapacity to give consent**(point 4.2);** and finally the new legal resources that should be introduced; **(point 4.3).**

[1]Some members of the Committee chose the term « mandatory », others « substitute of the person suffering from dementia». They have agreed on the term "representative" to indicate the threefold function: guidance, support and representation of the person suffering from dementia, according to the severity of his situation. The legislator will choose the term considered most suitable.

Relating to the required special protective measures in the case of dementia, the members of the Committee offer the following recommandations

1. Proposed measures to overcome the decline as regards the ability to give consent

a) The procedure for prior consent with the appointment of a "trusted representative"as now discussed in Belgium is aimed at a regulation for the problem of the termination of life that was desired by persons who, hic et nunc, were totally incapable of expressing their will. In its advisory report no. 9 of 22 February 1999 the Committee reported on the various opinions of its members in this respect. The policy guidelines of that advice are explained in chapter I.2.2.a.) of the present advice.

b) Persons suffering from dementia see their autonomy and their decision capacity gradually decline over a period that can be very long. The legal tools of which Belgium disposes take no account of the progressive character of the extent of incapacity to decide about the provision of care and about all sorts of questions concerning the quality of life. In the spirit of the draft law on patient rights that is now being discussed, the members of the Committee recommend that the law sets up a procedure where, with the drawing up of prior consent, the appointment of a "representative" to ensure its application is encouraged. For reasons of terminological clarity, most members of the Committee choose to use the term "representative of the person suffering from dementia". They go further than the abovementioned draft law, and are of the opinion that the justice of the peace should ratify the appointment of the "representative of the person" selected by the person suffering from dementia when he/she was still capable. In the absence of such a choice, he should ex-officio appoint a "representative of the person": this is in order to maximally respect the autonomy of which the person suffering from dementia still disposes, and to make clear which person is responsible for the decisions. The "representative of the person" would have the task of supporting the person suffering from dementia by consulting the care providers and the kin of the patient, just as the latter would have done himself if he would still be capable. One must therefore fully understand that the proposal for the appointment of a "representative of the person" is not a sign of any mistrust *a priori* with respect to the natural guardians of the person suffering from dementia, and in particular in relation to his family. The "representative of the person" will indeed in many cases be able to be a near family member. The recommendation of the legal appointment of a representative who is authorised to take decisions has the purpose of clarifying the situation of the person suffering from dementia by clearly identifying a person responsible for the decisions.
In cases where disputes originate between different next of kin, as sometimes happens, where necessary decisions could be prevented or delayed, the "representative of the person" would also be authorised to take the necessary decisions, for the purposes of an optimum quality of life and taking into account his former choices.
c) The members of the Committee remind of the fact that the law of 18 July 1991 offers the opportunity if appropriate of the justice of the peace appointing a "provisional administrator" for the management of the property of the person suffering from dementia. The law does not determine that the administrator acts in the place of the persons suffering from dementia for other issues than the management of their property; the administrator is indeed not authorised to do this.

2. General measures with respect to the provision of care and the quality of life of persons suffering from dementia

a. Social solidarity

The members of the Committee stand unreservedly in favour of the option of solidarity for which our society has chosen, in particular with regard to persons suffering from dementia. It therefore recommends that the option is maintained now the number of persons with dementia is increasing, and consequently that the necessary financial resources are also made available.

b. Training of care providers

The complexity of dementia and the recently acquired insight in combination with the rise of the number of cases have as a consequence that too few care providers have the necessary ability to treat the cases. Great efforts are therefore required, both with regard to ordinary and advanced training. Improvement is required on the following points:

- the skills needed to make the diagnosis of dementia,
- knowledge of the social, psychological and neurophysiological factors that influence the evolution of the disorders,
- the assessment of the decision capacity of the patients.

c. Home help and day hospitals

In many cases it can be decided to keep the patient at home as preferable to moving him, this both to slow the evolution of the diseases and comply with the patient's wishes. At different places in the country home care, day hospitalisation and alternating admissions are not possible. These are nevertheless necessary elements to be able to keep the patient at home in good circumstances and to support the kin.

d. Standards and financing of homes

Sometimes the admission of the person suffering from dementia is required. We all too often observe that the establishments to which patients are admitted have insufficient personnel and insufficient skills, particularly when the patients can make no personal financial contribution. The standards and the financing of the establishments must therefore be corrected.

e. Subsidies for interdisciplinary teams

The increasing incapacity to decide among persons suffering from dementia requires medical, but also social measures: home help, assistance with the care, assistance when managing property, accommodation, etc. The members of the Committee are of the opinion that the competence of multidisciplinary teams is required to help the patients, families and carers when taking appropriate decisions.

They recommend the subsidising of a flexible system according to requirements as was set up in the Flemish Community (the "Samenwerkingsinitiatieven Thuiszorg"). This system enables flexible and pragmatic payments in situations where the different persons whose competence is required to manage a certain situations come together and meet.

f. The "ethical reflection groups"

Finally, among demented persons, it is often the case that the taking of medical decisions is difficult because the line between therapeutic persistence, so-called extraordinary treatments, and ordinary treatments, is difficult to draw.

The Committee finds that for these cases the use of "ethical reflection groups" must be encouraged. At establishments where this method is applied, a physician in a difficult situation can quickly bring a number of people together to help him with his reflection. Obviously the reflection group never acts in the place of the physician calling upon its assistance: he retains complete freedom and responsibility for his decisions.

The members of the Committee believe that this practice can also take place outside hospitals, in particular in rest homes and among physician's associations.

Chapter III. Experimentations with persons unable to give informed consent

To tackle this issue, the advice first gives a summary of the national and international rules and directives in this field. From the summary of the provisions it appears that experimentations with persons not able to give their consent are acceptable, even if there is no direct benefit for the parties involved, provided that very strict limitations are included.
The advice then reminds of the general rules on human experimentation which the Committee has already drawn up in its opinion no. 13 of 9 July 2001. In the following chapters we look at the specific ethical problems inherent to the pathology of persons suffering from dementia. The ability to consent, experimentations with persons not able to consent, any replacements for the consent, the term minimum burden and least risk, the benefit that a patient may or may not be able to enjoy from an experimentation and the protection of his vulnerability form the policy guidelines of these considerations. The following recommendations are a summary of the opinions of the members of the Committee.

Recommendations of the Committee with respect to experimentations with persons suffering from dementia

1. The general rules

The general rules that must apply in the case of human experimentations as the Committee reminds in its opinion no. 13 of 9 July 2001 all remain in force in the case of persons suffering from dementia, with the reservation of the special considerations as further mentioned. In that advice the Committee expressed the wish that experimentations with people should be regulated by a framework law.

2. The problem of informed consent

The rule according to which each experimentation is subjected to the informed consent of the person concerned, conflicts with the fact that the capacity for thought of persons suffering from dementia is affected, so that they to a more or less serious extent are no longer able to give such informed consent. With regard to this difficulty, there is unanimity among the members of the Committee on certain recommendations, while opinions diverge on others.

2.1. The consensual recommendations

The members of the Committee are agreed in the two following cases:
a.
A person suffering from dementia *who is still able to consent to* an experimentation must be treated as an ordinary citizen. His ability to consent must be considered separate from his legal capacity to act. If the person in question is under legal guardianship, however, the agreement of the guardian is also required.
Such a person can also consent to an experimentation without direct benefit. The members of the Committee emphasise, however, that one must approach the situation with great caution in view of the sensitivity and the variability of the situation of the parties involved.
b.
The members of the Committee are of the opinion that experimentations with persons not able to consent and who have provided no prior consent *can be justified when the direct benefits expected of the research are considerable* and when the principle of proportionality between

risk and benefit is observed. The "representative of the person suffering from dementia" referred to in the last chapter, would also be able to give his consent here.

2.2. The non-consensual opinions

The opinions of the members of the Committee diverge with regard to the legitimacy of experimentations with a person suffering from dementia who is not able to consent and for whom there is no direct benefit.

a. Opinions of the advocates of experimentations without direct benefit

a.1. Without prior consent

Some believe that knowledge about dementias and about the incapacity to decide that they result in can only improve by experimenting with the ill in this situation. They believe that a radical prohibition of experimentations without direct benefit comprises discrimination against and the abandonment of persons suffering from dementia, so that they are sentenced to the situation of being incurably ill. For these reasons the members opt for a stringent and restrictive context for such experimentations, but not for a full prohibition. In that context experimenting with the ill who would not be able to consent would be prohibited, except when the following conditions are met: the ill person is not opposed to this; the experimentation entails only a minimum burden and a minimum risk; the experimentation cannot take place with a comparable effect when conducted on persons able to consent; the experimentation concerns the pathological situation of the ill person; progress is expected so that in due course persons in a similar situation can gain benefits from the experimentation. Obviously when the demented person is under legal guardianship the agreement of the guardian is required. More specifically, if new legal provisions would introduce a "representative of the person" appointed by the justice of the peace, as recommended in the last chapter, he could consent to experimentations without direct benefit.

The members of the Committee supporting the standpoint of experimentations without direct benefit therefore join with the standpoint of the World Medical Association (Helsinki Treaty, review of Edinburgh, October 2000) and the Treaty of the Council of Europe on Human Rights and Biomedicine (Oviedo 1997). We mention that Belgium has not ratified this treaty.

a. 2. In the event of prior consent

The members of the Committee who support allowing experimentations without direct benefit with persons suffering from dementia who are not able to consent are of the opinion that one must encourage the introduction of the procedure of prior consent. Here they see considerable progress as regards respect for the autonomy and the dignity of persons suffering from dementia who, at a time when they are still able, state through such prior consent that they are prepared to cooperate on general welfare, also if they are affected by illness. In this case it would be extremely desirable that the persons appoint a "representative of the person" beforehand.

The opinions of these members of the Committee diverge as to how far such experimentations may go.

- Some believe that the autonomy of the individual deserves the fullest respect, and that only the person in question himself may decide which discomforts and which risks he wishes to expose himself to, however considerable they are. They therefore accept that an ill person who has drawn up prior consent in which he requests the termination of life in the case of advanced dementia, and has furthermore specified that he agrees to be subjected to dangerous experimentations before his death, is included in risk-entailing research into his illness. Obviously the expected result of such an experimentation must be very great, and strict control by an ethical committee is required. The supporters of this standpoint believe that even if the agreement of the representative is formally indispensable, that nevertheless the

written will of the person he represents must be complied with. If he does not agree to an experimentation, his non-acceptance must be based on the fact that the experimentation is insufficiently relevant and not on the danger level.

- The others believe it is not ethically justified that an individual is prepared to accept serious risks to his health or welfare just to serve science. They therefore do not agree that prior consent can allow such an experimentation, not even within the context of a request for termination of life. They are of the opinion that this never merely concerns an individual problem, because here also the ethical attitude of the researchers and of the other parties involved in research are involved. The latter cannot, without impairing their own dignity, use other persons as tools in such as way as to expose them to considerable discomforts and serious risks. In such cases the members of the Committee are behind this standpoint, preferably keeping to the rule of the minimum burden and minimum risks.

b. Standpoints of the opponents of any experimentation without direct benefit

Some members of the Committee adopt a more restrictive standpoint with respect to experimentations without direct benefit with persons suffering from dementia who are not able to consent. They question whether experimentations of which in due course one can expect a real advantage for the group of persons suffering from dementia, require use to be made of persons who are no longer able to give their consent. They are particularly of the opinion that respect for each person suffering from dementia and for his welfare must have priority over future hypothetical advantages for the patient group. They believe that the permitting of exceptions to that principle would create a dangerous precedent as regards the protection of persons who are already highly vulnerable. They are suspicious of an atmosphere of overhaste, where the hope to in the short term discover new therapies would soon turn into a premature impression of urgent necessity. Finally, they fear that the financial interests of research could too easily lead to patients being subjected to extra suffering. They also believe that each experimentation with persons suffering from dementia without benefit to the persons must be prohibited.

As regards the problem of prior consent, there are two more trends associated with the supporters of that standpoint.

b.1.

The one person believes that such a declaration of consent is a valid expression of the will of the person now suffering from dementia that must be respected. They accordingly accept that such a declaration of consent allows experimentations without direct benefit. They do, however, respect the strict conditions mentioned under *a.* and insist on the principle of the minimum burden and the minimum risk being observed.

b.2.

Other members of the Committee believe that neither prior consent nor the prior appointment of a "representative" by the person in question can permit experimentations with patients who are now no longer able to give consent and therefore themselves will have no direct benefit. They not only point out the general ethical objections with regard to consent already mentioned, they also fear that when so much priority is given to experimentations, even when based on prior consent, the trend to use people as resources in the name of scientific or financial interests will still increase. They believe that the trend is already too emphatically present in our society, and they ask accordingly that the law forbids all experimentations on persons suffering from dementia who are not able to consent and will have no direct benefit from such experimentations.

3. Other specific recommendations concerning experimentations with persons suffering from dementia

3.1. Psychological traumas

When assessing the risks and the discomforts of experimentations, it is important to pay sufficient attention to the psychological traumas such an experimentation can cause among persons who due to their dementia are very vulnerable.

3.2. Financing of research on relational and social aspects

To prevent researchers, care providers and the public from too quickly considering dementia from a biological standpoint, the government must release sufficient resources for research into the relational and social aspects of the diseases, aspects that have a strong influence on the welfare and dignity of persons suffering from dementia. It is indeed clear that in this respect few benefits could be expected from private sponsors.

3.3. Vigilance of researchers

The vulnerability of persons suffering from dementia, the fragility of their consent and their limited expression capabilities require committees for ethics to emphasise to researchers that it is important to closely monitor persons participating in experimentations. One must very specifically ensure that each person suffering from dementia who is part of an experimentation can at all times withdraw from the experimentation if he should express the wish, even indirectly.

3.4. No costs for treatments discovered with experimentations

Persons suffering from dementia involved with an experimentation must be able to continue with treatments free of charge or continue to use tested products if they appear beneficial to their health.

4. Legal recommendations

The framework law recommended by the Committee in its opinion no. 13 of 9 July 2001 on human experimentations should contain special provisions on persons suffering from dementia.

- All members of the Committee are of the opinion that before starting an experimentation with a person suffering from dementia who is not able to give consent, his legal status must first be regulated. Just as in its opinion about treatments, the Committee would like the law to innovate by providing for the function of "representative of the person", who is authorised to decide in the place of the person suffering from dementia having regard to his situation. We again suggest that it is preferable for the representative of the person to the extent possible to have been appointed by the person himself when he was still able. Otherwise, the justice of the peace would make an ex-officio appointment.
- All members of the Committee are of the opinion that the representative of the person could permit experimentations of which a direct benefit for the person suffering from dementia is expected.
- The opinions of the members diverge with respect to experimentations without direct benefit on persons not able to consent.

Some believe that such experimentations are justified, and that the representative can allow them subject to compliance with the above-mentioned strict conditions.

Others wish such an experimentation only to be allowed providing that the person suffering from dementia has expressed this in a declaration of consent made when he was still able to take decisions. Such a written document would be able to go together with the appointment of the representative of the person.

Others believe experimentations without direct benefit on persons suffering from dementia who are not able to give their consent are in all cases unjustified; even prior consent and the appointment of a representative cannot make this acceptable. They would like this type of experimentation to be prohibited by law.

SECOND PART: EXPLANATION AND DISCUSSION

Chapter I. INTRODUCTION

1. Clinical demarcation of the diseases concerned

1.1. The dementias

The DSM IV (Diagnostic manual of the American Psychiatric Association 1994) sees the clinical picture of dementias as characterised by:

a loss of intellectual capacities that is sufficiently serious to have repercussions on social and professional functions. The deficit has different aspects and concerns the memory, judgement, abstract thinking and a whole of other higher functions. Changes of personality and behaviour can also occur.

This definition is solely based on clinical symptoms and has no predictive connotation. In that perspective dementias are the consequence of transient or permanent cerebral dysfunction.

The Committee has opted to concentrate on the matter raised by Minister M. Colla, being Alzheimer's disease, but to extend this to cover clinical situations entailing similar problems. This advice therefore concerns patients suffering from all forms of currently irreversible dementias that are the consequence of the progressive organic degeneration of the brain: the forms of dementia among patients with Parkinson's disease or Huntington's Disease, dementia with Lewy bodies, cerebrovascular dementias, Korsakoff's syndrome, Creutzfeldt-Jakob disease or any similar dementia that we will indicate with the term "Alzheimer-like". In the continuation of the text, we will use the term "person suffering from dementia" to indicate these diseases**.**

In its advice the Committee accordingly does not cover the issue of psychiatric patients in general, nor those of persons with a serious congenital mental disability.

The prevalence of an illness shows which part of a population is suffering from the disorder at a given time. The prevalence rate for dementia varies based on recent studies between 6.3% and 9.3% of the population older then 65 years.

For the Belgian population this means an absolute number of approximately 150,000 persons who now suffer from the illness. Taking into account the increasing greying of the population, one can assume that this number will be 275,000 in 2010. Further forecasts have little use because we know very little about the treatments that will be available by then. Within the group of persons suffering from dementia there are 50 to 70% with Alzheimer's disease. Dementia is therefore an important issue in public health.

1.2. The aging of the population

It is known that aging can be associated with cognitive disorders, in particular memory disturbances. With ordinary aging the disorders are not associated with the significant affecting of the capacity to understand, judge and reason. They therefore result in no incapacity in an ethical or legal sense.

It is a fact that in certain situations it can be difficult to draw a line between what is a part of the ordinary aging process and what refers to a degenerative affliction, all the more as the past of the person and his environment play a part in any memory disturbances. The problems are often poorly known by physicians who are not specialised in this domain. The Committee therefore considers it appropriate to point out that the diagnosis of a degenerative illness must

always take place with the necessary competence and care.

1.3. Progressiveness, variety and variability of dementia disorders

Degenerative brain illnesses with cognitive disorders show signs of great progressiveness, variety and variability of the clinical pictures.
The progressiveness of the affliction can differ greatly.
The extent to which the cognitive capacity is affected is often influenced by the relational context in which the patient lives: in a positive affective context, the patient is often capable of much more than when he is in a situation that makes him fearful or aggressive.
Other factors of which little is still known influence the capacities of the patients. Certain patients, who are sometimes in a very serious condition, have short very striking moments of clarity in comparison with their normal situation.
From the observations it appears that one must adopt a very cautious approach to the patients. One should absolutely ensure that the diagnosis is as accurate as possible. Each decision must be adapted to each patient case by case.

2. General ethical problems inherent to the situation of patients suffering from dementia

Depending on the extent of their illness, persons suffering from dementia lose the ability to assess their own welfare and act accordingly to different extents. They are no longer able to take care of themselves (eating, hygiene), or manage their property or live up to the obligations of their social life. Their mental ability to live a normal autonomous life is affected. Their environment and society must therefore protect their autonomy de jure in a situation of vulnerability de facto.
Dementia raises two ethical problems:

- Within the context of the provision of care to persons suffering from dementia, how must the rule of informed consent be used to ensure respect for and the autonomy of the patients? Informed consent is at the same time a deontological requirement and an essential principle of law for guaranteeing the ethical character of each action, more specifically of each medical action. Legal reality translates in a very particular way for persons unable to give informed consent, because the progressive character of the incapacity forms the specific nature of various dementias. In this advice we analyse if a derogation from the consent rule is legitimate from an ethical viewpoint: how must we take account of the wishes of the patients, knowing that their judgement capacity can be affected by the dementia?
The Committee unanimously proposes that a justice of the peace proceeds with the appointment of a representative of the person – preferably indicated beforehand by the person in question himself - who is responsible for taking the necessary decisions in the place of the patient and complying with the prior consent he may have provided. The members of the Committee differ of opinion about the weight that one must give to the declaration of consent. Depending on their philosophical conviction some are and others are not prepared to take account of the request for the termination of life or experimentations without direct benefit for the person in question, irrespective of whether risks to his health and/or actual discomfort are involved.
- On the basis of the conviction that the more vulnerable the patient has become due to his disorder, the greater the social solidarity with him must be, we must ascertain what the pragmatic possibilities are for affirming this solidarity in terms of justification. One of the challenges of this advice consists of determining the conditions for expanding solidarity with an ever-increasing group of persons suffering from dementia. We must keep the coherence of our values in mind, which are not merely based on an atomistic vision of the person de jure.

We see the person in a network of social contacts within a specific community. Different questions can therefore arise. To which point must the community ensure care for persons suffering from dementia? To what point must one support the life of persons who no longer appear to dispose of the ability to give themselves meaning to their life? The Committee unanimously argues for real solidarity with regard to all persons suffering from dementia. Some members believe that the solidarity must be effected separate from the written expression of the will of the person involved. For others the expression of solidarity can never go further than the will established beforehand.

2.1. The ethical values

The Committee requires effective solidarity in relation to all persons suffering from dementia, taking into account the costs for the community of the solidarity, just as for the patients as for others. This solidarity also entails the costs of technologies and medicines being kept within reasonable limits. The solutions proposed for the ethical problems, in particular the solution one wishes to provide to the impossibility of granting consent, with which many persons suffering from dementia suffer, differ particularly in regard to the order of priority different persons assign to different values. The Committee deems it appropriate to remind of the values here, but also mentions that with regard to the options described there are no sharply demarcated groups in evidence among the members: it is usually the case that the values hierarchy of each member is the result of the person's own choice from the various standpoints.

Autonomy as the source of human dignity

In line with a strong philosophical trend that has already developed over practically three centuries, some see the source of human dignity primarily in the autonomy the person in question is capable of. Autonomy here means the capacity of each individual to choose and give form to the values on the basis of which he wants to arrange his life. Dementia raises the question of respect for the autonomy of persons who have lost this ability.

First of all one may not conceive respect for autonomy in the extreme sense. It cannot be the intention out of respect for autonomy to allow the person suffering from dementia to expose himself or others to dangers; but neither may one use the dementia suffered by the person to ignore his wishes. Autonomy is an ideal that must take account of human finiteness and therefore biological and social determinations.

The advocates of respect for autonomy suggest that each person, irrespective of his situation, has the right to live in the best possible circumstances and not suffer needlessly. For those among them inspired by utilitarianism, the ethical value of an action even depends on the extent to which the welfare of the parties involved benefits. Here one does not refer to the welfare of a single individual, but of all for whom the action in question has consequences. It is not principles, rights and obligations that form the starting point of the ethical approach, but the question of what the consequences of it are for the individual happiness of the greatest possible group of persons (consequentialism). As regards persons suffering from dementia, terms such as “autonomy”, “value”, “entitlement to life”, etc. are only usable to the extent to which they appear relevant to the subjective happiness and welfare of the parties involved. To the members it is evident that when a person suffering from dementia has made no appointment from which it can be concluded that his subjective welfare cannot be reconciled with a situation of dementia, the person must be able to enjoy the best care up to the end.

Others believe it is important to keep the memory alive of what the persons were at the time when their capabilities and autonomy were still unaffected.

At a more fundamental level, some emphasise the role of solidarity in the structure of the

autonomy concept. This concept not only implies the safeguarding of the_person's own autonomy, but also responsibility with regard to the autonomy and the welfare of others. In this line of reasoning, the respect for the other is not one-way traffic from the healthy to the patient. Otherwise one would deny that the patients are able to exercise their autonomy, by voluntarily demonstrating their solidarity with regard to the patient. This standpoint will, as we will see, also arise in the debate about the meaning one gives to the procedure of prior consent by persons suffering from dementia.

The term shared dignity as a condition for relational exchange

Others believe that human dignity has its basis not primarily in the autonomy of the individual, but in the need for and the obligation of solidarity binding the members of each society**.** They believe that the taboo of murder not only involves others not being allowed to be subjected to violence, but that one has the positive obligation to strive for a high quality life for his fellow-man. To them dignity is first and foremost a relational given, because it gains concrete form through respect, esteem and the desire to live, values which interact between people.
In this perspective the rule of informed consent does not only have the function of safeguarding autonomy. At a deeper level this rule forms a contemporary translation of the social solidarity contract. It is one of the procedures that enables people to together usefully supplement the term dignity. It furthermore forms a counterweight for the objectifying of the human person, to which the technique sometimes causes an initiative, or a measure of his contribution to the collective interest. They also underline the fact that the protection of the dignity of the weak, for each individual and for the group, contributes in a subjective manner to the respecting of their own dignity. Contempt for persons suffering from dementia, a lack of solidarity with them, or worse still mistreating them have negative repercussions on the solidarity within the group and on the respect that everyone must show for the dignity of every other living being.
The defenders of the notion therefore more strongly put the emphasis on the affective quality of relationships with persons suffering from dementia than on the deterioration of their cognitive capacities. According to them, their capacity to be happy or to suffer is determined by the care administered to them and the efforts one provides to raise a discussion about the wishes they still can express. In the relationships they see the concrete realisation of the dignity of the persons suffering from dementia and of their environment.

The term dignity as transcendent dimension

Finally, some seek the basis of the dignity of everyone in a metaphysical notion of the person, also that of the person suffering from dementia. They assign a transcendent or spiritual dimension to each individual that in any case transcends everyone's physical and psychological capacities.
Among the supporters of this standpoint are the believers in the main religions in our society. According to them, the dignity of the person suffering from dementia has its basis in the transcendent dimension that makes him equal to healthy people.

2.2. Prior consent

We remind that prior consent is a written document that a person draws up at a time when he/she still has his/her decision capacity for the purposes of establishing or influencing decisions relating to care – in the broadest sense of the term - at a time when the person will no longer be able to decide himself/herself. It is usually recommended to have prior consent

associated with the appointment of a “trusted representative” who has the task of interpreting the wishes formulated in the text with medical staff or paramedics. Usually considered as an extension to the domain of prior consent is the purely official appointment, by a person still competent to this end, of a “trusted representative” who has the responsibility of making the intentions of the former person known at a time when the person is no longer able, and without the person in question having necessarily established his desiderata in writing.
Many are of the opinion that the procedure of prior consent allows the autonomy of a person suffering from dementia to be better respected and offer an answer to his current incapacity to decide. The procedure is already used in certain countries: in most states of the United States, in five Canadian provinces, in four Australian States, in Denmark and the Netherlands as well as in different Swiss cantons, as a guide when taking therapeutic decisions concerning persons who due to their pathology *hic et nunc* are no longer able to give informed consent.
As for persons suffering from dementia, the members of the Committee are of the opinion that the ethical value of the procedure of prior consent in combination with the appointment of a "trusted representative" varies depending on the objective striven for by the procedures. Obviously the procedures in any case give the person the possibility of being heard, and have his autonomy apply up to the phase of life in which this is no longer possible. A request for termination of life, for example, raises other ethical problems to a request with respect to placement or comfort. Seen practically, someone who wants to appoint a family member for his comfort will not necessarily want that family member to have the task of asking in his place for termination of life if the pathology becomes more serious. If the property of a person suffering from dementia must be managed, yet other requirements apply.
Therefore the members of the Committee believe that a distinction must be made between the following categories

a. Prior consent concerning the termination of life
The ethical problems with respect to termination of life with incapable persons were already explained in advisory report no. 9 that the Committee published on 22 February 1999. We believe it useful here to refer to the most important ethical standpoints in that advisory report:
According to some members "prior consent", ethically seen, is in principle not opportune when this concerns decisions about the ending of life, because either the physician is asked for the termination of life and that comes down to a violation of what they consider the prohibition of killing, or one wants to prevent therapeutic persistence with a declaration of consent, a practice that is in any case prohibited by the codes of medical ethics. They argue that a declaration of consent drawn up by a person in good health, so merely imaginary, cannot be applicable in circumstances in which this person is so to speak no longer “the same”. Finally, the physician-patient relationship originating through such a declaration is no more than a « relationship on paper », a merely administrative document that replaces the actual and tangible relationship, and that the physician binds himself with respect to his patient, even if at that time he is not able to make his wishes known.
According to other members, prior consent is a valuable basis for the decision the physician must take, even if one can never give this document the same weight as a request at the time itself. They reject the argument that an expression of will is not current: the incapable person is the same as when he was capable, and his wishes cannot be changed exactly because with incapacity, the will no longer exists and prior consent was drawn up to accommodate this. They are also of the opinion that such a declaration of consent gives the patient the opportunity of having his outlook known with respect to therapeutic persistence, extraordinary treatments, undignified situations, etc. In this way he gives the physician important indications concerning the decision the latter will have to take. According to its advocates, the declaration of consent of the patient must as a result be legally and

deontologically taken into consideration in the decision process of the physician.
With the presumption that the prior consent would be legally recognised, among the participants in the discussion, there is significant agreement on the following two points:
1) Such a declaration of consent must to the extent possible be associated with the appointment of a trusted representative. The appointment of such a mediator would then be a complement to the declaration of consent, because one cannot expect this to give a decisive answer to all situations in which the patient can arrive. It also enables the continuation of the dialogue between physician and patient in a true enough incomplete, but nevertheless real way, and this dialogue forms the basis of high quality medical practice.
2) Such prior consent may have no compelling legal force for the physician responsible for the final decision. It is as a result information with which the physician must take account and include in a wide decision process where any trusted representative plays an essential role.
On the other hand, there remains a clear difference of opinion between the advocates of legal recognition of prior consent. The one person views the prior declaration of consent as an integral ingredient of the "colloque singulier" between the physician and any trusted representative, and it must allow the patient to require the termination of life. Others believe that this must be raised in the consultation with the kin, care providers and trusted representative with the objective of having the intentions of the patient better known and to give him a dignified death to the extent possible, but that this not may allow a double frontier to be crossed, being that of therapeutic persistence and that of the termination of life.
The members of the Committee therefore remain divided about the ethical legitimacy of prior consent in which termination of life is requested. The problem does, however, become yet more complicated when the person concerned is suffering from Alzheimer's disease. We indeed know that the disorder entails progressive incapacity in the patient. Both the advocates of the legitimacy of the termination of life and those who only accept the possible stoppage or not starting of therapeutic actions of lethal intercurrent disorders are of the opinion that it must also still be ascertained whether the current situation of the patient corresponds to what he would consider an unbearable situation of decline and indignity at the time that he made his declaration. In this case the possible use of a trusted representative would seem extremely desirable; in this way ethical dialogue with the care providers and the kin can be concluded for the purposes of the maximum respecting of the wishes and the interests of the patient.

b. Prior consent concerning ordinary medical and social measures
For persons suffering from dementia, prior consent is not only important for issues with respect to the end of life. It also concerns consent to different kinds of care and to any placement. The members of the Committee believe that the procedure of prior consent would enable the better taking account of the wishes of the persons suffering from dementia as regards medical care and social measures that their situation requires.
Here one must take account of the fact that persons suffering from dementia gradually see their autonomy and decision capacities decline, sometimes over long periods. The legal tools of which our country disposes take no account of the progressive character of the situations of incapacity to decide about the provision of care and about all sorts of questions concerning the quality of life. A “trusted representative” appointed by the patient when he was still capable often finds himself with a difficult task that can extend over a long period. He must indeed to the extent possible comply with the wishes that the person suffering from dementia can still express, and assist with his incapacity where necessary. Now this task is fulfilled by the so-called “natural guardians” of the patient: family, physicians, sometimes also the management of the rest homes. Without wanting to minimise the devotion of most people, the members of the Committee do believe that this does not always form the best guarantee of the autonomy of the persons suffering from dementia and for the expression of their wishes.

Hence the members of the Committee recommend that, in the spirit of the draft law of Minister M. Aelvoet on patient rights now being discussed, a legal procedure should be introduced where the drawing up of prior consent with the appointment of a "representative" to ensure its application is encouraged. For reasons of terminological clarity, most members of the Committee choose in this case to use the term "representative of the person suffering from dementia". They therefore go further then the abovementioned draft law and are of the opinion that, to be efficient, the role of the representative must be controlled by law. To this end, the justice of the peace would be able to ratify the appointment of the "representative of the person" if the person suffering from dementia appointed him when he was still able. In the absence of such a choice, he would ex-officio be able to appoint a "representative" in order to give maximum respect to the autonomy of which the person suffering from dementia still disposes, and to make clear which person is responsible for decisions.
There are, however, a number of differences of opinion between the members of the Committee concerning the weight that must be given to the consent the patient may have drawn up, and concerning the scope of the power of decision of the "representative". In fact the "representative" would have the task of guiding the person suffering from dementia and taking all decisions the patient would no longer be capable of, and this for the purposes of the best possible quality of life and taking into account the previous choices of the person involved. Furthermore, the representatives who must apply the prior consent may not be regarded as pure instruments; they are in dialogue with the kin and the care providers. The latter must also abide by their own deontology and the rules prevailing in society.
For all these reasons the members of the Committee cannot agree with extreme positions: not where the prior consent and the appointment of a "representative" is regarded as worthless, nor where they obtain almost imperative power. They are of the opinion that one must assess each situation in its specific context. They desire the legal regulation of the procedure of prior consent and of the appointment of a "representative". This legislative context can, however, never replace the ethical debate that remains required in each clinical situation.
Finally, the more specific question of whether or not the "representative" will be able to decide if a person suffering from dementia person is subjected to medical experimentations is discussed in chapter III that covers the issue.

c. The management of goods

The members of the Committee mention that the law of 18 July 1991 makes it possible, if necessary, for the justice of the peace to appoint a "provisional administrator" of the property of the person suffering from dementia. Some believe the measure to be sufficient to accommodate the incapacity to decide of the person suffering from dementia as regards the quality of life. We must then mention that by law it is not determined that the administrator acts in the place of the person suffering from dementia for other questions than the pure management of his property, questions for which he is indeed not competent. Neither does the law provide for the procedure of prior consent in this area, nor the prior appointment of the provisional administrator.

Chapter II. FIRST QUESTION

Does a seriously disturbed psychological situation such as Alzheimer's disease justify special protective measures being taken?

We will examine the following issues in turn: the quality of life of persons suffering from dementia, the treatments at the end of life, the cost of certain treatments, and finally, from an ethical and legal standpoint, the consent to care, a problem that is central to patients of which their cognitive capacities are affected.

1. The quality of life

Placement or treatment at home
Learning ability is one of the fastest declining cognitive capacities among persons suffering from dementia. Because placement entails adaptation to a new environment, this often goes hand in hand with a considerable decline in the capacities of the patients. Furthermore, among many placement creates a feeling of affective absence. Therefore, the majority of consulted persons feel that one in most cases can best protect the quality of life of persons suffering from dementia by keeping them in their usual environment for as long as possible. Based on our information, 80% of Alzheimer patients are accordingly cared for at home. Some social workers do, however, suggest that for a number of patients it can be helpful to already place patients at the start of their dementia when they are still able to adapt to the new environment where they will spend the last days of their life. For some patients, placement is also required because of the danger they form to themselves or others. As a result, decisions regarding placement are taken case by case after considering all the different elements.

Alternatives to placement
One may not underestimate the burden these patients form for their kin. To be able to keep them in their natural environment, home care and day centres are indispensable. All experts consulted are agreed that this type of assistance is absolutely inadequate in most districts. The consequence of this is that many persons suffering from dementia receive poor care or are even mistreated. It is clear that we must look again at care for these patients within a comprehensive social project that creates practical possibilities for solidarity between the generations. The government must create the possibility of ensuring a real choice between home care and treatment in a establishment, where they may also not overlook alternating placement.

Improvement of the multidisciplinarity of the decisions
Many decisions concerning persons with Alzheimer's disease go beyond the medical context and concern daily living conditions. Hence, multidisciplinary teams consisting of a few family members, the physician, the nursing staff, the social assistants, physiotherapists, jurists, etc. can ensure better decisions that are more efficient and tie in more closely with the wishes of the patients. These teams would also be more suitable for solving any conflicts.
In this perspective the Committee refers to the importance of the initiative of the Flemish Community, that enables such teams to be brought together in a flexible manner and case by case around an ill person, where they are paid depending on the time they spend on the required consultation. (Samenwerkingsinitiatieven Thuiszorg - S.I.T.)
It is important to understand that this initiative of the Flemish Community has an exclusive pragmatic purpose in mind: bringing different persons together whose capabilities can be

effectively applied in specific situations and to make payments for these meetings. It is, on the other hand, by no means the intention for these multidisciplinary groups to assume the rights and the responsibility to decide by the patients themselves, their family or the physician.

The placement conditions

Placement in a establishment can be inevitable when the illness becomes too serious or the environment cannot give the necessary support. Based on the descriptions of the current situation given by the persons consulted, we must determine that the institutional framework and the professionalism of personnel all too often are seriously inadequate to appropriately accommodate these patients who are physically and strongly affectively dependent. Furthermore, the quality of the provision of care differs greatly depending on the establishment, and often depends on the admission cost**.** Economic selection can create a decrease in the quality of care to the detriment of the least affluent.

The Committee believes that our society, if it wants to respect the ethical standards it has set itself, being the same dignity for everyone and solidarity with the weakest, must urgently improve medical and social assistance for persons suffering from dementia.

2. Therapeutic persistence, discontinuation of the treatment and request of termination of life

It is often the case that a person suffering from dementia, independent of his degenerative pathology, displays another intercurrent disorder. If the disorder is serious, the question can arise of if one must treat them or leave them to their normal fatal destiny. The members of the Committee first of all unanimously remind that one must always ensure that the suffering of the patient is relieved to a maximum. The fact that one may decide against curative treatment does not in any way mean that one must not administer appropriate palliative care to persons suffering from dementia at the end of their life. Because one is not sure that the persons is able to suffer pain – or express their suffering – one may not exercise negligence or withhold action.

When a person is suffering from serious dementia, has completely lost his autonomy and is apparently no longer capable of normal psychological contact with the environment, it obviously seems absurd to want to lengthen his life by starting heavy treatments that may further aggravate his suffering without improving his quality of life. However, most medical situations with persons suffering from dementia are not so clear-cut. We give as an example the decision of whether or not to proceed with a diet for a person who is no longer able to swallow.

To the question of so-called extraordinary care there is no simple answer. It is only legitimate in the case of benevolence with respect to the patient. The severity of dementia can differ greatly from individual to individual. The anticipated unavoidable decline also displays individual differences**.** The suffering and the affective relief of a person suffering from dementia can also differ greatly. The intercurrent medical pathologies vary greatly: from the most banal to the most serious. On the other hand, the therapeutic capabilities of medicine are constantly increasing, and treatments that were long considered exceptional are becoming constantly more banal.

Besides all the uncertainties, there is still also the inevitable subjective character of the way in which people see the quality of life of persons suffering from dementia. Those who more relate this quality of life to the exercising of autonomy or the ability to play a role in interactions that contribute to general welfare will not see this in the same way as those who rather see the quality of life in the light of affective interactions, even if the ability to express this has been seriously impaired.

We may therefore no longer base ourselves on objective rules or conditions to decide whether something is therapeutic persistence or not. Each case must be solved taking into account the specific characteristics and the sensitivity of the patients concerned, and of the other parties with respect for democratic pluralism. Indeed, the members of the Committee are uniformly opposed to therapeutic persistence and believe that it is ethically justified to stop certain curative treatments or not apply them and in certain cases allow the patient to die. This is, however, without ever neglecting to relieve the suffering of the patient.
The members of the Committee indicate that with respect to their welfare the wishes of the person suffering from dementia must apply to the extent possible as high priority criteria when making therapeutic choices. In this context they emphasise that the quality of the choices greatly increases when they do not have to be made under pressure of time. We must therefore strive to have carers and other parties discuss the problems with the persons suffering from dementia in a serene climate before the situation becomes critical**.** The fear of illness and death that is particular to our society often makes this type of dialogue more difficult This therefore requires appropriate education for both carers and the people.
This does not detract from the fact that the taking of medical decisions is often difficult because the line between therapeutic persistence, so-called extraordinary treatments, and banal treatments is not simple to draw. The Committee wishes in these cases to encourage the use of "ethical reflection groups". At establishments where one applies this method a physician in a difficult situation can quickly convene a number of persons: another physician, a nurse or a member of the local committee for ethics to help him with his reflection. Obviously the group never acts in the place of the physician, and the latter retains complete freedom and responsibility for his decisions. The members of the Committee believe that this practice can also simply take place outside hospitals, in particular in rest homes and among physician's associations.
We also want to point out that numerous members of the Committee are of the opinion that the procedure of prior consent can offer a practical answer to the ethical dilemmas inherent to the decisions that must be taken with regard to a patient unable to give informed consent, where the will of the patient is given priority over medical knowledge**.**
Finally, the problem of the termination of life arises among a number of patients. Some persons suffering from dementia who are still able to express their wishes in an efficient way request euthanasia. Others, who are no longer able to do this, have requested this in prior consent. The ethical legitimacy of the approach was discussed in the previous chapter. For the problem of the termination of life in its entirety the Committee refers to the two advisory papers published in 1997 and 1999 on persons able to give informed consent and persons unable to give informed consent respectively.

3. The cost of the treatment

With the ageing of the population the number of persons suffering from dementia is increasing year after year. The population therefore ensures increasing costs of medical care, accommodation, guidance and assistance in daily life. Our society has chosen to bear the costs. The members of the Committee are in agreement with the option of solidarity. They point out that if one wishes to follow this path, the required financial resources and investments must be provided within the bounds of the available resources, taking into account the cost of technologies and medicines for other patients.
Some neighbouring countries (United Kingdom, the Netherlands) appear to prefer a system where above a certain age some major treatments are no longer reimbursed. In our country the refunding of a new specific medicine against Alzheimer's disease was recently refused because it was too expensive and the improvements resulting from the medication were but of a temporary nature. The members of the Committee are therefore of the opinion that this

problem must be tackled.
The idea of limiting access to certain treatments for elderly person or persons suffering from dementia appears to some to be based on an economic evaluation of the productivity of the persons. Irrespective of the considerations above concerning the futility of a number of treatments among persons suffering from dementia, the members of the Committee believe that one prejudices the equal dignity of all should one use the rule of the economic or social productivity of the individual for the sharing of the available resources. They believe that the option of solidarity, which our society has chosen, requires special attention for non-productive persons. Furthermore, the refusal of certain reimbursements can only encourage social inequality, because only well-off persons could afford to pay for treatments that are not repaid.
In addition, we must note that most costs inherent to dementia are caused by ordinary medical treatments and the social care of the patients. The budgetary efficiency of the decision to refuse major treatments can in their case therefore be called into question.
Therapeutic persistence on the other hand has no ethical legitimacy at all, as we have already mentioned above (chapter II, 2). From information gathered from experts and persons close to patients, it appears that persons suffering from dementia are subjected to pointless and sometimes expensive experimentations and treatments. The Committee does not dispose of the necessary information to establish how often such situations occur. One can accordingly ask the question as to how one can best avoid these situations. From this perspective, we must emphasise that the financing system for hospitals and care homes may not be of such a nature that their financial balance may be jeopardised, so they feel compelled to carry out futile treatments. The Committee reminds here that for difficult decisions, the use of the abovementioned "ethical reflection groups" is encouraged.

4. Consent of the persons suffering from dementia for the provision of care
For persons suffering from dementia the specific ethical problem is that their cognitive capacities have been impaired, so also their capacity to in an informed way consent to the medical and social care required by their situation. One must therefore attempt to best use their capacity to consent to the extent this is possible. If not, the law must determine how one can act in the place of a person suffering from dementia with the safeguarding of his rights.

4.1. Maximally using the capacity of consent
With regard to persons suffering from dementia, the first rule is that one may not underestimate their capacity to accept a treatment or otherwise. We have already mentioned that the cognitive capacity can vary greatly from person to person. This variability concerns the amount and the extent of brain damage, but also the various options the patients have to use compensatory cognitive resources. The capabilities depend on the localisation of the damage, but just as much on the personal history of the patient and of his current cognitive and affective context. The brain damage suffered by a person may accordingly not be the only measure of his capacity to consent. Progress in molecular biology, the genetics of the dementias and the associated therapeutic expectations may not have us forget that relational and social dimensions play a fundamental role in the consent process and in the quality of life of the person suffering from dementia.
Neither may one confuse the capacity to consent to a certain treatment with any status of legal incapacity of an ill person**.** Someone can, for example, no longer be able to manage his property at all, but still be able to consent or not to a medical treatment.
The consent of the person suffering from dementia to the medical and social assistance he is offered must be carefully striven for, to the extent possible taking into account each actual situation. In this field, particularly in the Anglo-Saxon world, much research has been done

with the objective of determining the various criteria of capacity. In a large number of cases, the assistance of the kin with an affective bond with the person suffering from dementia and who know his history and personality well is of great value.
The experts and associations of families of persons suffering from dementia consulted by the Committee unanimously regret that in this respect very many social workers are insufficiently trained and competent. Knowledge concerning the relational and social factors that affect the capacities of persons suffering from dementia is quite recent; as is the strong increase in pathologies. Hence, considerable efforts must be made within the context of the basic and advanced training of physicians, nursing staff and social assistants in order to give them the necessary ability to effectively treat dementias and to obtain the consent of the patients.

4.2. The current legal solutions in the case of incapacity to consent to the treatments

When the consent of a person suffering from dementia cannot be obtained for the provision of care that is nevertheless required, the question arises as to who can decide and according to which criteria. Now the decisions in most cases are taken after open consultation between the persons affectively closest to the patient, the physician and any nursing and social personnel concerned. The decisions are aimed at giving the person suffering from dementia the best possible quality of life with a minimum burden. Irrespective of the quality of the decisions, they do not ensure the legal protection of the persons suffering from dementia. It is also too often the case that such consultation does not take place, either because the carers are insufficiently trained, because there is no family or because the families are in conflict. All experts consulted by the Committee agree that various social and legal innovations could simplify the decision process in such situations.
The law has always been confronted with the problem of mental decline, and has accordingly provided for different systems of incapacity to offer protection to persons who do not or no longer dispose of sufficient power of discernment. The legislator has always indicated that this concerns exceptional rules and that capacity is the rule.
When one must protect the incapable person himself and simultaneously the society in which he lives, there inevitably rises a conflict between the safety aspect of the planned arrangements and the fundamental principle of individual freedom. The legislator is properly aware of this, and therefore does not specifically intervene for the whole population categories: alcoholics, drug addicts, but also somatic patients who refuse care because they do not see the necessity of the proposed treatments.
Specific to persons suffering from dementia is that the inevitable degenerative process of which they are the casualty very sharply accentuates the problem of the gradual loss of their autonomy. The current legal instruments offer no answer to that specific characteristic. Besides extended minority which is clearly not applicable here, the following written laws are applicable:

A. The law of 26 June 1990 concerning the protection of mentally ill persons

The law provides for the compulsory placement of the mentally ill who, because of their situation, form a danger to themselves and to others. The treatment following compulsory placement is obviously also compulsory.
Normally the placement is enforced by the justice of the peace.
In urgent cases the public prosecutor can decide that the patient be admitted for observation in a psychiatric department indicated by him (articles 11 and 12). The decision must be confirmed by the justice of the peace in the following days. Then, after he has heard the patient, his lawyer and even his psychiatrist/legal adviser, the justice of the peace can decide that the person involved be admitted for forty days. The decision must then again be

confirmed every two years (articles 13 and 14).
The law is not really effective for the accommodation of persons suffering from dementia. Psychiatric hospitals are not usually suitable for the treatment of dementias. The immediate proximity of other mentally ill persons is not favourable for them. According to the spirit of the law, only treatments may be used that are required to restore the autonomy of the mentally ill so that he no longer forms a danger and can leave the hospital as soon as possible.

B. The declaration of incapacity: article 489 and the following of the Civil Code

"An adult who is in a constant state of inanity or derangement must be declared incapable, even when clear intervals occur in his condition." (art. 489 Civil Code).
"The person declared incapable is considered equivalent to a minor as regards his person and his property: the laws on the guardianship of minors are applicable to the guardianship of persons declared incapable." (art.509 Civil Code).
"The income of a person declared incapable must principally be used to lighten his load and speed his recovery." (art. 510 Civil code).
It is clear that declaration of incapacity only comes into consideration in the most serious cases of dementia, where the person in question is definitively no longer able to autonomous decide. Furthermore, the law is mainly aimed at protecting the property of the patient and himself against the danger he forms. This law is unsuitable to manage situations of progressive and partial incapacity for the purposes of the optimum quality of life for the patient and maximum protection of the mentally capacities he still disposes of.

C. Royal decree of 14 February 1893 concerning the sequestration (isolation) of the mentally ill at home

The family or each person concerned can request the justice of the peace to isolate a person suffering from dementia at home, and this based on a certificate in which declares "that it is necessary, both for the health of patient and for public safety, to isolate the named X at home in accordance with the law of 1873*".*
The law is practically out of use. It mentions nothing about measures that must be taken to place the patient elsewhere than at home to guarantee him the required care and a good quality of life.

D. The law of 18 July 1991, article 488bis of the Civil Code concerning the provisional administration of the property of an adult

The justice of the peace appoints a provisional administrator for the adult who, in view of his health situation, is no longer able to manage his property. The members of the Committee are of the opinion that, in general, the provisional property rule offers a satisfactory solution for the actual protection of the financial resources of the patient, even if a number of small improvements can still be made. The spirit of this law and the administrative procedure clearly state that the provisional administrator is not authorised to take decisions concerning placement or treatment. He has no competence whatsoever to become involved with the private life of the person, and his appointment is only justified if the patient disposes of property that must be managed.

4.3. The legal resources to be used: prior consent and representative of the person

We therefore establish that a certain legal vacuum exists regarding the care of persons

suffering from dementia. Very many decisions concerning them are taken without legal protection. Protectionist interventionism in the name of the person suffering from dementia, even if well intended, is not the best way to protect his interests.
The gradual decline – that can take many years – of the decision capacities of a person suffering from dementia raises particularly difficult ethical and legal problems: who must decide in his place and according to which procedure? The autonomy and the options relating to the quality of life of this person must to the extent possible be respected, and at the same time one must act in the place of the patient when his capacities are failing him.
The current legal arsenal is poorly adapted to these situations. The application of the term "natural protector" appears inadequate to guarantee compliance of the autonomy of the person suffering from dementia. The procedure of the declaration of incapacity makes the person equivalent to a fully incapable minor. The law on the protection of the mentally ill is to enable treatment in a psychiatric hospital. This is not a suitable solution for most of these persons. The law of 18 July 1991, that enables the appointment of a provisional administrator, does not provide for the latter taking responsibility for the management of the quality of life of the person concerned.
We must therefore simultaneously draft flexible and effective procedures.
The procedure of prior consent combined with the appointment of a "trusted representative" would possibly be able to solve this problem. According to the discussions currently taking place in our country, this procedure – and the terms it uses – is attempting to provide a solution for the prior request for termination of life with a person who at that time is fully incapable of expressing this request. The different standpoints on this subject within the Committee were presented in advisory report no. 9 of 22 February 1999, and are included in this advice in chapter I.2.2.
The question concerning the quality of life of a person suffering from dementia entails different problems. Therefore, numerous members of the Committee deem it a necessity to keep a distinction between the procedure of prior consent and the appointment of a trusted representative as currently being discussed, and the procedures of representation with the gradual incapacity of a person to take decisions about his daily life: place of residence, general care, medical, care, etc.

For this representation, numerous members of the Committee argue for a new procedure to be established that is inspired by the current draft law on the rights of the patients. The latter provides for the patient being able to appoint a "mandatory", who in his place exercises his personal rights if he should become incapable to the extent of and for the duration of this incapacity. Numerous members prefer the term "representative" of the person suffering from dementia to "mandatory" in order to avoid the legal confusion these terms could bring.
This "representative" would to the extent possible be appointed by the person concerned himself/herself on the basis of prior consent when he/she is still able to do this. This declaration of consent would also entail the ability to express the wishes of the person. The "representative" would have the task of speaking about all decisions that the latter can no longer take in the name of the person suffering from dementia. Depending on the choice of the party concerned, this "representative of the person" may or may not be the same person as the "trusted representative" possibly appointed within the context of a request for the termination of life. This choice remains completely free.
Numerous members of the Committee would like to go further than the draft law, and consider it desirable that the justice of the peace intervenes in confirming the choice of the appointee "representative" so he obtains a clear legal status. In addition, they propose that in situations in which the person suffering from dementia has appointed no "representative", the justice of the peace would ex-officio appoint one. The legislator will have to define according

to which procedure this case will be submitted to the justice of the peace.
Such a "representative" has the benefit of being a specific and reliable partner in dialogue who expresses the wishes of the person suffering from dementia for the purposes of his welfare. He acts in the case of the different decisions about care, support and any placement, as the person himself would have done, in consultation with the carers and the environment. After this consultation he must take decisions that appear to protect the interests of the person suffering from dementia as well as possible.
In the eyes of some members of the Committee, the appointment of such a "representative" also enables certain problems to be solved with respect to experimentations with persons suffering from dementia, as we will see in chapter III that is devoted to this problem.

The recommendations resulting from this chapter are included in the first part of this opinion: "Summary and recommendations".

Chapter III. SECOND QUESTION

Issue of experimentations with persons suffering from dementia

We now remind of the second question of minister M. Colla:
"Only persons who can autonomously give permission of their own free will and in an informed manner may participate in non-therapeutic experimentations. Hence, patients with a serious form of Alzheimer's disease cannot do this. One would, however, be able to derogate from this principle under very strict conditions providing the experimentation would represent a minimal risk and burden for the patient. This also means that the experimentation or the specific measures concerned would be stopped as soon as the patient refuses his participation. I would appreciate your advice in this respect.".

The problem of experimentations with persons unable to give informed consent concerns not only persons suffering from dementia, but also various other categories: children, mentally disabled persons, persons in a coma, etc. The members of the Committee have, however, decided to keep this advice only to persons suffering from dementia because of the specific characteristics of the group. With dementia the incapacity is progressive and can vary having regard to the decisions to take. As we have already seen, the legal status of the persons is often ambiguous and not well adapted to the reality of their situation. Finally, persons suffering from dementia have in principle had the opportunity to draw up prior consent while they were still in good health. The advice of the Committee takes account of all the specific elements**.**
In a first part, we will give an overview of the rules in this area that now apply in International Law and in Belgian Law. In the following part we examine the problem of the ethical legitimacy of experimentations with persons suffering from dementia. Finally, we will examine a further number of actual particulars of the situations.

1. The existing rules

A. The international rules

- Standpoints of the World Medical Association (WMA)

It is interesting to first draw attention to the standpoints of the WMA relating to the general rights of patients. In its declaration of Lisbon (1981) the WMA specified in the introduction that "*Whenever legislation, government action or any other administration or institution*

denies patients these rights, physicians should pursue appropriate means to assure or to restore them.". One notes that in the text it is not only required that the physician respects the rights of the patient to the extent possible, but that he also actively defends his rights.
As regards patients with mental disorders, the WMA states in its Bali declaration (1995) that the therapeutic relationship must always be based on reciprocal trust: "*the physician must inform the patient of the nature of his situation, the therapeutic resources (…) and the expected results*." Also stated is that (art. 2)*: "a patient with mental illness should not automatically be considered to be legally incompetent. His/her judgement should be respected in areas where he/she is capable of making decisions.".*
We therefore note that, even for ordinary treatments, the principle of informed consent is emphatically defended. In the case of consent to experimentationation the physician will have to even more closely check compliance with this principle.
Specifically as regards experimentations with persons not able to give consent, the Helsinki declaration of the WMA of June 1964 has been repeatedly revised, the last time in October 2000 in Edinburgh. The review determines (art. 24): "*For a research subject who is legally incompetent, physically or mentally, the investigator must obtain informed consent from the legally authorised representative in accordance with applicable law. These groups should not be included in research unless the research is necessary to promote the health of the population represented and this research cannot instead be performed on legally competent persons. (art. 25): When a subject deemed legally incompetent, such as a minor child, is able to give assent to decisions about participation in research, the investigator must obtain that assent in addition to the consent of the legally authorized representative.*". Article 26 finally determines that research on individuals from whom it is not possible to obtain consent should be done *only if the physical/mental condition that prevents obtaining informed consent is a necessary characteristic of the research population".*

• Convention of the Council of Europe on Human Rights and Biomedicine (Oviedo, 1997)[2].

Article 6, §1 of the treaty starts by stating that "*an (in this case therapeutic) intervention may only be carried out on a person who does not have the capacity to consent for his or her direct benefit".*

Article 17 of the chapter about research starts by adopting the same standpoint: §1: "*Research on a person without the capacity to consent may be undertaken only if all the following conditions are met:*

i: *the conditions of article 16 are fulfilled* (this involves the general conditions for any research);

ii: *the results of the research have the potential to produce real and direct benefit to his or her health;*

iii: *research of comparable effectiveness cannot be carried out on individuals capable of giving consent;*

iv: *the necessary authorisation provided for under Article 6 (of the legal representative) has been given specifically and in writing, and*

v: *the person concerned does not object."*

This last statement can dumbfound: how can a person unable to give informed consent object? In fact a person can, even if incompetent, display resistance to having himself subjected to certain procedures required for experimentations. In this case one cannot compel him.

The Convention of the Council of Europe allows in §2 of article 17 an important exception to the rule that experimentations with persons unable to give informed consent are only allowed

[2] We remind that this treaty has not been ratified by Belgium.

if a benefit is expected: "*Exceptionally and under the protective conditions prescribed by law, where the research has not the potential to produce results of direct benefit to the health of the person concerned, such research may be authorised subject to the conditions laid down in paragraph 1, sub-paragraphs i, iii, iv and v above, and to the following additional conditions:*

i : *the research has the aim of contributing, through significant improvement in the scientific understanding of the individual's condition, disease or disorder, to the ultimate attainment of results capable of conferring benefit to the person concerned or to other persons in the same age category or afflicted with the same disease or disorder or having the same condition.*

ii : *the research entails only minimal risk and minimal burden for the individual concerned."*

We observe that here the Council of Europe wants to leave open the possibility of carrying out research without benefit for the health of patient who is not able to consent. We clearly note that the terms "minimum risk" and "minimum burden" are not more specifically described in the text. In the recommendations preceding the text of the convention (September 1996), a number of examples are mentioned along with the following: *"The abovementioned examples of medical research cannot be considered as ordinary treatments(…); they can, however, be ethically acceptable if they suffice with regard to the strict protective provisions mentioned above".* Finally, article 26 of the Convention states that a State who has signed the Convention may place no single restriction on the rights and protective measures referred to in article 17. Article 27 then determines that each State may grant a wider measure of protection.

A draft protocol appended to the Convention on Human Rights and Biomedicine on biomedical experimentations has been released for consultation to the signatories to the Convention. Some additions are specifically applicable to persons not able to give their informed consent. Besides the specification of a minimum risk and minimum burden in article 20 and the emphasis of the fact that all information must be provided to those who must give consent for the experimentation – and to the extent possible to the person concerned - point IV of article 18 specifies that one must take account of the prior wishes and refusals expressed by the person in question who is no longer able to consent to experimentations. This article also specifies that an adult who is not able to give consent must nevertheless be involved to the extent possible with the consent procedure.

B. In Belgium

Our country does not yet have specific legislation relating to experimentations with people. Various statutory provisions make it indirectly possible to protect patients on whom experimentations are conducted. No law, however, explicitly covers experimentations with persons not able to consent.

In the code of medical ethics of the Nationale Raad van de Orde van Geneesheren (review 1995), in articles 89 to 94 the general rules concerning experimentations with people are described. The problem of incapable persons is only described in very general terms in article 91: "*Without their consent or, if they are competent for this purpose that of someone responsible for them, (*patients) *may not be subjected to experimentations of which they may suffer the slightest discomfort without this being of direct benefit.*"

Furthermore, at the meeting of 20 June 1998 the Nationale Raad van de Orde tackled the problem of informed consent within the context of clinical tests with persons suffering from dementia, this further to a question from the Belgische Vereniging van Gerontologie en Geriatrie. It repeated the ethical foundations of its standpoint relating to experimentations

with people, and this irrespective of the whether or not Belgium ratifies the European Convention. *It believes that in the case of the legal incapacity of the demented person, the advice must be requested of the provisional administrator representing the protected person (law of 18 July 1991) in all his legal acts".*
The members of the Committee remind (see chapter II of this advice, point 4.2 D) that, according to the spirit of the law, the role of the provisional administrator does not cover all legal actions, but mainly consists of the management of the property of the patient. For persons suffering from dementia without personal possessions no provisional administrator is indeed usually appointed.

Although the general tenor of the rules prevailing in our country states that great caution must be exercised with experimentations with incompetent persons, and in particular with persons suffering from dementia, there nevertheless appears to be no specific texts to explicitly protect these persons.
Summarising from the overview of the national and international provisions in this area it appears that experimentations with persons not able to consent can be allowed, even if there is no direct benefit for the persons, providing that strict limitations are provided. It must be pointed out that the texts relate to all categories of persons unable to give informed consent and not specifically persons suffering from dementia.

2. Ethical discussion about consent

2.1. The general rules concerning experimentations

The Consultative Committee has discussed the general ethical rules of experimentations with people in its opinion no. 13 of 9 July 2001. We accordingly refer to that opinion for a detailed presentation of the discussion, but we deem it useful to remind of the essential components:

"*The medical experimentation is a contentious area between on the one hand the freedom of research and therapeutic progress one wishes to obtain in the interest of everyone, and on the other hand respect for and the protection of persons. If one wants to accept the advantages of scientific medicine, in particular the relieving of suffering, one must simultaneously consent to the methods and the activities that enable benefits, that undoubtedly as regards the acquisition of knowledge have much better results than the empirical searches of the previous centuries. Confirming the legitimacy of the experimentation implies that one accepts the contentiousness between values that are initially not reconcilable, that must be weighed against each other and placed in the correct context. Ethics and the law thereby each have their own role to fulfil in accordance with their own specificity. The rules they formulate keep the professional conscience permanently alert with the increase in medical experimentations.*
With experimentations with people the question immediately arises: how to conduct experimentations and at the same time respect the autonomy and vulnerability of the test subjects? This general question in fact forms the synthesis of different aspects which require attention and alertness, both on an ethical and legal level. The conflict that is inherent to the experimentation may not be reduced to a set-off between the freedom of research and the autonomy of the person. The 'primum non nocere' principle and the collective interest may not be left out of account. Pursuing the collective interest implies that one takes account of the justification principle that compels us to ensure that the advantages and disadvantages of biomedical research are shared among the population in a fair way, and that structures originate that enable all people to have access to high quality health care in an equivalent way […]."

To evaluate the experimentation subjects "*the frame of reference for the committees for medical ethics is based on four fundamental principles:*

A. THE VALIDITY PRINCIPLE: thanks to the experimentation will one actually obtain more knowledge concerning the problems that are the subject of the experimentation?
B. THE PRINCIPLE OF SCIENTIFIC ACCURACY: the research must take place in a effective scientific context by means of a strict methodology.
C. THE "NO HARM" OR "PRIMUM NON NOCERE" PRINCIPLE: the experimentation may not affect the health situation of the test person and the risks must remain limited to and commensurate with the benefit hoped for.
D. THE AUTONOMY PRINCIPLE : this requires the obtaining of the free and informed consent of the test person. This assumes that the test person has the possibility to autonomously think, and that the physician provides information in a clear and enlightening way.".

2.2. Ethical problems particular to experimentations with persons suffering from dementia

It is obviously here that the ethical problem of experimentations with people are most strongly highlighted. Depending on the characteristics of the situations considered, the members of the Committee share the same standpoint or they are on the other hand in complete disagreement with each other.

2.2.1. The consensual opinions

a. Some persons suffering from dementia remain in a condition to consent
Although it is clear that with a large number of persons suffering from dementia the problem with medical experimentations exactly involves their incapacity to consent, it would still be wrong to generalise this. *Not each diagnosis of degenerative brain damage (dementia) therefore automatically means that the person in question is no longer able to give informed consent, and certainly not in the initial stage of the illness*. The observation is very important in different aspects.
This initially brings us to repeat that with research, one must generally choose test subjects to the extent possible among persons able to give free and informed consent. This also applies for tests relating to dementias. In addition, persons with starting dementia can very often get the most benefit from new medications.
Secondly, the observation brings us to again emphasise the competence and care with which the ability of a person suffering from dementia to consent must be assessed. As we have already have mentioned with respect to the treatments, one may not confuse the ability with the legal status of the person. The ability often varies depending on the affective context and the subject about which his decision must be requested. Because of the inconstancy and the diversity of consent to which persons suffering from dementia are able, with each experimentation they must be the subject of very meticulous follow-up and the patient must have the possibility to at any time withdraw from the experimentation. With experimentations with persons suffering from dementia who are still able to consent, one must guard against two dangers: on the one hand excessive caution, so one prematurely deprives the persons of their autonomy and of their right to possibly benefit from experimentations, and on the other hand carelessness where one is satisfied with vague consent and little account is taken of their vulnerability.
Should he/she so wish, a person suffering from dementia who is still able to consent must be

able to participate in both experimentations from which he/she can gain a direct benefit and experimentations without direct benefit for him provided that these precautions are taken.

b. Certain experimentations can give the patient a direct benefit
The members of the Committee are of the opinion that, if the likelihood is great that an experimentation will give the person suffering from dementia a real therapeutic benefit, it would be unjust to exclude the person from participation in the experimentation because he is not able to consent. The decision to experimentation must be taken case by case, based on a very careful and meticulous assessment of the balance between the risk to be taken and the expected benefit. Any "representative" of the person, as mentioned above, would also be able to consent.

2.2.2. The non-consensual opinions
The opinions of the members of the Committee differ as regards the legitimacy of experimentations with a person suffering from dementia who is unable to give informed consent without direct benefit for the person in question.

a. The standpoints of the advocates of experimentations without direct benefits

a.1. When there is no prior consent
According to some members of the Committee, knowledge of dementias and the incapacity that is a consequence can only progress by experimentationing on patients in the situation. They believe that a radical prohibition of experimentations without personal benefit comes down to discrimination and the neglect of the patients, and sentences them to their situation of incurable patients. For these reasons the members prefer no full prohibition, but a strict and restrictive context for such experimentations. Experimentations with patients who are not able to consent must be prohibited, except when the following conditions are met: the experimentation entails only a minimum burden and a minimum risk; it cannot be conducted with persons able to consent; it relates to the pathology of which patient is suffering; progress is expected so that in due course persons in a similar situation can gain benefits from the experimentation. Finally and obviously, if the person suffering from dementia is under legal guardianship, the agreement of the guardian is also required. It is particularly the case that if new statutory provisions were to introduce a “representative of the person" appointed by the justice of the peace, as recommended in the previous chapter, the latter would be able to consent to experimentations without direct benefit, but his agreement would be required.
These members of the Committee therefore agree with the standpoint of the World Medical Association (Declaration of Helsinki, review of Edinburgh, October 2000) and of the Convention of the Council of Europe on Human Rights and Biomedicine (Oviedo 1997). We mention that Belgium has not signed this treaty.

a.2. When there is prior consent
The members of the Committee advocating experimentations without direct benefit for the person suffering from dementia who is not competent to consent judge that the introduction of the procedure of prior consent must be encouraged. Here they would see considerable progress as regards respect for the autonomy and dignity of the persons suffering from dementia, who at a time when they were still able make known by such a declaration of consent that they were prepared to cooperate on general welfare when the illness would affect them. In this case the prior appointment of a "representative of the person" by these persons would appear extremely appropriate. The opinions of the members of the Committee do, however, differ about the scope of experimentations that such consent would allow.

- Some believe that one must respect the autonomy of such a person to the full, and that he himself decides how much discomfort and risk he wants to expose himself to, however considerable. They accept that an ill person who has drawn up prior consent in which he/she requests the termination of life in the case of advanced dementia and in which he/she furthermore agrees that he/she may be subjected to dangerous experimentations before his/her death is included in an investigation concerning his/her disorder that entails considerable risks. It is naturally the case that the expected_results of such an experimentation must be great, and that a strict control must take place by a committee for ethics. For the members with this opinion, it does however remain that although the consent of the representative of the person is formally required, the latter must respect the written declaration of consent of the person he represents. If the representative of the person objects to such an experimentation, his non-acceptance must be reasoned by the lack of relevance of the research and not by the degree of danger.
- Others believe it to be ethically unjustified for a person to subject his health and welfare to serious risks for the scientific value of an experimentation. They therefore do not accept that prior consent allows this, even within the context of a request for euthanasia. They believe that the problem is never merely individual, because the ethical position of the researchers and other parties to the research is also involved. The latter cannot, without jeopardising their own dignity, use other persons as a tool in exposing the person to a considerable burden or serious risks. In such cases these members wish to keep to the rule of minimum burden and minimum risks.

b. The standpoints of the opponents of any experimentation without direct benefit

Other members of the Committee take a more restrictive position with regard to experimentations with persons suffering from dementia. They believe that sufficient research can take place with a real benefit in due course for the group of persons suffering from dementia without having to use this group who is no longer able to give its consent. They are of the opinion that respect for each person suffering from dementia and for his welfare must have priority over future hypothetical advantages for the patient group. They believe that the permitting of exceptions to that principle would create a dangerous precedent as regards the protection of persons who are already highly vulnerable. They fear a climate of overhaste, where the hope to obtain new therapies in the near future could lead to hasty decisions. They also fear that the financial interests involved with the experimentation could also too easily be a cause of new suffering for patients. They therefore believe that each experimentation with persons suffering from dementia without direct benefit for the person must be prohibited.
The question of prior consent also divides these opponents with two lines of thought.

b.1.

Some believe that such consent validly represents the will of the person suffering from dementia at that time in the same way as if he was still able to consent, and that this will must be respected. They therefore accept that this consent gives permission for experimentations without direct benefit. They do, however, subject this to the strict conditions described in *a,* and emphasise that the rule of minimum burden and minimum risks be observed.

b.2.

Other members of the Committee think that neither prior consent, nor the prior appointment of a "representative" by the person can legitimise experimentations with patients no longer able to consent if these experimentations entail no direct benefit for them. Besides the general ethical objections with regard to such a declaration of consent as already previously discussed, they fear that when one attaches so much importance to the experimentations, even

if based on prior consent, the inclination to use people for scientific or financial interests will increase, while this inclination according to them is already too manifest in our society. They therefore want a prohibition of all experimentations without direct benefit on persons suffering from dementia who are incapable of giving their consent.

3. Some additional ethical aspects particular to experimentations with persons suffering from dementia

3.1. Minimum risk – Minimum burden

Both terms "minimum risk" and "minimum burden" apply in the European Convention as conditions for the conducting of experimentations with persons not able to consent and who will have no benefit from the experimentation. As we have already seen, some members of the Committee support this standpoint.

The term "minimum burden" concerns the known burden inherent to the procedures of the research in question, for example blood or other physical samples or more or less painful experimentations.

The term "minimum risk" concerns physical injury or psychological traumas that can occur as a result of the tested diagnostic procedure or the product tested in the research. Based on prior knowledge one can normally anticipate certain risks of an experimentation without, however, knowing whether or not the risks will occur. There are risks that cannot be anticipated. The term "minimum risk" means that unanticipated risks may well be very limited, and that the anticipated risks are not of such a nature that they will endanger the health of subject.

Obviously the assessment of the minimum risk and minimum burden has a subjective dimension, so any accurate description is a priori impossible. We remind in this context that the advice of the Committee about general conditions for experimentations with people refers to the existence of international research teams who are working on the more accurate definition of the assessments (Good Clinical Practice). Moreover, in the US Code of Federal Regulations (title 45 CRR Part 460) the terms "minimum risk" and "minimum burden" are described as follows: *"(when) the probability and the extent of the expected discomforts of an experimentation are not greater than those which normally occur in daily life, or those which can be associated with routine medical and psychological testing*". Some members point out in this respect that the excessive protection of persons suffering from dementia against normal risks and burdens can result from paternalism, which also conflicts with the respect they are entitled to.

We also note that the abovementioned terms "minimum risk" and "minimum burden" only take account of risks which relate to direct suffering that a person suffering from dementia could experience. With certain experimentations, genetic for example, there are also a number of sometimes serious psychosocial risks for the family or other persons, as well as for the image of the tested person with regard to his environment. These risks must also be taken into account.

3.2. The benefit for the person

The benefit that a patient can expect from an experimentation can be described as the hoped for improvement of his health, or the relieving of the disorders inherent to the pathology of which he suffers.

In the case of dementias any financial compensation for participation in an experimentation must be excluded. Such practice would not only lead to a higher level of exploitation of the patient, but particularly a further increase in the inequality of the situation of the needy and the serious reduction of their freedom of choice that has already been affected by the dementia.

Further, in accordance with the review of Edinburgh (October 2000, art. 30) the members of the Committee judge that, when it appears that a product tested in an experimentation has real benefits for a patient, from an ethical perspective after the experimentation the patient also must easily or free of charge be able to obtain the product that must obviously remain available to him. It is indeed from a human point of view hardly acceptable for a person whose situation has noticeably improved after taking part in an experimentation to then no longer benefit from it because of a lack of resources, and this with such a serious pathology as dementia.

3.3. The research objectives

Knowledge in the field of dementia disorders is evolving extremely quickly. Accordingly, great – and difficult too acquire - expertise is required both for the estimation of the possible advantages for the patient and the risks he is exposed to. The members of the Committee emphasise the importance of expertise on the part of the research leaders, because without this expertise the likelihood is great that the assessment of the balance between risk and benefit for the patient becomes a purely rhetorical question.

A point often neglected with such assessments is the possible psychological trauma inherent to this type of experimentation. The criteria to ascertain the efficiency are often based on the testing of the memory, reasoning capacity, affective stability, etc. Certain persons suffering from dementia, particularly with a slight or moderate form, experience their decline with great fear and know that its course is fatal. The test procedures and the impartation of their results can increase or lessen this fear depending on how this is approached. One must therefore carefully take account of this aspect with the assessment of the proportions between the risk and the benefit.

The deterioration of cognitive capacities among persons suffering from dementia does not exclusively depend on the extent of brain damage. As we have already emphasised, the quality of the cognitive and affective environment has an important influence on capacity. At a therapeutic level programs of psychotherapeutic support and cognitive rehabilitation can considerably slow the decline of this capacity. It would therefore be hoped that these domains are not neglected when conducting research. The government must always take account of this when giving credits for the research. We indeed know that biological research obtains financing much more easily because private companies expect that discoveries in this field will yield them a profit.

Only having attention for the biological aspects of dementias entails the danger that the carers, the environment and the population lose sight of the relational, familial and social dimensions of dementia. These dimensions are nevertheless essential to the quality of life and the dignity of the persons suffering from dementia.

3.4. The research framework

The members of the Committee believe it necessary to concentrate attention on the context within which an experimentation takes place. Because they are highly vulnerable, with an experimentation patients suffering from dementia must be much more closely monitored than with other forms of research. They are less able than others to impart what may be troubling them and make clear that they want to withdraw from the experimentation. Because they have difficulty in expressing themselves, it is also more difficult for physicians to observe any disorders.

Experimentations with persons suffering from dementia therefore require the parties involved to be very closely monitored. The researchers and committees for ethics must take these requirements into account.

Many persons suffering from dementia are cared for in rest homes or care homes. When

experimentations are carried out on these persons, just as with experimentations in hospitals the advice of a committee for ethics must first be sought and the same rules for care must be observed..

3.5. Financial aspects

Financial backers, including the pharmaceutical companies, often invest considerable amounts in research into persons suffering from dementia. With a positive result they can often count on big profits because the number of potential persons suffering from dementia in our society represents an important market. Sometimes the establishment conducting the research and the researchers themselves can gain various material advantages from the research.

The safety of the test subjects, who are highly vulnerable in the case of dementia, requires strong guarantees concerning the financial independence and objectivity of those involved in the research. For example, financial backers often have the most relevant information concerning the potential risks and advantages of an experimentation. It is therefore necessary that they make all information they have available to the researcher. For their part, the researches must take care in ensuring minimum discomfort for the test subjects because they only have attention for the expected advantages of an experimentation. Accordingly, it is also necessary that committees for ethics who give advice on an experimentation have real independence on an ethical level.

These requirements indeed apply for each experimentation, but they are particularly appropriate to persons suffering from dementia.

4. Legal considerations

In its advisory report no. 13 of 9 July 2001 the Committee declared the desire for a framework law which controls experimentations with people. We refer to the text in which the different general areas are discussed for which such a framework law should apply. Some specific considerations with respect to persons suffering from dementia must still be included.

Some members of the Committee wish the law to allow experimentations with persons suffering from dementia who are not able to consent. In this case it must determine which person has the right to take the relative decisions on behalf of the patient. As the Committee has already emphasised concerning consent to ordinary medical and social assistance, there is now a certain legal vacuum so the environment and carers often act *de facto* on behalf of the patient without them having clearly described legal protection.

The Committee is therefore of the opinion that, prior to starting an experimentation on a person suffering from dementia who is not able to consent, his legal status must first be established. Neither the law of 1991 concerning the provisional management of the property of an adult, nor article 509 of the Civil Code, according to which a person suffering from dementia is as regards his person and property made equivalent to a minor, can offer a sufficient legal basis for this. The current provisional administrator appointed by virtue of the law of 1991 in article 488bis of the Civil Code to manage the property of the incapable person does not appear to be the appropriate person to decide about questions such as treatment or, a fortiori, experimentations. The procedure for the declaration of incompetence referred to in art. 489 of the Civil Code, that is indeed highly laborious, appoints a guardian who in general has more authority to manage the property of the patient than his health situation and quality of life. The Committee therefore believes, just as it has proposed for treatments, that the law must innovate by the introduction of the position of "representative of the person", who would take decisions on behalf of the person suffering from dementia having regard to his situation. Ideally the representative would be officially appointed by the person himself when still

capable of doing so. If this has not happened he must be appointed by the justice of the peace.
All members of the committee believe that experimentations that will probably have a direct benefit for the person suffering from dementia can be accepted by the representative.
The members do not agree on experimentations without direct benefit on persons not capable of giving consent.
Some believe that such experimentations are legitimate and can be accepted by the representative of the person, provided that the abovementioned restrictive conditions are complied with.
Others believe that such experimentations may only be acceptable on the condition that the person suffering from dementia has proposed this himself/herself in prior consent that was written when he/she still disposed of his/her capacity to decide. Such a document could accompany the appointment of the representative.
Others believe that experimentations with persons suffering from dementia unable to give informed consent without direct benefit for themselves, are justified under no circumstances, and even that prior consent and the appointment of a representative should not allow this. They would like this type of experimentation to be prohibited by law.

The recommendations resulting from this chapter are included in the first part of this advice: "Summary and recommendations".

The opinion was prepared by select commission 98/4, consisting of:

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- Ms S. Henry, head of the non-profit organisation "Ligue Alzheimer"
- Dr. A. Haekens, physician, Heverlee
- Mr P. Erauw, Senior Deputy at the Public Prosecutor in Brussels

The work documents of select commission 98/4 – request for opinion, personal contributions of the members, minutes of meetings, documents consulted – are stored as Annexes 98/4 at the Committee's documentation centre, where they may be consulted and copied.