

The Budapest Meeting 2005

Intensified Networking on Ethics of Science

The case of Reproductive Cloning, Germline Gene Therapy and Human Dignity

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Keywords: ethics of science, networking, reproductive cloning, germline gene therapy, human dignity

ABSTRACT: *This paper reports on the meeting of the Sounding Board of the EU Reprogenetics Project that was held in Budapest, Hungary, 6-9 November 2005. The Reprogenetics Project runs from 2004 until 2007 and has a brief to study the ethical aspects of human reproductive cloning and germline gene therapy. Discussions during The Budapest Meeting are reported in depth in this paper as well as the initiatives to involve the participating groups and others in ongoing collaborations with the goal of forming an integrated network of European resources in the fields of ethics of science.*

There is an abundance of information, creativity and researcher enthusiasm just waiting to be tapped in the many EU-funded projects relating to the ethics of science. Coordinators of relevant projects are exploring possibilities of increasing the value of these resources through structured interactions.

The process began at a meeting organized by the EU Reprogenetics project that took place in Budapest on November 6-9, 2005. Reprogenetics is an EU funded project that started in 2004 and will end in 2007. The project is studying the ethical aspects of two controversial issues: the use of human cloning as a means for reproduction (often called “human reproductive cloning”) and the use of human gene therapy, which

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ISSN 1353-3452 (2006) Opragen Publications, POB 54, Guildford GU1 2YF, UK. <http://www.opragen.co.uk>

involves making a genetic correction that is transmitted to subsequent generations (often called “human germline gene therapy”). Both technologies are currently banned.

The Reprogenetics research team believed that they would benefit from the experience and input of other EU funded projects that were investigating similar or complementary issues, or using similar methodologies. This is why Reprogenetics organized a ‘Sounding Board’ meeting in Budapest and invited a large group of EU project coordinators to discuss the major topics with them.^a During the many formal and informal discussions, the Reprogenetics researchers learned much more than they had ever believed was possible. The invited coordinators and research leaders of other projects had a similar experience. They found out that they are not sufficiently aware of the results of other projects and that a structured interaction between ongoing projects could have a major impact on their own work and results.

Following The Budapest Meeting, initiatives were taken to explore the possibility of organizing regular contacts and of preparing regular overviews of what is going on in EU projects. Participants who could not attend The Budapest Meeting endorsed the initiative to find ways to keep the momentum alive. The possibilities were also discussed with the European Commission, the World Science Forum and the Science Policy Division of UNESCO.

During a Workshop in Brussels on March 17-19, 2006, a group of EU researchers, international experts, the World Science Forum and UNESCO endorsed the plans *to develop* a new annual series of ‘The Budapest Meeting’. This meeting will take place in a European city and will make a contribution to the events of the World Science Day for Peace and Development organized by UNESCO every year on November 10th. It will also make a contribution to the World Science Forum, which is organized every two years in Budapest as a major event of the World Science Day.

This article provides a summary of the discussions that took place during The Budapest Meeting and it explains the subsequent networking that has grown up around this event. This summary article is divided into five parts:

1. Context of The Budapest Meeting
 - 1.1 The Objectives of the Reprogenetics project
 - 1.2 Preliminary Conclusions
 - 1.3 Sounding Board
2. Interaction Sessions on the Topics in Focus
 - 2.1 Reproductive Cloning. The world in 2025
 - 2.2 Germline Gene Therapy. The world in 2025
 - 2.3 The United Nations and Human Dignity
3. Interaction Sessions on Ethical Values in Context
 - 3.1 Clinical testing and hospital care
 - 3.2 Ambient Intelligence, computers and nanotechnology

a. See www.embeddingethics.net for more information about The Budapest Meeting 2005 and its follow up. The website also contains the project posters of the different EU projects on ethics that are mentioned in the present summary article and that were discussed during the meeting.

- 3.3 Nature, animals and food
- 3.4 Brain research and dementia
- 3.5 Old age, Intensive Care Units and death
- 4. Interaction Sessions on Ethical Decision-Making
 - 4.1 Do we need intercontinental collaboration?
 - 4.2 Does the integration of the EU's New Member States require specific action?
 - 4.3 Is there a role for the religious traditions?
 - 4.4 Is there a role for the media and the general public?
 - 4.5 Can stakeholders speak a common ethical language?
- 5. Outcomes
 - 5.1 Conclusions and Recommendations of the Sounding Board
 - 5.2 World Science Forum
 - 5.3 A new annual series of "The Budapest Meeting"

Executive Summary

1. Context of The Budapest Meeting provides basic information about the objectives and preliminary conclusions of the Reprogenetics project and about the initial plans to organize a sounding board. The Reprogenetics project is studying the widely endorsed conviction that human reproductive cloning and human germline gene therapy should be permanently banned for ethical reasons. The aim of the project is to determine the extent to which such an "ethical ban" can have an impact on the daily scientific practice of the researchers involved or, in general, how ethical reflection, debate and regulation should be organized to optimize their impact on the ethics embedded in scientific practice.

The case of reproductive cloning and germline gene therapy presents many challenges. There appears to be a disproportion between the strength with which the ban is imposed and the strength – or rather the weakness and vagueness – of the arguments put forward to justify it

Even researchers who would be willing to unconditionally respect an absolute ban imposed by society, cannot always know exactly which research or clinical procedures are banned and which procedures are allowed or even encouraged.

2. Topics in Focus is a more detailed report on the first three Interaction Sessions that took place during The Budapest Meeting. Each session focused on one of the three Topics in Focus that were selected by the Reprogenetics project.

Interaction Sessions (1) and (2) dealt with the research scenarios and plans that are currently being drawn up in the world of cloning and gene therapy. It turned out that the difficulty of linking ethics and science in a clear way may in part be due to the fact that the scientific research itself is not so straightforward as the ethicists, lawmakers or society at large often assume. For example, while the distinction between "reproductive cloning" and "therapeutic cloning" is widely known among ethicists, in scientific

practice the cluster of different cloning procedures and scenarios is much more complicated and is continuously evolving. Contrary to common belief, if an adult person were to be cloned, the clone would not just be a look-alike. Moreover, cloning would be a reproductive tool not only for single people, but also for couples, whereby both father and mother would contribute in an equal way to the genetic makeup of the child. Furthermore, while it is convenient for ethicists and politicians to distinguish between different fields of activity such as cloning, gene therapy, stem cell research and fertility research, in scientific practice they overlap and intermingle. Contemporary scenarios for gene therapy make use of cloning and embryonic stem cells. Some fertility treatments already apply genetic corrections that will be transmitted to subsequent generations. The news of such pioneering treatments did not shock society, even though they can be classified as “germline gene therapy”. Interaction Session (3) addressed the notion of Human Dignity in a recent Declaration by the United Nations that issued a ban on reproductive cloning. This session dealt with the problem that the notion of “Human Dignity” as it is used in this Declaration would never work as a basis for scientists to determine what society wants them to ban, and what society would allow or even encourage them to do.

At the organizational level, this first series of Interaction Sessions resulted in the conclusion that a network for structural collaboration between EU projects in ethics is urgently needed, and that such a network should include structural links to projects in the so-called “hard sciences”.

3. Ethical values in context summarizes the discussions on EU funded research projects in five different social and scientific contexts: (1) Clinical testing and hospital care, (2) Ambient Intelligence, computers and nanotechnology, (3) Nature, animals and food, (4) Brain research and dementia, (5) Old age, Intensive Care Units and death. These five fields were selected because in the general literature they are intimately linked with the notion of Human Dignity, which plays a central role in the ethical ban that Reprogenetics is studying. For each field, a separate Interaction Session was organized. During each session, the participants were asked to identify the major ethical issues involved in the field and the approaches developed in the relevant EU projects. They were also asked to indicate the extent to which the notion of Human Dignity played a role in the project. As to this last question, most projects did not go further than the tacit assumption or formal acknowledgment that scientific practice should not run counter to the principle of Human Dignity. Only one project (“Dignity and Older Europeans”) explicitly used the notion to clarify the ethical issues at hand.

At the organizational level, each session revealed that several projects were doing similar work or were using similar notions, and that the different teams could learn a lot from the intermediate results and methodological decisions of the others. There was a growing conviction that it would be in the interest of all parties concerned if the interaction were not dependant on accidental collaboration or meetings, but were rather organized in a structural and permanent manner.

4. Ethical decision-making summarizes the discussions on methodological questions linked to the organization of ethical reflection and debate. Five questions were addressed: (1) Do we need intercontinental collaboration? (2) Does the integration of the EU's New Member States require specific action? (3) Is there a role for the religious traditions? (4) Is there a role for the media and the general public? (5) Can stakeholders speak a common ethical language? For each question, one specific Interaction Session was organized. In each of the sessions (1) to (4), the group endorsed the need to establish strong links with the social actors under study, and explored the limits and possibilities of such interaction. Session (5) endorsed the suggestion that it would be wrong to believe that "open and constructive exchange of information" is only possible when all partners involved use the same words in exactly the same sense. The group emphasized that the most important prerequisite for "speaking the same language" is the structural context and the attitude of mind in which people feel that they are developing and implementing common goals.

At the organizational level, the sessions resulted in the conclusion that a strong operational network should not only organize structural links between EU projects in ethics and EU projects in the so-called hard sciences, but that it should also develop strong links with leading programs worldwide, with the religious traditions and with lay people. Furthermore, special attention must be paid to capacity building in the EU's New Member States. Without ignoring the importance of clear language, the goal of the network should not be to develop a merely verbal consensus, which may be void of real communication, but rather to develop a pluralist platform of collaboration in an effort to exchange information, to allow the participants to clarify their own assumptions and to develop common approaches and common goals whenever possible.

5. Outcomes summarizes the conclusions of the sounding board, the links with the World Science Forum and the plan to develop a new annual series of "The Budapest Meeting".

1. CONTEXT OF THE BUDAPEST MEETING

1.1 The Objectives of the Reprogenetics project

Reprogenetics is a research project funded by the European Commission under The Sixth Framework Programme (FP6). It started on April 1st, 2004 and will end on March 31st, 2007. The project addresses the ethical issues linked to ‘human reproductive cloning’ and to ‘human germline gene therapy’. There is a broad consensus that the ethical concerns linked to these developments are so serious that research in these fields should be banned. In many countries this research is illegal, or else it has been made nearly impossible through the cutting off of public funding. Many scientists, ethicists, public authorities and representatives of the public believe that it would be a waste of time to analyze or discuss the ethics of this research. They are convinced that it does not help to have more discussion. They believe that the only possible conclusion of further discussion is that the research should be permanently banned. Hence, for them, any debate would be a loss of time. On the other hand, several studies and meetings that have analyzed the issue concluded that the available justifications for the ban are in fact very weak. If society believes that the ban is needed, then a better justification is also needed. Otherwise, the ban will simply vanish over time.

Reprogenetics does not ignore this discussion. But its objective is not to start another debate among philosophers and ethicists to investigate, once again, just how strong or weak the reasons for the ban really are. Reprogenetics wants to go further. It does not focus on the ethical position that philosophers or policy makers have developed or can develop. Rather, it focuses on the ethical position that is embedded in the scientists’ research itself. It also analyzes how this ethical position is generated and how the results of ethical research and policy making can play a role in this process. When policy makers decide that a ban is needed, how can this ban become operational? How can scientists know what exactly society wants them to ban? And how can policy makers impose the ban? Or, in general, how can the results of a broad ethical debate become embedded in scientific practice?

The Reprogenetics Project was designed and coordinated by Guido Van Steendam (IFB, Leuven, Belgium). The project was conceived and planned in the course of two earlier activities coordinated by Van Steendam: a research project, GENTEP, funded by the Department for Social Research of the VIB (Flemish Institute of Biotechnology) (1999-2003), and a workshop on the ethics of germline gene therapy, co-organized together with Eric Juengst during the Annual Meeting of the American Association for the Advancement of Science (San Francisco, 2001). Some of the leading research teams in the field joined. Jacques Mallet (CNRS, National Center for Scientific Research, Paris, France) ensured the direct link with biological research. John Harris (IMLAB, Institute of Medicine, Law and Bioethics, University of Manchester, Manchester, UK) is drawing up an overview of the ethical approaches. Carlos Romeo Casabona (Inter-University Chair in Law and the Human Genome, Deusto University and University of the Basque Country, Bilbao, Spain) is analyzing the relevant legislation and regulations. Matthias Kaiser (NENT, National Committee for Research

Ethics in Science and Technology, Oslo, Norway) is studying the input of lay people into a technical discussion on the ethics of cloning and gene therapy. Paolo De Nardis (Faculty of Sociology, University La Sapienza, Rome, Italy) is analyzing the press coverage. Ferenc Oberfrank (KOKI, Institute of Experimental Medicine, Hungarian Academy of Sciences, Budapest, Hungary) is organizing a network of contacts in the EU's New Member States. Judit Sándor (Center for Ethics and Law in Biomedicine, Central European University, Budapest, Hungary) played a key role in the creation of the project and has continued to play a role as advisor. Guido Van Steendam is developing a Social Map of the ethical values that are embedded in the practices of each of the actors involved.

1.2 Preliminary Conclusions

The first years of work in the Reprogenetics project confirmed earlier findings that the ban – as it is now expressed – is too weak to survive for a long time. One particular weakness is the specific way in which the notion of ‘human dignity’ is used in this context. It is used as a justification to ban specific scientific procedures such as reproductive cloning and germline gene therapy, but it remains vague and impalpable. One immediate consequence of this vagueness is that researchers who would be willing to implement such a ban cannot figure out exactly which scientific practices or procedures society would want to ban and which it would allow. Part of the problem may be that neither ‘cloning’ nor ‘gene therapy’ is a single, clearly identifiable and straightforward technological procedure. In order to see and discuss the complexity of the research possibilities, researchers and society are developing a vocabulary to distinguish several types of cloning or several types of gene therapy. Technological and scientific developments, however, are organic processes that are continually evolving. Terminologies and distinctions that were informative and clear in the past, may become ambiguous as these developments continue. Thus, even a statement that appears to be more precise like “the practice of human reproductive cloning (or of human germline gene therapy) is contrary to the principle of human dignity” may, after all, not be clear enough to inform scientists as to which procedures society would like to ban. Furthermore, it is not clear why reproductive cloning or gene therapy is significantly different from so many other medical practices and types of research for which no ban has been issued or that society even wants to encourage. When scientists continue to develop the accepted work in other fields, such as for example infertility treatments, they might end up doing – under another name – just what others would call ‘reproductive cloning’ or ‘germline gene therapy’.

All this suggests that, in the long run, the current ban will probably have no real impact on the ethics of science or on ongoing or planned scientific developments. This requires our full attention. We might be misled by the fact that scientists are currently not engaged in any serious attempts to carry out reproductive cloning or germline gene therapy. We should, however, not mistake this restraint as a sign that they are observing a ban out of respect for human dignity. The current restraint of the researchers probably has more to do with other ethical values that are already strongly

embedded in scientific practice. Safety issues may play a major role, along with numerous other social values that are embedded in the scientists' work and ambitions. If society wants to remain involved in the construction of ethical values that will guide science, it cannot just rely on a general ban that does not provide guidance to the real work of scientists. It must also develop a strong interaction with the explicit and implicit ethical values and goals that drive the work of the researchers involved. Furthermore, if society believes that some research must be banned, then the current ban must be redefined and made stronger. Moreover, if the notion of 'human dignity' is to play a very specific and technical role in the practice of scientists, then we need an operational, observable definition. In one way or another we will have to link human dignity to clearly identifiable research procedures. Otherwise the notion cannot guide the work of researchers. Even scientists who would give their lives to defend human dignity may not see how this notion applies to their own work. Finally, if some technologies are indeed a threat to human dignity, then a stronger and more convincing defense of human dignity is needed. Researchers must not only know which technologies society wants to ban in the name of human dignity, but also why. They should be able to experience and design their work as part of a larger social practice that they wholeheartedly endorse.

1.3 Sounding Board

Before starting the publication phase of the project, Reprogenetics set up a 'Sounding Board' meeting to get broader input from research teams that may have dealt with similar problems in different contexts. A large group of coordinators of other EU projects enthusiastically accepted the invitation to join the discussions. They were willing to share their expertise and knowledge and to prepare conclusions and recommendations that could possibly be helpful to the Reprogenetics project research team. The Reprogenetics researchers hoped that the open discussions would not only help the Reprogenetics project, but would also be helpful and inspiring for the coordinators and researchers involved in other projects who had been invited.

The Reprogenetics Sounding Board meeting became a large conference of EU project coordinators and international experts. Lay people and young researchers played a key role in keeping the participants' minds open. The meeting took place in Budapest from Sunday 6 November to Wednesday 9 November 2005 under the general title "Embedding ethics in scientific practice". Guido Van Steendam (IFB, Leuven, Belgium), coordinator of Reprogenetics, was the general chair. The Hungarian Academy of Sciences and the Collegium Budapest were the local hosts. A variety of interaction sessions constituted the backbone of The Budapest Meeting. Each session of the Meeting corresponds to one section in this summary report.

Three sessions addressed the Topics in Focus that were selected by the Reprogenetics consortium and presented the context of the work and the preliminary results of the project: (1) Reproductive Cloning. The world in 2025, (2) Germline Gene Therapy. The world in 2025, and (3) The United Nations and Human Dignity. (The summary of these sessions constitutes part 2 of the present summary report.)

Five sessions on “Ethics in Context” dealt with the ethical aspects of other types of research: (1) Clinical testing and hospital care, (2) Ambient Intelligence, computers and nanotechnology, (3) Nature, animals and food, (4) Brain research and dementia, (5) Old age, Intensive Care Units and death. (The summary of these sessions constitutes part 3 of the present summary report.)

Five sessions on “Ethical Decision-Making” discussed the potential contribution of different actors: (1) Do we need intercontinental collaboration? (2) Does the integration of the EU’s New Member States require specific action? (3) Is there a role for the religious traditions? (4) Is there a role for the media and the general public? (5) Can stakeholders speak a common ethical language? (The summary of these sessions constitutes part 4 of the present summary report.)

Each session started with one or more brief introductions. The major part of the time was spent on open discussion and comparing the results of the different projects that were represented. In a special session on the last afternoon, the invited experts identified the major conclusions and recommendations that they wanted to propose to the Reprogenetics team. In the meantime, the Reprogenetics team organized an internal business meeting to plan the publication phase of the project.

The Budapest Meeting had been organized as a satellite meeting of the World Science Forum. This increased the visibility and impact of The Budapest Meeting and prepared the possibility of creating stronger links in the future. The World Science Forum is organized in Budapest every two years in collaboration with UNESCO and The International Council for Science (ICSU). It is a key activity of UNESCO’s World Science Day, which is celebrated each year on 10 November. The Hungarian Academy of Sciences is responsible for the organization. The World Science Forum was established to function as a bridge between research, industry and policy makers. It provides an ideal platform for creating links with the ethics of the designers of real life research. All participants in The Budapest Meeting were invited guests of the World Science Forum. The coordinator of Reprogenetics was invited to speak at the World Science Forum where he also attended several business meetings in which ongoing sessions and follow-up activities were planned.

The outcome of the Budapest experience was not only that the Reprogenetics project received input from the best sounding board possible, but also that it gave birth to the idea of holding such interaction meetings on a regular basis. The idea was enthusiastically embraced by all the participants, as it would benefit their own research and the dissemination of the results. The coordinators also felt that such a structured interaction between ongoing projects would have a major impact on the efforts of researchers in the ethics of science. Furthermore, there is a clear need and obligation for large integrated projects or networks of excellence in the natural or biological sciences to develop ethical work packages. These efforts will be strengthened by linking up to the dedicated ethical projects. Conversely, the structured interaction with projects in the so-called ‘hard’ sciences will strengthen the dedicated ethical projects by providing a reality check. A stronger interaction between the EU projects will generate a critical mass that can become a leading source of inspiration for research at the global level. This is not only of interest to academia, but also to industry and policy makers. The World Science Forum and UNESCO have endorsed the plan to develop more intensive links between the EU projects and their annual World Science Day and biennial World Science Forum.

2. INTERACTION SESSIONS ON THE TOPICS IN FOCUS

The 2005 Budapest Meeting started with three interaction sessions on Topics in Focus, which illustrate key elements and preliminary results of the Reprogenetics project: (1) Reproductive Cloning. The world in 2025 (a session on the ongoing and potential research scenarios relevant for human reproductive cloning), (2) Germline Gene Therapy. The world in 2025 (a similar session for germline gene therapy) and (3) The United Nations and Human Dignity (a session on a recent official declaration on reproductive cloning).

The first two sessions (on reproductive cloning and germline gene therapy) not only addressed the traditional ‘ethical’ aspects, but also dealt with more technical issues concerning the way research is actually developing. The discussion in each of the sessions clearly revealed the need for a renewed interaction between EU projects in ethics and in the so-called ‘hard sciences’. Projects on the ethics of science tend to use the state of the art provided by ‘scientists’ as a safe starting point for an ethical analysis. More is needed. Science itself is not a static entity consisting of fixed knowledge and clear technologies, but rather a dynamic process that is continually generating new terminology, new knowledge and new technology, and that is also continually adapting this new terminology, knowledge and technology to new findings, new possibilities and new expectations. Projects that clarify the ethical aspects of scientific developments need to engage in an ongoing interaction with the work of the scientists involved. On the other hand, projects in the natural sciences, biomedical sciences, social sciences or any other sciences are continually developing scientific tools, theories, terminology and objectives that imply ethical choices. A structural interaction with researchers that explicitly addresses the ethical aspects will increase the quality of their work.

The report on these sessions reflects the more technical nature of the discussions and uses some technical biological vocabulary, even though no prior knowledge of biology or medicine is required. Readers whose interests lie not so much in the specific developments in the fields of cloning or gene therapy, or readers who first want to get a general impression of The Budapest Meeting, can go directly to section (3), which describes the third Topic in Focus: the United Nations and Human Dignity.

2.1 Topic in Focus 1: Reproductive Cloning. The world in 2025

András Dinnyés (Department of Animal Biology, Agricultural Biotechnology Center in Gödöllő, Hungary) gave the introductory lecture. András Dinnyés is an expert in animal reproduction and in the cloning of farm animals. In 2000-2001 he was a project leader in the team of Ian Wilmut (Roslin Institute, Edinburgh, UK) that five years earlier cloned the sheep Dolly. It is known that Ian Wilmut himself strongly opposes

any attempt to use the same technology to clone a human being.^b He is not alone. The mere prospect that some researchers might sooner or later want to create a human clone generated a very negative response in the general public, the media and political circles. The technology was soon banned, and in most countries of the world it is currently a criminal act to attempt such procedures. One participant noted that in France the law stipulates a sentence of up to 30 years imprisonment and a fine of up to 7 million euros for anybody cloning a human being. By contrast, with a few exceptions, homicide is punishable by a sentence that is not to exceed 20 to 22 years.

INTERACTION

Nuclear transfer

For the general public, a human clone is a genetic carbon copy of another human being. We will see later that biologists have a different take on this. But let us assume for a moment that biologists share the view of the general public. This will make it easier to explain the scientific basis of a potential cloning procedure. Later we will have to correct this assumption. In general terms, the ‘reproductive cloning’ of a human being would involve a technological procedure to program an embryo with all of the genetic information of the adult person who wants to be cloned and to implant this embryo into the uterus of a woman, where the embryo would develop into a new baby. This baby would have exactly the same genetic information as the adult person whose information was used to program the embryo.

Biologists know the technical procedures that would make it possible to realize this general scenario. First of all, it is not so difficult to get a biological copy of all the genetic information of an adult person. This information can be found in each of the normal body cells, the ‘somatic’ cells, of that person, or, more precisely, in a special structure within each cell: the nucleus. (Within the nucleus of a human body cell, this information is stored in twenty to twenty-five thousand ‘genes’, which are in fact thin strings of a DNA molecule and which are grouped and coiled up in 46 chromosomes.) Accordingly, the procedure to program an embryo with the ‘genetic information’ of the adult person would consist of creating an embryo that contains the nucleus of a normal body cell of the person who is to be cloned. To create such an embryo, scientists would start with the required nucleus of a normal body cell and with a human egg. They would remove the egg’s own nucleus (in technical terms: ‘enucleate’ the egg) and insert the nucleus of the body cell into the egg (in technical terms: perform a ‘transfer of the nucleus’ or ‘nuclear transfer’ from the body cell to the enucleated egg). Once the embryo is created, scientists could stimulate the embryo to divide. After 5 days the human embryo would have divided 6 to 7 times and would have become a little ball of about 64 to 128 cells, called a blastocyst. In theory, if this ball of cells were placed in a woman’s uterus, it would possibly implant: its outer layer of cells would stick to the uterus and develop into the placenta. Once implanted, the inner cells of the blastocyst would form a fetus.

b. Wilmut, I. & Highfield, R. (2006) *After Dolly. The uses and misuses of human cloning*. Little, Brown, London.

It is clear that after ‘nuclear transfer’ the chromosomes in the nucleus of the embryo are identical to the chromosomes in the nucleus of the person who is to be cloned. But this does not mean that the organism that is born will be a carbon copy of the donor of the nucleus. The biological development of an organism depends not only on the genetic material in the donor nucleus, but also on the conditions of the environment in which the embryo, and later the child, develops. Furthermore, the woman whose egg is used to create the embryo would also to some extent contribute to the genetic makeup of the child. This is the case because it is not completely true that *all* the genetic information of a person is located in the nucleus. A limited amount of genetic material is located in other cell structures, more particularly in the ‘mitochondria’. Such mitochondrial genes cannot be ignored. The genes in the mitochondria may even play an important role in degenerative diseases and aging. The procedure of Nuclear Transfer does not remove the mitochondria from the egg. So, if nuclear transfer were used for reproductive cloning, the donor of the egg would also to some extent contribute to the genetic makeup of the child that would be born. All of this explains why the differences between the donor of the nucleus and the clone are greater than the differences between identical twins. Twins share the same womb as fetuses, and normally they also share the same environment as growing children. A human clone would have a different mother from the donor of the nucleus. This mother would have different eating habits and a different lifestyle, which means that the conditions in the womb would be completely different. Furthermore, the clone would grow up in a completely different environment. This is why biologists do not speak of “making a genetic carbon copy” or of “cloning”. They speak rather of “nuclear transfer from a normal body cell” or, more technically, of “Somatic Cell Nuclear Transfer” or, in short, “SCNT”.

Genetic reprogramming

Nuclear transfer is not a new technique. Briggs and King developed the technique more than 50 years ago to transfer the nucleus of an embryonic cell of a frog into an enucleated egg of a frog.^c This helped them to study the embryonic development of frogs. This technique was only successful with the nucleus of an embryonic cell. Once the embryonic cell starts to develop, the genetic material in its nucleus starts to develop as well. While embryonic cells can still split and develop into all types of body cells that an animal or human needs, this very process of developing different cells with specific characteristics requires that the genetic program of the cells changes. Once the embryonic cells have differentiated to become muscle cells, or liver cells or any other type of cell, they can only generate other cells of the same type. When we put the nucleus of a differentiated adult cell into an egg and expect it to develop into a complete embryo, this nucleus must be ‘genetically re-programmed’. Researchers at the Roslin Institute were the first to transfer a nucleus taken from a differentiated cell of an adult animal into an enucleated egg, which then developed into a live animal.

c. Briggs, R. & King, T. J. (1952) Transplantation of living nuclei from blastula cells into enucleated frogs’ eggs. *Proceedings National Academy of Sciences USA* **38**: 455–463.

This resulted in the birth of the cloned sheep Dolly on 5 July 1996.^d In the meantime, the procedure has also proved successful for other animal species.

The procedure is not straightforward. Attempts to produce genetic reprogramming of the nucleus often result in genetic aberrations leading to abnormal fetal development of the cloned animal. Some aberrations may also become visible only in the course of adult development, once the animal is born. For a calf, the current birth rate from cloned embryos is around 10 %, but for most species this figure is below 1%.

Three major points of discussion

The discussion and clarification of the scientific developments can be summarized in three major points.

1. Safety issues

Experts in animal reproduction do not believe that under the present circumstances, the reproductive cloning of humans is an ethical choice. Most of them emphasize the fact that nuclear transfer creates an unacceptable risk for the newborn human. Some also stress the unacceptable burden on the pregnant woman. Researchers believe that these technical difficulties will persist for several years to come. Some are of the opinion that the problems with genetic reprogramming will never be solved.

2. Identical human beings

Researchers in animal reproduction are less impressed by the arguments that cloning or ‘nuclear transfer’ should be banned “because cloning results in the production of one or more carbon copies of a human being”.

As explained above, the clone is never a carbon copy of the adult who is cloned. Biologists will explain that the genetic makeup of a clone is never identical to the genetic makeup of the so-called unique parent. Some genes of the clone come not from the transplanted nucleus but rather from the enucleated egg.

Furthermore, genes are not stable entities. They are continuously changing. At best, we can only say that at a specific moment most of the genes of the clone were identical to the genes of the parent. But from that moment on, the genes of clone and parent evolve independently.

Moreover, even if we were to assume that the genes of the clone are identical to the genes of the parent, the physical appearance, brain structure and mental characteristics would still be different. The development of a human body and mind is guided by a large number of factors of the internal and external environment in which the embryo develops. The genes are only one, be it very important, element. At most, a clone would only be like a younger identical twin of its parent.

What is more, as will be explained in the next paragraphs, it is likely that some exceptional procedures for cloning or ‘nuclear transfer’ can be developed in which the child that is born is as different from the donor of the nucleus as children in standard families are different from their parents.

d. Campbell, K.H.S., McWhir, J., Ritchie, W.A. and Wilmut, A. (1996) Sheep cloned by nuclear transfer from a cultured cell line. *Nature* **380** (6569): 64-66.

One example of such new forms of nuclear transfer is currently being tested in animals and might be applied later to fertility treatments, for example to help a woman with a total lack of eggs. In animal experiments, biologists take the nucleus of a normal body cell of a female animal and insert it into a donor egg from which the original nucleus has first been removed. This results in a strange egg cell with twice the normal number of chromosomes. In the following step, half of the genetic material of this newly composed cell is taken away. To achieve this, biologists interfere in a natural phase of the developing egg cell during which the cell reorganizes its 46 chromosomes in two so-called 'polar bodies' each containing the genetic material of 23 chromosomes. When such polar body is extruded, the remaining cell contains the normal amount of genetic material of any unfertilized normal egg. After successful fertilization of such newly created egg, the fertilized egg could be implanted in the mother. When the animal is born, one-half of the genetic material comes from the mother, the other half from the father. So, while the technology of 'nuclear transfer' was used, the siblings are not a genetic copy of either the father or the mother. In this situation, the resulting children would be as different from the parents as in standard families. The same would be true for different cloned children of the same parents.

A second example of an alternative cloning procedure starts in the same way as the general procedure; researchers perform a nuclear transfer from an adult cell into an enucleated egg and stimulate the new cell to divide. After a number of divisions, the cell becomes a blastocyst. In this alternative procedure, researchers do not try to implant the blastocyst, but rather they harvest the inner cells of the blastocyst and maintain them in vitro. These inner cells are known to be 'pluripotent'. They have not yet developed into any of the specialized cells, like liver cells, brain cells, muscle cells or blood cells. They can be cultured in the laboratory and left to divide for indefinite periods. When specific conditions are realized, they begin developing into one of the specific types of cells, which then generate specific organs or tissues. These are called 'precursor cells' or 'stem cells', because other cells in the body stem from them. Stem cells that are harvested from the inside of a 5-day-old blastocyst are called 'embryonic stem cells'. They can give rise to all of the various types of cells that make up the body. This is why in the technical literature they are referred to as 'pluripotent stem cells'. (Not all stem cells are pluripotent. When the stem cells of a blastocyst form a fetus, they first develop a series of more specialized stem cells, such as blood stem cells, which can give rise to the different types of blood cells, or skin stem cells, which can give rise to the different types of skin cells. Such more or less specialized stem cells are no longer 'pluripotent', though they are still 'multipotent' because they can still develop into a – more limited – variety of specialized cells.)

Scientists do not need cloning to obtain human embryonic stem cells. The first team that, in 1998, developed the technique for isolating and growing human embryonic stem cells (James Thomson)^e derived its stem cells from surplus embryos

e. See the following report: James A. Thomson, Joseph Itskovtz-Eldor, Sander S. Shapiro, Michelle A. Walenitz, Jennifer J. Swiergiel, Vivienne S. Marshall, Jeffrey M. Jones, Embryonic Stem Cell Lines Derived from Human Blastocysts, *Science*, 6 Nov. 1998, Vol. 282, no. 5391, pp. 1145-1147.

donated by fertility clinics.^f Linking the technique to cloning would turn stem cells into powerful tools for biomedical research and clinical applications. The study of stem cells can help to clarify the mechanisms of embryonic development. The use of stem cells taken from people who have specific diseases can be very helpful in efforts to understand the genetic and embryonic origin of some disorders. Researchers also hope to use stem cells to treat damage or disease of organs and tissues such as brain, internal organs, bone and blood. Once they can generate stem cells from the patient in need of an organ transplant, they may try to achieve the conditions required to enable the stem cells to develop the specialized cells that are needed to repair the organ, or perhaps even to develop a new 'copy' of the organ itself. Because the adult, the stem cells and the new specialized cells or organs all share the same genetic characteristics, the risk of rejection of the implanted organ is zero. Diseases that may be treated include heart disease, liver disease, Alzheimer's and Parkinson's disease, spinal cord injury, osteoporosis, diabetes and leukemia. Researchers warn that they do not expect that in the near future they will be able to grow a complete liver. They do expect, however, that they will likely be able to take some of the stem cells from a patient and grow them into specialized cells, such as heart muscle cells, that can then be injected directly into the heart of a patient who has suffered a heart attack and whose heart is weakened. They may also be able to grow cells that manufacture insulin for diabetic patients.

During The Budapest Meeting, András Dinnyés mentioned this stem cell cloning scenario as an example of a cloning or 'Somatic Cell Nuclear Transfer' procedure in which the child that is born is not a look-alike of the unique parent. This may seem strange. Indeed, in what we have seen up to now, the outcome of the present cloning procedure is not a baby, but rather a supply of stem cells, and probably some tissues, such as blood, skin or (sooner or later) more complex cells and organs such as liver cells. The research scenario he describes does, however, illustrate the point he wants to make. To understand this, we have to go one step further. Let us first point out that many researchers emphasize the fact that the present cloning procedure is different from the traditional cloning scenario because it lacks the perspective of reproduction. They have even coined new terms that express this difference. They have started to call it "nuclear transfer to produce human pluripotent stem cell lines" to emphasize the fact that this type of cloning produces stem cells and not babies. They are also calling it "research cloning" to focus on the use of this procedure as a research tool, or "therapeutic cloning" to emphasize the therapeutic perspectives of the procedure. This distinction has also been emphasized by calling the 'traditional' cloning procedure 'reproductive cloning'. This is more than a linguistic issue. Confronted with the promising perspectives of this type of cloning, several countries that ban 'human cloning' have decided to make a distinction between 'reproductive cloning' and 'therapeutic cloning'. These countries have limited the ban on cloning to the "reproductive cloning" that produces babies, and have allowed 'therapeutic cloning'. Other countries and public bodies have explicitly rejected the distinction. Some claim

f. Thomson, J.A., Itskovitz-Eldor, J., Shapiro, S.S., Waknitz, M.A., Swiergiel, J.J., Marshall, V.S., Jones, J.M. (1998) Embryonic Stem Cell Lines Derived from Human Blastocysts. *Science* **282** (5391): 1145-1147.

that so-called ‘therapeutic cloning’ is in fact ‘reproductive cloning’ where the embryo is killed in the first weeks in order to harvest its stem cells.

In 2000, the European Parliament also rejected any distinction between ‘reproductive cloning’ and ‘therapeutic cloning’. In a resolution on human cloning dated 7 September 2000, the European Parliament described the use of the word ‘therapeutic cloning’ as an “attempt ... to use linguistic sleight of hand to erode the moral significance of human cloning”.^g The controversy is not over yet.

The Budapest Meeting did not attempt to provide an overview of the ethical issues linked to this debate. It focused rather on the context in which the condition that is treated by ‘therapeutic cloning’ is infertility, and in which ‘therapeutic cloning’ is used in a ‘reproductive’ context. In mice it is already possible to use embryonic stem cells to produce eggs and sperm. If applied in humans, this technology might also be used to create fertile eggs, for example for women without ovaries, or fertile sperm, for example for men with low sperm quality. The eggs or sperm produced by stem cells would have the genetic characteristics of either the father or the mother. They could be used in normal In Vitro Fertilization procedures and would result in the birth of a “cloned baby”, with a normal genetic contribution by the father and the mother. In this context there is no simple distinction between cloning with a “therapeutic” objective and cloning with a “reproductive” objective, as the procedure would simply be a tool in assisted reproductive technology. Moreover, in this context “cloned children”, as the term is commonly understood, would be an incorrect term since the children would be as different from the parents and from their brothers and sisters as in standard families.

Other nuclear transfer procedures may still bring with them new types of ethical problems. Currently, the mixing of human and animal genetic material has been used in attempts to achieve ‘therapeutic cloning’. The ethical and safety issues related to these technologies are currently being addressed in the ‘Chimbrids’ EU FP6 project,^h coordinated by Jochen Taupitz (IMGB, Institute for German, European and International Medical Law, Public Health Law and Bioethics, University of Mannheim, Mannheim, Germany).

For researchers, it is obvious from these examples that the technological developments using nuclear transfer are offering more and more avenues for fertility treatments. When ethical analysis is intended to clarify the real life work of researchers, a close link between ethical researchers and researchers in biology and medicine must be maintained. Without such links, ethical projects run the risk of generating splendid ideas about scientific developments that are no longer in use, and scientific researchers may feel the need to make ethical decisions about their own work without any further clarification on the basis of ethical research.

g. European Parliament (2000). *European parliament resolution on human cloning*. Brussels: European Parliament, [adopted on 07/09/2000]. Available at:

http://www.europarl.europa.eu/omk/omnsapir.so/pv2?PRG=CALDOC&TPV=PROV&FILE=000907&TXTLST=1&POS=1&SDOCTA=8&Type_Doc=FIRST&LANGUE=EN

h. Project website: <http://www.chimbrids.org/>

3. Human dignity

Researchers in animal reproduction are aware of arguments against human reproductive cloning which claim that this technique is a threat to human dignity.

Here again, they are not so impressed. The argument of human dignity is often expressed in vague terms, which makes it difficult for scientists to understand which scientific action is seen as going against human dignity and why. For the moment, there is no immediate danger. Nowadays, the weakness of the vague plea in favor of human dignity is compensated by strong arguments against human cloning based on the high technical risk. It is not clear what will happen when the technological situation changes, when some scientists will have a feeling that the technology is becoming safe. The argument in favor of human dignity may also be challenged by interest groups fighting for the right to reproduction and fertility treatments. If the argument against cloning on the basis of human dignity contains some deep ethical wisdom, then there is an urgent need to elaborate on this wisdom. On the other hand, if in this context the argument turns out to be empty, then it would be better to acknowledge this fact and be more modest in the conclusions we draw.

STRUCTURAL CONCLUSIONS

It is impossible to assess the impact of the different new developments that have been described, or to make a complete list of the new challenges. It is clear, however, that the study of the ethics of cloning requires a continuous update of the ethical, legal and safety analyses. If researchers in ethics of science want to develop stronger links between their projects, then the real cutting edge research projects in the natural sciences (in the broad sense of the word) should be linked up as well.

It should remain clear that the objective of such intensified interaction can never be to create a rigid super-network that pretends to have the final word about science or ethics. The real goal of an intensified interaction should be to create an open and organic platform where up-to-date information will be readily available, not only about recent findings but also about continually changing views and approaches. The platform will provide an opportunity for specialists from all the disciplines involved to have in-depth discussions, to disseminate the results of ongoing work and to continue to develop and adapt their thoughts to recent developments in science and ethical analysis. Without a structural link to the work of the 'hard scientists', solid ethical and legal analyses will gradually become obsolete and beside the point. Without a structural link to the work of the ethical disciplines, the ethical choices made by well-intended researchers in the natural sciences will gradually become less informed and less adapted to promoting the society that people want. By 2025 we can expect to see rules and regulations that are significantly different from the rules and regulations that are presently in force.

András Dinnyés emphasized the fact that the impact of the large structural interaction that is urgently needed depends not only on the capability of the social scientists to understand what is going on in the natural sciences, but also on the willingness and capability of scientists in general to understand the larger ethical issues

at stake, to identify relevant elements of their own work, and to be involved in open multidisciplinary discussions. Knowing that scientists are not trained in ethics or social debate, he stressed the urgent need to integrate such training into the education of researchers, and to develop training programs for scientists in action. A network of leading EU researchers linked to peer reviewed projects and interaction sessions, such as those organized in Budapest, would provide an ideal basis for developing such ongoing activity.

2.2 Topic in Focus 2: Germline Gene Therapy. The world in 2025

The Reprogenetics project is studying the ethics of human reproductive cloning as well as germline gene therapy in humans. Germline gene therapy is a type of gene therapy that cures not only the patients who are treated, but also their offspring. The same technology is also known under different names.

The team of Jacques Mallet (CNRS, National Center for Scientific Research, Paris, France) prepared a foresight study about what is currently going on in this field and what can be expected in the next 20 years.

INTERACTION

Micro-organisms

When human gene therapy was first discussed, the typical technology then in use was a kind of 'recombinant DNA technology' developed in the 1970s. In the early years, this technology allowed the researchers to cut the DNA of a living organism and to insert new pieces of DNA from any natural or artificial source.

If the genetic code of the DNA is compared to a long sentence written with an alphabet of only four letters (A, C, G and T), this technique is comparable to the treatment of a text by a word processor. The cutting and pasting of genetic information, however, cannot be done with a keyboard. Researchers need specific molecular tools, which consist essentially of specialized enzymes that produce changes in the DNA molecule. This process is called 'recombinant DNA technology' because existing pieces of genetic information are recombined.

Initially, this technology was used to insert a recombinant DNA molecule into a micro-organism such as a bacterium or a virus. This micro-organism treated the inserted DNA as its own DNA. When the inserted DNA contained a code for a specific biological molecule, the biological characteristics of the micro-organism were changed. The micro-organism executed the code of the inserted gene, as well as the code of its natural DNA. The micro-organism also started to make identical copies of the foreign DNA in the same way as cells normally duplicate their own DNA. Once one recombinant DNA molecule was created and accepted by a living biological system, an unlimited number of identical copies could be generated. This is why this procedure was also called "cloning of DNA".

Higher organisms

Soon researchers succeeded in inserting recombinant DNA molecules into the DNA of the cells of higher organisms. To do this, they made use of the capacity of viruses to infect other organisms. They inserted recombinant DNA molecules into micro-organisms and used the modified micro-organisms to smuggle the recombinant DNA into higher organisms. In this way they were able to modify the genetic material, first of plants and later of animals. When the plant or animal was modified in an early phase of its development, the complete organism was changed. This resulted in “transgenic organisms”. Transgenic organisms transmit the genetic modification to all their progeny.

Humans

In the meantime, the technology has entered the human domain. It has been successfully applied to treat children with genetic diseases. When a child is ill because he or she does not have a functional copy of an important gene, it is possible to insert the required gene into a virus and to infect certain specific cells of the child’s body with the virus, thus introducing the gene into the genome of the child. The technology is becoming even more refined. Sometimes the genetic disease of a child is not linked to the absence of a required gene but rather to the disturbing activities of a defective gene. In this case it is now possible to insert an operational gene into a virus and to start a procedure that finds the defective gene and replaces it with an operational copy. (In technical language this substitution of a defective gene is called “homologous recombination”.)

Combined with ‘therapeutic cloning’

Gene therapy in humans can also be combined with other technologies. This increases the possibilities. One intensive line of research involves combining gene therapy with the technology that is often called “therapeutic cloning”. As previously explained, this procedure makes it possible to develop new organs and tissues for patients. Let us briefly recall some of the advantages of this procedure and then discuss what gene therapy can add to it.

We already know that the organs and tissues produced by therapeutic cloning are ideal transplant material. The organs have the same genetic material as the patient because they are derived from eggs in which the nucleus is replaced by the nucleus of a cell from the patient (the so-called process of “nuclear transfer”). Consequently, after a transplant, these organs are not attacked by the patient’s immune system, whose function is to kill foreign living cells that enter the body. In other words, they are not ‘rejected’ by the patient, because the patient’s body does not consider these organs to be foreign material.

Gene therapy can improve the quality of the transplant material when the patient’s defective organs are the result of a genetic defect. It does this by substituting an operational gene in the place of the defective gene in the cells that are to be used to

produce the new organ, (i.e. in the pluripotent stem cells of the blastocyst obtained by nuclear transfer from the patient's somatic cells). Thus new transplant material is generated that is not rejected by the patient and that is also devoid of the deleterious effect of the defective gene.

Combined with pre-implantation diagnosis

Gene therapy can also increase the possibilities of genetic counseling. Since the 1960s, specialized centers have been providing professional help to parents with genetic problems who want to avoid transmitting the genetic disorders to their children. Let us take the simple example where one of the parents has a defective gene that causes a disease. The children of this couple have a 50% risk of inheriting this dominant gene and the disease linked to it. A large number of options are open, ranging from having a child and running the risk, all the way to giving up the idea of having children. The parents can also decide that the parent who is the source of the 50% genetic risk will not be involved in the reproduction process. In this case they can opt for Artificial Insemination with Donor sperm (AID) or In Vitro Fertilization (IVF) with donor eggs. The development of "prenatal diagnosis" created a brand new possibility. Prenatal diagnosis is a technology used to test for the presence of a defective gene before the baby is born. This is now possible for a growing number of genetic diseases. When prenatal diagnosis is available, parents can choose to start a kind of "conditional pregnancy". In our example of one parent who is the source of the genetic risk, there is a 50% probability that prenatal diagnosis will reveal a genetic defect. In that case the parents can decide to stop the pregnancy and start all over again. Because of its link to abortion, this procedure is not without criticism.

Gene therapy can add a completely new perspective. When the parents choose to use In Vitro Fertilization (IVF), it is even possible to test the fertilized egg before it is implanted, and thus before the pregnancy ever starts. This is the so-called "pre-implantation diagnosis". In our example, there is a 50% probability that the fertilized egg will contain the defective gene. Here, gene therapy can replace the defective gene with an operational gene. Doctors can carry out a new 'pre-implantation diagnosis' after the gene therapy. If the gene therapy is successful, then they can implant the embryo, which will develop into a child without the defective gene.

Technically, doctors can only perform a pre-implantation diagnosis four days after the fertilization of the egg, when the embryo has developed into a compact ball of around 16 to 32 cells. In this phase, the embryo looks like a 'blackberry' or 'mulberry' (in latin: mora) and is therefore called 'morula' (little berry). One day later, the morula will have developed into a blastocyst, with 'pluripotent' stem cells. We have already discussed the fact that pluripotent stem cells can develop into each of the cells types that are needed in an organism. We should add, however, that pluripotent stem cells have already lost one important possibility: a single pluripotent stem cell can no longer start a new process of embryonic development. In fact, pluripotent stem cells are already specialized to become the inner layer of the blastocyst and from thereon to develop into a fetus. The inner layer cells of the blastocyst can no longer develop into

outer layer cells of the blastocyst, which form the placenta and are needed for implantation. Once the morula cells have differentiated into either inner layer cells or outer layer cells, the difference between the cells is irreversible. This differentiation has not yet happened in the morula phase, in which all the cells are still capable of developing either into an inner layer blastocyst cell or an outer layer blastocyst cell. This is why the cells of a morula are not just called ‘pluripotent’ stem cells but rather ‘totipotent’ stem cells: they can do ‘everything’. They still have the full capacity of the fertilized egg. These characteristics make it possible to check the reliability of a gene therapy at the morula phase. When gene therapy is applied to a morula, we can expect that it will be successful in a number of morula cells. To identify the cells that have been cured, each of the morula cells can be isolated and each individual morula cell can be stimulated to divide. Each cell will then develop into a new morula. Testing one of the cells of each of these new morulas enables the researchers to identify a developing embryo in which the gene therapy has been successful. When the therapy has been successful, the embryo can be implanted. The child that will be born will not have the disease.

Because this gene therapy prevents a genetic disease from being transmitted to the next generation, the procedure is often called “germline gene therapy”. “Germline gene therapy” can also be achieved in other ways.

Gene therapy is not a simple technology. Even though it has already been applied to cure a limited number of diseases, it is not a routine clinical procedure. Each treatment remains an experiment that can only be applied under very strict conditions. And even when doctors believe that an experiment has been successful, it is not sure whether the genetic correction will be stable and will not result in new genetic anomalies. Nothing is known about the stability of a genetic change when it is transmitted to the following – or later – generations. Most researchers readily accept that it would be too risky to start up germline gene therapy programs. They accept that such changes could threaten the genetic and biological stability of the future generations born out of genetically manipulated cells.

Thus “germline gene therapy” is seen to be “a bridge too far”. Human gene therapy in a morula has not been used yet. Even a well-prepared gene therapy experiment to treat a developed fetus had to be cancelled. After an extensive study of the situation and after several public hearings, the US government decided not to fund the experiment because of the risk that it would result in germline gene therapy. Germline gene therapy shares this controversial status with the technology of reproductive cloning. However, should both technologies be further refined, it is possible that some patients with a hereditary disease will express the desire to clone themselves and to apply gene therapy before the newly created embryo is implanted in the uterus of the woman. This combination of “reproductive cloning” *and* “germline gene therapy” would result in a practice that is “two bridges too far”.

Cosmetic therapy

A “logical” consequence of these types of genetic intervention is that “cosmetic” germline gene therapy may be requested by future parents attempting to ameliorate the genetic make-up of their progeny. However, the implementation of such an approach, which would be aimed at complex, so-called ‘multifactorial’ genetic traits such as intelligence, the ability to reason, and cognitive capacities, will require a detailed knowledge (which is not yet available) both of the genetic factors and of the environmental factors whose interaction determines these characteristics. Moreover, since the interaction of these variables may be utterly stochastic, their modification by gene therapy may be too unpredictable to become manageable in the near future.

Three major points of discussion

The discussion of the new technologies did not stop at the end of the session, but rather continued in the following days during coffee breaks and informal moments. Some of the challenges can be summarized in the following three points, which are in some way parallel to the major elements of the discussion on reproductive cloning.

1. Safety issues

Much of the resistance to germline gene therapy is linked to a more widespread fear that recombinant DNA is never safe. Genetic modification of bacteria, plants, animals and humans has always been the subject of ethical debate, and sometimes of explicit bans, including even a self-imposed ban by the researchers themselves in the early years. The story of this self-imposed ban is well documented and widely remembered down to the present day as an unprecedented move in the world of biology. Some people have said that Recombinant DNA was for biology what the Atomic Bomb was for physics: “Biology lost its innocence...”. Safety issues played a major role from the very first scientific meeting, the Gordon Conference on Nucleic Acids (New Hampton, New Hampshire, USA, 1973), where Stanley Cohen and Herbert Boyer announced that they had created genetically modified bacteria.¹ The presentation of their recombinant DNA work started a long discussion about the potential applications, but also about safety issues. We can summarize the major concerns in two groups. A first group of concerns was that modified bacteria might become pathogenic and cause cancer. It was known in the 1970s that some genes could cause cancer. Researchers did not yet know too much about it, but they feared that if such genes were to be inserted into research bacteria, then these genes might easily disseminate to the bacterial populations in humans and in this way increase the incidence of cancer. This could even result in an epidemic of cancer. A second group of concerns, expressed in 1973, was that modified bacteria may not only become pathogenic, but may also become too “clever” and too “strong” to be stopped by antibiotics. The procedure for recombinant DNA work

i. Cohen, S., Chang, A., Boyer, H. and Helling, R. (1973) Construction of biologically functional bacterial plasmids in vitro. *Proceedings of the National Academy of Sciences of the United States of America*, **70**: 3240-3244.

required that modified bacteria used during the experiments be made resistant to some antibiotics. When these researchers created the recombinant DNA molecules, they also inserted a little string of DNA that created the resistance. The possibility cannot be excluded that such a string could be transmitted to other bacteria and spread all over the world, in this way undermining one of the pillars of medical treatment.

The organizers of the Gordon Conference decided to improvise a special session on the following day. When opening the special session, Maxine Singer, the co-chair of the conference, summarized the general feeling that the new technologies “raise moral and ethical issues because of the potential hazards such molecules may engender”.^j After an intensive debate, the researchers concluded that “although no hazard has yet been established, prudence suggests that the potential hazard be seriously considered.”^k In July 1974, after more than a year of intensive study of the hazards, twelve leading researchers in the field, including those who invented the technology, confirmed that “there is serious concern” that some recombinant DNA molecules in bacteria “could prove biologically hazardous”.^l They made a more systematic description of the potential risks and asked the scientific community not to initiate experiments along this line. They also announced that a large international meeting would be organized to study the issues in detail. This meeting took place seven months later, in February 1975, in the Asilomar Conference Center on the Pacific coast of California.^m In Asilomar, 140 researchers laid the groundwork for procedures to organize recombinant DNA work in a safe way. This would enable the very promising recombinant DNA work to proceed. The basic approach was to treat modified bacteria in the same way that high risk labs were treating dangerous viruses. The researchers developed methods to build laboratories and to design experiments in such a way that bacteria could not escape from the lab. In this way, the pathogenicity or antibiotic resistance of potentially dangerous bacteria would never be hazardous for the outside world.

This started the process of lifting the self-imposed ban. Recombinant DNA work gradually resumed. This recombinant DNA work, done under severe conditions of containment and safety, helped researchers to gain more knowledge about cancer, viruses, infections and other elements that in the earlier years had compelled the biologists to be extremely cautious and to ban further experiments. On the basis of the results of new genetic work, researchers learned to distinguish dangerous from non-dangerous genetic modification. They learned that for a growing number of recombinant DNA experiments, the high level of containment was not required. Today, the genetic modification of micro-organisms has become standard practice in academia and pharmaceutical companies. Researchers are convinced that recombinant DNA

j. Quoted by Maxine Singer: Singer, M. (1977) Scientists and the control of science. *New Scientist* **74** (1056): 631-634.

k. Singer, M. & Soll, D. (1973) Guidelines for DNA Hybrid Molecules. *Science* **181** (Sept 21): 1114.

l. Berg, P. et al (1974) Potential Biohazards of Recombinant DNA Molecules. *Science* **185** (July 26): 303.

m. Berg, P., Baltimore, D., Brenner, S., Roblin III, R.O., Singer, M.F. (1975) Asilomar Conference on Recombinant DNA Molecules. *Science* **188** (June 6): 991.

work can be done within the generally accepted safety margins of standard research and standard clinical practice.

The genetic modification of plants is now a widely accepted practice, even though in some countries a number of strict rules apply. Hundreds of human gene therapy experiments have been funded by public money, after first being carefully screened and monitored. The knowledge that some types of genetic modification of plants and animals can be dangerous has meant that attempts to start gene therapy in human patients have been highly controversial. Under strict conditions, a number of experimental therapies have been successfully developed. The technology has not yet become standard practice, however.

Germline gene therapy is still widely rejected for safety considerations. While researchers can more or less test the biological stability of a genetic modification for one generation, many believe that it is in principle impossible to test the stability and safety of the therapy for a larger number of generations. We simply do not have the time. This means that for many researchers, germline gene therapy can never be considered safe and should never be applied to humans. Other researchers agree that germline gene therapy should at present not be attempted. They believe however that the situation will change and that even the difficult safety issues will probably be solved in the course of the next 20 years.

2. Decisions on behalf of future generations

A second type of argument against germline gene therapy is based on the belief that the present generation should not make decisions about the genetic constitution of future generations. By choosing for germline gene therapy, we irreversibly remove a gene from a specific line of offspring because we believe that the effect of this gene is bad. Future generations may have a different opinion. And while under certain circumstances it may be acceptable that parents make decisions on behalf of their children, people do not believe that parents should make decisions on behalf of later generations. The conclusion is that germline gene therapy should be banned. This argument is often considered to be particularly strong and convincing.

In principle, numerous ethicists and the public at large endorse this reasoning. In practice, they appear to be more tolerant. When, in March 2001, it was announced that genetically altered babies had been born,ⁿ nobody appeared to be shocked. The US team of scientists involved confirmed and emphasized the fact that the babies were healthy. The news was not kept secret. In May 2001, the BBC announced the “germline modification” on its homepage. Nor was it kept secret that germline gene therapy was controversial. On its website, the BBC explained that in most countries this would be illegal and that the US government does not provide funding for any experiment that intentionally or unintentionally alters inherited genes.^o And yet,

n. Barritt, J.A., Brenner, C.A., Malter, H.E. and Cohen, J. (2001) Mitochondria in human offspring derived from ooplasmic transplantation: Brief communication. *Human Reproduction* **16** (3): 513-516. Available at: <http://humrep.oxfordjournals.org/cgi/reprint/16/3/513>

o. Genetically altered babies born. BBC News, Friday, 4 May, 2001. Available at: <http://news.bbc.co.uk/1/hi/sci/tech/1312708.stm>

nobody was shocked. This was not the beginning of an intensive national or worldwide debate. People accepted that this technology was safe. The technology was simple. The gene therapy did not attempt to substitute a defective gene that was located somewhere deep in the chromosomes of the nucleus. It was known that some hereditary diseases were linked to defective genes that were located in other structures of the cell, such as the mitochondria. The therapy was intended to help a woman who wanted to become pregnant but had defective genes in her mitochondria. To ensure that the defective genes were not transmitted to her children, the doctors used In Vitro Fertilization of the egg of the mother and the sperm of the father. The fertilized egg had a perfectly normal nucleus, with the genetic material from the mother being combined with the genetic material from the father. So far so good. The problem to be solved was that the cell not only contained a nucleus, but also other little cell structures, including the mitochondria from the mother. So the doctors used only the nucleus of this fertilized egg and implanted it into a donor egg, after first removing this donor egg's own nucleus. The doctors were then able to safely implant the egg. The child that was born had in fact three parents, the mother from whom the nucleus of the egg was used, the father whose sperm was used, and a third parent, a woman, who delivered the egg, from which the doctors removed the nucleus. There was no risk that the defective genes from the mitochondria of the mother would be transmitted to the child. There was also no risk that the future child would later transmit the defective genes to his or her own children. In more controversial language: the defective gene was once and for all removed from the "germline".

In the whole issue of cloning by nuclear transfer, germline therapy and the combination of the two techniques, it seems that there is a sort of continuum, apparently ranging from what people find definitely unacceptable to what people simply accept.

3. Human dignity

For germline gene therapy, just as for reproductive cloning, much resistance is based on the notion of Human Dignity. Here again, the notion is never developed in a way that clearly shows society and the researchers which scientific procedures exactly are a threat to Human Dignity and why. The notion does not play an operational role. This does not mean that the reference to Human Dignity is without meaning. The notion may express a deeper ethical wisdom that has not yet been made fully explicit. The notion may serve as an excellent trigger to keep the eyes of researchers and society open, and to make them continue to think about what really matters in human life.

STRUCTURAL CONCLUSIONS

Just as in the case of 'reproductive cloning', the case of gene therapy demonstrates that the discussion of ethics of science and intensified networking in this field should not be limited to a strong interaction between legal specialists, ethicists, philosophers and other social scientists, important though such strengthened interaction can be. It is imperative that strong structural contacts are also developed with the natural scientists,

their laboratory work, their integrated projects and their networks of excellence. This is an important niche, into which the results of ongoing ethical reflection should be embedded. This is also an important source of information that cannot be ignored without the risk of discussions becoming irrelevant.

2.3 Topic in Focus 3: The United Nations and Human Dignity

This session discussed the *UN Declaration on Human Cloning* adopted by the General Assembly on the 8th of March 2005,^p which was about half a year prior to The Budapest Meeting. This declaration makes an explicit link between the notion of Human Dignity and Human Cloning and rejects Human Reproductive Cloning. During this session the participants in The Budapest Meeting discussed whether this official document could help them learn more about the real strength of the argument against cloning based on human dignity.

Carlos Romeo Casabona (Inter-University Chair in Law and the Human Genome, Deusto University and University of the Basque Country, Bilbao, Spain) chaired the session and gave an initial analysis.

INTERACTION

Strong weakness

Carlos Romeo Casabona presented the general context and content of the Declaration and analyzed the role and relevance of the notion of Human Dignity in the following key sentences near the end of the document.

The General Assembly,

...

Solemnly declares the following:

- (b) Member States are called upon to prohibit all forms of human cloning inasmuch as they are incompatible with human dignity and the protection of human life;
- (c) Member States are further called upon to adopt the measures necessary to prohibit the application of genetic engineering techniques that may be contrary to human dignity;^q

Casabona explained that at first sight this declaration may look very strong. We may say that it explicitly addresses “all forms of human cloning” and in this way bans both reproductive and therapeutic cloning. On the other hand, the declaration is also weak and ambiguous because of the constraints that start with the words “inasmuch”

p. United Nations Declaration on Human Cloning. Resolution 59/280. Available at: <http://daccessdds.un.org/doc/UNDOC/GEN/N04/493/06/PDF/N0449306.pdf?OpenElement>

q. United Nations Declaration on Human Cloning. Resolution 59/280. Available at: <http://daccessdds.un.org/doc/UNDOC/GEN/N04/493/06/PDF/N0449306.pdf?OpenElement>

and because no clear definition of Human Dignity is given. Thus human cloning is only banned *inasmuch* as it threatens human dignity, which may allow most if not all current applications or plans to apply cloning to humans. Whether or not a particular procedure is admitted depends on how the reader interprets the notion of human dignity. This doubt whether cloning should in fact be banned is even stronger in other official languages such as Spanish (“en la medida *en que sean incompatibles*”) or French (“dans la mesure *où elles seraient incompatibles*”).

Casabona regretted that the UN declaration did not attempt to clarify the notion of Human Dignity. A UN declaration is never a legally binding statement, but it would have been a stronger document if it had reached a broad consensus on a meaningful use of the term Human Dignity and on specific implications for human cloning. Now the declaration is more an empty statement, leaving it to the reader to determine what use he makes of it. It is a missed opportunity that weakens the prestige of the UN.^r

In fact, the Declaration was adopted by a recorded vote of 84 in favor, 34 against and 37 abstentions, which means that there was no real large majority in support of the Declaration. The 6th Committee of the General Assembly that prepared the declaration could also have developed a more explicit statement that would have been more widely endorsed. Of the EU, 10 countries voted in *favor* (Austria, Germany, Hungary, Ireland, Italy, Malta, Poland, Portugal, Slovakia, Slovenia), and 14 voted against (Belgium, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Latvia, Lithuania, Luxembourg, Netherlands, Spain, Sweden, United Kingdom). Furthermore, 1 EU country (Greece) was absent but informed the UN secretariat that it would have voted against. There is no overriding single reason why most EU countries voted against. A more detailed explanation would require another article.

In search of Human Dignity

The discussion about a deeper and more operational meaning of Human Dignity started with two short lectures by Ana María Marcos (Universidad Nacional de Educación a Distancia, Madrid, Spain.) and Iñigo de Miguel (of the team of Carlos Romeo Casabona). They explained the Kantian view of Human Dignity as the intrinsic and sacred value of the life of every human individual. They indicated that this view may not be enough to grasp the power of the concept of human dignity, but at least it helps to get a better idea of what human dignity means and to identify some possible concerns linked to cloning.

During the discussion, the participants endorsed the idea that the ‘right to life’ can be linked to our conviction that autonomy should be protected and that our belief in the ‘right to life’ and ‘autonomy’ is probably an important reason why we also believe that human dignity should be protected. The right to life is also mentioned in relevant charters, such as the Hungarian Constitution. The link between human dignity and autonomy is well documented in philosophical literature such as the work of Hans

r. See further: -- (2005) The United Nations Declaration on Human Cloning (Editorial). *Law and the Human Genome Review* 22: 15-24.

Jonas or the renaissance thinker Pico della Mirandola, the author of the influential *Oratio de hominis dignitate* (Oration on the Dignity of Man.)

Some participants did not believe that it makes sense to develop a good definition of the human dignity of an individual person. They questioned whether it makes sense to say that the human dignity of an individual can be endangered. When we take the notion of the human dignity of each individual person seriously, can we then say that a cloned baby will ever have less human dignity than other children? Can society really do anything to diminish the human dignity of individuals? Even slavery is probably not enough to take the human dignity of the slave away. It was then proposed that human dignity may make more sense when the concept is applied to society as a whole: the human dignity of the society may be diminished when the society becomes more crude or barbaric. Others held that it still makes sense to link human dignity and diminished human dignity to individuals. They argued that the dignity of individuals is clearly endangered when their autonomy is diminished. More is needed to make the notion operational. And certainly more is needed to find out whether or not each type of human cloning would diminish the autonomy and endanger the human dignity of the cloned babies.

The group also discussed what should be done as long as we can only stick to some intuitive notion of human dignity, which makes it impossible to define whether and how human dignity is endangered by which kind of human cloning. Can we then simply say that there is no reason to ban human cloning? Or should we take account of the intuitive notion that human reproductive cloning is 'a bridge too far' and take a precautionary approach anyway?

The discussion on the precautionary principle itself started during the break after the session. Some researchers explained that the precautionary principle may be as vague as the notion of human dignity. It was not clear how far this principle would require us to go. Should we also apply it to the cloning of animals? It may be possible that the concept of human dignity understood as autonomy is too anthropocentric and too closely linked to the philosophy of the Renaissance and modern times. Would the proponents of animal rights not claim that it is unacceptable that we consider the burden of cloning too high for humans while we accept it for animals? Can we really just assume that the welfare and lives of animals do not count?

STRUCTURAL CONCLUSIONS

The discussion on the UN declaration was another clear example of the desirability of linking different research initiatives, even when they are using completely different approaches and are addressing completely different issues. Even the analysis of a short legal fragment on cloning soon leads to notions like 'the precautionary principle', 'animal welfare', and 'autonomy', which have already been studied in great detail in other contexts. Specialists in the analysis of one type of issues can inspire others with their successes or can warn them about the limits of highly attractive solutions that appear to be strong but turn out to be weak.

3. INTERACTION SESSIONS ON ETHICAL VALUES IN CONTEXT

The “Interaction Sessions on the Topics in Focus” presented the general context and the preliminary conclusions of the Reprogenetics project. One important challenge was to find out the extent to which the notion of Human Dignity can be helpful for clarifying the ethical aspects of reproductive cloning and germline gene therapy. As a contribution to clarifying this point, EU projects in five different domains were discussed: (1) Clinical testing and hospital care, (2) Ambient Intelligence, computers and nanotechnology, (3) Nature, animals and food, (4) Brain research and dementia and (5) Old age, Intensive Care Units and death.

A “Leitmotiv” document that was available to the participants of The Budapest Meeting illustrated the use of the notion of human dignity in each of the five domains. The starting questions for each session were the same. What are the major ethical issues revealed in the projects? Does the notion of human dignity help to clarify these issues? In each of the sessions, the discussion went far beyond the expectations of the organizers. The present summary report cannot pretend to provide a complete overview of the complex content of the interaction sessions. What follows is an illustration of the variety of EU projects that were presented, the major ideas that were discussed, and the organizational conclusions that were arrived at.

3.1 Ethics in Context 1: Clinical testing and hospital care

Sometimes adult patients complain that they are being dealt with inhumanely and treated like little children. Nazi experiments on prisoners generated the reaction that the human rights of patients should be protected. Does contemporary work in the ethics of hospital care and clinical testing help us to understand the concept of human dignity?

Josef Kuře (University Centre for Bioethics, Masaryk University, Brno, Czech Republic) chaired the session. Daniel Sinclair (Hebrew University, Jerusalem, Israel) was rapporteur.

INTERACTION

Representatives of several EU projects presented their work. One project, the European Hospital-based Bioethics Program,^s had prepared a textbook on clinical ethics. The project was coordinated by Giovanni Putoto (Department of Training and International Projects, University Hospital, Padova, Italy). The project was presented during The Budapest Meeting by one of the partners, Zbigniew Zalewski (Department of

s. Holm, S. (2004) Importance of bioethics education for (hospital) health care personnel in Western European countries. *European Society for Clinical Investigation (ESCI) 38th Annual Scientific Meeting – Workshop on the European Hospital (-Based) Bioethics Programme – EHBP*. Utrecht.

Philosophy and Bioethics, Jagiellonian University, Krakow, Poland). The project has ended. The book is in print.^t The project showed that ethical consensus may not always be impossible. While the project was designed to take account of the different ethical approaches in different EU countries, the research showed that there was an international agreement on all relevant issues in clinical ethics. The real differences were between the different stakeholders, such as the nurses, the physicians and the hospital administrators.

Zbigniew Zalewski also presented another project, Nurses' Codes,^u which had just been finished and was coordinated by Arie van der Arend, (Capacity Group Health Care Studies, Section Health Care Ethics and Philosophy, University of Maastricht, Netherlands). The aim of this project was to create a Pan-European code of nursing. In this project, the researchers had to accept that there was no uniformity whatsoever. In some countries there were no codes at all. They did not give up hope, however. The group discussed whether it makes sense to try to generate a universally accepted ethical guide. Many participants believed that it is impossible to generate such universal ethics. They also believed that this should not stop us from trying to make universal professional codes or laws. A code was even seen as a tool for emancipation. When there is a code in a specific country that specifies the responsibilities of nurses, this typically affects the way they actually work and the way doctors treat them. There appears to be a clear link between the availability of a code and the professional status of nurses.

Eurosocap,^v another project, focuses on medical confidentiality. It was presented by Colin Harper, a member of the team of the coordinator Roy McClelland (Division of Psychiatry and Neuroscience, Queen's University Belfast, Northern Ireland, UK). The project involves 20 countries and aims to create a new set of European Standards and Guidance on Confidentiality and Privacy in Healthcare. (In the meantime, these standards have become available.)^w The discussion addressed the contexts in which medical confidentiality is threatened. Traditional situations include genetic counseling sessions in which a medical test of a young girl reveals that her presumed parents are not her biological parents. Newer contexts of conflict are linked to terrorism.

The TWR project, coordinated by David Edbrooke (Intensive Care Medicine, Royal Hallamshire Hospital, Sheffield, UK), will organize a training workshop in clinical trials. The workshop, which is being organized through intensive networking

t. Pegoraro, R., Putoto, G. and Semplicini, A. eds (2006) *Hospital Based Bioethics: A European Perspective*. Piccin Nuova Libreria, Padova. (in press).

u. Arend, A. van der (2003) Content and use of codes of ethics in nursing. *Nursing Ethics* **10** (1): 97-98. Research abstract

Project website: <http://www.zw.unimaas.nl/ecn/>

v. Project website: <http://www.eurosocap.org/>

w. McClelland, R. et al (2005) *European Standards on Confidentiality and Privacy in Healthcare*. Available at: <http://www.eurosocap.org/Downloads/European-Standards-on-Confidentiality-and-Privacy-in-Healthcare.pdf>

McClelland, R. et al (2005) *European Guidance for Healthcare Professionals on Confidentiality and Privacy in Healthcare*. Available at: <http://www.eurosocap.org/Downloads/European-Guidance-for-Healthcare-Professionals-on-Confidentiality-and-Privacy-in-Healthcare.pdf>

activity, will be held in Brno. Josef Kuře (University Centre for Bioethics, Masaryk University, Brno, Czech Republic) explained that the project had just started. The Budapest Meeting provided an ideal opportunity to intensify the project's networking activities.

The *Global Forum on Bioethics in Research* is coordinated by Bella Starling (Wellcome Trust, London, UK).^x The Global Forum is an informal international partnership established by a number of organizations such as the US National Institutes of Health (NIH), the Medical Research Council (UK), the Wellcome Trust, the Rockefeller Foundation, the World Health Organization and several universities. They have a shared interest in the ethics of conducting research involving human beings in developing countries, and they are organizing regular meetings to review and strengthen the protection of human participants in medical research.

The attention of the participants was also drawn to EURECA, a project coordinated by John Harris (IMLAB, Institute of Medicine, Law and Bioethics, University of Manchester, Manchester, UK).^y This project addresses the ambiguity of the word 'research' and investigates the question: "When should an activity count as research?" The answer to this question is important because classifying an activity as research will sometimes mean that stricter ethical and legal regulations apply, though in other circumstances such classification could mean that it becomes exempt from certain rules and regulations. The project is analyzing case studies not only from biomedicine, but also from information technology, social sciences, databases and biobanks. The project was not explicitly discussed, but the project poster was presented.

During the discussion, much time was spent on the comparison of the different methodologies that were used in similar projects and on the exploration of the possibilities and limits of each. The participants also discussed whether it is a realistic objective for a project to aim at creating an ethical consensus. Whenever a specific overlap or common issue was found between two projects, the participants made arrangements to organize either an exchange of documents or a separate meeting.

STRUCTURAL CONCLUSIONS

Nowhere did the notion of Human Dignity come up spontaneously. When the chair explicitly asked whether the notion played some role in some of the textbooks or codes, the answer was still 'No'. The same negative answer came when the researchers were asked whether it would help. They said that they have all the words they need to come to an operational consensus, or to organize a rewarding discussion. The participants involved in these research projects also believed that it is better to keep it this way. They fear that the use of the notion human dignity is too vague to be operational, and that it would create more confusion than it would help.

x. Cross, L. (2005) *The 6th Global Forum on Bioethics in Research: "What happens when the research is over? Post-trial responsibilities of researchers and sponsors."*: Summary of feedback from delegates. [The 6th Global Forum on Bioethics in Research: 17-19 March 2005, Blantyre, Malawi]. Available at: <http://www.wellcome.ac.uk/assets/wtx027291.pdf>
Website: <http://www.gfbronline.com/>

y. Project website: <http://www.eureca.manchester.ac.uk/>

What was more helpful to the different researchers was the discovery that other groups were doing similar work, and that the different teams could learn a lot from the intermediate results and methodological decisions of the others. Each of the projects plans to publish the results online. The researchers would like to have convenient electronic platforms that would help them and other users to easily localize the web publications. The researchers expressed the hope that structural help would be provided to facilitate real life interaction between projects through interaction sessions of the kind organized in Budapest.

Links between projects currently depend on the accidental fact that one research team, like the group of Zbigniew Zalewski, is a member of two related projects. This situation does not promote interaction between all relevant projects. Furthermore, being involved in two similar projects is excellent for the researcher in question, but it does not promote interaction and the exchange of ideas at the level of the projects. Only the organization of some *structural* link would provide a real solution. Such a structural link should respect the independence of the different projects, but offer a well designed platform for more intensive and open interaction. An annual meeting could serve as an excellent beginning.

3.2 Ethics in Context 2: Ambient Intelligence, computers and nanotechnology

Humans are no longer the only intelligent decision makers on earth. Numerous decisions are being made by the visible and invisible microchips that are increasingly present everywhere in our working and living environment. Soon they will be hidden not only in our dishwasher and our mobile phone, but also in our furniture, clothing, shoes and walls. Ubiquitous computing is becoming a buzzword. All intelligent agents in our environment can make their own decisions. Continuously in communication with one another, they are guided by adaptive software to ensure that the result of their cooperation is a helpful, intelligent service to the user of the environment. These microchips are linked to a host of sensors, which minimizes the need for the users to interact with the computers. There is no need for keyboards or screens or menus. The intelligent environment has already heard what we said to the visitor, it has already noticed that we are leaving the building. The environment knows how it should behave, before we even think of giving an order. Such intervention greatly enhances our human comfort and our possibilities for managing the environment. Small tools can become active everywhere, even in our body. They can monitor, take over, correct or enhance our normal bodily functions. Numerous EU projects are developing the technology to realize this. Guido Van Steendam (IFB Leuven, Belgium) chaired on behalf of Eörs Szathmáry (Collegium Budapest, Budapest, Hungary), who was unable to attend the session.

INTERACTION

Using the posters with the summaries of relevant EU projects, Guido Van Steendam summarized the approach and goals of 8 projects.

A first project studies the ethics of automated identification of persons by means of ‘biometrics’, which is the technology to analyze and measure biological data, such as hand geometry, facial patterns, voice patterns, eye retinas and irises, behavioral traits. The project BITE (Biometric Identification Technology Ethics) started in 2004 and is coordinated by Emilio Mordini (Centre for Science, Society and Citizenship, Rome, Italy). Biometric identification methodologies are becoming increasingly common in airports, hospitals, banks, schools and consumer electronics. Security and convenience appear to be the driving forces. The project addresses key ethical issues such as the potential threats to privacy, especially when different databases are linked, and the ‘informatisation of the body’. The project also explores the urgent need for a bioethical code for acceptable use of ongoing developments in the field.

Four other projects (ECAgents, Neurobotics, Alfebiite, Respect) study the technological and social frameworks linked to ongoing developments in information science.

ECAgents,^z contributes to the development of a new generation of microchips hidden in the environment: “Embodied and Communicating Agents”. The project is coordinated by Stefano Nolfi (Institute of Cognitive Sciences and Technologies, National Research Council, Rome, Italy). The project is investigating the basic properties of communication systems, ranging from animal communication to human language and technology-supported human communication. This will result in new design principles for existing technological artifacts such as mobile phones, WI-FI devices and robots.

The goal of another project, Neurobotics,^{aa} is to systematically explore the possibilities of making strategic alliances between Neuroscience and Robotics. It aims to go beyond “robotics” and link robots to the human body. Its goal is to augment and enhance the capacities of the human body and brain by linking it to machines. The project is coordinated by Paolo Dario (Advanced Robotics Technology Systems Lab, The Sant’Anna School of Advanced Studies, Pisa, Italy).

The third project, Alfebiite,^{bb} ended in 2003. It was coordinated by Jeremy Pitt (Department of Electrical and Electronic Engineering, Imperial College of Science, Technology and Medicine, London, UK). The project was focused on the behavior of human users involved in communication and trading activities in an electronic society.

z. Project website: <http://www.ecagents.org/>

aa. Project website: <http://www.neurobotics.info/>

bb. Pitt, J. ed. (2002) *D5: Communicative Framework; D6: Agent Society Framework*. ALFEBIITE Consortium.

Pitt, J. ed. (2002) *Deliverables D5 & D6: Annex 1 Workpackages Progress Reports*. ALFEBIITE Consortium.

Available at: <http://alfebiite.ee.ic.ac.uk/Templates/publicdocs.htm>

Project website: <http://alfebiite.ee.ic.ac.uk/>

The project used empirical psychological studies about trust, identified social relations and commitments linked to specific types of communication, and it provided the basis for regulating the activities of users of information in specific sub-communities of the “Universal Information Ecosystem”.

The fourth project of this series, Respect,^{cc} ended in 2004. It was coordinated by Ursula Huws (Institute for Employment Studies, University of Sussex, Brighton, UK). It produced professional and ethical codes of practice covering intellectual property and data protection. Its objectives included the promotion of common European Standards and benchmarks and the development of a contribution to ethical and professional debates within the socio-economic research community.^{dd}

Finally, three projects were presented that focus on nanotechnology.

Nano2Life,^{ee} the first project, is a network of excellence that focuses on the understanding of the nanoscale interface between biological and non-biological entities, and on the development of integrated sensor technologies for a number of life related fields such as health care, pharmaceuticals, environment, defense, and food safety. The project started in 2004 and is now funded until 2008. It is coordinated by Patrick Boisseau (French Atomic Energy Commission, Paris, France).

Nanologue,^{ff} the second project, aims to facilitate the dialogue between researchers, business and civil society. Its focus is to inform non-scientists about the potential of nanoscience and nanotechnology to improve the quality of life and create wealth. It will also assess the potential societal impact of the different applications. The ultimate goal of the communication is to help civil society to adapt its ethical, legal and social requirements to the new possibilities and to create a real competitive advantage for European Industry. Nanologue is coordinated by Volker Türk (Wuppertal Institute for Climate, Environment and Energy, Wuppertal, Germany).

cc. Project website: <http://www.respectproject.org>

dd. Dench, S., Iphofen, R., Huws, U. (2004) *An EU-Code of ethics for socio-economic research*. IES Report 412. Institute for Employment Studies, Brighton. Available at: <http://www.respectproject.org/ethics/412ethics.pdf>

Schryvers, E., Van Gyes, G., Vandenbrande, T. (2004) *Functional map of a European socio-economic research project*. IES Report 414. Institute for Employment Studies, Brighton. Available at: <http://www.respectproject.org/quals/414qualsmap.pdf>

ee. Bruce, D. (2005) *Nano-2-Life Ethics: A Scoping Paper on Ethical and Social Issues in Nanobiotechnologies*, [Word-file]. Available at:

<http://files.nanobio-raise.org/Downloads/nanodb.doc>

Hauptman, A. and Sharan, Y. (2006) *Envisioned developments in Nanobiotechnology: expert survey*. Interdisciplinary Center for Technology Analysis and Forecasting (ICTAF) at Tel-Aviv University, Tel-Aviv. Available at: http://www.ictaf.tau.ac.il/N2L_expert_survey_results.pdf

Project website: <http://www.nano2life.org>

ff. Türk, V., Kaiser, C., Liedtke, Chr., Knowles, H., Murray, V., Schaller, S., Wallbaum, H., Kastenholz, H., Köhler, A.R. (2006) *Nanologue: Opinions on the Ethical, Legal and Social Aspects of Nanotechnologies: Results from a Consultation with Representatives from Research, Business and Civil Society*. [Wuppertal Institute, etc.].

Available at: <http://www.nanologue.net/index.php?seite=111>

Project website: <http://www.nanologue.net/>

NanoBioRAISE,^{gg} the third nanotechnology related project that was presented, is focusing on “nanobio-technology”, which is the application of nanotechnology to the life sciences. The project is coordinated by David Bennett (European Federation of Biotechnology, Delft, Netherlands). It brings together the key players in the field of “nanobio-technology”. It is clarifying the ethical issues linked to the new developments, organizing discussion groups with the public, developing ethics and public communication training courses for nanobiotechnologists, and preparing relevant actions for future Framework Programs of the European Union.

In the time between The Budapest Meeting 2005 and the publication of this report, in September 2006, two other EU projects on Nanotechnology were started.

NanoCap (Nanotechnology Capacity Building) focuses on nanotechnology in relation to environment and workplace hygiene. The project is coordinated by Pieter van Broekhuizen (IVAM, Amsterdam, the Netherlands).

Deepen (Deepening Ethical Engagement and Participation in Emerging Nanotechnologies) will study nanosensors and nanomedicine and will focus on engaging civil society in the ethical reflection on nanoscience. The project is coordinated by Phil Macnaghten (Institute for Hazard and Risk Research, Durham University, Durham, UK).

Most of this work was unknown to the participants in The Budapest Meeting. Their interest in applied ethics for nanotechnology and Information Science and Technology is rather new. Many of the traditional ethical issues linked to science and technology appear to apply. It was clear that issues of privacy will be important. Another issue is who is in control. Most of us know very well the irritation we experience when our word processor is making decisions for us, capitalizing words that we want to be written in lower case letters or adding strange bullets when we only want to add a number. We learn to survive, and some of us even learn to customize the software. But what will happen when our total environment comes to behave like a “user-friendly” word processor that is continuously making irritating decisions about the structure and behavior of everything around (and even inside) us? Should we take the social and perhaps also physical risk of letting communicating agents take over control of our world – and even of our bodily functions? Are these developments really intended to help people? How do we ensure that the industries developing these technologies really care about people and not just about profit?

STRUCTURAL CONCLUSIONS

The major structural conclusions of the session were that information and interaction sessions with the researchers involved in the technologies under study are urgently required. As to the possibility of using these discussions to learn more about human dignity, most participants agreed that this notion would not be helpful, at least not as long as we do not know what exactly the term means.

gg. Bennett, D.J. and Schuurbiens, D. (2005) Nanobiotechnology: responsible action on issues in society and ethics. *NSTI-Nanotech* 2: 765-768.
Project website: <http://nanobio-raise.org/>

3.3 Ethics in Context 3: Nature, animals and food

In the aftermath of World War II and the revelation of how National Socialism had used prisoners for cruel medical experiments, strong rules and regulations were issued to protect human beings within the medical and research context. Under the flag of human rights and human dignity, the use of animal experiments became obligatory. Do recent discussions on “animal welfare” and “animal rights” suggest that we should also respect “animal dignity”? And does the recent concern for nature suggest that we should also respect the “dignity of nature”? Jan Vorstenbosch (Ethics Institute, Utrecht University, Netherlands) chaired the session.

INTERACTION

Three projects were presented to open the discussion. For the first project, Animalsee,^{hh} the coordinator, Flavia Zucco (Institute of Neurobiology and Molecular Medicine, National Research Council of Italy, Rome, Italy) had asked Jan Vorstenbosch to represent her. This project ended in the months before The Budapest Meeting. It addressed the ethical and social issues relating to the so-called “Three Rs principle”, which claims that animal experiments should be Replaced, Reduced and Refined. The objective of the project was to assess the impact of recent developments of alternative methods in animal research on this 3Rs model. Jan Vorstenbosch gave a detailed account of the results of the project and explained how the project results are now being communicated in a series of publications. The network continues to collaborate even though the project is over.

The second project, Ethical Traceability,ⁱⁱ is aimed at conceptualizing the idea of the traceability of food products. Thus the project wants to rethink the principle of informed choice in the context of safe and ethical food. The coordinator of the project, Christian Coff (Centre for Ethics and Law in Nature and Society, Copenhagen, Denmark), gave more details about the Radio Frequency IDentification (RFID) tags that are being used. He explained how the project is studying the philosophical, sociological and practical dimensions of traceability, and how it is addressing not only the issue of food safety control, but also consumer perception and interest.

The third project, Eadgene,^{jj} is a network of excellence in agriculture. It addresses the European livestock industries and focuses on the improvement of animal health and

hh. Zucco, F. et al (2004) *Alternative methods in animal experimentation: evaluating scientific, ethical and social issues in the 3Rs context: final report and recommendations D8*. Available at: http://ec.europa.eu/research/biosociety/pdf/anim_al_see_final_report.pdf

Project website: <http://www.inemm.cnr.it/animalsee/presentation.html>

ii. Coff, Chr. *Ethical Traceability and Informed Choice in Food Ethical Issues*, [Project information / introduction].

Available at: <http://www.ethiclaw.dk/publication/Ethical%20Trace%20homepag%233EF35.pdf>

Project website: <http://www.food-ethics.net/>

jj. Pinar-van der Laan, M.-H. *Genomics to advance animal health: Eadgene: Network of Excellence*.

the use of new genomic tools. The network of excellence will ensure that all partners have easy and durable access to the best available facilities, biological resources, technological platforms, software, analytical tools and knowledge. The coordinator of the project, Marie-Hélène Pinard-van der Laan (INRA, French National Institute for Agricultural Research, Paris, France), presented the work. The project is in its first year and will end in 2009. It was too early to present results. The coordinator confirmed that the project is linked to several ethical dilemmas. It deals with balancing the quality of life of animals and of human beings, and the meaning of animal welfare. It deals with what is good for consumers and how they perceive their health and health risks. It also deals with confidentiality and transparency.

Other relevant projects, such as Propeur,^{kk} have not been explicitly discussed. The project poster was available. Two project partners, Aitziber Emaldi Ciri3n (Deusto University, Bilbao, Spain) and Peter S3kora (University of S. Cyril and Methodius, Trnava, Slovakia), who were active participants during The Budapest Meeting, made sure that relevant elements were presented during the discussions. The coordinator of Propeur is Donna Dickenson (Centre for the Study of Global Ethics, University of Birmingham, Birmingham, UK). The overall objective of the project is to compile and analyze new approaches in ethics and law as applied to “tangible and intangible property” in food technologies, plant genomics, human genome research, the Internet, etc. ...

A project poster was also available for the project Babas,^{ll} which was coordinated in the 1990s by David Bennett (European Federation of Biotechnology, Delft, Netherlands). This was one of the first authoritative networks of leading experts to carry out studies on the bioethical aspects of biotechnology as applied to agriculture, fisheries and the food industries.

Available at:

[http://www.eadgene.org/HNB/eadgene/eadgene.nsf/container/1/\\$file/Fiche_EC_TP5-NOE-EADGENE.pdf](http://www.eadgene.org/HNB/eadgene/eadgene.nsf/container/1/$file/Fiche_EC_TP5-NOE-EADGENE.pdf)

Pinard-van der Laan, M.-H. *Eadgene: European Animal Disease Genomics Network of Excellence for animal health and food safety. [Introduction to the project. Power Point Presentation]*.

Available at: <http://www.fp6-food.ru/symposium/docs/es-report/20%20Van%20der%20Lann.ppt>

Project website: <http://www.eadgene.org>

kk. -- (2004) *Property Rights in Plant and Animals Genomes, with special attention to Sustainable Development, Biodiversity and Food Production: Ordre Public and the Commons as Models of Regulation in Intellectual Property Rights: 27-28th November 2004, Orenas Castle, Lund, Sweden*. Available at: <http://www.propeur.bham.ac.uk/theme3.htm>

(2005) *PropEur Workshop on Property Rights in Human Tissue: Property Regulation in European Science, Ethics and Law (PropEur): Workshop I: Donation/gift and Conditional Gift Models of Regulation in Intellectual Property Rights: 21-22nd January, 2005, Tuebingen Castle, Tuebingen, Germany: Workshop Report*. Available at: <http://www.propeur.bham.ac.uk/theme4.htm>

Project website: <http://www.propeur.bham.ac.uk/>

ll. BABAS (1999) *Ethical Aspects of Agricultural Biotechnology*. European Federation of Biotechnology, The Hague. Available at: <http://files.efbpublic.org/downloads/ethical.pdf>

There was also a poster for a more recent project, Ethical Bio-TA Tools,^{mm} coordinated by Volkert Beekman (Agricultural Economics Research Institute, The Hague, Netherlands). This project, which was in its last months, aimed to develop and improve tools for the ethical assessment of new technologies in agriculture and food production in general, and of modern biotechnologies in particular. In the meantime, the final report has become available.ⁿⁿ Matthias Kaiser (NENT, National Committee for Research Ethics in Science and Technology, Oslo, Norway), who was an active participant in The Budapest Meeting, was one of the project partners.

Of specific importance was the poster on the “Cloning in Public” project,^{oo} coordinated by Peter Sandøe (CeBRA, Danish Centre for Bioethics and Risk Assessment, Royal Veterinary and Agricultural University, Frederiksberg, Denmark). The project is preparing a state of the art report on farm animal cloning as well as a foresight study. It is making an exhaustive overview of the ethical, legal and social aspects of the developments, creating ways to foster an informed public debate in Europe, and preparing recommendations for European policy makers. The project will organize some workshops and conferences and develop a project website.

The presentation of the projects by the coordinators was followed by a long discussion to identify the major ethical issues. It is impossible to summarize or structure this intensive interaction. The following three issues, which are all interlinked, may be the most important elements that require follow-up.

1/ The first issue is the question of the ethical and philosophical underpinning of the current use of animals in various contexts like research, husbandry and biometrics. Can there be a creative win-win solution for human and animal interests? Is it possible to make use of animals while serving our ‘anthropocentric concerns’ about food safety, the danger of viral epidemics and nature management? This leads to the question as to how the interaction between the different stakeholders can be organized. Animal breeders want to combine the production of high quality safe food with respect for

mm. Project website: <http://www.ethicaltools.info/>

nn. Beekman, V., Bakker, E. de, Baranzke, H., et al. (2006) *Ethical Bio-Technology Assessment Tools for Agriculture and Food Production : Final Report Ethical Bio-TA Tools (QLG6-CT-2002-02594)*. LEI, The Hague. Available at:

[http://www.ethicaltools.info/content/ET1%20Final%20Report%20\(Binnenwerk%2059p\).pdf](http://www.ethicaltools.info/content/ET1%20Final%20Report%20(Binnenwerk%2059p).pdf)

oo. Gjerris, M. & Vajta, G. *The Science and Technology of Farm Animal Cloning: A review of the state of the art of the science, the technology, the problems and the possibilities*. [Danish Centre for Bioethics and Risk Assessment (CeBRA)].

Meyer, G. *Why clone farm animals? Goals, motives, assumptions, values and concerns among European scientists working with cloning of farm animals*. [Danish Centre for Bioethics and Risk Assessment (CeBRA)].

Institute of Prospective Technological Studies (DG JRC-IPTS, Sustainability in Agriculture, Food and Health Unit), Danish Centre for Bioethics and Risk Assessment (CeBRA) & DG RTD (Biotechnology, Agriculture and Food directorate) (2005) *Animal Cloning: Technology, Applications and Ethics: Expert Workshop Conclusions*. [European Commission, Seville]. Available at: <http://www.sl.kvl.dk/cloninginpublic/index-filer/Page460.htm>

Project website: <http://www.sl.kvl.dk/cloninginpublic/index-filer/Page361.htm>

animal welfare and respect for the environment. What can be the role of ethicists and philosophers in this process? How exactly can the social sciences contribute?

2/ The second issue concerns the interface between science and society at large. The relationship between science and the public is not evident. Public opinion exerts pressure on animal issues and, following several crises in food safety, the public does not trust the scientists. To regain a relationship of trust, the scientists have to develop a better understanding of what they are doing and how they can communicate this to the public. Society has to develop and put in place instruments (such as those relating to ethical traceability) and models (such as animal review committees) which enable a process of open communication and sharing of ethical concerns between science and the public.

3/ The third issue concerns the notion of risk. What exactly is risk? What can science, ethics and politics say or decide about risk (or conversely about safety)? The risk concept has become very important. It is at the heart of our current stage of scientific and evolutionary development. It plays a role not only in issues of food safety or care for the environment, but also in clinical trials and clinical care, and in gene therapy and human cloning. Nevertheless there seems to be a growing gap between the risk perception of scientists and society at large. Moreover, risk remains a difficult notion that is often confused with uncertainty or probability. Furthermore it is not easy for the public and for political authorities to accommodate new insights in risk and to translate them into trustworthy, stable and reliable institutions.

STRUCTURAL CONCLUSIONS

The discussion showed that several so-called technical networks of excellence or integrated projects have developed a genuine interest to integrate ethical aspects into the technical work. To keep this interest mobilized, a structured possibility for regular open discussion with “professionals in ethics” is required. The exchange of ideas should not be limited to ethical specialists in food or animal or environmental ethics. Other fields of human action share the same ethical issues. Interaction with the ethics of nanotechnology or human cloning or clinical trials may help to deepen our understanding of the ethical issues at stake.

3.4 Ethics in Context 4: Brain research and dementia

Brain research is on its way to becoming the key technology of the 21st century. Brain researchers are not only improving our understanding and treatment of neurological diseases. They also believe that their work will help us to understand what it is to be human. More than the genes, the brain may be the key to understanding human identity. More than geneticists, brain researchers may be able to dig into the deeper levels of our private world and read our minds. More than gene therapy, brain

technology may be able to change not only the personality of the individual, but also the definition of mankind. More than genetic manipulation, brain manipulation may come to endanger human dignity.

The ethical study of brain research is still in its infancy. This session focuses on the way recent studies are attempting to clarify the situation, and whether we can learn something from this new field to deepen our understanding of the ethics of reproductive cloning and gene therapy. Péter Molnár (Medical and Health Sciences Centre, University of Debrecen, Debrecen, Hungary) chaired the session.

INTERACTION

The session was exclusively devoted to the discussion of Meeting of Minds (ECD),^{pp} a recent EU project on the ethics and social perception of brain research. The project is coordinated by Tinne Vandensande (King Baudouin Foundation, Brussels, Belgium). The project was interesting, not only because it addressed a challenging new topic, Brain Research, but also because of its broad consultation among the European public. Péter Molnár is a partner in the project. Els Van den Cruyce, (viWTA, Office of Technology Assessment, Flanders Parliament, Brussels, Belgium) is another partner. She explained the procedure and preliminary results. The project organized a series of meetings of a national citizen panel in 9 countries. Each national panel consisted of 14 citizens chosen at random, but using mechanisms to ensure that a broad range of age, gender and profession was represented. All groups together formed a European Citizens' Panel consisting of 126 lay people. No specialists in the field of brain science or brain ethics were invited to sit on the panels. Experts were available as advisors or expert resources. In a first round, the different groups met in their own countries and made up a list of ethical issues that should be addressed. During an intensive two-day European Convention, the national lists were compiled and rearranged into a summary list of six challenging topics. The list was not really new. It contains the traditional issues of regulation, public information, equal access, right to choose treatment, pressure from economic interests, and the difference between normal and abnormal traits. What is new is not only that the list was generated by non-specialists, but also that the citizens felt challenged to go back to their countries to develop informed and reasoned opinions on the topics. A second round of national meetings was planned to prepare a new two-day European Convention, where the citizens would discuss the national results and prepare a common "European Citizens" Assessment Report.^{qq}

pp. Raeymaekers, P., Rondia, K., Slob, M. eds. (2004) *Connecting Brains and Society : the present and future of brain science : what is possible, what is desirable? : European Workshop 22 and 23 April 2004 Amsterdam the Netherlands, Proceedings and Synthesis report*. King Baudouin Foundation [etc.], Brussels [etc.].

Project website: <http://www.meetingmindseurope.org>

qq. Dickson, E., Rondia, K. & Slob, M. eds (2006) *European Citizens' Assessment Report: complete results: 37 recommendations on Brain Science*, Meeting of Minds Partner Consortium, [Brussels].

This second European Convention was planned for January 2006, two months after The Budapest Meeting. It was intended to present the results to the European Parliament.

The rest of the interaction focused on mental illness. The participants felt that we may not sufficiently realize that mental disease is a disease that causes discomfort and pain for the patient. It is more than a mere empty state of diminished consciousness. The citizens felt a lot of compassion for people who suffer from a mental illness. The question was raised as to what extent euthanasia should be available for these patients. Even after a long intensive exchange of ideas, the participants could not reach agreement.

During the discussion, nobody felt the need to refer to the human dignity of patients who are mentally ill. The notion did not play any substantial role in the project either. Several project documents were already publicly available at the time of The Budapest Meeting. The ethical issues were never discussed in terms of “human dignity”. On the other hand, the Meeting of Minds project group did not try to avoid the notion. When in January 2006, two months after The Budapest Meeting, the European Citizens’ Panel formulated its own ethical opinion, human dignity was clearly mentioned in two of its recommendations. In one passage, the panel recommends: “Every piece of research and every treatment should be designed to maintain the quality of life and *dignity* of the patients”. In another passage they state: “For reasons of solidarity and human dignity the right to equal access was emphasized by each panel alike”.¹¹ Reprogenetics planned to make an in-depth study of the reasons why the notion of “human dignity” was used and to what extent this concept helps to clarify the ethical questions or the ethical position of the citizens.

The discussion of the Meeting of Minds project revealed that citizens accept brain research, even though it is linked to deep ethical problems, and that citizens are both ready and capable of being involved in the process of designing proper ways to deal with the ethical issues. The citizens even encouraged the professional philosophers and ethicists to educate themselves about brain research.

STRUCTURAL CONCLUSIONS

This session illustrated the importance of having lay people around whenever a structural network is created to address the ethical issues of science. The principle was accepted by all the participants. Researchers in ethics recognize the potential input of citizens. Participants in The Budapest Meeting experienced that the input of non-experts enriched the discussion in several ways. Reprogenetics had invited a group of lay people who had been active in national focus groups of the Reprogenetics project. Generally speaking, lay people can enrich the discussion in a large variety of ways.

Est, R. van & Fischer, A. eds (2006) *European Citizens’ Deliberation on Brain Science: January 20-23, 2006: Brussels, Belgium: European Citizens’ Assessment Report*.

ource: http://www.meetingmindseurope.org/europe_default_site.aspx?SGREF=16

11. Est, R. van & Fischer, A. eds (2006) *European Citizens’ Deliberation on Brain Science: January 20-23, 2006: Brussels, Belgium: European Citizens’ Assessment Report*: 38.

Some contributions may be modest, but even the mere presence of lay people during a discussion is already helpful. Their presence forces experts to explain their ideas in simple words. This helps the experts to rephrase their own ideas and to deepen their own understanding. On the other hand, the questions of lay people may reveal the weaknesses in the ideas and theories of the experts. The experts can then strengthen their ideas. But there is more. In many cases, lay people are users or potential users of a technology and thus relevant stakeholders. Furthermore, while it may be true that lay people are by definition non-experts in the field under study, they may be experts in other social practices, like running a shop, organizing a family, developing a business, or painting or photography. They may even be linked to research as amateur scientists or researchers in a completely different discipline. In their own field of expertise, they have to solve problems, they have to design and implement balanced solutions. This expertise and experience is a rich source of inspiration for finding solutions to similar problems in a specific field of science and its functioning within society.

While in theory and in principle many experts are open to the input of non-experts, when practical and structural decisions have to be made, the input of lay people is often neglected. If future sessions of The Budapest Meeting are organized, it will be necessary to maintain and strengthen the role of lay people in them.

3.5 Ethics in Context 5: Old Age, Intensive Care Units and Death

Much work in early bioethics focused on the beginning and the end of life. “Dignity of the elderly” and “death with dignity” are contemporary topics of discussion. What exactly are the ethical issues that are currently being studied in EU projects? Can the ethical analysis of dealing with critically ill people, the elderly or death help us to understand the deeper meaning of our defense of human dignity? It is clear that little work has been undertaken so far in these areas and clinicians are keen to learn more. This is especially important with the ageing of the population, and this is reflected in the patients admitted to the Intensive Care Units (ICUs). David Edbrooke (Intensive Care Medicine, Royal Hallamshire Hospital, Sheffield, UK) chaired the session.

INTERACTION

Two projects were presented.

The first project, Dignity and Older Europeans (DOE),^{ss} explicitly addressed the “dignity” of human beings. The project had just been completed. The coordinator was Win Tadd (Department of Geriatric Medicine, Cardiff University, Cardiff, UK).

One of the major objectives of the project was to clarify the meaning of the notion “human dignity” and to find out how this notion can increase the quality of life among

ss. Project website:

http://www.cardiff.ac.uk/medicine/geriatric_medicine/international_research/dignity/

the Elderly. Human dignity proved to be a complex concept that was difficult to define. The notion has also occupied a central place in recent ethical debate and in international conventions on bioethics. This notion promises to be useful in attempts to define the social conditions that will allow older people to experience dignity in health and social care, as well as in other aspects of their lives. The project intended to clarify the complexities of the concept and to show how the concept can become operational.

On the basis of a study of the philosophical literature, the project identified four major meanings of the word ‘dignity’: the dignity of *Menschenwürde*, the dignity of merit, the dignity of moral stature and the dignity of personal identity. On the basis of this theoretical framework, a list of questions was prepared to start a discussion on “human dignity” in 91 focus groups of elderly people in six European countries, involving 391 people. The focus group discussions were recorded and transcribed. Despite the different countries and despite the different backgrounds of the people involved, there was substantial agreement about the meaning and experience of human dignity. The overarching themes that were identified were: respect and recognition (from others and for oneself), participation and involvement, and dignity in care (and the impact of dependency and loss of autonomy). A workshop translated these and other project results into recommendations for policy makers.^{tt}

The second project, Eldicus, addressed the way in which Intensive Care Units (ICUs) deal with the Elderly. Eldicus is studying the process of triage in the ICU: i.e. the process of deciding which patients should be admitted to the ICU and which should not. This general study is based on an empirical study of the admission practices in 17 ICUs in 12 countries throughout Europe. The empirical study is complemented by a study of the cost of admitting patients to the ICU and an analysis of the ethical literature on triage. The project will result in a clear triage scoring system that will help doctors to make the right triage decisions. This scoring system will be used to find out whether current ICU admission practices involve unfair discrimination against the elderly. The coordinator of the project is Charles Sprung (General Intensive Care Unit, Department of Anesthesiology and Critical Care Medicine, Hadassah University Hospital, Jerusalem, Israel). David Edbrooke, who is a partner in this project and is responsible for the cost study, gave a detailed description of the work done. It was too early to give an overview of the results. David Edbrooke remarked that he noticed a large gap between the type of discussions that ICU doctors are used to and the discussions that were held during the interaction sessions of The Budapest Meeting.

tt. -- *Operational model of Human Dignity : Dignity and Older Europeans (QLG6-CT-2001-00888) : Deliverable 23.*

Available at:

http://www.cardiff.ac.uk/medicine/geriatric_medicine/international_research/dignity/project_findings/Human_Dignity_An_Operational_Model.pdf

Tadd, W. *Policy recommendations [Dignity and Older Europeans]*. DOE Consortium.

Available at:

http://www.cardiff.ac.uk/medicine/geriatric_medicine/international_research/dignity/project_findings/Policy_Recommendations.pdf

ICU doctors do have a real interest in ethics, but in their triage decisions they tend to focus on medical criteria.

The participants were surprised by the large consensus that the DOE project was able to reach about the meaning and value of the concept of human dignity. Reprogenetics plans to make a detailed analysis of the results of DOE and to check, in collaboration with the researchers involved in DOE, whether their results can also help to clarify the relevance of “human dignity” within the context of human reproductive cloning and germline gene therapy.

As for the world of ICU, the discussion focused on the large gap between ICU doctors and social analysis. ICU doctors feel the need to get a better understanding of their patients, of their families and of the concerns of society. But it appears that there are not enough opportunities to realize this. They would like to be closer to the families of the patients and understand more of the psychology of loss. They would like to have more opportunities to talk to social scientists and ethicists. This would require better communication skills, both on the part of the social scientists and on the part of the medical doctors. It would also require better training in ethics. It is true that ethics is taught in the medical curriculum. It is also fairly clear that medical students do not take this instruction in ethics terribly seriously. It is a sort of afternoon off from anatomy and physiology. We cannot accept this state of affairs. The way ethics is taught must be changed. The group suggested making the course truly “embedded” by organizing a co-teaching arrangement involving both physicians and ethicists as co-teachers. They also suggested organizing the course at a later stage in the curriculum.

STRUCTURAL CONCLUSIONS

At a structural level, the session confirmed the general feeling that each of the projects would benefit from a more structural interaction between the projects. The group emphasized that we should not forget to create links to the lawyers and lawmakers. “At this moment some intensivists are in prison for manslaughter, while they were doing their job in the best way they could.”

4. INTERACTION SESSIONS ON ETHICAL DECISION-MAKING

The rise of bioethics is a combined process consisting of at least two components. One component involves providing an ethical clarification of developments in biomedical research and practice. Another component involves designing the tools, methods and criteria that are required to organize the ethical clarification. The same is true for the ethics of science, for technology assessment and probably for any human activity that involves monitoring or evaluation. Like several other EU projects on ethics of science, the Reprogenetics project felt the need to pay attention to both lines of reflection. This is also reflected in the structure of The Budapest Meeting.

In a separate series of five interaction sessions, The Budapest Meeting addressed five methodological or meta-ethical or organizational questions about ethical decision-making: (1) Do we need intercontinental collaboration? (2) Does the integration of the EU's New Member States require specific actions? (3) Is there a role for the religious traditions? (4) Is there a role for the media and the general public? (5) Can stakeholders speak a common ethical language? The following pages illustrate the ideas that were discussed.

4.1 Ethical decision-making 1: Do we need intercontinental collaboration?

The world is becoming smaller. Trade and tourism are organized on an intercontinental basis. But should ethics follow this trend? It is easy to understand the importance of talking to people who are in the same situation. This can help to clarify personal choices. It is also not difficult to see that it helps to talk to people with different opinions. This helps to avoid one-sidedness. On the other hand, it is not evident that we can learn from people from totally different cultures.

The Reprogenetics project did not plan a specific work package for studying intercontinental collaboration, but it did invite experts from different continents to join its meetings, and it is its ambition to link up to worldwide organizations. That is why The Budapest Meeting was prepared in collaboration with the World Science Forum and it is also why it was organized as a satellite meeting. The contacts were intensified in the months after the meetings.

The session, dedicated to exploring the general context of intercontinental collaboration, was chaired by Judit Sándor (Center for Ethics and Law in Biomedicine, Central European University, Budapest, Hungary). She was involved in designing the Reprogenetics project. She has also been active in the Ethics Division of the UNESCO headquarters in Paris.

INTERACTION

The BIG Project (Bioethical Implications of Globalization process) has an obvious reason for aiming at intercontinental collaboration: it studies the ethical concerns linked to globalization.^{uu} The project is coordinated by Emilio Mordini (Centre for Science, Society and Citizenship, Rome, Italy). Emilio Mordini was actively involved in the preparation of The Budapest Meeting. A project poster was available during the meeting.

Four other posters presented projects that are linked to developing countries: BeSha, CTC-Ethics, EDCEP and Nebra.

BeSha (Genomics and Benefit Sharing with Developing Countries) contributes to the implementation of international guidelines that encourage the equitable sharing of benefits from genetic resources with local communities.^{vv} In spite of such guidelines, in most developing countries, indigenous peoples strongly protest against the exploitation of their genetic materials by developing world peoples. The project was coordinated by Doris Schroeder (Centre for Professional Ethics, University of Central Lancashire, Preston, UK.). Miltos Ladikas, who was a member of the coordinator's team, was an active participant in The Budapest Meeting.

The aim of two projects coordinated by Reidar K. Lie (Department of Philosophy, University of Bergen, Bergen, Norway) was to build capacity for ethical review in developing countries. An earlier project, CTC-Ethics (Ethical issues in Clinical Trial Collaborations with developing countries),^{ww} made a number of overviews of the organization of clinical trials and of the ethical problems linked to it. EDCEP (European and Developing Countries Ethics Partnership) organized training and capacity building workshops.^{xx}

uu. Novotny, T.E., Mordini, E., Chadwick, R., Pederson, J.M., Fabbri, F., Lie Reidar, Thanachaiboot, N., Mossialos, E., Permanand, G. (2006) Bioethical implications of globalization: An international consortium project of the European Commission. *PLoS Medicine* 3: e43. Available at:

<http://www.globalhealthsciences.ucsf.edu/about/bios/Bioethical%20Implications%20of%20Globalization.pdf>

Project website: <http://www.bigproject.org/>

vv. -- (2005) *Sharing the fruits of genomics with the developing world [Leaflet; Project information]*. Available at:

http://www.eubueno.de/arbeitsbereiche/wissenschaftundgesellschaft/projekte/Download/dat/_fil_1300

Project website: <http://www.uclan.ac.uk/facs/health/ethics/staff/publications/doris%20besha.htm>

ww. -- *The CTC Ethics Focus Group Discussion Guide*. Available at:

http://www.bioethics.it/pdf/pu_4/the_ctc_ethics_focus_group_discussion_guide.pdf

-- *Ethical issues in clinical trial collaborations with developing countries: Focus group report*.

Available at: http://www.bioethics.it/pdf/pu_4/ctc_ethics_focus_group_report.pdf

Project website: <http://www.ethica.uib.no/level/ctc.html>

xx. -- *EDCEP: European and Developing Countries Ethics Partnership, [Introduction]*. Available at: http://www.bioethics.it/pdf/pc_4/edcep_pagina_introduttiva.pdf

Lie, R.K. et al (2003) European and Developing Countries Ethics Partnership: EDCEP, [Project Proposal Part B]. Available at: http://www.bioethics.it/pdf/pc_4/edcep.pdf

François Hirsch (INSERM, National Institute for Health and Medical Research, Paris, France) coordinates a similar project that focuses on the situation in Africa: Nebra (Networking for ethics on biomedical research in Africa).^{yy} The project is making an overview of the existing ethical review capacity in Africa, exploring the possibilities for strengthening it where it already exists and for developing it where it is lacking. François Hirsch was an active participant in The Budapest Meeting.

Judit Sándor emphasized that intercontinental collaboration may also be important to develop a common understanding of ethics and to develop common policies to implement such ethical consensus. She mentioned the UNESCO Declaration on Bioethics and Human Rights^{zz} which was adopted by the General Conference of UNESCO two weeks before The Budapest Meeting, on 19 October 2005. Sándor wondered whether this declaration could play the same role as the Universal Declaration of Human Rights^{aaa} and become internationally accepted as a reference for action. It may be important to explore whether and under which conditions this would be possible. It is not evident that schools or codes of bioethics, can have the same influence as international human rights.

STRUCTURAL CONCLUSIONS

At the organizational level, this session emphasized the need for a European network to promote the ethics of science and to develop strong links with leading programs worldwide, international institutions and stakeholders around the globe.

This will help European researchers in their own work to take account of the great diversity of cultures, ethical approaches, levels of welfare and social needs that exists worldwide. This will also be an important channel for the dissemination of European knowledge and experience.

yy. -- (2005) Ethics of research overseas, in: *Medical Research Council : Annual Report and Accounts 2004-2005*, The Stationary Office, London: 36. Available at: http://www.mrc.ac.uk/pdf-annual_report_2004_2005.pdf

INSERM (2005) *Partenaires africains et européens s'unissent pour favoriser l'éthique dans la recherche médicale*, [Press release]. Available at:

<http://ist.inserm.fr/basispresse/CPI/CPI2005/27janvier2005.pdf>

Shette, P. (2005) *Africa and Europe create ethics network*. Available at: SciDev.Net: <http://www.scidev.net/News/index.cfm?fuseaction=readnews&itemid=1886&language=1>

zz. UNESCO (2005) *Universal Declaration on Bioethics and Human Rights*. Available at: http://portal.unesco.org/shs/en/file_download.php/46133e1f4691e4c6e57566763d474a4dBioethicsDeclaration_EN.pdf

aaa. United Nations (1948) *Universal Declaration of Human Rights*, adopted on 10 December 1948. Available at: <http://www.unhchr.ch/udhr/index.htm>

4.2 Ethical decision-making 2: Does the integration of the EU's New Member States require specific action?

The Reprogenetics project wanted to find out whether the scientific, cultural and ethical situation in the New Member States (NMS) was significantly different from the situation in the Old Member States. Does the situation in the NMS reveal some new ethical aspects linked to human cloning and gene therapy? Do we need other methodologies to address ethical and legal issues in the NMS?

Reprogenetics organized a specific NMS core group to investigate these questions. The coordinating partner of this NMS networking is Ferenc Oberfrank (KOKI, Institute of Experimental Medicine, Hungarian Academy of Sciences, Budapest, Hungary).

Ferenc Oberfrank also chaired the session. At the time of the Budapest meeting this NMS networking was still restricted to the NMS from Central Europe. Malta and Cyprus were not yet involved. One representative from each of the 10 Central European NMS countries attended the Budapest meeting. This group of 10 representatives organized preparatory meetings to discuss the specific analysis that each member had made of his or her own country.

INTERACTION

The main message of the representatives of the New Member States (NMS) can be summarized in two points.

1. On the one hand, the New Member States are not a single unified entity:

Too often, Western European countries speak of the NMS or of the Central European countries as if they were one homogeneous block. In reality, the different Central European Countries have different cultural traditions and different historical backgrounds. They have different levels of economic development. They also have different languages. Most legislation is not translated. Traditional ethical and philosophical literature is published in the different national languages. This means that there is no shared body of Central European ethical thought. The heterogeneity of the NMS comes to appear even larger when we also consider Malta and Cyprus. Judit Sándor remarked that this lack of shared ethical convictions among NMS is clearly illustrated in the recent Eurobarometer, published in June 2005, which presents the results of a survey on attitudes towards social values, science and technology.^{bbb} Question 11 of this survey asked whether the decisions about science and technology should be based primarily (1) on an analysis of the risks and benefits involved, or (2) on the moral and ethical issues involved. Greece is the country with most citizens (70%) who believe that the analysis of the risks and benefits involved is most important. Greece is immediately followed by Hungary with 67 %. We also find New

bbb. European Commission. Directorate General Press and Communication (2005) *Social values, Science and Technology*. (Special Eurobarometer 225, June 2005). Available at: http://ec.europa.eu/public_opinion/archives/ebs/ebs_225_report_en.pdf

Member States among the countries with the lowest number of citizens who choose answer 1: Poland (41%), Malta (41%) Lithuania (41%), Latvia (42%) and Estonia (43%). But here we also find Old Member States like Ireland (41%) Luxembourg (45%) and Finland (46%).^{ccc} The answer to question 16.1 provides an even more extreme picture. Here EU citizens are asked whether we have a right to exploit nature for the sake of human well being. Countries with most citizens who agree with this statement can be found in Slovakia (77%), Poland (70%) and France (67%). Countries with the lowest number of citizens who agree are Hungary (10%), Austria (12%) and Germany (12%).^{ddd} Western Europe has already gone through a long process of unification. It makes sense to promote specific networking in NMS countries. But at this moment such a network does not exist. Western Europe cannot link up with the NMS in one single step, as if only a single larger block had to be attached. Each NMS will require an individual approach.

2. On the other hand, the Central European Countries do have a common recent history:

They share the legacy of communism, which was a form of state socialism in which the political class had a strong influence on the professional and ethical decision-making process, and in which there was no tradition of public discussion. They were not involved in the development of bioethical thinking or in the open analysis of scientific developments. Their ethical institutions are still weak and there is hardly any ethical networking. On the other hand, the representatives of the NMS stressed that the Central European Countries have also developed a sense of self-irony and a sense of criticism. They have the capacity to learn quickly from good examples and from the experience of others. They are convinced that the future will be better than the past. Sándor remarks that this point is also illustrated in the special issue of the Eurobarometer on social values, science and technology. When asked whether the next generation will enjoy a better quality of life than we do now (Question 7.2), an overwhelming majority of citizens in Lithuania (87%), Estonia (82%), Latvia (78%), Hungary (75%), Poland (75%) and the Slovak Republic (74%) say yes. On the other extreme we find most Old Member States with France (34%), the Netherlands (35%) Luxemburg (37%) and Sweden (42%).^{eee}

The members of the NMS network of the Reprogenetics project expressed the hope that their work would not be lost. They are willing to contribute to other efforts that strengthen the internal NMS networking. They helped to prepare NMS related activities in other projects such as TWR and BioTethed.

TWR, the project coordinated by David Edbrooke (Intensive Care Medicine, Royal Hallamshire Hospital, Sheffield, UK), will organize a network-based “Training Workshop for Researchers” in New Member States. Josef Kuře (University Centre for Bioethics, Masaryk University, Brno, Czech Republic), who is a member of the NMS

ccc. See page 37 of *Social values, Science and Technology*. (Special Eurobarometer 225, June 2005)

ddd. See page 22 of *Social values, Science and Technology*. (Special Eurobarometer 225, June 2005)

eee. See page 55 of *Social values, Science and Technology*. (Special Eurobarometer 225, June 2005)

Network of the Reprogenetics project, will be the major NMS contact for TWR and will host the workshop.

BioTethed is a project coordinated by Franco Celada (University of Genoa, Genoa, Italy). It is the continuation of BioTethics,^{fff} and is also coordinated by Franco Celada. Both projects develop educational projects on biotechnology ethics. Guido Van Steendam is a partner in both. When BioTethed was designed, he created a specific workpackage that will prepare tools to support continued capacity building on ethics in NMS and that will promote the complete integration of the NMS networks into the Western European networks. Members and contacts of the NMS network or the Reprogenetics project accepted the responsibility to help to develop these tools. Key players here are Eugenijus Gefenas (Department of Medical History and Ethics, Vilnius University, Vilnius, Lithuania), Imre Szezik (Institute of Behavioral Sciences, Semmelweis University, Budapest, Hungary) and Josef Kuře (University Centre for Bioethics, Masaryk University, Brno, Czech Republic). During The Budapest Meeting, Eugenijus Gefenas was represented by Eimantas Peicius (Department of Philosophy and Social Sciences, Kaunas University of Medicine, Kaunas, Lithuania). It is evident that the projects and the three NMS networks remain independent and have their own objectives. The different networks are all aimed at creating a maximum of synergy and collaboration.

STRUCTURAL CONCLUSIONS

At the organizational level, the lesson from this session is that a European network to promote the ethics of science should pay special attention to linking up with the relevant resources in the New Member States. The New Member States, which represent a large variety of cultures are not a single homogenous block of countries. This means not only that intensified networking will result in a widely diversified input, but also that linking up with them may require different structures in different countries and not just a single homogeneous approach intended to reach each of the new countries all at once.

4.3 Ethical decision-making 3: Is there a role for the religious traditions?

Many people today wish to limit the role of religion in public debates about scientific and biomedical research. They fear that religious considerations will complicate political discussions with needless speculative objections relating to human nature or unscientific assumptions about human life at its earliest stages. Others, however, welcome religious views, not necessarily because they agree with what is said, but rather because they recognize the need to deepen public discussion by introducing philosophical and religious motifs.

fff. Project website: <http://130.251.107.180/biotethics/>. The consortium produced a textbook in Biotechnology Ethics: Landeweerd, L., Houdebine, L.-M., Termeulen, R. eds. (2005) *BioTechnology-Ethics: an introduction*, Pontecorboli, Florence.

The Reprogenetics project will produce an overview of the different approaches on the ethics of cloning and gene therapy. Religious traditions will be included in this overview, which is being prepared by the team of John Harris (IMLAB, Institute of Medicine, Law And Bioethics, University of Manchester, Manchester, UK).

Ron Cole-Turner chaired the session on religion during The Budapest Meeting. Ron Cole-Turner is a Protestant theologian from Pittsburgh Theological Seminary (Pittsburgh, USA). The introductory lecture was given by Daniel Sinclair, rabbi and professor of Jewish Law and Comparative Biomedical Law at Hebrew University (Jerusalem, Israel).

INTERACTION

Ron Cole-Turner explained that religions hold various opinions on science and biomedical advancement. For the most part, the religions support scientific progress, especially when applied to human healing. More surprising, perhaps, is the fact that some religious assessments of human germline genetic modification are positive. Statements from the Vatican, as well as statements from highly-regarded Protestant theologians, show qualified support for the goals of germline modification. Catholic statements insist that the intervention must be therapeutic for the embryo itself, and never for the benefit of another (opposing, therefore, the use of embryonic stem cells as a technique of germline modification). Furthermore, religious scholars are raising concerns about enhancement scenarios, even while recognizing the difficulty of distinguishing excessive enhancement from defensible therapy. But if safe and moral means can be developed, and if the limits are carefully considered, then the central concept of germline modification will be supported.

Reproductive cloning has far less support from religious institutions and scholars. Even if safety concerns could be resolved, the idea of reproductive cloning strikes most religious commentators as offensive or as an unneeded and inappropriate form of reproductive technology, and particularly inappropriate in the context of grief. Whether these concerns justify a legal ban or merely a religious advisory against cloning is a matter of debate.

Another focus of debate is whether a moral distinction should be made between human cloning for reproduction and human cloning for research, for instance to produce cloned human embryonic stem cells. Catholic objections to all embryo research are well-known. This is best understood not as opposition to science, but as a commitment to protect the most vulnerable members of society. Some Protestants and members of other religious traditions (especially Judaism) encourage embryo research with discarded embryos and even with cloned embryos created for research. Beyond the question of the morality of the source of the stem cells, there is the growing question of future human self-modification or “trans-humanism”, to which religious scholars are turning with increasing seriousness.

During the discussion, two helpful distinctions were put forward.

The first distinction is between ‘religious traditions’ and ‘religious arguments’. Quite often “religious arguments” are used against science. It is not clear, though, that

these arguments are the expression of religious traditions. Sometimes people who may not be particularly religious themselves may object to science or to biotechnology or to GM food or to cloning. They will often manufacture religious arguments, or arguments that sound vaguely religious like: “Oh, you know, scientists are playing God. They shouldn’t do that.” This does not mean that the religious traditions themselves are opposed to technology. What these arguments show is that religion often gets misused, just as – in other contexts – scientists get misused as well.

A second distinction is between the ‘religious traditions’ and ‘religious institutions’. Let us first acknowledge that institutions have a role to play in each social practice or movement or country. This does not mean, however, that institutions should or can contain the complete ethos and inspiration of the social practice, movement or country. Institutions often create the impression of power. In fact, the role of institutions within a practice is more modest than that. The presence of institutions within religious traditions may give the impression that religion wants to be involved in the ethical discussion because it wants to control it. In fact, religious traditions are not interested in controlling the world. They may want to interfere in the discussion about scientific and technological developments and ask difficult questions like “Have you thought about the weakest, the most vulnerable?” This question is not “Have you listened to our voice?” but “Have you listened to the voice of the voiceless, the people who cannot speak for themselves?” Religious traditions do not even want credit for the question. They are even pleased when other groups, including non-religious or anti-religious groups, ask the same questions. The reason why religions want to ask difficult questions is not to find ways to hinder science. Furthermore, religions do not claim that they have an easy answer to these questions. While all Christians agree that society should take vulnerable people into consideration, they often disagree about the best way to do it. Some Christians will say: “Well, the most weak, the most vulnerable of all persons is the human embryo. We are here to defend the embryo against scientific developments that may not leave the embryo untouched.” Others would agree that religion should speak up for those who have no voice. But they would rather think of the sick, the poor and those who are excluded from power, and not so much of the embryo. Both visions may serve as inspiring elements in the discussion. They do not claim, however, to provide the final answer.

Can religious traditions play a constructive role? This depends on their ability to generate inspiring questions and to provide inspiring elements in the search for answers.

STRUCTURAL CONCLUSIONS

At the organizational level, this session resulted in the conclusion that a European network to promote the ethics of science should also develop appropriate links with the religious traditions. It is not clear yet how this can be realized. The network should avoid losing a lot of time with what some participants in The Budapest Meeting called “misuse of religion”. The network can be inspired and gain credibility by listening to challenging questions asked by the religious traditions, and by discussing their tentative contributions to these questions.

4.4 Ethical decision-making 4: Is there a role for the media and the general public?

Many experts in the natural sciences or in ethics believe that is impossible to take science and ethics seriously if we want to accept lay people as real partners. They emphasize that developing solid scientific or ethical theories is a specialized critical activity that requires the necessary skills and knowledge that are only acquired in the course of long and intensive training. By definition, lay people are people who do not have these skills and knowledge. So, the reasoning continues, there is no place for lay people in science. Following the same reasoning, most of us would not ask our neighbor, whom we respect as an excellent pianist or creative cook or gardener, to decide whether or not a newly designed airplane wing is safe. Researchers often feel that this is exactly what the public wants: to impose their non-informed opinion in matters that require specialized knowledge.

The discussion on genetically modified micro-organisms, mentioned in the report on Topic in Focus 2, provides an excellent example. When biologists met in Asilomar,^{ggg} they invited the press as a witness. While the main intention of the scientists was to develop strategies to guarantee safe conditions to continue the work, the press and the public were dumbfounded when they learned about the existence of potential dangers that appeared to be so serious that even the scientists involved had decided to stop their work. Public and press continued along this line and created new scenarios of danger and threat. They not only made stronger versions of the potential threats to human health that the biologists were already discussing, but they also created scenarios about the total collapse of the biosphere, and the total confusion of the evolutionary process. As the press and people assumed that the technology would not be limited to bacteria, but would later involve plants, animals and men, they feared that the social order would be destroyed, and that society would not be able to cope with the new possibilities. Recombinant DNA was seen as the biological version of the atomic bomb. The only appropriate answer is not to engage in this line of research. When researchers started to recognize that they could master the potential health hazards they first mentioned, and that numerous experiments were in fact safe, the public did not follow. The public continued to mobilize politicians and philosophers and ethicists to stop the scientists. This triggered a number of reactions. Some researchers complained that the real problem was no longer to keep the dangerous bacteria out of their work, but to keep the public away. Others realized that they needed to organize public relations activities to charm the public. A general reaction emphasized the need to develop good programs of science information and science popularization, that scientists have to learn how to talk to the public at large, and that they also have to listen. It is possible that the public was wrong when they continued to be afraid of health hazards and started to talk about other types of hazards. It cannot be ignored that people are involved in science, that they have their own opinions and

ggg. See above: Topic in Focus 2: Germline Gene Therapy: The world in 2025. (Three major points of discussion: 1. Safety issues)

expectations of science, and that, when suddenly confronted with recombinant DNA research, the public reacted.

Reprogenetics includes two work packages that address the link between science and the public at large. One workpackage, led by Matthias Kaiser (NENT, National Committee for Research Ethics in Science and Technology, Oslo, Norway), investigated the limits and possibilities of organizing a European Consensus Conference of lay people. Five different European countries had organized 1 to 3 focus groups and discussed the ethics of cloning and gene therapy. Each focus group had sent one representative to The Budapest Meeting. Another workpackage, led by Paolo De Nardis (Faculty of Sociology, University La Sapienza, Rome, Italy), studied the news coverage about cloning and gene therapy.

István Hargittai (University of Technology and Economics, Budapest, Hungary) chaired the session. István Hargittai is not only a Professor of Chemistry but also a science writer. He has published several widely read books of interviews with leading researchers. The session addressed the question as to what we can expect from informing and involving lay people.

INTERACTION

Alessandra Sannella of the team led by Paolo De Nardis presented the results of the analysis of the media coverage on cloning and gene therapy. Her introduction was rather alarming. It confirmed the feeling that newspapers did not bring a nuanced account of the real scientific developments, or of their limits and possibilities. The ethical comments in the newspapers did not come close to rendering the analysis that is discussed among experts or in groups of informed lay people like the focus groups. This does not mean that there was never a high quality review in some reputable newspapers. But these exceptions did not often reach the general public. If the media are to play a more constructive role in informing and involving society at large in meaningful ethical discussions, much will have to be changed.

After a short introduction, Matthias Kaiser gave the floor to the members of the focus groups who were attending The Budapest Meeting. Each of them was interviewed. They were asked about their motivation to join a focus group that would study the ethics of reproductive cloning and germline gene therapy. They were also asked to elaborate on the way the groups were selected, on the progress of the work and on the organizational difficulties, as well as on the preliminary results of their discussions. The other participants, most of whom were experts in biology or ethics, were impressed by the nuanced and solid way in which the lay people expressed their opinions. The experts challenged the non-experts by asking them more detailed questions and by confronting them with more specialized philosophical and ethical issues. They remained impressed. There was no doubt that lay people are not only able to understand complicated ethical issues linked to specialized science, but are also able to identify the issues, join high level discussions, and contribute to the clarification of the problems. This strong conclusion in favor of the contribution by lay people was not a complete surprise. Jan Vorstenbosch mentioned a study conducted in the Netherlands

in the 1990s where both experts and focus groups addressed issues linked to animal research. It appeared that very similar points were taken up both by lay people and by experts.^{hhh}

During the remaining time in the session, the participants tried to find out to what extent experts can do more or better than the public. Why do we still need experts? One strong element of the combined input of experts and lay people may be the complementarity of the evidence they bring in. The researchers in the study on animal research mentioned above indicated that experts take a point seriously when they can link it to some more systematic background, to some kind of method, or sometimes even to some quantitative data. For the lay people involved in the study, the presence of this systematic context seemed to be irrelevant. What they put forward as a valid argument was a reference to common sense or to practical knowledge or to direct experiences from daily life.

It was not clear how far this complementarity can go. Is there a moment in the further clarification of a specialized ethical issue where only experts can continue and where lay people can no longer follow or no longer contribute? Some studies indicate that the political world will only trust an analysis by experts, while, in general, the citizens' opinions do not have any real impact on decision-making. Are experts needed to check the reliability of the citizens' opinions? Or to help the citizens to start their discussions? Or to do the technical work of implementation, for example in laws or regulations?

During the lunch break the participants in the session on the media and the general public discovered that the session on brain research shared the enthusiasm for the contribution of the lay people. Both sessions belonged to two different series of sessions that were organized in parallel during The Budapest Meeting. One series dealt with the ethics of one specific type of scientific developments (ethics in context) and the other series dealt with methodological issues (ethical decision-making). Throughout the entire meeting the participants had to choose between two alternative sessions. It was mere coincidence that the two sessions that emphasized the strengths of the contribution of citizens both took place on Tuesday Morning, 8 November 2005, from 10.00 to 12.00. The possibilities of intensified interaction between experts and non-experts became a major topic of discussion over lunch in the Wine Museum on Buda Hill.

STRUCTURAL CONCLUSIONS

At the organizational level, all participants strongly recommended continuing the attempts of The Budapest Meeting to integrate lay people into the discussions carried on by acknowledged experts. More preparatory work must be done to study the most effective mechanisms for realizing this goal and for integrating the contribution of lay people into a European network to promote the ethics of science.

hhh. Voorthuizen, L. van (1993) *The signaling and articulation of ethical aspects regarding genetic modification of animals. A comparative study of an organized public debate and the opinion of ethicists*. Center for Bioethics and Health Law (now Ethics Institute Utrecht), Utrecht. The report is only available in Dutch

4.5 Ethical decision-making 5: Can stakeholders speak a common ethical language?

Ethical concerns are addressed and discussed in a variety of ways. Some ethical discourse is presented as a discussion of values or goals. Sometimes people focus on rules, “absolute musts” or laws. Sometimes ethics is discussed in terms of possibilities, opportunities and recommendations. The differences may depend on a variety of elements such as the topic under discussion, the type of stakeholder, or the type of result one is aiming at. Are all these languages “incommensurable”? Can different stakeholders who are used to speaking different types of ethical languages exchange views?

Reprogenetics deals with these questions in the workpackage led by Guido Van Steendam (IFB, Leuven, Belgium), who is also the coordinator of the Reprogenetics project. He is taking the approach of making a “Social Linkage Map”. A Social Linkage Map maps the goals and ambitions of the different stakeholders who are collaborating in a shared social practice. This is conceived as an operational tool to help stakeholders make common decisions. A discussion on the Social Linkage Map will be postponed until an operational demonstration is available.

When preparing The Budapest Meeting, Reprogenetics was intrigued by a challenging project called XENO that studied Xenotransplantation.ⁱⁱⁱ The XENO project, which ended in 2004, was coordinated by Beate Littig (Department of Sociology, the Institute for Advanced Studies, Vienna, Austria). Beate Littig also chaired the session.

INTERACTION

The objective of the XENO project was to introduce and evaluate an instrument of public debate. The proposed instrument adopts elements of the traditional Socratic Dialogue of Plato. It integrates them into a modern concept of inter-subjective communication. The resulting instrument is called the “neo-Socratic Dialogue”.

Beate Littig explains that this neo-Socratic Method is expected to be suitable for the clarification of large public debates about science, where several people have their own interests and speak their own language. The method is designed to be adapted to the challenges of a democratic federal society. In a nutshell, the method provides guidelines to help people to clarify their own assumptions, values and experiences, and to develop common thinking. But instead of giving a long theoretical introduction,

iii. Hüsing, B. (2003) *Increasing Public Involvement in Debates on Ethical Questions of Xenotransplantation: Monitoring of International Developments in Xenotransplantation: Baseline Evaluation*. Institute for Advanced Studies (IHS), Vienna. Available at: http://www.ihs.ac.at/departments/soc/xeno-pta/xeno_huesing.pdf

Santos, D. and Munoz, E. (2003) *Increasing Public Involvement in Debates on Ethical Questions of Xenotransplantation: National Report Baseline Evaluation: Spain*. Institute for Advanced Studies (IHS), Vienna. Available at: http://www.ihs.ac.at/departments/soc/xeno-pta/xeno_Spain.pdf

Beate Littig started the session with a little demo of the type of neo-Socratic Dialogue designed in the XENO project. As a test case, she proposed to tackle the overall question of the session: “Can stakeholders speak a common ethical language?” The participants were asked to gather practical experiences of ethical debates in which they have been involved and where they believed that the different stakeholders, each with their own different personal experiences, were speaking a common language. Time was too short for a detailed discussion of one of the situations that was mentioned. But even the little experiment was enough to come up with some challenging elements of a tentative answer. The participants elaborated on the hypothesis that speaking “a common language” does not necessarily mean that people have to develop a common set of words with a strictly defined and stable meaning, i.e. some “neutral standard” that everybody must use to communicate. The participants emphasized that people do *not* even need to use the same words in order to speak “a common language”, and, conversely, that “using the same words” does not in itself guarantee that people will be speaking the same language and understanding one another.

What is really needed is to reach some kind of agreement, some feeling that people are working together, that they have some common goals and values. The language should be clear enough to enable people to make themselves understood and to understand the others. The most important factor of “speaking the same language”, however, is that people realize that they are involved in a shared project. The instructions for a “neo-Socratic Dialogue” are intended to facilitate this process.

The hypothesis that was discussed during this session is not without consequences for the problem of the vagueness and ambiguity of the use of ‘human dignity’ in the context of science. Should this hypothesis prove to be true, the problem with the notion of human dignity would not necessarily be solved by the theoretical exercise of developing and promoting one single and clear definition. Less – and more – would be needed. Less, because it would be enough that the notion is clear enough to function and to be understood. More, because the real test of the notion would be the role that it plays in the development and implementation of social projects endorsed by the different stakeholders involved in a scientific practice.

STRUCTURAL CONCLUSIONS

At the organizational level, this session contained a strong warning against the temptation to focus on theoretical purity. While not ignoring the importance of clear language, the goal of a European network to promote the ethics of science should not be to develop a merely verbal consensus, which may be devoid of real communication. The goal of a network should rather be to develop a pluralist platform of collaboration in an effort to exchange information, to allow the participants to clarify their own assumptions and to develop common approaches and common goals whenever possible. The network should do justice to the diversity of the work of the different partners and should not impose specific methodologies or specific terminologies.

5. OUTCOMES

During the preparation of The Budapest Meeting a plan was made to valorize the results of the meeting in three different ways: by preparing Conclusions and Recommendations of the Sounding Board, by creating an active link to the World Science Forum, and by planning relevant conference publications. During the meeting and in the weeks after the meeting, a broader process was started up that resulted in the structured plan to establish a new annual series of “The Budapest Meeting”, with an annual meeting of EU project coordinators as its basis and with a strong link to the World Science Forum and UNESCO.

5.1 Conclusions and Recommendations of the Sounding Board

The initial reason for organizing The Budapest Meeting in 2005 was to organize a Sounding Board meeting that would allow a number of invited experts to formulate Conclusions and Recommendations for the researchers of the Reprogenetics project. The Reprogenetics project wanted to know what researchers involved in the study of similar or complementary issues had to say about its preliminary results and approach. This goal was realized during the many intensive discussions and interactions that took place between the Reprogenetics team and the other participants. At the end of The Budapest Meeting, a special session was organized where the participants could hold a final discussion without the participation of the Reprogenetics team. In this session the participants answered the question concerning what they see as the most important conclusions and recommendations to be addressed to the Reprogenetics team. Miltos Ladikas (Centre for Professional Ethics, University of Central Lancashire, Preston, UK) chaired the session. Later, he communicated the following priorities for further work in the field.

Ethical issues to be studied in more depth

1. *Human Dignity*

The concept of “human dignity” is widely used in relation to cloning (e.g. in UN declaration 59/280), but in an arbitrary manner. There is no common understanding of this concept and how it can help clarify ethical issues. Hence, the concept of “dignity” requires further clarification before being used in relation to this technology.

2. *Creation of stem cells*

Despite common beliefs, there is no real difference between the scientific processes involved in therapeutic cloning and those involved in reproductive cloning. It is evident, however, that the existing stem cell lines are not adequate for quality research and, therefore, new ones need to be created. Ethical issues associated with such a development (e.g. embryo dignity, donor consent, beneficence, etc) need to be taken into consideration.

3. *Enhancement*

Transhumanism (belief in the enhancement of human beings) is a rational approach that is gaining popularity internationally. Very little research has yet been done on this phenomenon and its repercussions for the theory and practice of cloning.

4. *Religious perspectives*

Despite the common perception that religion is negatively inclined towards stem cell research (and even towards science as a whole), as a matter of fact, this perception is not true. Religious arguments have been used by many people, but this is not the same as a religious perspective. It is important to have a religious perspective in the debate, as such a perspective usually represents the voice of the “voiceless” (e.g. the fetus).

5. *Animal experimentation*

The issue of animal experimentation is controversial, as it appears that there are differences of perception between the scientists working in the area and the general public. There is, therefore, an urgent need to investigate the ethical aspects and stakeholder perceptions in the debate.

Other priorities:

6. *Develop EU-wide ethical standards*

There is a lack of EU-wide ethical standards in relation to medical ethics (particularly in the areas of confidentiality and data protection) and nursing codes. There is also a lack of understanding of the variety of socio-cultural influences in the practice of such professions. Studies aimed at understanding these differences need to be carried out on a Europe-wide basis and in a more systematic way.

7. *Intensify the integration of New Member States*

The new European member states present unique challenges in the area of ethics in scientific practice. It has been argued that these states have few ethical institutions, that they lack a culture of public debate on the relevant issues, and that they generally have a weak civil society. On the other hand, they also have a great willingness to learn from other countries' experience. There is, therefore, an urgent need to explore issues relating to the integration of the New Member States with the rest of the European Union in this area.

8. *Intensify the popularization of science*

There is a lot of public misinterpretation in many areas of scientific research, and few efforts are being made to popularize science in an objective manner, particularly in the New Member States. More research effort is needed in opening up a dialogue between the scientists and the public.

9. *Continue to develop strategies for public participation*
There is a lot of scope in developing strategies for public participation / public consultation in the field of stem cell research. Some experimental methods that have been tried (e.g. consensus conferences) appear promising, but more such initiatives are required.
10. *Establish a regular platform of discussion*
Initiatives such as The Budapest Meeting are pivotal in exchanging experiences and ideas in the area of ethics of science. Such meetings should acquire a regular character so that relevant projects and researchers from all over Europe would find the appropriate platform to develop and promote European research in the field.

5.2 World Science Forum

On the final day of The Budapest Meeting on Embedding Ethics, the results were also summarized in the presence of representatives of the World Science Forum. Maurizio Salvi, (then: Science and Society, European Commission; now: Policy Advisor to President José Manuel Barroso of the European Union and Head of the Secretariat of the EGE, the European Group on Ethics in science and new technologies), emphasized that the European Commission attaches great importance to Europe-wide networking in ethics within a worldwide context. He explained that the European Commission shares the objective to investigate the ethical values that are embedded in scientific practice itself and to explore how specific ethical research projects can help researchers to improve the ethical quality of their work. The Executive Director of the World Science Forum, Balázs Gulyás (Department of Clinical Neuroscience, Karolinska Institute, Stockholm, Sweden), stressed the fact that the World Science Forum welcomed the input of the Meeting of EU project coordinators. He expressed the hope to explore how more intensive collaboration can be planned for the future. This future collaboration was also discussed with UNESCO (Division of Science Analysis and Policies), which was the co-founder of the World Science Forum and the creator of the Annual World Science Day celebrated each year on November 10th.

5.3 A new annual series of “The Budapest Meeting”

The organizers of The Budapest Meeting have started to explore the structural possibilities of networking, in contact with many participants who have continued to support the idea and with a number of coordinators and other experts who could not attend the meeting in 2005, but who hoped to join a similar initiative in the future. Tanja De Coster (then: Loyens & Loeff Lawyers; now: eBay) helped to design a legal framework. The type of information products that are appropriate for a research network were discussed with Hans Roosendaal (NIKOS, Dutch Institute for

Knowledge Intensive Entrepreneurship, University of Twente, Enschede, Netherlands). Roosendaal previously served Elsevier Science as Publisher and Deputy Group Director, responsible for long-term planning and acquisitions. He previously served the University of Twente as Director of Science Information and as Vice-President, and is now professor of Strategic Management, specializing in information products.

The perspectives of future networking were discussed during a workshop convened by Guido Van Steendam (Belgium) in Brussels on 17-19 March 2006. The Workshop was covered in the local press and was followed by an Academic Session for a large audience of experts and non-experts. During the Workshop, two new interaction sessions on Genetics and Brain Research provided a further test case for the importance of linking different fields, and the possibilities of interaction and valorization. The results will be published in another summary article. The workshop attempted to clarify the issues linked to neurobiology by linking them to the results of ethical studies in the fields of genetics, gene therapy and cloning. Introductions on research and ethics were given by Jean-Pierre Changeux (Institut Pasteur and Collège de France, Paris, France), Eric Juengst (Department of Bioethics, Case Western Reserve University, Cleveland, Ohio, US) and Daniel Callahan (Hastings Center, Garrison, New York, US). A delegation of project coordinators and researchers who attended The Budapest Meeting joined the discussion. René von Schomberg (Science and Society, European Commission) gave an update on the preparation of the next Framework Programme and informed the participants about the efforts of the European Commission to strengthen ethical research.

The organizers of the World Science Forum and UNESCO's World Science Day also attended the Workshop. Balázs Gulyás, the Executive Director of the World Science Forum, confirmed that the World Science Forum very much appreciated the link with The Budapest Meeting of EU project coordinators. The World Science Forum hopes that a renewed and more intensive collaboration will be possible in the future. The next World Science Forum will be held in Budapest, 8-10 November 2007. The title of this next meeting is "Investing in Knowledge: Investing in the Future." The World Science Forum will focus on the value of Knowledge as a driving force for social and economic development. It will discuss how society can safeguard its future by increasing the investment in Knowledge. Ethics cannot be left out of this project. Within this context, an initiative undertaken by a group of EU projects could lead to worldwide action. Diana Malpede, from UNESCO's Science Policy Division Unit, is the coordinator of UNESCO's World Science Day for Peace and Development. She explained that in adopting a Resolution for such a Celebration, the General Assembly of UNESCO was emphasizing that the mission of the World Science Day should be linked to the overall goal of UNESCO: to build peace in the minds of men. The Celebration of the day is also an opportunity for worldwide reflection on the ethical dimensions of science. World Science Day is not about promoting science, as such. It is rather about promoting science as an important tool for realizing peaceful development. This is clearly expressed in the complete name: World Science Day for Peace and Development. Diana Malpede confirmed that the joint efforts of the EU project coordinators would contribute to realizing the objectives of World Science Day

and would find a welcome niche in the main event. This main event usually takes place in Paris, though it can be organized in any other city in the world.

The participants in the Workshop endorsed the plans to develop a new annual series of “The Budapest Meeting”. The core of the project will be a combination of a focused exploration of central issues emerging from ongoing EU research and an open intensive interaction between EU projects, a combination that was explored during the meeting that took place in Budapest in November 2005 and is illustrated in the present summary report. The meeting will also serve as a platform to link up with leading research initiatives in other continents. It will take place in a European city and gain impact by having direct access to the events of the World Science Day and the World Science Forum.

This new series of “The Budapest Meeting” will provide a structural basis for valorizing the abundance of information, creativity and enthusiasm that is available in European research projects. It will promote the quality of the ethics embedded in scientific practice. It will result in an integrated network of European resources in the fields of science and ethics of science, and will be well connected with leading programs worldwide. This new network will give Europe an opportunity to take the lead in a major global Ethics of Science initiative.

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