



Nationale Ethikkommission im Bereich Humanmedizin
Commission nationale d'éthique pour la médecine humaine
Commissione nazionale d'etica per la medicina
Swiss National Advisory Commission on Biomedical Ethics

First Report on the Activities of the Swiss National
Advisory Commission on Biomedical Ethics
NEK-CNE

covering the period July 2001 - January 2003
for the attention of the Federal Council and the general public

Prepared in May 2003, approved by
the Commission on 3 July 2003

Foreword

The present report gives an account of the activities of the Swiss National Advisory Commission on Biomedical Ethics during the first year-and-a-half of its existence – from its establishment in July 2001 to the completion of its work on the Embryo Research Law in January 2003.

During this period, the Commission had to be duly constituted and structures developed in the course of the initial projects. The topics to be addressed were stem cell research and, more broadly, experimental embryology. The Commission thus prepared a series of papers, for a variety of readerships and focusing on several different questions: on imports of human embryonic stem cells, on the harvesting of embryonic stem cells from so-called surplus human embryos, on the Embryo Research Law (specifically for the parliamentary debate), and finally on reproductive human cloning. As part of this process, an Opinion was also prepared on the legalization of first-trimester abortion. Given the relevance of this subject to the ethics of embryo research and the fact that the debate coincided with the referendum on first-trimester abortion, the Commission felt that this issue needed to be examined for the benefit of the public.

The Commission was faced with the task of defining its role as an advisory body for policymakers and the public. Although the framework is established by the relevant legislation (Reproductive Medicine Law, Art. 28, and the NEK-CNE Ordinance), some latitude remains as to how specific topics are to be approached in practice. The task of making creative use of this freedom has been welcomed by the Commission as an opportunity. In the process, we have tried out various forms of communication and discussion diverging from the «classical approach» of calling a press conference when an Opinion is published: notable examples include the «Café philosophique» held at the Expo.02 and the special event for parliamentarians at the Federal Assembly building. Our experience – favourable overall – has been evaluated in detail.

In the period under review, as well as producing a number of publications, the Commission began more wide-ranging explorations of several different areas: ethical questions arising in modern end-of-life healthcare («deciding to die»), the implications of pre-implantation genetic diagnosis in connection with in vitro fertilization, and ethical issues relating to the patenting of gene sequences and human cells.

As these intense efforts proceeded, one point emerged quite clearly: the multiplicity of questions to be considered places a considerable burden on a National Ethics Commission, substantially exceeding the capacity of its infrastructure and the resources that were initially allocated. If the Commission is to be able to fulfil its legal mandate with a suitably broad remit, greater resources and increased staffing will be required in the years to come. To date, the work of the Commission has only been possible because administrative expenses have been borne – as an unbudgeted item – by the Biomedicine unit of the SFOPH.

The Commission's work should be seen as a contribution to a shared learning process. Its purpose will have been achieved if the ethical transparency of our society's decision-making in the areas of medicine and biomedical research is enhanced.

A handwritten signature in black ink, appearing to read 'Christoph Rehmann-Sutter', with a long horizontal flourish extending to the right.

Christoph Rehmann-Sutter, Chairman

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Legal basis and mandate

On 3 July 2001, the Federal Council established the Swiss National Advisory Commission on Biomedical Ethics (NEK-CNE) and appointed its members. The Commission was duly constituted at a meeting held on 31 August 2001. The NEK-CNE, which has an advisory function, was assembled on an interdisciplinary basis to represent all sections of society: it comprises 21 experts from various areas, with a third drawn from the field of ethics, another third from medicine, and the remainder from allied disciplines such as law, biology and psychology and from patients' groups. The mandate of the NEK-CNE is to identify ethical issues emerging from developments in medicine and the biomedical sciences, and to formulate opinions pointing the way ahead.

The legal basis for the NEK-CNE is provided by Art. 28 of the Reproductive Medicine Law of 18 December 1998 and the Ordinance on the National Advisory Commission on Biomedical Ethics of 4 December 2000. In carrying out its tasks, and especially in forming its opinions, the NEK-CNE is obliged to remain independent of political, industrial and scientific interests. It serves a consultative function. Its first term of office lasts until the 46th legislative period is concluded at the end of 2003.

The main emphasis of the Commission's work during the first year and a half was placed on embryonic stem cell research. To fulfil its legal mandate, the Commission not only provided information for the public on this subject through media conferences and the publication of a booklet but also organized public debates and regularly expressed its views in contributions to the media. In the period under review, recommendations concerning legislation were prepared for the Federal Council and the Federal Assembly in five substantial papers. By being represented at numerous discussions on this topic, the NEK-CNE sought to promote the discussion of ethical questions within society.

In future, the NEK-CNE wishes to continue its efforts to highlight ethical dilemmas, make these issues amenable to debate, provide guidance, and identify possible solutions.

Composition of the Commission

Professor Christoph **Rehmann-Sutter** (molecular biologist and philosopher), Director of the Centre for Ethics in the Life Sciences, University of Basel, was appointed as Chairman of the NEK-CNE by the Federal Council.

The following were appointed as members of the NEK-CNE by the Federal Council:

Dr Andrea **Arz de Falco** (theologian), Chair of the Swiss Ethics Committee on Non-Human Gene Technology (ECNH) (until February 2003)

Christiane **Augsburger** (nurse), Head of «Ecole la Source» – Swiss Red Cross school of nursing, Lausanne

Dr Ruth Ella **Baumann-Hölzle** (theologian), Director of the Interdisciplinary Institute for Healthcare Ethics, Zurich

Professor Alberto **Bondolfi** (theologian), Professor of Theological Ethics, University of Lucerne, Director of the Centre for Medical Ethics, University of Zurich, and the Lausanne Ethics Centre (CLE)

Professor Jean-Claude **Chevrolet** (physician), Professor and Director of the Medical Intensive Care Division, Cantonal University Hospital, Geneva

Professor Johannes **Fischer** (theologian), Professor of Theological Ethics and Head of the Institute of Social Ethics, University of Zurich

Dr Carlo **Foppa** (philosopher), clinical ethicist at the University Hospital Centre of Vaud (CHUV), Lausanne

Professor Sabina **Gallati** (biologist), Professor of Medical Molecular Genetics and Molecular Biology and Director of Molecular Human Genetics, Inselspital, Berne

Professor Olivier **Guillod** (lawyer), Professor of Civil Law and Director of the Health Law Institute, University of Neuchâtel

Professor Daniel Hell (psychiatrist), Professor of Clinical Psychiatry and Clinical Director of the Psychiatric Clinic (PUK), University of Zurich

Silvia Huber (community development worker), Head of the Contact Office for Self-Help Groups (SG, AR, AI) in St. Gallen

Dr Silvia Käppeli (nurse), Head of the Centre for Nursing Research and Development, University Hospital, Zurich

Dr Margrit Leuthold (biologist), Secretary General, Swiss Academy of Medical Sciences, Basel

Dr Jean Martin (physician), Cantonal Medical Officer (until April 2003) and privatdocent at the University of Lausanne

Professor Alexandre Mauron (molecular biologist), Professor of Bioethics, University of Geneva

Dr Carola Meier-Seethaler (philosopher and psychotherapist), Berne

Professor Hansjakob Müller (physician), Professor of Medical Genetics, Director of Medical Genetics Division, Children's Hospital (UKBB), Department of Clinical and Biological Sciences (DKBW), University of Basel

Dr Judit L. Pók Lundquist (physician), Senior Consultant Gynaecologist, University Hospital, Zurich

Franziska Probst (lawyer), Cantonal Legal Secretary, Zurich

Dr Brigitte Weisshaupt (philosopher), Lecturer in Philosophy and Ethics, University of Applied Sciences, School for Social Work, Zurich (HSSAZ), and Lecturer in Philosophy and Rhetoric, Federal Institute of Technology, Zurich

Non-voting guest (from March 2003):

Dr Andrea Arz de Falco (theologian), Head of Medical Ethics unit, SFOPH

For administrative purposes, the NEK-CNE office is attached to the SFOPH. Operationally, however, the Commission is independent.

Scientific/Executive Secretary: Georg Christoph Amstutz (Germanist and political scientist)

Administrative Secretary (from April 2002): Csongor Kozma (theology undergraduate)

Secretary (until April 2002): Margrit Bourqui

According to the Ordinance, the Commission may comprise 18 to 25 members; since its establishment, it has consisted of 21 members (11 women and 10 men). The various language regions are represented as follows: 12 members from German-speaking, 7 from French-speaking and 2 from Italian-speaking Switzerland. The first term of office lasts until the end of the legislative period in December 2003.

On the basis of the Commission's experience to date and the topics to be addressed in the future, the NEK-CNE wishes to recruit not only an expert in theological ethics to fill the place vacated by Dr Arz de Falco but additionally experts in other fields. Reinforcement would be particularly welcome in the areas of clinical research and general medical practice. In the course of 2003, the appropriate nomination and consultation procedures will be initiated by the Commission's Secretariat in conjunction with the SFOPH.

Secretariat/Office

The NEK-CNE Secretariat reports to the Chairman of the Commission, and for administrative purposes it is attached to the SFOPH. The Office is run by the Executive Secretary, Georg Amstutz; from October 2001 to April 2002, Margrit Bourqui was responsible for administration, and since April 2002 this function has been carried out by Csongor Kozma. The Secretariat provides technical support to the Commission, maintains contacts with official agencies and organizations in Switzerland and abroad, and acts as a press office and public information centre. It performs administrative tasks and assists the Commission particularly in organizing public events and providing information for the public.

Plenary meetings

Since its inception, the Commission has held plenary meetings on the following dates:

2001 31 August: constitutive meeting in Berne
24 & 25 October: Tramelan
2002 30 & 31 January: St. Gallen
20 March: Berne
22 & 23 May: Bellinzona
5 August: Berne (extraordinary session)
22 August: Neuchâtel
16 & 17 October: Lausanne
20 November: Berne
2003 15 & 16 January: Berne

The NEK-CNE was also invited to attend a series of two-day closed-door meetings with representatives of the cantons of St. Gallen, Ticino and Vaud, which provided opportunities to establish valuable and fruitful contacts.

Working groups

In accordance with the Commission's responsibilities, working groups were established to address the following topics: embryonic stem cells, first-trimester abortion, assisted dying, pre-implantation diagnosis and patenting.

The activities of the «embryonic stem cells» and «first-trimester abortion» working groups were completed in the course of 2002 with the presentation of their respective reports (cf. Section 3). The «assisted dying», «patents» and «pre-implantation diagnosis» working groups will remain active in 2003.

Topics addressed

Publications

31 August 2001	Opinion 1/2001: Research involving imported embryonic stem cells
2 May 2002	Opinion 2/2002: First-trimester abortion
19 June 2002	Opinion 3/2002: Research involving embryonic stem cells
December 2002 / January 2003	Ethical aspects of the Embryo Research Law – 6 points for the parliamentary debate
16 January 2003	Opinion 4/2003: Reproductive human cloning

Opinions issued under consultation procedures on:

- Draft «Federal Law on Research Involving Surplus Embryos and Embryonic Stem Cells» (Embryo Research Law/EFG)
- Draft «Federal Law on Patents for Inventions» (Patents Law, PatG)
- Draft «Protocol on Biomedical Research» (Additional Protocol to the Convention on Human Rights and Biomedicine)

Opinion 1/2001: Research involving imported embryonic stem cells

The establishment of the NEK-CNE happened to coincide with the emergence of the debate on stem cell research. In Switzerland, as elsewhere, fundamental decisions were due to be taken that would have far-reaching implications for the development of a new field of medicine. At its first (constitutive) meeting, the NEK-CNE stated its position on the decision that was shortly to be taken by the Swiss National Science Foundation (SNF) as to whether a grant application should be approved for a research project involving embryonic stem cells. The opinion expressed by the NEK-CNE neither supported nor opposed stem cell research as such, but concerned the decision-making process. A majority of the Commission recommended that the research project in question should be neither accepted nor rejected, but that it should be deferred until the fundamental legal and ethical questions had been clarified. A minority had no reservations provided that the decision related only to a research project. Three days after the publication of the Commission's Opinion, the SNF – contrary to the recommendation of the majority of the NEK-CNE – decided to provide funding for the project.

Opinion 2/2002: First-trimester abortion

On 2 June 2002, the Swiss electorate voted in a referendum on two proposals relating to abortion. The parliamentary bill (which was approved by the electorate in preference to a restrictive popular initiative) called for the decriminalization of abortion during the first 12 weeks of pregnancy. The proposed law takes account of two aspects: the pregnant woman's autonomy and the protection of the unborn. The initiative «For mother and child», rejected by the electorate, wished to see abortion largely banned: under this proposal, it could only have been legally performed in cases where an acute threat to the mother's life could not be averted by other means. In its Opinion published on 2 May 2002, the NEK-CNE unanimously supported the basic principle of legalized first-trimester abortion and pointed out the ethically relevant distinctions between the areas of abortion and embryo research.

Opinion 3/2002: Research involving embryonic stem cells

On 19 June 2002, the NEK-CNE published – in booklet form – a fundamental opinion on research involving embryonic stem cells. In this publication, a majority of the Commission recommends that the use of stem cells from «surplus» embryos should be permitted by legislators for purposes of research and treatment, with certain conditions being stipulated. The main reason cited is that the fate of the embryos is not altered in any way by the harvesting of stem cells. Under the Reproductive Medicine Law, the «surplus» embryos that arise as a rare but inevitable by-product of the in vitro fertilization process would otherwise have to be left to die.

The NEK-CNE proposes that ten conditions be stipulated for the use of stem cells from «surplus» embryos for research and therapeutic purposes:

The parents concerned must have been fully informed and have given their voluntary consent to the embryo being used in this way. An inquiry may only be made to the couple once it is clear that the embryo can no longer be used to induce pregnancy. The research project must meet the highest scientific standards and involve fundamentally important goals. In the course of research, embryos are only to be permitted to develop as far as the blastocyst stage. In addition, the patenting of embryos, organs, cells or cell lines is not to be permitted, and trade in embryos and cells directly derived therefrom is to be prohibited. Any such research project must have been reviewed by an ethics committee for compliance with all of these conditions and have been judged to be acceptable.

This position is not shared by a minority within the NEK-CNE, which recommends that basic constitutional rights to health and self-determination should also be applied to embryos at an early stage, and that a general ban should be imposed on «destructive» experiments involving embryos. In the view of this minority, embryos have become supernumerary «artificially», and neither this circumstance nor their de facto lack of prospects of development can justify their being instrumentalized for extraneous purposes.

In addition to the question of embryo protection, stem cell research also poses a cultural challenge. The effects of so-called regenerative medicine should be

examined in depth at an early stage. It will certainly have an impact on our conception of human beings and the human body, and on models of human identity. Perceptions of disease, disability and even death may be changed. A regenerative medicine that holds out the promise of replacing human tissue could also alter the social nature of medicine, our sense of mortality and immortality, and solidarity both within societies and worldwide. These questions need to become a subject of ethical debate.

Ethical aspects of the Embryo Research Law – 6 points for the parliamentary debate

In January 2003, preliminary parliamentary deliberations on the Embryo Research Law began in the relevant Federal Assembly committees. In November 2002, despite the keen interest shown in its Opinion published in June 2002, the NEK-CNE decided to summarize for the benefit of the public and Parliament six key points concerning the draft Embryo Research Law presented by the Federal Council in November 2002. In particular, the following topics were covered: harvesting of stem cells, the scope of the law, linking of stem cell harvesting to specific research projects, patentability, human dignity and commercial use of stem cells.

At the beginning of 2003, several members of the NEK-CNE were invited by the deliberative committees of the National Council and Council of States to attend the hearings on the Embryo Research Law.

Opinion 4/2003: Reproductive human cloning

The announcement of the birth of what was claimed to be the first cloned human baby («Eve») was prominently reported in the media. The question of whether reproductive cloning is ethically acceptable was also widely discussed by the public around the world and by the United Nations. The NEK-CNE takes the view that reproductive human cloning is to be unequivocally rejected and condemned on ethical grounds – including any efforts to develop reproductive human cloning. The Commission cited five specific objections: the risk of children being instrumentalized, the acceptance of damage to health and/or deformities as an inevitable part of the process, the creation of false expectations, the predictability of the resultant genetic makeup, and the absence of any therapeutic justification.

Despite its complete rejection of this method, the NEK-CNE felt it important to point out that were a cloned individual to be created, it would enjoy the full status of a human being and its fundamental human rights would have to be recognized.

Additional Opinions

In the course of consultation procedures, the Commission issued Opinions on the draft «Protocol on Biomedical Research» (Additional Protocol to the Convention on Human Rights and Biomedicine), the Embryo Research Law and the Patents Law.

Opinions 1 – 4 are available online (in French, German and Italian) on the Commission's website (www.nek-cne.ch) or can be ordered by e-mail (nek-cne@bag.admin.ch).

Dialogue with the public/public events

A close dialogue with the public was pursued through a variety of channels. In addition to well over 100 media appearances, participation in parliamentary committee hearings, and contributions to discussions at Federal Assembly party meetings, special attention was paid to contacts with the general public.

The presentation of the booklet on «Research involving embryonic stem cells» aroused considerable media interest. The publication itself was ordered enthusiastically and was also used for teaching purposes in schools and universities. At the Swiss National Exhibition (Expo.02), the NEK-CNE hosted a «Café philosophique» on the following topics: «The perfect life – fantasy or nightmare?», «Research: what is feasible, what is permissible?» and «Prolonging life at any cost?». On each issue, discussions took place between interested members of the public (approx. 60 people) and representatives of the Commission.

In addition, the executive secretary and the Chairman of the NEK-CNE participated in a project organized by the «Science et Cité» Foundation, which was designed to stimulate public debate on the subject of research involving human embryos and stem cells.

National and international contacts and cooperation

During the initial phase of its activities, the NEK-CNE cooperated with numerous federal bodies (the Swiss Ethics Committee on Non-Human Gene Technology, the SFOPH, the Federal Office for Social Security and the Federal Office of Justice) and with many other national and international institutions.

Members of the Commission took part in several national and international meetings, including the 6th European Conference of National Ethics Committees/COMETH (Cyprus, November 2001); as an expert member of the Swiss delegation at the UN negotiations concerning the banning of reproductive human cloning (New York, February and September 2002); as an expert member of the Swiss delegation to the Council of Europe's Steering Committee on Bioethics/CDBI (Strasbourg, December 2002); at the kick-off meeting on Ethical, Legal, and Social Implications (ELSI) of the Austrian genome research programme/GEN-AU (Vienna, November 2002); and at the 4th Global Summit of National Bioethics Commissions (Brasilia, November 2002).

Experts consulted/expert reports

In the course of its work on various subjects, the NEK-CNE consulted the following experts:

Dr Verena Schwander, SFOPH, 24/25 October 2001

Dr Marisa Jaconi, Biology of Aging Laboratory, Geneva University Hospital, 24/25 October 2001

Professor Franco Cavalli, National Councillor, Chief of Oncology Division, San Giovanni Hospital, Bellinzona, 16/17 October 2002

Monica Fliedner, Institute of Nursing Science, University of Basel, 16/17 October 2002

Marcia Leventhal, Institute of Nursing Science, University of Basel, 16/17 October 2002

Dr Bara Ricou, Surgical Intensive Care Unit, Cantonal University Hospital, Geneva, 20 November 2002

Dr Markus Zimmermann-Acklin, Institute for Social Ethics, University of Lucerne, 15/16 January 2003

Dr Georg Bosshard, Institute of Legal Medicine, University of Zurich, 15/16 January 2003

Dr Barbara Skorupinski: «Nationale Ethikkommission Humanmedizin und ihre Rolle im öffentlichen Meinungs- und Willensbildungsprozess» [Role of the NEK-CNE in public opinion-forming and policy development processes], study commissioned by the NEK-CNE, July 2002

Markus Christen: editorial work and design of the booklet on research involving embryonic stem cells, June 2002

Theresa Stirling: journalistic preparation and editing of an online dossier on assisted dying, scheduled to be published in the autumn of 2003

Budget and staffing

The permanent staff consists of Georg Amstutz (80%) and Csongor Kozma (50%). The Head of the Medical Ethics unit, Andrea Arz de Falco, holds a 20% position at the NEK-CNE office. Given that the NEK-CNE Secretariat is overstretched, an expansion of expert capacity is urgently required. The volume and urgency of forthcoming issues and the assignments expected from the Federal Council and Parliament will necessitate additional staff and financial resources.

	Budget	Expenditures	Deficit
2002	186,940	290,160.95	103,220.95
2003	178,791		

As the Commission only drew on part of its budget for 2001 (CHF 186,940), a substantial surplus remained at the end of that year. This was due to the fact that the Commission's activities only commenced with its constitutive meeting on 31 August 2001.

By contrast, the Commission's budget for 2002 (CHF 186,940) was exceeded by 55% (total expenditure: CHF 290,160.95). The deficit of CHF 103,220.95 was kindly rectified by the Biomedicine unit of the SFOPH, which agreed to bear the Commission's administrative expenses. For 2003, a budget of CHF 178,791 is available to the Commission. Fixed costs (allowances for meetings, Chairman's remuneration, office rental costs, travel expenses, refreshments for meetings, costs of website support and general supplies) total approx. CHF 134,000. As a result, the amount remaining to cover the costs of translations, publications (layout and printing), events, chairing of discussions, expert assignments and research is only about CHF 45,000. This is an inadequate sum.

Outlook for 2003

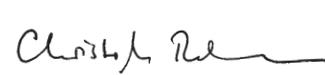
In the initial phase following its establishment, the Commission was concerned not only with the workings of the new institution but with the development of working relationships among the members. The climate within the Commission is one of tolerance and mutual respect. Combined with the high levels of personal commitment displayed by a number of members, this will facilitate intense and productive efforts in the coming months and years.

Thanks to its composition, the Commission has largely been able to meet the widely varying technical demands that have been placed upon it to date. In future, it will continue to call in external specialists to provide additional expertise as required.

In 2003, the Commission will be addressing the following priority issues:

- End-of-life decisions (broadly defined, including assisted dying)
- Transplantation medicine
- Pre-implantation diagnosis
- Patent legislation
- Research in human subjects

The Annual Report was approved by the members of the Swiss National
Advisory Commission on Biomedical Ethics (NEK-CNE) on 3 July 2003.



Professor Christoph Rehmann-Sutter
Chairman



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