

# Nordic Health Law in a European Context

– *Welfare State Perspectives  
on Patients' Rights and Biomedicine*



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# The Nordic Committee on Bioethics

By Sirpa Soini, University of Helsinki<sup>1</sup>

## 1 Introduction

The Nordic Committee on Bioethics (subsequently referred to as the Bioethics Committee)<sup>2</sup>, as we know it today, was established in 1996. Its roots, however, are in the Nordic Collaboration Programme for Biotechnology 1988-92 when an independent Nordic Committee for Ethics related to Biotechnology (*Nordisk utvalg for etikk innen bioteknologi*) was created.

The birth of such a committee was a characteristic of the time at the beginning of 1990s. Both the national and world communities were confronted with rapidly emerging new biotechnological inventions and applications, e.g. gene patenting, cloning, a variety of novel *in vitro* fertilisation techniques and applications, genetically-modified organisms, and the human genome project, just to name a few. These developments raised fears in the public and the research community as regards how to ensure the appropriate use of novel techniques and assess their potential threat to humanity.

In order to respond to new needs to monitor and discuss bioethical issues, the Council of Europe set up an *ad hoc* Committee of experts on Bioethics (CAHBI) in 1985, which later became the Steering Committee on Bioethics (CDBI) in 1992. UNESCO, for its part, established the International Bioethics Committee (IBC) in 1993. Both the CDBI and the IBC are also highly influential today and contribute towards policy-making. Sweden and Denmark were among the first countries in Europe to found national ethical councils; Sweden founded the National Council on Medical Ethics (*SMER - Statens Medicinsk-Etiska Råd*) in 1985 and Denmark founded the Danish Council of Ethics (*Det etiske råd*) in 1987, just few years after France had established its National Consultative Ethics Committee (*CCNE - Comité Consultatif National d'Ethique*) in 1983.

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<sup>2</sup> [www.ncbio.org](http://www.ncbio.org).

The need for Nordic collaboration in the field of biotechnology was expressed at a meeting of Nordic Prime Ministers and Collaboration Ministers held in November 1986. Subsequently, the Nordic Council of Ministers appointed a programme committee to work on a collaboration plan on 14 May 1987. National priorities were worked out. The programme committee made a proposal for a concrete Nordic Biotechnology programme.<sup>3</sup> The Nordic Council of Ministers approved the idea and initiated a Nordic collaboration programme for the period 1988-92, and gave it an annual budget.<sup>4</sup> In addition, the Nordic Council of Ministers had appointed *ad hoc* committees in 1988 and 1990 to address patenting issues in biotechnology.

## 2 Mandate of the Nordic Committee on Bioethics

### 2.1 Organisation

The Nordic Council of Ministers initiates the Bioethics Committee. Its activities and budget are included in the annual action plan of the Nordic Council of Ministers.<sup>5</sup> The mandate of the Bioethics Committee has, since being established in 1996, continued in three-year periods; 1996-1998, 1999-2001, 2002-2004, 2005-2007, 2008-2010. The current and sixth mandate started on 1 January 2011.

The Nordic Council of Ministers was formed in 1971 as a collaboration organisation between the Nordic governments. Nordic cooperation started in 1952 when Denmark, Iceland, Norway, and Sweden established the Nordic Council; Finland joined in 1955. In 1962, the Nordic countries formalised their co-operation by drafting the Treaty of Co-operation between Denmark, Finland, Iceland, Norway and Sweden (the Helsinki Treaty). The Faroe Islands, Greenland, and Åland are also represented in the Nordic organisations.

The Bioethics Committee has two members from each Nordic country.<sup>6</sup> The Nordic Council of Ministers appoints the committee members for three-year periods on the basis of nominations made by the respective national governments. In addition, the Faroe Islands holds observer status on the Bioethics Committee. Members can be appointed for a maximum of two consecutive terms of office. The Bioethics Committee's aim is a multidisciplinary discourse, thus its members represent, for instance, philosophy, medicine, sociology, biology, theology, and law. The Bioethics Committee selects its chair from its members and the chairmanship rotates annually between the Nordic countries. The Bioethics Committee also appoints a secretariat.<sup>7</sup> The committee members are not paid for their work; however, their travel expenses are reimbursed.

<sup>3</sup> *Nordisk Programkomité for Bioteknologi* 1987.

<sup>4</sup> *Nordisk Programkomité for Bioteknologi* 1991, p. 14.

<sup>5</sup> *Nordiska ministerrådet* 2011, pp. 95-96.

<sup>6</sup> The author of this text is the other Finnish committee member, currently serving her second term of office.

<sup>7</sup> Since 2008, the secretary has been Lotta Knutsson Bråkenhielm, a Swedish PhD student of theology.

## 2.2 History

As mentioned above, the Nordic Collaboration Programme for Biotechnology was established for the period 1988-92 at the initiative of the Nordic ministers in 1986. The programme was arranged into three sub-programmes under the responsibility of the Nordic Programme Committee for Biotechnology (*NBP – Nordisk programkomité for bioteknologi*), the Nordic Fund for Technology and Industrial Development (*NI – Nordic industrifond*), and the Nordic Senior Executives Committee for Agricultural and Forestry Questions (*NEJS – Nordisk embetsmannskomite for jord- og skogbruksspørsmål*). The NBP had the overall, and coordinating, responsibility.

At the time, the programme prioritised the following areas<sup>8</sup>:

- Gene technology
- Protein Engineering
- Plant Cell biotechnology
- Biotechnology applied to domestic animals
- Aquaculture
- Food biotechnology
- Bioprocessing and enzyme technology
- Environmental biotechnology

Human Genomics (HUGO) and genetically-modified organisms (GMOs) would soon be considered deserving of special attention, too.<sup>9</sup>

The proposal for a collaboration programme emphasised the significance of a joint Nordic evaluation of the ethical norms that would form the basis for biotechnological research and application. It suggested the creation of a separate organisation to promote an inter-Nordic debate on ethics and biotechnology.<sup>10</sup> Consequently, the Nordic Committee for Ethics Related to Biotechnology was founded (*Nordisk utvalg for etikk innen bioteknologi*). It was to function as a central and integral part of the collaboration between the three sub-programmes. The committee was financed by the NBP and they collaborated closely. It was a predecessor of today's Bioethics Committee.

The Nordic Committee for Ethics Related to Biotechnology had its first meeting in May 1989. Its first representatives were; Karen Højte Jensen and Else Marie Sejer Larsen from Denmark; Paula Kokkonen and Matti Sarvas from Finland; Jorunn Erla Eyfjörð and Arnor Hannibalsson from Iceland; Gudbrand Bakken and Jul-

<sup>8</sup> Supra note 4, p. 7.

<sup>9</sup> Supra note 4, p. 9.

<sup>10</sup> Supra note 4, p. 48.

ie Skjæraasen from Norway; and Göran Herméren and Lars Rask from Sweden. Johs Kjosbakken was its first secretary.

The committee concretised its mandate as follows:

- 1) To collect and draft background material for fruitful discussions on ethical issues in the Nordic countries.
- 2) To examine possible joint Nordic reference points for the ethical assessment of biotechnological research and applications.
- 3) To contribute to ethical risk-assessments relating to biotechnology.
- 4) To advise the NPB within the sphere of the Nordic Biotechnology Programme.<sup>11</sup>

### 2.3 Development of the mission and the tasks of the Bioethics Committee

Finally, the Bioethics Committee was established in 1996, for a three-year period, to replace the previous Nordic Committee. Unfortunately, given the timeframe, the documentation relating to its establishment could not be located and accessed for this overview. The minutes, annual reports, and other documents (mandates and their drafts, seminar material, and correspondence) of the Committee, since 2000, are being stored in the Finnish National Archives. During the early years, the secretariat moved from country to country, and it is not known whether documents have been archived or not. This will be a subject for further research. Still, documents in the Finnish archives show that the continuation of the mandate and the development of the tasks have been at the initiative of the Bioethics Committee.

In 1998, the Bioethics Committee drafted a paper *Nordisk bioetikk inn i det 21. århundrede. Förslag till mandat 3.2.1998*<sup>12</sup> (Nordic bioethics in front of 21<sup>st</sup> century. A proposal for a mandate 3.2.1998) for the Nordic Council of Minister to propose continuation of its activities for the next term. In the paper, the Bioethics Committee discussed the importance of continuing its work, describing its mission, tasks, and working methods. As its mission, it set the fostering of Nordic co-operation and information exchange regarding the ethical aspects of biotechnological R&D and application between researchers, MPs, and moulders of public opinion.<sup>13</sup> The current mandate and mission of the Bioethics Committee are still based on this paper.

The paper designated the following tasks for the Bioethics Committee:

- identifying ethical problems arising from genetic and other biotechnology research; the development and modification of microorganisms, plants, animals and humans.
- promoting Nordic collaboration between researchers, moulders of public

<sup>11</sup> Supra note 4, p. 49.

<sup>12</sup> Helland and Erland 1998.

<sup>13</sup> Ibid.

opinion, and parliamentarians on bioethical issues by means of cooperating with national research institutions, authorities, and ethics committees, and, by the same token, creating opportunities for the exchange of information.

- contributing to a joint Nordic debate on bioethical questions by disseminating material that can be used in constructive discussions about bioethics issues.
- monitoring biotechnological developments, both in the Nordic region and internationally.
- keeping abreast of the Nordic and international debate on ethical questions arising from biotechnology R&D and application.
- following legislative developments within the sphere of biotechnology in the Nordic countries.

Working methods were proposed as follows:

- The Committee would have regular internal meetings.
- The Committee would be able to assign of experts vis-à-vis its activities.
- The Committee would arrange working groups, hearings, conferences, symposia, and public lectures to support the exchange of information between researchers, MPs, and moulders of public opinion concerning contemporary bioethical issues.
- The Committee would publish reports and other background papers in order to start up a Nordic debate on bioethical issues.

Further, it was proposed that the Bioethics Committee would consist of two members from each Nordic country and represent broad knowledge in the area of biotechnology and bioethics. The chairmanship would circulate.

## 3 Activities

### 3.1 General

The Bioethics Committee holds regular internal meetings, arranges conferences and workshops, publishes books, follows national and international debates and developments, and collaborates with national ethics committees.

Human biomedicine has been a prevailing theme in the activities of the Bioethics Committee, even though the initial mandate was not limited to the directly human application of biotechnology. However, there have also been conferences or workshops on the following themes; ‘Bioprophecy’, ‘Bioethics of the Sea’, in 2004,

'Bioethics of the Sea II', in 2008, and 'Bioethics and Bioenergy', in 2009. In 2010, the Bioethics Committee showed that it was following the latest bioethical trends by arranging a conference on Public Health Ethics, thus responding to demands to broaden the bioethical discourse.

### *3.2 Mapping the legislation*

The Nordic countries have adopted different regulatory approaches to sensitive biotechnological issues, e.g. in assisted reproduction and stem cell research. Bioethics was the main theme for the Nordic Council's 52nd session in 2000. As one outcome of the meeting, the Nordic Council recommended charting the legislation and regulations pertaining to biotechnology in the Nordic countries. The Bioethics Committee started up the process in 2001 as regards assisted reproduction and preimplantation genetic diagnostics, genetic testing and gene therapy, biobanks and embryo research, stem cell research, cloning, during the second stage adding preimplantation genetic diagnosis, abortion, prenatal diagnosis, clinical research on humans, and animal experimentation. The first report was published in 2003, with a second, broader overview coming in 2006.<sup>14</sup>

The Bioethics Committee also assigned a researcher to conduct a study on assisted reproduction in the Nordic countries<sup>15</sup>. The aim of the study was to look into the various backgrounds and processes that have led to different legal situations with regard to assisted reproduction in the Nordic countries. There have been some motions even to harmonise the legislation, but these have not succeeded.<sup>16</sup> Dr. Riitta Burrell from Finland, who was assigned to conduct the study, examined the social, cultural, and political processes behind perceptions and the regulation of assisted reproduction in the Nordic countries. The report was presented at a seminar entitled Nordic Biolaw – Focus on Assisted Reproduction, in 2005.

In 2007, the Bioethics Committee reported to NordForsk on stem cell research in the Nordic countries. It demonstrated the national moral approaches to embryo research within the Nordic bloc. In addition, legislation and regulations relating to stem cell research in the Nordic countries were systematically examined.<sup>17</sup>

### *3.3 Teaching bioethics as a specific theme*

Since the early days of the Bioethics Committee, it has held the teaching of bioethics as one of its prioritised activities. It arranged a conference entitled Teaching Bioethics, in 2001, in order to obtain an overview of what was being done in the field

<sup>14</sup> Nordic Committee on Bioethics 2006a.

<sup>15</sup> Nordic Committee on Bioethics 2006b.

<sup>16</sup> *Ibid.*, pp. 73-74.

<sup>17</sup> Lötjönen et al. 2007.

of bioethics education within the Nordic bloc. This conference indicated gaps in bioethics education; additionally, quality and quantity seemed to vary between the countries. Based on the findings and results of the conference in 2001, the Bioethics Committee arranged a workshop in 2003. Presentations and summaries of both occasions were compiled into publications.<sup>18</sup>

In 2008, the Bioethics Committee moved its work forward by arranging a third thematic meeting concerning bioethics teaching, this time entitled Teaching Material in Bioethics. The purpose of the workshop was to identify excellent educational resources in bioethics which were already available in one or more of the Nordic languages, Finnish included; resources that could be translated and modified in order to make them available in all the languages used in the Nordic countries. The Bioethics Committee decided to establish a working group that would give it specific advice on how to continue the work of developing teaching materials. The working group advocated the importance of teaching bioethics at schools because “[e]thical discussions are an important part of young people’s training to become involved citizens in our democratic societies. Working with bioethics is a means of training in critical and creative thinking that can improve the active participation that is an important part of democratic citizenship.”<sup>19</sup> The development of teaching materials for primary school pupils and teachers is included in the Bioethics Committee’s Action Plan 2011.<sup>20</sup>

Furthermore, an idea raised at the pan-Nordic meeting of the national ethics committees in 2011 would influence politicians in such a way that bioethics would be included in the undergraduate schools’ curriculum, as already is in Norway.

### ***3.4 Collaboration with national ethics committees, councils, and boards***

One of the tasks of the Bioethics Committee is to correspond with the national ethics committees in order to promote joint Nordic collaboration. The ways of doing this are manifold: members of the Bioethics Committee collaborate in their respective national contexts, representatives of the national ethics committees participate in conferences and workshops organised by the Bioethics Committee, sharing material they have developed with each other. Many of the members of the Bioethics Committee are also members of some national committees, so information and news circulate on a regular basis. Sometimes, they arrange joint conferences, e.g. Chimera Research - ethical and legal aspects, arranged with the Danish Ethical Council in Copenhagen in 2008, and Prenatal Diagnosis - Individuals and Society, arranged with the Norwegian Biotechnology Advisory Board at Holmenkollen in 2010.

<sup>18</sup> Nordic Committee on Bioethics 2002; Erland and von Troil 2004.

<sup>19</sup> Nordic Committee on Bioethics 2008.

<sup>20</sup> *Supra* note 5.

The Bioethics Committee has invited national committees to attend meetings in order to enhance collaboration, to discuss contemporary issues, and to identify national anxieties. In 1999, the Bioethics Committee arranged a workshop with national ethics committees in Copenhagen to discuss their activities, prioritisations, and working methods. This workshop resulted in a publication giving an overview of the bioethics committees of the Nordic countries.<sup>21</sup> A similar meeting was arranged in Copenhagen in March 2011. The national committees introduced their work and listed some ethical questions arising in the context of biobanks, and various types of registers, genetic tests, including whole genome sequencing, prioritisation in healthcare, clinical trials, euthanasia, emergency research, and the role of children in research.

In 2003, the Bioethics Committee organised the seminar Biomedical Research Ethics, in order to discuss ethical challenges in contemporary research, with the national RECs from both the Nordic and Baltic regions.

However, joint meetings face a challenge in the fact that none of the national ethics committees are alike. They have different tasks, focuses, and obligations. For instance, the role of the National Ethical Advisory Committees, Councils, or Boards is very different to that of the (Medical) Research Ethics Committees (RECs) which are usually statutory public agencies tasked with previewing research protocols within the framework of specific legal regulation<sup>22</sup>. Instead, the mission of the advisory councils is to discuss, reflect, and raise awareness of the bioethical issues in society, and to give their opinions, for instance<sup>23</sup>. Even though the RECs also need to appraise the ethical aspects of a given protocol, the process is formal compared to the free discourse of the National Ethics Committees. The different needs were once again evident at a meeting convened by the Nordic Committee on Bioethics in Copenhagen on 21 March 2011 because it was difficult to identify issues that would be beneficial to both RECs and Councils having an advisory role.

Given the mission of the Nordic Committee on Bioethics, its activities are more in parallel with national ethical advisory boards such as the National Advisory Board on Social Welfare and Health Care Ethics (*ETENE*), in Finland, the National Council on Medical Ethics (*SMER*), in Sweden, the Danish Council of Ethics (*Det Ethiske Råd*), and the Norwegian Biotechnology Advisory Board (*Bioteknologinemnda*). In Norway, the Biotechnological Advisory Board has both an advisory and a statutorily authoritative role. Iceland is currently lacking a national ethical council with a general advisory mission similar to that of the other Nordic countries. The Danish Council of Ethics and the Norwegian Biotechnology Advisory Board both seem to have gained wide societal recognition and their contribution has truly influenced and stimulated public debate. In Finland, it is the opposite, *ETENE's* impact as an initiator of public debate has remained relatively vague. The reason, however, is not only

21 Erland and Helland 1999.

22 Launis 2008, pp. 47-52.

23 Kappel 2008, pp. 27-29.

its modest way of addressing the issues, the Finnish public simply seems to be rather uninterested in bioethical issues.

## 4 The future

Is the Nordic Committee on Bioethics needed in the Nordic debate? Is Nordic bioethics different to that of central Europe? In my opinion, the answer is yes to both questions. Our societies are based on a welfare model and trust in the state. Biomedical regulation is relatively permissive and the Nordic people are very much *pro science*. The Eurobarometer survey carried out in 2010 further indicated the positive public perceptions that exist of science in the Nordic countries, even though attitudes to bioethical issues vary to some degree between the Nordic countries.<sup>24</sup> Given our cultural, social, political, and intellectual atmosphere, our approach to bioethical issues is different to that of many other societies. We have excellent research and we rapidly adopt novel techniques, but we also need to discuss them openly.

Our key challenge lies in maintaining Nordic trust. The stakeholders are many; from laymen to the scientific community, funders, politicians, interest groups, industry, and government. It is very important in the biotechnological arena to openly address the ethical and scientific issues. But how will the information be disseminated, and by whom? Who can be relied on? These questions were on the agenda at two conferences arranged by the Nordic Committee on Bioethics; Business and Bioethics, in 2006, and Bioethics or Biopolitics?, in 2007. The first conference was aimed at identifying roles and potential conflicts of interest between scientists, the biotechnological industry, and policy-makers. The latter analysed the decision-making patterns and the interrelationship between bioethics, politics, and other players in the field, e.g. the media and expert organisations. Presentations given at the two conferences resulted in a publication called *Bioethics, Politics and Business*, in 2008<sup>25</sup>.

The Nordic Committee on Bioethics exists in order to respond to this challenge. It should keep up its work of addressing bioethical issues and collaborating with national ethics committees in order to stimulate public debate. It could also take a more active role in drawing the attention of the Nordic Council of Ministers when it thinks an issue needs more political handling, or even intervention. In fact, the Nordic Council and the Bioethics Committee once jointly arranged a seminar to discuss Nordic Biopolitics with parliamentarians in 2005.<sup>26</sup> This kind of discussion should be on the agenda in the future, too.

The feedback from the Nordic Council of Ministers regarding the activities of the Bioethics Committee has been positive. In 2011, this work will be evaluated and we are excited about what the conclusions will be.

<sup>24</sup> Gaskell et al. 2010.

<sup>25</sup> Lötjönen and von Troil 2008.

<sup>26</sup> Klingenberg 2005.

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