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REPORT

on the ethical, legal, economic and social implications of human genetics

Temporary Committee on Human Genetics and Other New Technologies in
Modern Medicine

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PROCEDURAL PAGE

At the sitting of 13 December 2000 Parliament pursuant to Article 150(2) of the Rules of Procedure, adopted a decision on setting up a temporary committee on human genetics and other new technologies in modern medicine.

To comply with its brief, the temporary committee appointed Francesco Fiori rapporteur at its constituent meeting of 16 January 2001.

It considered the draft report at its meetings of 27 August, 10 September, 2, 8 and 10 October, 24 October and 5 and 6 November 2001.

At the last meeting it adopted the motion for a resolution by 18 votes to 13, with 3 abstentions.

The following were present for the vote: Robert Goebbels, chairman; Ria G. H. C. Oomen-Ruijten, Karin Scheele and Antonios Trakatellis, vice-chairmen; Francesco Fiori, rapporteur; Nuala Ahern (for Jillian Evans), Luis Berenguer Fuster (for Gérard Caudron), Hiltrud Breyer, David Robert Bowe, Hans Blokland, Willy C.E.H. De Clercq (for Diana Wallis), Jean-Maurice Dehousse, Gianfranco Dell'Alba (for Jean-Claude Martinez), Avril Doyle, Concepció Ferrer, Marialiese Flemming (for Françoise Grossetête), Geneviève Fraisse, José María Gil-Robles Gil-Delgado, Evelyne Gebhardt, Marie-Thérèse Hermange, Eija-Riitta Anneli Korhola, Peter Liese, Jules Maaten (for Luciana Sbarbati), Minerva Melpomeni Malliori (for Eryl Margaret McNally), Emilia Franziska Müller, Riitta Myller (for Dagmar Roth-Behrendt), Elena Ornella Paciotti, Bernd Posselt (for Paolo Pastorelli), John Purvis, José Ribeiro e Castro (for Sergio Berlato, pursuant to Rule 153(2)), Dana Rosemary Scallon (for Jonathan Evans), Astrid Thors, Elena Valenciano Martínez-Orozco and Demetrio Volcic (for Carlos Candal, pursuant to Rule 153(2)).

The report was tabled on 8 November 2001.

The deadline for tabling amendments will be indicated in the draft agenda for the relevant part-session.

MOTION FOR A RESOLUTION

European Parliament resolution on the ethical, legal, economic and social implications of human genetics

The European Parliament,

- having regard to its decision of 13 December 2000 to set up a temporary committee on human genetics and other new technologies in modern medicine¹,
- having regard to the following Community documents:
 - the Treaty on European Union (TEU) and in particular Articles 5, 95, 152, and 163 to 173 of the Treaty establishing the European Community (TEC),
 - the CE Convention for the Protection of Human Rights and Fundamental Freedoms, as amended by Protocol No 11, adopted in Rome on 4 November 1950,
 - the Charter of fundamental rights of the European Union, in particular Articles 1, 3, 8, 13, 21, and 35 thereof,
 - Directive 95/46/EC on the protection of individuals with regard to the processing of personal data and on the free movement of such data²,
 - Directive 98/44/EC on the legal protection of biotechnological inventions³,
 - Decision No 182/1999/EC of the European Parliament and of the Council concerning the fifth framework programme of the European Community for research, technological development and demonstration activities (1998 to 2002)⁴,
 - Council Decision 1999/167/EC adopting a specific programme for research, technological development and demonstration on quality of life and management of living resources (1998 to 2002)⁵,
 - the proposal for a decision of the European Parliament and of the Council concerning the sixth multiannual framework programme 2002-2006 for research, technological development and demonstration activities (COM(2001) 94)⁶ and the proposals for decisions concerning the specific programmes (COM(2001) 279)⁷,

¹ OJ C 232, 17.8.2001, p. 75.

² OJ L 281, 23.11.1995, p. 31.

³ OJ L 213, 30.7.1998, p. 13.

⁴ OJ L 26, 1.2.1999, p. 1.

⁵ OJ L 64, 12.3.1999, p. 1.

⁶ OJ C 180 E, 26.6.2001, p. 156.

⁷ OJ C 240 E, 28.8.2001, p. 259.

- its various resolutions and, in particular, its resolution of 7 September 2000, relating to the issues under consideration¹,
- European Parliament and Council Regulation 45/2001/EC on the protection of individuals with regard to the processing of personal data by the Community institutions and bodies²,
- the proposal for a Council directive establishing a general framework for equal treatment in employment and occupation (COM(1999) 565)³ and Parliament's resolution thereon (A5-0264/2000)⁴,
- having regard to the following international documents:
 - the United Nations Convention of 5 June 1992 on Biological Diversity,
 - the World Trade Organisation Agreement of 15 April 1994 on Trade-Related Aspects of Intellectual Property Rights,
 - the Universal Declaration on the Human Genome and Human Rights, issued by the United Nations Educational, Scientific, and Cultural Organisation on 11 November 1997,
 - the World Health Organisation resolution of 16 May 1998 on the ethical, scientific, and social implications of cloning for human health,
 - the Council of Europe Convention of 4 April 1997 on Human Rights and Biomedicine and the Additional Protocol of 12 January 1998 and the Council of Europe Resolution of 20 September 1996 on Biomedicine,
 - Recommendation 1046(1986) of the Parliamentary Assembly of the Council of Europe on the Use of Human Embryos,
 - the Declaration of Helsinki on Ethical Principles for Medical Research Involving Human Subjects, adopted by the World Medical Association in June 1964 and amended in 1996,
 - the Nuremberg Code and the trials of war criminals before the Nuremberg Military Tribunals under Control Council Law No. 10. Nuremberg, October 1946–April 1949,
 - Council of Europe Convention No 108 of 28 January 1981 on the protection of individuals with regard to automatic processing of personal data,
- having regard to opinion No 13 of the European Group on Ethics in Science and New Technologies (EGE) on ethical aspects of the use of health-related personal data in the information society and opinion No 15 on 'Ethical Aspects of Human Stem Cell Research

¹ OJ C 135, 7.5.2001, p. 263.

² OJ L 8, 12.1.2001, p. 1.

³ OJ C 177 E, 27.6.2000, p. 42.

⁴ OJ C 178, 22.6.2001, p. 270.

and Use’,

- having regard to the bill approved by the US House of Representatives banning the creation of human embryos by means of nuclear transfer, which is currently being debated in the US Senate,
- having regard to the hearings from January to May 2001 held by the Temporary Committee on Human Genetics and attended by experts in the field,
- having regard to the meetings with representatives of the national parliaments of the Union Member States and the applicant countries, and with representatives of civil society, held respectively on 18 and 19 June and 9 and 10 July 2001,
- having regard to Rule 150(2) of its Rules of Procedure,
- having regard to the report of the Temporary Committee on Human Genetics and Other New Technologies in Modern Medicine (A5-0391/2001),

As regards genomic research

- A. having regard to the need for research to enable the genuine and continual advance of medicine and the improvement of the quality of life for the individual and for civil society,
- B. whereas respect for human dignity dictates that people cannot be reduced to biological aspects, assessed exclusively according to biological criteria or made subject to utilitarian considerations,
- C. whereas the fundamental ethical principles with regard to bioethics issues must be applied and interpreted and whereas, in their interpretation, there may be differing views on individual questions,
- D. whereas the existence of differing views on bioethics issues must constitute the starting point for a rational, reasoned dialogue between persons holding those views,
- E. whereas the interpretation of fundamental ethical standards and principles will again and again have to address new issues that arise as biosciences develop,
- F. whereas, in its resolution adopted on 7 September 2001, the European Parliament considered that ‘any temporary committee set up by this Parliament to examine the ethical and legal issues raised by new developments in human genetics should take as a starting point the views already expressed in resolutions of this House’, and whereas the committee should consider issues on which Parliament has not yet adopted a clear position,
- G. whereas in the Charter of fundamental rights, on the basis of the Convention on the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine, the EU has taken fresh steps to lay down Europe-wide ethical guidelines; whereas Article 3 of the Charter states that ‘Everyone has the right to respect for his or her physical and mental integrity’ and that ‘In the fields of medicine and biology, the following must be respected in particular: ... the free and

informed consent of the person concerned, according to the procedures laid down by law, ... the prohibition of eugenic practices, in particular those aiming at the selection of persons, ... the prohibition on making the human body and its parts a source of financial gain, ... [and] the prohibition of the reproductive cloning of human beings' and whereas these principles represent minimum requirements for EU legislators and do not constitute an exhaustive list of all necessary regulations,

- H. whereas knowledge of the human genome marks decisive progress in the understanding of the way in which the human gene complex functions and interacts with the environment; whereas such understanding could eventually make it possible to diagnose, and possibly prevent, and treat many diseases much more accurately, by a far more personalised approach, and much more effectively than is at present the case; whereas, however, the benefits to humankind, in terms of health, as well as the significant economic advantages for the Union will be impossible to exploit unless Europe creates the right general conditions for research in this sector, based on respect for human dignity, equality and the value of human life; whereas these advantages can be reaped to the full only if an open and informative debate is permitted and if members of the public are given a greater chance to understand opportunities and risks associated with the new methods,
- I. whereas in the context described above, coordinated and integrated approaches are desirable; whereas 'integration' in this area must not simply be taken to mean closer cooperation in which academic researchers, the private sector – ranging from small biotechnology firms to large drugs companies – and the medical profession seek to integrate research and development stages - although freedom of research must be maintained and the public benefit of medical research must always remain the most important objective and, as such, must not be subordinated to commercial considerations - but must also aim to be such as to enable regulatory authorities to play an active role at the right time with a view to laying down the necessary standard-setting frames of reference and policies, as well as making for dialogue with end-users and social players,
- J. whereas substantial efforts are required to increase the general public's knowledge of genetic issues, as progress has been so rapid and discoveries so numerous in recent years; whereas an open dialogue between members of the public, their organisations, legislators, researchers and industry could create a climate of greater trust; whereas independent and impartial information is important with a view to fostering public confidence,
- K. whereas there are often substantial differences between men and women as regards the causes and courses of diseases and disorders, whereas, therefore, in accordance with the gender mainstreaming principle that is firmly established in the European Union, preventive and therapeutic measures, as well as research activities, in the field of modern biosciences must at all levels take account of gender-specific differences, and whereas, in particular as regards reproductive medicine and downstream technologies, the specific health interests of women must be taken into consideration,

As regards the common ethical principles

- L. whereas respect for human dignity is the foundation of all international and European legal instruments relating to fundamental rights, the foundation of all EU constitutions and the aim of all Member States; whereas freedom of research is also acknowledged as

an important ethical principle essentially subordinate to the principle of respect for human dignity; whereas biomedical research should always be carried out on the basis of freedom of conscience and must not be subject to illicit political or financial constraints,

- M. whereas, although scientific research, as guaranteed by the European Union Charter of fundamental rights, is to be free of constraint, that fundamental right in no way justifies any acts violating human dignity which, in the words of the Charter, is inviolable and must be respected and protected,
- N. whereas over the course of its history the Union has developed, in addition to shared values and ethical principles, an inbuilt cultural, ethical and religious pluralism that:
- reflects the richness of its traditions;
 - imposes the requirement of mutual respect and tolerance;
 - is fully compatible with the further development of common ethical dimensions and positions;
 - is consistent with Article 22 of the Charter of Fundamental Rights and Article 6 of the TEU,
- O. whereas in Europe there is consensus regarding fundamental ethical standards and principles which have found expression in particular in the Charter of Fundamental Rights, and whereas organisations such as the United Nations Educational, Scientific, and Cultural Organisation (Unesco), the World Health Organisation (WHO), the Council of Europe, and the European Union itself use as their guiding principles ethical principles which include in particular the inviolability of human dignity, individual self-determination (implying that a person must give his or her free and informed consent, privacy must be respected, and personal data must remain confidential), the necessity of research, protection of public health, free access for all to necessary health care, respect for the disabled and their right to independence and to integration into society, and non-discrimination on the grounds of genetic, racial or religious features,
- P. whereas there is an international consensus on the two conditions under which human genetic research and treatment may be carried out:
- it must not be permitted to apply gene therapies to ova and spermatozoa (the germ line), since the effects would otherwise be passed on to future generations; treatment should be confined solely to somatic cells which act only on the person treated;
 - it must be permitted to use the therapies only to cure diseases, including hereditary diseases, and not to influence characteristics that do not constitute a health problem,¹
- Q. whereas there is no difference between cloning for therapeutic purposes and cloning for the purposes of reproduction, and whereas any relaxation of the present ban will lead to

¹ Cf. the Council of Europe Convention on Human Rights and Biomedicine, the Unesco Declaration on the Human Genome, and the opinions of the European Ethics Group and the national ethics committees.

pressure for further developments in embryo production and usage,

- R. whereas the European Union has a duty to encourage research in biotechnologies and human genetics; whereas fundamental research must not be left solely to the commercial sector, and whereas the public interest requires strong support for all forms of research likely to increase knowledge of the human being and, in time, to help to devise new therapies; whereas national prohibitions relating to certain types of research must not prevent the European Union as a whole from supporting such research in those countries in which it is lawful ; whereas only research leading to the cloning of human beings and changes to the germ line should be prohibited, and whereas therapies should be developed only with a view to treating serious diseases and not to improving new human characteristics,

As regards the Union's powers and responsibilities in the field of human genetics

- S. whereas the Treaty on European Union does not contain any provisions referring specifically to human genetics; whereas, however, without undermining the subsidiarity principle (Article 5 TEC), the Union has powers to the extent that it can adopt measures relating to human genetics under the heading of public health (Article 152 TEC) or for the purposes of funding research (Articles 163 to 173 TEC) or of the operation of the internal market (Article 95 TEC), or in connection with the freedom of establishment (Article 47(2) TEC), the freedom to provide services (Article 47(2) in conjunction with Article 55 TEC) and workers' rights (Article 137(1) and (2) TEC),
- T. whereas the Member States and the Union need to make joint efforts to develop and expand the human genetics sector serving the needs of human health and of finding cures for the sick, with due respect for human dignity, and to determine the areas in which European action would be appropriate.

As regards the work of the temporary committee

- U. whereas the Temporary Committee on Human Genetics had the task of giving its views on the ethical, legal, economic and social issues arising in connection with developments in modern biomedicine and thus to provide Parliament with detailed analyses which would enable it to take genuine political decisions and to lay down precise guidelines, with due account being taken of the public interest; whereas in keeping with the brief conferred on it, the committee has been focusing chiefly on the following areas:
- the use of genetic tests for predictive and diagnostic purposes
 - the development and application of new genetic therapies
 - the processing of genetic information
 - the allocation of financial resources for research under the sixth framework programme
 - the patentability of products and processes derived from living beings

- establishing ethical guidelines required by the new developments of biotechnology and its application in Europe,

As regards genetic tests and genetic screening

- V. whereas a growing number of laboratories in Europe are offering genetic testing and analysis services; whereas such practices are becoming increasingly more frequent, following a trend that is bound to gather pace; whereas it would be appropriate to analyse the consequences thereof on people's physical and social development; and whereas such predictive testing practices must never be allowed to replace existing preventive policies in the field of public health,
- W. pointing to the potential benefits of genetic information and therefore wishing to prevent selective practices on the employment market or by insurers from deterring employees or customers from having genetic tests carried out,
- X. whereas use of genetic testing poses specific ethical questions in the case of pre-natal tests and pre-implantation genetic diagnoses,
- Y. whereas, in view of the extremely rapid growth of knowledge in the field of genetics with its concomitant legal, social, ethical and economic implications, the European Parliament should continue its work on human genetics in whatever way it deems appropriate,
- Z. whereas there are at present no common European rules or regulations to guarantee that genetic testing and analysis services will conform to a minimum standard; whereas these services lie outside the scope of Council Regulation (EEC) No 2309/93 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and Directive 98/79/EC on *in vitro* diagnostic medical devices, which applies only to products to be marketed; whereas, therefore, other provisions should be introduced or the directives covering the field of genetic tests and biotechnological medicines should be revised, to bring them into line with the provisions of the relevant directives,
- AA. whereas abuse of genetic testing, in particular pre-natal and pre-implantation diagnoses, gives rise to the risk of eugenic practices being carried out, and whereas, for that very reason, PID is illegal in several European countries,
- AB. whereas although genetics specialists and professional organisations have made many moves to promote quality assessment, genetic testing services are provided under widely varying conditions and regulatory frameworks in the individual Member States,
- AC. whereas genetic testing may be offered only in association with competent and full counselling which must cover medical, ethical, social, psychological and legal aspects,

As regards biotechnological medicines

- AD. whereas the fact that every stage from development to the clinical trial is governed by a plethora of different national rules which are at variance or at any rate not wholly consistent implies an ethical debate and is recognised to pose a severe limitation that makes developing and testing new biotechnological medicines on an EU-wide scale a difficult activity that cannot be properly regulated¹,
- AE. whereas the first steps towards harmonisation of regulatory requirements have been taken where gene and cell therapy is concerned, since the European Agency for the Evaluation of Medicinal Products has drawn up guidelines for 'good practice'; whereas, however, there is still no regulatory framework at national or Community level to govern new fields such as tissue engineering, artificial organs, and genetic testing,

As regard stem cells

- AF. whereas the use of stem cells may become established as a new method for treating diseases and injuries; whereas the aim of the therapy is to develop differentiated cells or tissues to be transplanted into patients suffering from conditions such as diabetes, Alzheimer's disease, Parkinson's disease, coronary heart disease, leukaemia, strokes, spinal injuries or damaged cartilage, for which there are today no adequate treatments; whereas, however, the necessary measures must be taken in order to avoid the dangers and risks associated with possible stem cell therapies,
- AG. whereas the use of germ cells may become established as a method of in vitro evaluation of the effect of drugs,
- AH. whereas, with regard to the origin of stem cells, a distinction must be made between embryo stem cells and adult stem cells; whereas research on adult stem cells constitutes a promising and ethically acceptable alternative to the use of stem cells from human embryos; and whereas research on adult stem cells must therefore be accorded unconditional priority,
- AI. whereas the development of methods which could reduce the health, i.e. physical and psychological, burdens due to in vitro fertilisation (IVF) and reduce, or even prevent, the production of 'supernumerary embryos' must be encouraged,
- AJ. whereas the conditions for the production and collection of stem cells principally jeopardise the integrity of the female body when therapeutic cloning is involved using supernumerary embryos,
- AK. having regard to the decision of the US President, George W. Bush, to authorise federal funding for adult stem cell research and for a number of cell lines obtained from 'surplus' embryos already used in the laboratory,

¹ The adoption of Directive 2001/20/EC on clinical trials, which lays down provisions for implementing 'good clinical practice' – defined as 'an international ethical and scientific quality standard for designing, conducting, recording and reporting trials that involve the participation of human subjects' – constitutes a first step towards harmonised regulation of biomedical research and development.

As regards the sixth research framework programme

AL. whereas genomics and biotechnology for health and general welfare is one of the ‘priority thematic areas of research’ set out in the proposal for a decision concerning the sixth framework programme, and other priorities set out in that proposal are also relevant to the work of the Temporary Committee,

As regards the use of genetic data

AM. whereas the use of genetic diagnoses should be authorised solely on purely medical grounds,

AN. whereas there has been a large increase in the availability and variety of genetic tests; whereas they can in some circumstances reveal important information not just about the persons examined, but also about members of their families and, in the final analysis, have a great impact on individual lives and lifestyles, not least as regards the decision whether or not to have children,

AO. whereas the possibility of third parties obtaining personal genetic information entails the risk of new forms of discrimination, raising problems related to privacy, the confidentiality of data, and informed consent; whereas, notably, this risk must be dealt with on the basis of the existing personal data protection legislation, in relation to such aspects as the justification for treatment, the limitation of ends, security measures and the individual rights affirmed by the Charter of Fundamental Rights of the European Union (Article 8),

AP. whereas it is desirable to harmonise the existing laws, regulations and administrative provisions of the Member States in this field, in view of the multinational character of the companies involved in handling genetic data, the need for such data to circulate across frontiers and the need to avoid divergences in national law whose effects would be incompatible with the proper working of the internal market,

As regards the patentability of processes and products derived from biological material

AQ. whereas mapping of the human genome, completed during the past year by the American company Celera Genomics and the Human Genome Project group, has prompted intense debate in the Union on the question of whether human genes should be patentable; whereas genome sequencing has sparked off an unprecedented race to the imminently expected ‘genetic loot’; whereas the ability to isolate, identify, and recombine genes makes it possible for the first time to tap a common stock of genes as a source of raw materials, the economic exploitation of which would be encouraged precisely by the possible award of patents,

- AR. whereas Directive 98/44/EC provides a guideline as to what is at present deemed contrary to public morality; whereas Articles 5 and 6 thereof define inventions which are not patentable; whereas a debate is in progress to determine what else should be considered unpatentable and what is to be patentable; whereas, however, at all events, the respect due to living matter and, a fortiori, to human matter may not be subject to types of ownership such as that conferred by the award of a patent; whereas, therefore, living matter must be deemed to be non-patentable; and whereas difficulties of interpretation of this Directive, because of its ambivalence and of the refusal of certain Member States to transpose it into their national law, create legal uncertainty on the issue of biotechnological inventions,
- AS. whereas, contrary to what happens in other sectors, biotechnological and biomedical innovations have to do with living organisms; whereas it therefore becomes more complicated to make the fundamental distinction between inventions and discoveries that serves to identify cases to which patent legislation applies and those to which it does not,
- AT. whereas despite the controversial interpretations of the provisions of the above-mentioned Directive it is expressly forbidden to patent:
- 'the human body, at the various stages of its formation and development, and the simple discovery of one of its elements, including the sequence or partial sequence of a gene' (Article 5);
 - new 'plant and animal varieties' and 'essentially biological processes for the production of plants or animals' (Article 4);
 - 'Inventions ... contrary to *ordre public* or morality' (Article 6), in keeping with Article 53 of the European Patent Convention (EPC), which has been incorporated into the corresponding national laws of the Member States that have acceded to the Convention; 'processes for cloning or modifying the germ line genetic identity of human beings'; 'uses of human embryos for industrial or commercial purposes'; and 'processes for modifying the genetic identity of animals which are likely to cause them suffering without any substantial benefit to man or animal',

The European Parliament:

As regards the preconditions for public debate

1. Considers that substantial efforts are required to increase the general public's knowledge of genetic issues, as progress has been so rapid and discoveries so numerous in recent years, and that Member States should promote access to independent and impartial information for members of the public;
2. To prevent the social debate on human genetics and its applications from taking shape in a random fashion and, more often than not, lagging behind the scientific developments, and in order to facilitate the development of ethical guidelines at European level, considers it necessary to take the following action:

- (a) essential ethical principles must be emphasised, in order – without disregarding the diversity of ideas and cultural traditions in the Member States – to serve as a basis for general assessment of the development and use of human genetics and for the laws rendered necessary in this area; it must be recalled that those basic ethical principles are laid down in the Charter of Fundamental Rights of the European Union and in the relevant international agreements, such as the Helsinki Declaration adopted in Edinburgh in October 2000, the Council of Europe Convention on human rights and biomedicine signed in Oviedo on 4 April 1997, the additional protocol outlawing human cloning signed in Paris on 12 January 1998, and the Universal Declaration on the human genome and human rights adopted by UNESCO;
- (b) researchers, business circles, standard-setters, ethical experts and social players need to be encouraged to engage in dialogue on the new leading-edge technologies as soon as they begin to be developed, so as to enable responsible choices to be made and supported by the appropriate policies implemented at the right time;
- (c) public debate needs to be launched on the use of molecular-genetic knowledge and techniques before they are applied on a large scale;

As regards the legal context

- 3. Notes the need for a uniform, legally binding framework in respect of human genetics and biotechnological issues based as a matter of priority on respect for the individual, equality, human dignity and the value of human life; all research that is contrary to human dignity must be prohibited;
- 4. Reaffirms the principle of the freedom of science and research within the above framework;
- 5. Considers that ‘regulating’, including through funding, the changes currently taking place in the context of developments in biotechnology and biomedicine is an essential task to be undertaken by legislators, whether operating at national and/or European level; recommends, therefore, that the relevant research be controlled by government and that it be the subject of the public debate referred to in paragraph 2;
- 6. Believes that the EU must establish binding minimum criteria to ensure the necessary protection of human beings, in accordance with the principles laid down in the Charter of Fundamental Rights and Article 5 of the Treaty;
- 7. Maintains that the aim of the outcome of biomedical research is to benefit humankind as a whole and future generations;
- 8. Points out that the subsidiarity principle applies to human genetics and maintains that the Union can and must exercise the powers which the Treaty has conferred on it as regards health (Article 152 TEC), the operation of the internal market (Article 95 TEC), and the financing of research (Articles 163 to 173 TEC), freedom of establishment (Article 47(2) TEC), freedom to provide services (Article 47(2) in conjunction with Article 55 TEC) and workers' rights (Article 137(1) and (2) TEC);

9. Considers that the handling of genetic data involves specific risks in terms of personal data protection and that uncoordinated action by Member States in this field could have restrictive effects which would run counter to the proper operation of the internal market and could undermine the principles of freedom of movement laid down in the EC Treaty;
10. Recognises that gene therapy will continue to be expensive for some time and calls on the Member States, if necessary, to take steps to ensure that all sections of the population have equal access to new therapies;

In support of a Union role in the field of human genetics

I. Human genetics: diagnosis and therapy

Genetic tests

11. Notes that genetic testing, analyses and diagnosis are medical procedures that must invariably conform to the rules of what is termed 'good clinical practice', and that high standards of genetic testing are essential, given that decisions having a crucial bearing on a person's life are taken in the light of the results; genetic testing must enable individuals to take independent decisions and make choices with full knowledge of the facts, where treatments and other factors which may determine a person's quality of life are concerned; however, if the advantages of genetic testing are to be realised, the forms of testing offered (tests must be accurate, and equal access to testing services afforded to all), the context (expert counselling services which do not encroach on personal self-determination), and technology may become equally important factors;
12. Considers specific standards to be necessary for the clinical use of DNA chips:
 - such chips are to be subject to reliability and validity criteria similar to those applied to normal DNA tests,
 - DNA chips may be used to investigate only those genes, or mutations therein, which are relevant for obtaining a clinical picture of a specific disease and for its treatment,
 - the use of DNA chips is to be subject to the same rules regarding indication as apply to the use of normal genetic testing,
 - multiple testing to establish genetic predisposition to a number of diseases is acceptable only if the same reliability, counselling and information requirements as apply to single tests are met;
13. Considers it essential, in order to make for a safe, beneficial, and responsible outcome in the new biomedical research, to lay down a harmonised regulatory framework to be recognised in all parts of Europe, providing for clear-cut rules focusing not just on development, but also on scientific and technological procedures, including guidelines on good laboratory, clinical, and industrial practice geared to the latest biomedical trends; calls on the Commission to review current practices in Member States which provide for the heterogeneity of genetic testing;

14. Believes, furthermore, that national and European rules governing this area ought to state clearly that genetic testing should be used only for investigative, preventive, therapeutic or medical research purposes, and on the basis of proper medical advice, as stipulated in Article 12 of the Council of Europe Convention on Human Rights and Biomedicine, as well as of full respect for the fundamental rights of the individual and, in particular, those relating to confidentiality and personal data protection, as already enshrined in law at national and Community level;
15. Stresses that the possibility of prenatal genetic testing must not be misused in order to plan every characteristic of a child, e.g. hair colour, eye colour, sex, etc., which have no bearing on its health;
16. Considers it particularly important to ensure that no woman is compelled to have prenatal diagnosis carried out and that any decision not to resort to such diagnosis is respected and supported;
17. Notes that genetic testing will in many cases be used for predictive purposes and that any discussion on the enormous medical, ethical, psychological and legal implications of inaccurate findings raises the need to determine a legal and regulatory framework at European and national level to:
 - (a) guarantee the quality and safety of genetic testing in Europe;
 - (b) afford equal access to information about the availability, usefulness, and limitations of genetic testing at national level;
 - (c) ensure compliance with essential values in human genetics, proceeding from the premise of individual self-determination (patients must give their voluntary and informed consent; they must not be subjected to pressures from individuals or society; the capacity to decide independently must be fostered; the rights and interests of individuals must take precedence over collective assets; privacy must be respected; and patients and their relatives must have the right to know and not to know);
 - (d) encourage Member States to provide expert and independent genetic counselling on the understanding that predictive genetic tests will not otherwise be recognised to be legitimate;
 - (e) promote comprehensive international training activities aimed at informing professionals and the public alike about the limitations as well as the risks and advantages of genetic testing, enlisting the assistance of public and private organisations, government sponsored or otherwise, and especially of national ethics committees, which must move closer to citizens and establish channels of communication using existing information technologies;
 - (f) ensure that society respects and supports genetic differences, in particular under the necessary fair safeguard laws encouraging their integration and prohibiting every form of negative discrimination against persons suffering from a specific condition and that such differences may be recognised as constituting the genuine identity of the person concerned and therefore worthy of respect in themselves;

- (g) encourage Member States to strengthen family and social solidarity systems, in particular by setting up social services to help deal with the medical, social and economic consequences of disabilities, even when the person concerned is an adult (support for parents, access to education, and job opportunities) and to expand the facilities available to people with disabilities or their parents for discussing problems or obtaining assistance;
 - (h) create disability awareness programmes aimed at both young people and adults, by organising with disabled persons, joint meetings and activities to be held in schools, as well as other initiatives;
 - (i) encourage measures which help improve the integration and acceptance in society of people with disabilities and help improve their personal situation;
 - (j) encourage research into the possible causes of diseases, e.g. environmental or social factors, and into ways of combating their effects;
 - (k) set up a European laboratory network with the competence to cover rare diseases and provide appropriate public funding where there is no private investment or where such investment is inadequate;
 - (l) promote the involvement of the authorities responsible for personal data protection and the European group in which those authorities meet under Article 29 of Directive 95/46/EC;
18. Calls, therefore, on the Commission to take the necessary steps as described above and to present initiatives with a view to plugging the current loopholes in the law, choosing, if possible, a legal basis (e.g. Article 152 (health) or Article 153 (consumer protection)) which leaves Member States free to introduce more stringent protection measures;
19. Calls also for the adoption of minimum standards on the use of prenatal genetic diagnosis, which, in addition to expert genetic counselling, also provide for independent psycho-social counselling and at least rule out the possibility of prenatal DNA tests being carried out in order to predict eye colour, hair colour, size and intelligence (even where a certain degree of probability exists); takes the view that determination of sex in connection with prenatal diagnosis should be permitted, if at all, only if there is a chance of serious gender-specific diseases;

20. Stresses that predictive tests which merely point to the risk of a disease occurring only later in life should not be used at the prenatal stage, at least in principle, since, on the one hand, it is not possible in such cases to predict that a disease will ever strike, and, secondly, it is perfectly conceivable, given advances in medical science, that diseases which are currently untreatable or difficult to treat could be treated effectively by the time when they might affect the future child;

Pharmacogenomics

21. Believes that the prospect of being able to provide personalised therapy, the aim of which would be to prepare and administer made-to-measure drugs to match profiles identified by means of what the jargon terms snips (single nucleotide polymorphisms), currently seems very promising;
22. Considers that it is equally important to take systematic account of and to continue research into the factors which are the root cause of diseases and which may not be genetic (factors such as daily hygiene, diet, smoking, etc.);
23. Recognises that pharmacogenetics (determining differences in individual reactions to drugs) and pharmacogenomics (development of customised drugs, - 'personal pills') could offer great benefits, first of all as a form of therapy that could help reduce suffering and counter side-effects and secondly from the economic point of view, both when drugs were being developed and when they were being administered, since patients would not be given drugs that would do them no good or might even do them harm;
24. Attaches great significance, in medical and economic terms, to disease genetics; research in the field of disease genetics is aimed at gaining an understanding of the links between the emergence and development of diseases from a genetic angle and at obtaining from such understanding pointers as to how to treat or prevent such diseases or develop medicines; disease genetics takes account of the many-sided processes of interaction between genes, gene products and environmental factors and opens up very promising prospects for effectively influencing pathological processes without intervention to modify the genome;
25. Points out that the fact that there is a plethora of divergent, or at any rate not wholly consistent, national rules applying at every stage from development to the clinical trial is recognised to pose a severe limitation, making it difficult to develop and test new biomedicines on an EU-wide scale, although these are activities that should be encouraged; takes the view, therefore, that, as a first step, the EU directive on clinical trials should be transposed into national law as soon as possible; if the opportunities are exploited to the full, Union citizens will be able to benefit from the significant health advantages of genetic research, and further investment will gravitate towards European science and the pharmaceutical industry, which are having to operate in an increasingly more competitive global context;
26. Calls on the public and private sectors to work in greater synergy so as to achieve the best possible results for all in the field of pharmacogenetics, as there is otherwise a danger that rigid or overcautious public policy rules might lead to a manifest loss of

benefits;

27. Believes that a harmonised regulatory framework needs to be established in order to give precedence to the interests of the public, health, and the research community, and to lay down strict and clear-cut rules to govern not only the development, but also testing and approval of new biotechnological drugs and reagents for genetic testing;
28. Considers it important to point out that, in some areas, human genetics could yield clear improvements for sick and disabled people; takes the view, however, that success in some areas will be a long time in coming and that, for biological reasons, even if unlimited use is made of therapy and eugenic selection, which would in any case be ethically unacceptable, it would never be possible to totally eradicate disabilities and diseases; considers there to be an urgent need, therefore, to make it clear that people with disabilities will be a part of our lives in the future, too, and that society must support them and members of their families by showing solidarity;

II. Use of personal data related to genetic characteristics obtained by direct or indirect genome analysis

29. Stipulates that predictive genetic tests may be performed only for strictly medical purposes or for purposes of medical research and subject to appropriate genetic counselling; recalls that everybody is entitled to the protection of their personal data and that any form of discrimination against a person on grounds of his or her genetic heritage is prohibited; therefore supports the amendment of Article 13 of the Treaty establishing the European Community when it is next revised;
30. Maintains that genetic research must be conducted with sufficient safeguards to protect the interests of individuals and future generations as well as enabling legitimate medical research activities that are of benefit to the individual and society to be pursued and making it possible to solve serious crimes with the help of DNA tests;
31. Urges that the use of personal genetic information and the access to it afforded to third parties be debated with a view to adopting future legislation based essentially on protection of the inviolability of the person and grounded in the requirement that the individual's free and informed consent must be obtained for the purpose of protecting his or her health or the health of his or her offspring (or medical research), ruling out any other purposes; but considers that, for example, in the case of research, it must be possible to know who is the donor and who the recipient of cells, without the persons themselves having this information;
32. Considers that there are grounds, in particular, for protecting employees against any demand for them to provide genetic information; as an employee is in a weaker position, he or she should be protected by legislation;

33. Draws attention to Directive 95/46/EC, which considers protection of personal data in the broader context of the guarantees underpinning fundamental rights and freedoms; agrees with the European Group on Ethics in Science and New Technologies (EGE), which has noted in its opinion No 13 on ethical aspects of the use of health-related personal data that there is as yet no specific European legislation to protect such data; and hopes that the Commission will draw up a directive in order to allow for the implications of their computerisation; calls therefore on the Commission to review new developments in data protection storage in the light of technical progress;
34. Believes that, although it must do so, such a directive should not merely set out general principles derived from the entire body of fundamental rights (data must never be compiled unless they are intended to protect health or research; tests may be used only in specific cases and/or for particular purposes; tests may not be carried out without the consent of the person concerned; the use of data for given purposes should be prohibited; rules should be laid down to govern access to data not compiled on a strictly individual basis and in particular to deal with the problem of access within a family group, among blood relatives), but also lay down procedures for defining, classifying, and overseeing genetic testing so as to ensure that it is not put to improper use and to prevent the emergence of disturbing 'genetic normality' parameters;
35. Believes, as regards public authorities, which do not have to obtain the consent of the person concerned, that they should not be entitled to process data unless there is a law which expressly permits them to do so, specifying the operations to be performed and the important aims connected with the public interest that may be pursued (ruling out the possibility that these might be deemed to include economic ends), and which ensures that such activities are placed under the responsibility and surveillance of the personal data protection authorities set up under Article 28 of Directive 95/46/EC;
36. Considers, bearing in mind that the number of genes seems far lower than previously thought, that much less importance should be attributed to the idea that genes are the sole or overriding contributory factor in given outcomes, which appear instead to result from complex interaction processes involving genes, proteins, and environment; once the emphasis on predictivity has been removed, the possibility of using genetic data to assess people's prospects should not be permitted, since the decisive relationship with proteins and environment is disregarded, producing distorted or incomplete images of the person in question; takes the view that an individual does, however, have the right to have genetic tests carried out;
37. Considers that if it were to become more difficult, owing to the use of genetic data, to take out life assurance or health insurance, the end effect would be to create new social hierarchies, in which individuals would be ranked according to their genetic aptitude, a change amounting to nothing short of scaled-down citizenship and a denial of the right to equitable access to health care of appropriate quality;
38. Stresses, therefore, that insurance companies should in no way be entitled to request, either before or after an insurance contract has been concluded, that genetic testing be carried out or that the findings of genetic tests already conducted be passed on to them; insists further that genetic testing should not become a precondition for an insurance contract; considers that insurers may ask to be informed about the genetic

data of which an insured person knows, where extremely high amounts are insured and there is any suspicion that the insured person is acting on the basis of such prior knowledge;

39. Notes that the issue of making available to insurance companies the results of genetic tests carried out before conclusion of an insurance policy is not governed by Community legislation and that national laws and practices vary from country to country; calls on the Commission, therefore, to propose suitable draft legislation on the basis of Article 47(2) in conjunction with Article 55 of the TEC, including a ban on the use of personal medical information such as genetic typology which might lead to discrimination with regard to the issuing of insurance policies, and the possibility of applying a limit on insurance in specific cases;
40. Points out that the implications of genetic tests for fundamental rights, respect for ethical principles, and the organisation of relations within society are equally significant where work is concerned; unlike the case of insurance, in which the grounds for using genetic data are of a purely economic nature, the key consideration in this instance is the interest of workers themselves, who should not be employed in harmful activities; however, the indications deducible from genetic data cannot replace policies on the working environment or the more general safety requirements to be met when hazardous activities are performed;
41. Proposes that discrimination against workers on the basis of genetic criteria and as a result of genetic screening in connection with medical check-ups be banned; genetic screening cannot be used as a basis for assessment in connection with insurance policies;
42. Considers that the deficiencies of rules based solely on informed consent are revealed most starkly in this area because, as is well known, an unemployed person is willing to accept any conditions simply in order to work; consent in such a case would be not so much an expression of freedom as stem from a material constraint; it is therefore necessary to allow those concerned a right to reconsider their decision, on the lines of the existing provisions for opposition to the treatment of personal data; official policies, whether at national and/or Community level, should seek to provide proper information not just to those directly concerned, but also to the public at large so as to increase collective awareness of the issues related to the use of genetic information and establish overall social control policies;
43. Notes that the growing tendency to gather genetic data highlights the problem posed by the spread of monitoring and control policies made possible by the different technologies; policies whereby genetic information is appropriated for private use cannot be considered admissible, even when they are accompanied by nominal guarantees to the effect that the rights of the persons concerned would be respected because the data would remain anonymous; it is becoming essential to lay down an institutional framework to enable access to tests to be geared to genuine health protection requirements and prevent the existing rules from being circumvented via direct access to tests which bypasses the need for information based on genetic counselling;

44. Recommends that the Member States protect the right of individuals to genetic confidentiality and ensure that genetic testing is used for purposes that benefit individual patients, their relatives and society as a whole; exceptions to this general principle of confidentiality should be permissible in cases where genetic indicators kept in DNA databanks are to be used to identify and apprehend criminals¹;

III. Patentability of processes and products derived from biological material

45. Recognises that patents – a traditional industrial policy tool to encourage private funding of research – which came into being in order to enable newly invented manufactured products to be exploited industrially on an exclusive basis, pose new problems when they apply to biological material and especially the human genome;
46. Notes that Directive 98/44/EC, on the legal protection of biotechnological inventions, is currently being transposed in the Member States' legislative systems, that four countries have transposed it to date and that the directive really only codifies existing practice with regard to biotechnology; notes that certain states have experienced difficulties in incorporating it, whereas in other countries the process has been relatively painless;
47. Recognises, notwithstanding the difficulties of interpreting the Directive and especially Article 5(1) and (2), and the debate concerning its interpretation, that there has to be a legal framework and harmonisation in this area; considers that the difficulties particularly apply where the patents granted are too all-embracing and therefore block other research;
48. Notes that the provisions which apply in Europe at present tend to be very heterogeneous, despite the existence of Directive 98/44/EC, but that the possible introduction of a Community patent could create a more uniform situation;
49. points out that if an invention is to be considered patentable under the European law in force, it must involve an inventive step and lend itself to industrial application, and has to be something more than a mere discovery, whatever complexity may be involved, of something already in existence;
50. Notes that, pursuant to Article 6(2)(c) of the Directive, 'uses of human embryos for industrial or commercial purposes' is to be considered unpatentable; urges the Commission to clarify, by issuing a guidance document, by amendment of Directive 98/44/EC or by additional legislation, that hybrids, chimera, human stem cell lines or treatments as well medicines, products or procedures derived from or developed by research on embryos created in vitro for any purpose other than bringing about a pregnancy, shall be excluded from patent protection;
51. Notes that the Commission is required to produce:
- (a) every five years a report on any problems encountered with regard to the relationship between ... Directive [98/44/EEC] and international agreements on the

¹ European Parliament resolution A5-0080/2001 on the future of the biotechnology industry.

protection of human rights to which the Member States have acceded;

- (b) two years after the entry into force of the Directive (30 July 1998) a report assessing the implications for basic genetic engineering research of failure to publish, or late publication of, papers on subjects which could be patentable;
 - (c) and, annually, a report on the development and implications of patent law in the field of biotechnology and genetic engineering; the Commission must send those reports to the EP and the Council (Article 16); that being the case, calls on the Commission not to delay any longer the submission of the first annual report, which was due on 30 July 2001, and to use that opportunity to report the results of expert meetings, including consultations held by the Commission, on the issue of the patenting of genetic sequences and to inform the House about any communication between the Commission and the Member States regarding the difficulties of interpretation raised by Member States;
52. Urges that a thorough evaluation be carried out of Directive 98/44/EC covering, in addition to its socio-economic effects, the consequences of broad definitions of patents for technological advances and innovations
53. Calls on the Commission to analyse, in the reports referred to in the previous paragraph, whether disparities in Member States' implementation of compulsory licensing are hampering balanced development or whether there are grounds for introducing new Community rules on compulsory licensing within the limits permitted by the TRIPS Agreement;

IV. Cloning and stem cell research

54. Maintains that reproductive cloning of human beings should be banned regardless of the technique used and urges the Commission and the Member States to take the initiative to lay down a ban on reproductive cloning in an international legally binding instrument;
55. Calls for a ban of any activities which:
- (a) are intended to result in the modification of the human germ line,
 - (b) aim at or involve the reproductive cloning of human beings,
 - (c) aim at the production of hybrids or chimera, or
 - (d) make use of embryonic stem cells or of human embryos where the embryo was created in vitro for any other purpose than bringing about a pregnancy;
56. Maintains that substantial public funding should be made available for the development and use of scientific methods which will help to avoid the production of 'supernumerary' embryos; Member States should also examine possibilities which would allow for the adoption of 'supernumerary' embryos by infertile couples;
57. Calls for a Community-wide ban on trade in human embryos, embryo stem cells and

ova and sperm cells;

58. Points out that the production of human embryos by nuclear transfer is the basis for reproductive cloning and that, technically, the implantation of embryos in the womb is a very simple procedure;
59. Reaffirms its position that, from an ethical viewpoint as well, therapeutic cloning poses a problem because it requires the availability of a large number of human egg cells, which can result in gender-specific exploitation of the human body, poses major risks for women and involves the production of human embryos solely for research purposes;
60. Reaffirms, therefore, its position that the most effective and credible way of combating human cloning is to exclude the possibility both of therapeutic cloning and of reproductive cloning of human beings;
61. Welcomes therefore the decision of the US House of Representatives to prohibit the production of human embryos by nuclear transfer and to impose heavy prison sentences on those who defy the ban, and calls on the Senate to endorse this decision as soon as possible;
62. Reaffirms its call for a ban on the cloning of human beings to be introduced worldwide, as far as possible;
63. Calls on Member States which have not yet done so to pass laws banning the production of genetically identical human embryos by means of cloning;
64. Asks the Commission, in the event of this not happening within a certain period of time, to verify whether a proposal for Community legislation with this objective would be possible, for instance on the basis of Article 152(4)(a) of the EC Treaty;
65. Calls for the production of human embryos to be permitted only in order to induce pregnancy;
66. Recognises the ethical dilemma that has arisen owing to the fact that in many Member States thousands of human embryos exist that were produced for the purpose of IVF but whose implantation is no longer possible for the genetic parents;
67. Acknowledges that both the destruction of those embryos and their being made available for use in research is controversial from an ethical viewpoint;
68. Calls therefore for alternatives to be studied which would allow such embryos to be made available to childless couples for whom conventional IVF is not possible for medical or other reasons, and for stringent rules to be adopted so that this does not result in a trade in embryos; considers also that techniques for treating sterility which do not require the production of supernumerary embryos and which minimise the burden on women's health must be developed;
69. Expresses its unreserved support for work with adult stem cells and notes with interest that such work has, in some fields of research (e.g. into leukaemia, the treatment of

cartilage and bone damage and probably also the treatment of coronary disease), already yielded cures for some patients, whilst embryo stem cell research has hitherto resulted in partial cures being found, and only in experiments on animals;

70. Calls on the Member States, the Commission and all researchers concerned to vigorously support and investigate possible alternatives to embryo stem cell research and considers it important that these include not only adult stem cells but also other scientific approaches;
71. Emphasises that, in its resolution of 12 March 1997¹, the European Parliament confirmed that 'the cloning of human beings cannot under any circumstances be justified or tolerated by any society, because it is a serious violation of fundamental human rights and is contrary to the principle of equality of human beings as it permits a eugenic and racist selection of the human race, it offends against human dignity and it requires experimentation on humans';
71. Recommends to international and regional organisations such as the United Nations and the Council of Europe that they define a human right to being genetically unique or one which specifically covers protection of the individual's genetic heritage;

V. The sixth research framework programme

Guidelines for an ethical frame of reference

73. Considers it essential to work out guidelines for an ethical frame of reference, proceeding from the provisions already laid down in the fifth framework programme (covering the period from 1998 to 2002) and in particular the 'quality of life' specific programme;
74. Notes, in this connection, the decisions made by the US President, George W. Bush, concerning authorisation of use of federal funds for research into adult stem cells and into a series of cell lines obtained from 'surplus' embryos already used in the laboratory;
75. Believes accordingly that all research activities under the sixth framework programme must be conducted in keeping with fundamental ethical principles, in particular:
 - (a) the principles stated in the Union Charter of Fundamental Rights and in the international conventions cited in paragraph 2(a) of this resolution;
 - (b) the laws of the Member States;
76. Observes that one of the purposes of the new research programme is, for the first time, to apply the procedure provided for in Article 169 of the EC Treaty whereby the Community may participate in cooperation projects in which only some and not all Member States are taking part; the Community should particularly be able to participate in these cases, in order to ensure that experiments benefit all residents of the Community;

¹ OJ C 115, 14.4.1997, p. 92.

77. Endorses the opinion of the European Ethics Group on ethical aspects of stem cell research, which makes the following recommendations:
- (a) the ethical acceptability of stem cell research depends not only on the objectives but also on the source of the stem cells;
 - (b) in view of the absence of an ethical consensus at the present moment as regards the creation of embryos by means of somatic cell nuclear transfer (therapeutic cloning) to meet the needs of cell therapy research, a vast field of research should be explored using other strains of human stem cells;
 - (c) a Community budget should be drawn up to finance research using these alternative sources, in particular adult stem cells;
 - (d) steps should be taken at European level to ensure that research findings are disseminated widely and not kept secret for commercial reasons;
 - (e) Community-funded stem cell research should be assessed from the ethical point of view before projects are launched and while they are being carried out;
78. Believes therefore, as far as stem cells are concerned, that research projects using adult stem cells should be treated as the priority for Community funding and that research projects using embryonic stem cells should not receive such funding;
79. Recommends that no Community funding be granted for research, technological development and demonstration activities involving:
- (a) the creation of human embryos from donated gametes for anything other than reproductive purposes;
 - (b) the creation of human embryos by means of somatic cell nuclear transfer (therapeutic cloning) and the cloning of human beings (reproductive cloning);
 - (c) research activities aimed at modifying the human germ line;
 - (d) intentional artificial creation of human embryos for any purpose other than bringing about a pregnancy;
 - (e) any other forms of consumptive research on human embryos.
80. Advocates a ban on human cloning, irrespective of the aim pursued and the techniques or methods used, and calls on the Commission to examine the legal scope for an EU ban on cloning;
81. Maintains that human cloning for reproductive purposes must be prohibited and calls on EU Member States to support the Franco-German proposal for a UN convention against such cloning;
82. Maintains that the distinction as to the reproductive or therapeutic purpose of cloning is of no significance with regard to the technique to be used;

Recommendations to the Union Member States regarding genomic research funding

83. Acknowledges that the issue of whether it is possible to regulate embryo research at European level is controversial from a legal point of view and, even if EU-wide rules were legally possible, it would only be realistic to adopt certain basic rules, so that, for the foreseeable future, it will be up to each Member State to either prohibit or authorise embryo research; stresses, however, that if such research is authorised, respect for human dignity implies that rules must be drawn up to prevent the risk of unlawful experiments in which human embryos are used as tools;
84. Takes the view that, out of respect for the ethical convictions of many European citizens and for the legal orders of the Member States, research activities should receive EU funding only if they are not regarded by any Member State as violating the fundamental ethical principles of its constitution;
85. Emphasises that research into combating infertility which does not involve the creation of ‘supernumerary’ embryos must be encouraged and funded at national and at European level;
86. Encourages the Member States to simplify adoption procedures, in particular by systematically proposing the adoption of currently deep-frozen embryos to couples willing to use IVF treatment or in whose case IVF treatment has proved unsuccessful;
87. Considers it important that biotechnological research should not be allowed to be concentrated in large multinationals; takes the view, therefore, that the public authorities at national, Community and international level should be called upon to:
 - (a) monitor concentration processes in this area and if necessary intervene if the public interest is being affected,
 - (b) safeguard the position of smaller companies and non-profit-making organisations;
 - (c) strive to promote strong, independent publicly funded research focusing on areas offering little prospect of profit in the short or medium term which are being neglected by the private industries, for example treatments for diseases affecting the least-favoured social strata or children, or which occur in developing countries, and treatments for rare diseases;
 - (d) promote research into the risks of biotechnology and the ways of avoiding such risks;
 - (e) foster public-private partnerships;
88. Takes the view that research in the field of biotechnology must not lead to a strengthening of the role of multinational undertakings, which are exempt from any form of monitoring, and insists, therefore, that the public authorities, at Member State and Union level, meticulously regulate all research carried out in this field, guarantee total transparency and provide information in this respect for the public debate referred to in paragraph 1 above;

89. Recommends that consideration be given to changes in public policy regarding public funding for truly independent and basic research that would ensure the existence of a vigorous and independent public scientific research enterprise;

Measures to be pursued using Community genomic research funding

90. Calls on the Union to establish a legal and regulatory frame of reference and earmark substantial funding for genomic research, as provided for in the proposal for a decision concerning the sixth research framework programme; accordingly considers it necessary to:
- (a) endorse the priority assigned to genomics and biotechnology for health and general welfare, though it must be made clear, preferably by introducing a new priority entitled 'Health research', that support must be given to other approaches to improving the health situation which do not need to have any direct connection with genetic technology or biotechnology;
 - (b) support cooperation among researchers from different milieux (universities, research centres, hospitals, enterprises and industry in general) at national and European level aimed at identifying the functions of genome data and developing new medical treatments;
 - (c) support non-normative research in the field of human genetics (quality assessment standards and quality guarantees for genetic testing);
 - (d) encourage regulatory authorities to play an active role at the right time by providing platforms to consider guidelines for the examination of new biomedical developments;
 - (e) set up centralised information and/or common material systems, employing procedures such as registration of data on new biotechnological drugs and genetic testing, including clinical trial data and information connected with the subsequent approval stage (for instance notes on adverse reactions), comparison with pharmacogenomic data (correlating specific genetic features with individual reactions to drugs), or the organisation of patient databanks or the development of central tissue banks;
 - (f) support research involving transgenic experimentation in order to meet medical treatment needs;
 - (g) support research which promotes an understanding of the legal, ethical, social and economic implications of new knowledge in the field of human genetics, which also helps meet the challenges involved more effectively;
 - (h) take account of gender-specific differences in research activities as well as preventive and treatment measures in the field of genomics and biotechnology;
 - (i) support initiatives seeking to foster a new consensus on life science applications, in order on the one hand to disseminate information on these sciences (e.g. in the media), so as to increase public understanding, and, on the other hand, to

encourage scientists to show greater awareness of public concerns and take account of them in their work;

- (j) support integrated multidisciplinary education and training; greater education and training in leading-edge technologies (for example pharmacogenomics, biocomputing, and nano-biotechnologies) and integrated education and training programmes in biomedical research/development/management, based on international cooperation between universities and industry, will afford opportunities to universities, industry, and society as genotype analysis, diagnosis, and therapy are combined to form an increasingly more unified whole;

- 91. Considers it essential to fund public information and education programmes which do not, as in the past, aim to facilitate acceptance of genetic engineering but rather to encourage informed public debate; recommends that such programmes be developed in close cooperation with representative organisations of disabled people;

VI. As regards the ‘European knowledge-based society’ and Union monitoring of developments in human genetics

- 92. Notes that the Heads of State or Government have decided to establish a ‘European research area’, a matter which cannot be left out of account when considering the methods of governing Europe and thus requires new forms of participation in public life on Europe’s various tiers of power and decision-making, based on interaction between public authorities and civil society;

- 90. Considers, therefore, that steps should be taken at Community level to:

- (a) devise fundamental ethical principles to govern human genetics in close collaboration with the European Ethics Group, taking into account the activities of the Council of Europe connected with the Euro-Forum on human genetics and its work to draw up the protocol on human genetics;
- (b) intensify public debate by involving patients and people with disabilities and their families, industry, investors, ethics experts, and the general public;
- (c) establish more organised links between national and European ethics committees;
- (d) enable the legislative activities of the Council of Europe and the Union to move closer together;
- (e) address an appeal to the Heads of State or Government to begin preparations with a view to drawing up an international convention on human genetics;
- (f) move towards a transparency undertaking on the part of research centres and companies aimed at reconciling industrial confidentiality with the sharing of information on research in progress with certain authorities;

- 94. Deems it indispensable to confer on the European Ethics Group a genuine interinstitutional status which would enable it to act as a European Advisory Committee on Ethics, at the interface between the various Community authorities, and,

furthermore, to maintain a dialogue and a permanent network for the exchange of information with national ethics committees in the Member States of the EU or in third countries, as well as with ethical committees set up by international governmental organisations (such as UNESCO's International Bioethics Committee or the Council of Europe's Bioethics Committee);

95. Believes that such a forum would guarantee an exchange of information and a public debate; using an 'integrated' working method, in other words taking account of all the parties concerned (scientists, industries, and non-governmental organisations), together with the European Ethics Group and the high-level working party on life sciences, and aided by permanent communication with the national parliaments of the Union, the forum, consisting of Members of the European Parliament and representatives from the Commission and Council, could meet twice a year for the purpose of evaluating the impact of research investment and taking action, via ad hoc contributions which could be taken into account by the competent decision-making bodies of the institutions concerned, on such ethical, legal, economic, and social problems as might periodically arise; with regard to the working methods of this forum, it must be ensured that it receives well-founded scientific assistance and meets the highest standards of transparency and parliamentary scrutiny;
96. Calls on the representatives of the Member States and of the European Union to initiate an international dialogue with the aim of protecting human dignity in view of developments in modern biomedicine and also to seek to influence countries such as China, which tolerate eugenic practices;
97. Considers it necessary for the European Parliament to continue its work on human genetics in whatever way it deems appropriate;
98. Instructs its President to forward this resolution to the Council and Commission, the governments and parliaments of the Member States and the applicant countries, and the Council of Europe.

EXPLANATORY STATEMENT

Foreword

This document summarises the work of the Temporary Committee on Human Genetics, set up on 13 December 2000. The rapporteur has thought fit to focus on the questions raised at the meetings attended by experts in the field and in particular on the key issue of the Union's role and Union action. Can rules and limits be imposed on a 'scientific revolution' comparable to so many other revolutions which have left their mark on human history? In an attempt to answer that question, this working document outlines some avenues for the committee to explore to help it draw up its final resolution.

The debate has centred on the ethical, social, legal, and economic issues stemming from human genetics. As we seek to address these problems, we are naturally led to consider whether and how Europe, and the Union in particular, can respond.

Comparison of all the views expressed in committee has highlighted a crucial point, namely the need to reconcile freedom of research and the principle of human dignity, both of which are unanimously recognised at international level and have been reaffirmed more recently in the European Union Charter of fundamental rights.

I. Introduction

Within the next few years the biotechnologies will come to play a key role. This prediction applies especially to genetic engineering, which could do much to improve human well-being and health. The enormous advances made in finding cures for a great many diseases will be impossible to translate into reality unless the public interest in terms of safety, ethics, and social justice is taken into account. Research strategies and the new technology applications in question are therefore a matter of fundamental importance.

The 'European research area' has become the frame of reference for aspects of research policy in Europe. The area, proposed by the Commission, was endorsed by the Heads of State or Government at the Lisbon and Nice European Councils and more recently, on 26 March 2001, in Stockholm. '... The ability of EU businesses to embrace technologies will depend on factors such as research, entrepreneurship, a regulatory framework encouraging innovation and risk-taking, including Community-wide industrial property protection at globally competitive costs, and the availability of willing investors, particularly at an early stage.

To that end:

- the European Council expresses its concern at the lack of progress on the Community patent and the utility model and urges the Council and the Commission to speed up work in accordance with the Lisbon and Feira conclusions and in full compliance with the existing legislative framework;
- the Commission, together with the Council, will examine measures required to utilise the full potential of biotechnology and strengthen the European biotechnology sector's competitiveness in order to match leading competitors while ensuring that those

developments occur in a manner which is healthy and safe for consumers and the environment, and consistent with common fundamental values and ethical principles.’

The proposal for a decision of the European Parliament and of the Council on the sixth research framework programme (covering the years from 2002 to 2006), under which the European research area is to be established, states that: ‘At the dawn of the 21st century, the immediate challenge facing science is to make use of the advances achieved in the analysis of the human genome and other living organisms, heralding the advent of the post-genomic era with all its spin-offs in terms of public health and the competitiveness of the biotechnology industries’.

Brief of the temporary committee

On 13 December 2000 the EP decided to set up a temporary committee on human genetics and other new technologies in modern medicine, which was to remain in existence for one year¹. According to the brief conferred on it, the committee has the tasks of²:

- ‘- compiling as complete an inventory as possible of new and potential developments in human genetics and of their uses, so as to provide Parliament with a detailed analysis of such developments necessary to enable it to assume its political responsibilities;
- examining the ethical, legal, economic and social problems posed by such new and potential developments and by their uses;
- examining and recommending to what extent the public interest requires a proactive response to such developments and uses;
- providing an orientation for Parliament and the other Community institutions with regard to research in human genetics and other new technologies in modern medicine and their uses, having regard to the positions already established by resolutions of Parliament’.

II. Human genetics: a scientific and technological challenge amounting to nothing short of a revolution

Ever since humans have sown crops or reared animals it has been obvious that every fertilised seed or egg must contain a ‘hidden plan or blueprint’ for the organism’s development. What is the nature of this plan, what form does it take, and what kind of instructions or information does it contain? In other words, how does the complete information required for offspring to develop derive from the parents? Why do children resemble their parents? And how is it that certain diseases can affect members of the same family?

From about 1860 a monk called Gregor Mendel experimented with the characters of garden pea plants by crossing plants with different characters. He carefully examined the characters produced by cross-fertilisation and discovered that the plants thus bred inherited characters from the parent plants according to specific patterns. Mendel suggested that the characters which he had studied had been brought about by discrete ‘units of heredity’ and, after examining the heredity patterns in more detail, put forward the theory that each character resulted from

¹ For chronologies listing developments in the field of human genetics and statements of views by the European institutions, see Annexes IV and V.

² Resolution B5-0898/2000 (European Parliament decision on setting up a temporary committee on human genetics and other new technologies in modern medicine).

two units of heredity originating from the two parent plants. Today these units of heredity are called **genes**. Towards the end of the 19th century biologists established that the *carriers of hereditary information* were **chromosomes**, which become visible in the nucleus when a cell begins to divide. However, the proof that the deoxyribonucleic acid (**DNA**), *the main ingredient of chromosomes*, was the *substance of which genes are made* did not come until later, in the mid-20th century.

II.1. DNA – Genes – Chromosomes

DNA is the principal constituent element of chromosomes and hence genes. It consists of just four subunits, the chemical substances (deoxyribonucleotides) containing the adenine (**A**), cytosine (**C**), guanine (**G**), and thymine (**T**) bases. These subunits, also called nucleotides, are linked together to form an extremely long strand. A typical DNA molecule consists of two long chains held together by interaction (complementary base pairing) of the A and T and the C and G bases. The spiral staircase-like structure of the DNA molecule is termed a ‘double helix’.

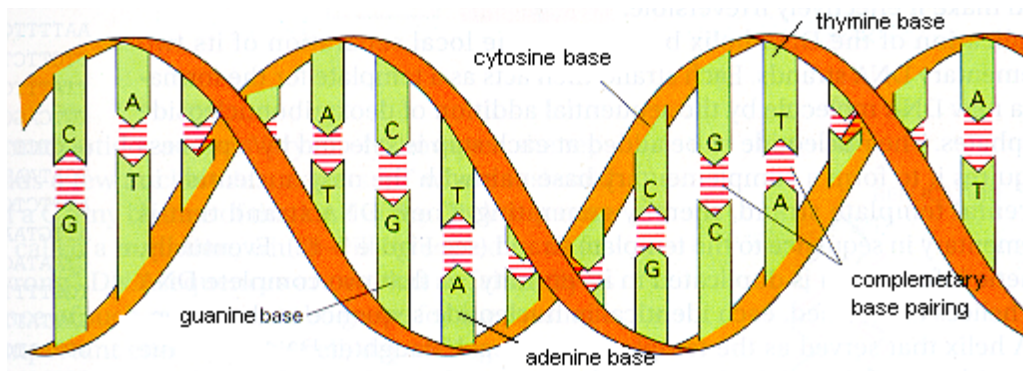


Figure 1: DNA. The A base pairs with the T base, and the C base with the G base to form a structure similar to a spiral staircase, the double helix.

This structure explains how information is passed on from a mother cell to a daughter cell. Given that each strand contains a nucleotide sequence exactly complementary to the nucleotide sequence of the partner strand, both strands carry genetic information. If two strands are termed A and A', strand A can serve as a template to produce a new strand A', and strand A' can serve in the same way to form a new strand A. Source: Alberts, Bruce, and others: *Molecular Biology of the cell*, third edition, 1994.

All the information contained in DNA is determined by the order in which the bases are arranged along the length of the DNA molecule. In the same way as the English alphabet consists of 26 letters, each nucleotide – A, C, G, or T – can be regarded as a letter in a 4-letter alphabet used to transcribe biological messages. These four letters are sufficient to generate immense biological variety, since a typical animal cell consists of approximately three billion nucleotides, equivalent to a metre of DNA. When a cell is about to divide, the DNA can be seen under a microscope in the form of **chromosomes**, in which the DNA molecules are organised. Chromosomes are thus made of DNA. **Genes**, *sections of DNA* arranged in line along the length of the chromosomes, carry the instructions that an organism needs in order to function. The following analogy could be used to illustrate the relationship between DNA, genes, and chromosomes in order to understand it more clearly: chromosomes can be likened to an audio cassette, DNA to the tape inside the cassette, and genes to the song recorded on the tape¹.

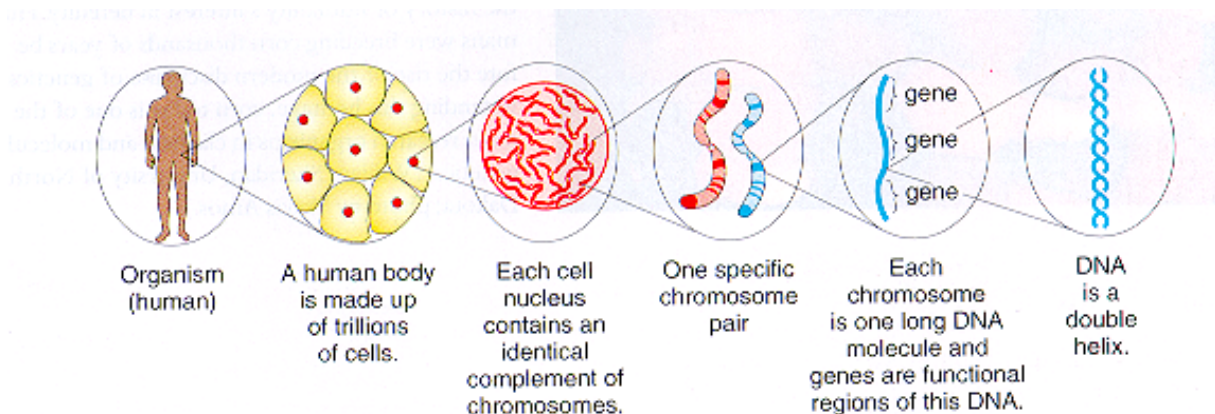


Figure 2: Relationship between DNA, genes, chromosomes, cells, and organisms

Source: Anthony J.F Griffiths and others, 'An introduction to genetic analysis', 6th edition, 1996

¹ 'Human genetics: Choice and responsibility' – British Medical Association, 1998.

II. Chromosomes

The genetic material as a whole contained in the set of chromosomes is called the **genome**. Most human cells have two sets of 23 chromosomes, one inherited from the biological mother and the other from the biological father, giving a total of 46 chromosomes. However, germ cells (the cells which give rise to ova and spermatozoa) have only one set of chromosomes (23 in all) made up of a mixture of genes received from the mother and the father. The combination of genetic material in each germ cell is consequently unique. During fertilisation, when an ovum fuses with a spermatozoon, the two sets of homologous genes are reconstituted, a process to which both parents contribute at random.

The 22 pairs of chromosomes (44 in all) which are the same in males and females are called autosomes. The remaining two chromosomes, however, determine the sex of the offspring and are thus called sex chromosomes. Females have two 'X' chromosomes, whereas males have one 'X' and one 'Y' chromosome; each of the two partners will pass on one of these chromosomes to their child. All ova contain an X chromosome (one of the mother's two X chromosomes), and a mother will therefore always pass on an X chromosome to her offspring. However, a spermatozoon can carry an X or a Y chromosome. An ovum fertilised by a spermatozoon carrying an X chromosome will thus produce a female (XX), whereas an ovum fertilised by a spermatozoon carrying a Y chromosome will produce a male (XY).

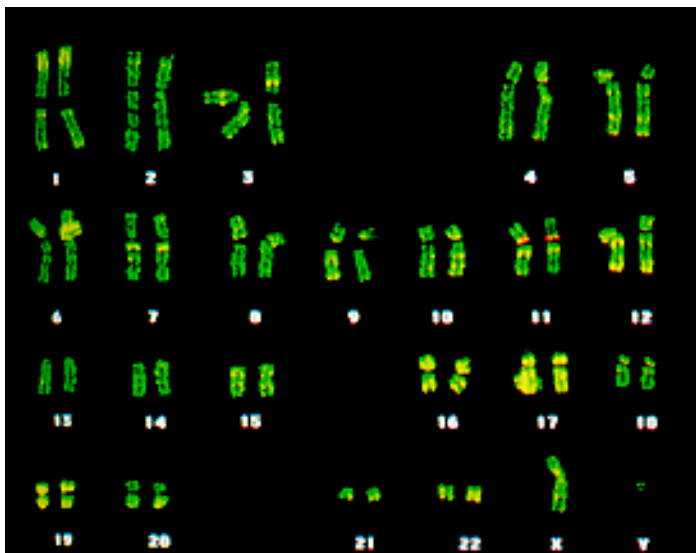


Figure 3: A man's complete set of chromosomes, made visible by microscopic staining

Source: Anthony J.F. Griffiths and others, 'An introduction to genetic analysis', 6th edition, 1996

II. Genetic diseases

In order to pass on its complete genetic information to the next generation, a cell, before dividing, has to duplicate the entire set of chromosomes. The mechanism which carries out that process is not perfect, and errors can consequently sometimes occur. The errors are called *mutations*. Mutations can affect whole chromosomes as well as individual genes.

- An example of **genetic mutation** caused by an error in the DNA replication process is the substitution of a single nucleotide within a DNA sequence. Instead of ... ATGGACG ...,

for instance, a daughter cell could inherit a slightly different version, ... ATGTACG ..., as a result of an error while the sequence was being copied. Though apparently normal, this phenomenon can cause severe defects: in cystic fibrosis patients, nucleotides have been substituted in the manner described above in the gene responsible for cystic fibrosis.

- An example of **chromosomal mutation** caused by an error during cell division is trisomy 21, also known as Down's syndrome. Chromosomal mutations generally involve parts of chromosomes which have been rearranged within the same chromosome or become attached to another chromosome or abnormal numbers of individual chromosomes or sets thereof.

It is now known that many individuals with chromosomal anomalies fail to survive birth. In other words, many chromosomal mutations cause a pregnancy to end before it has reached its full term, and only a small number of embryos with anomalies manage to survive. However, all human beings carry potentially harmful mutated genes. The possibility that a **genetic mutation** will cause a disease depends on several factors, namely:

- the way in which the disease is transmitted;
- whether the disease is caused by:
 - a defect in a one gene only (*single-gene disorder*),
 - a *polygenic dysfunction*, i.e. there has to be more than one defective gene to enable the disease to develop,
 - a *multifactorial dysfunction*, i.e. the genetic defect increases an individual's susceptibility to the disease, but whether he or she actually becomes ill depends on external factors such as diet, physical exercise, smoking, noxious substances in the environment, etc.

Manner of transmission

Every individual inherits two sets of chromosomes and hence two sets of homologous genes. An individual can thus inherit two normal copies of any given gene, or one normal and one defective copy, or two defective copies of that gene. Individuals with two normal copies of a given gene will **not** suffer from the disease associated with mutation of the gene. Individuals with two defective copies **will** contract the disease. However, when individuals have a normal copy and a defective copy, the possibility of developing the disease depends on the *way* in which the dysfunction in question is transmitted. Diseases caused by a defect in a one gene only (single-gene disorders) are governed by three common types of hereditary pattern, namely the **dominant** type, the **recessive** type, and the **X-linked** type.

Autosomal dominant diseases

An example of a dominant disease is *Huntington's chorea*. Individuals who inherit a single copy of the defective gene **will fall ill**. These persons will have a healthy copy and a defective copy of the gene. Half of their germ cells will therefore carry the healthy copy of the gene, whereas the other half will carry the defective copy. If an egg carrying the defective copy is fertilised, the resulting offspring will contract the disease, irrespective of the genetic make-up of the spermatozoon. Furthermore, if a spermatozoon carrying the defective gene fertilises a 'healthy' ovum, the offspring will become ill. The only offspring who will escape the disease are those resulting from fertilisation of a 'healthy' ovum by a 'healthy' spermatozoon. For

those who have the defective gene, the risk of producing a sick child will consequently be 50% (Figure 4).

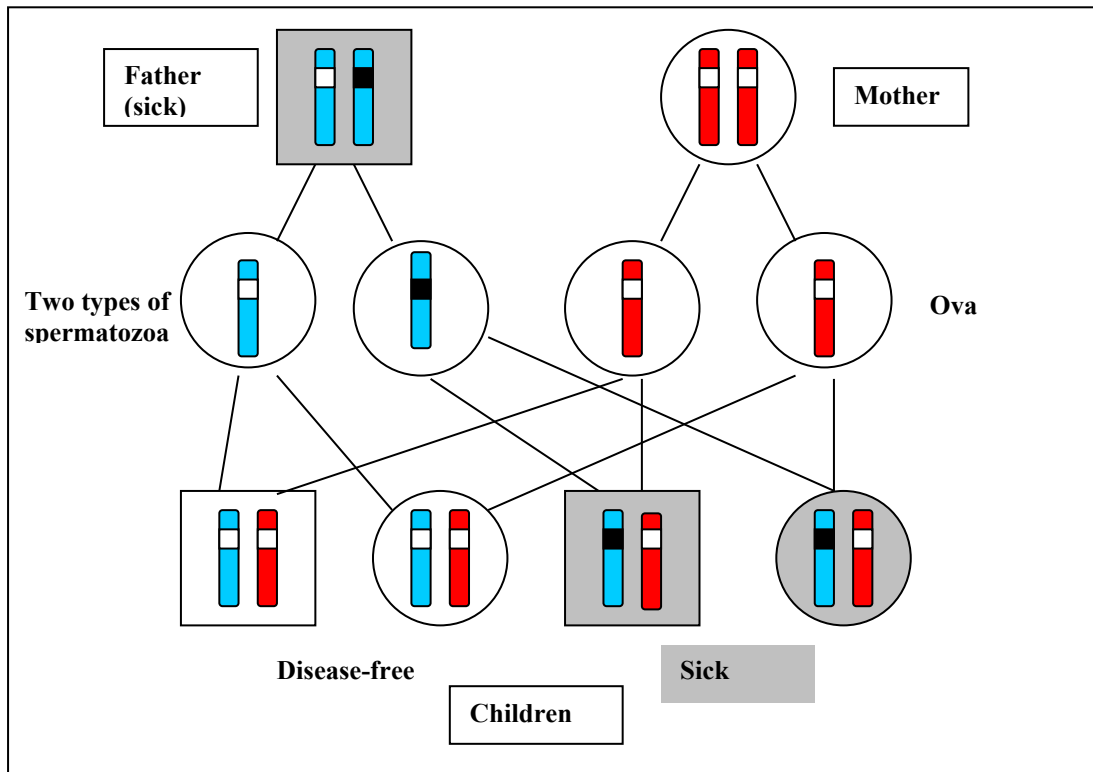
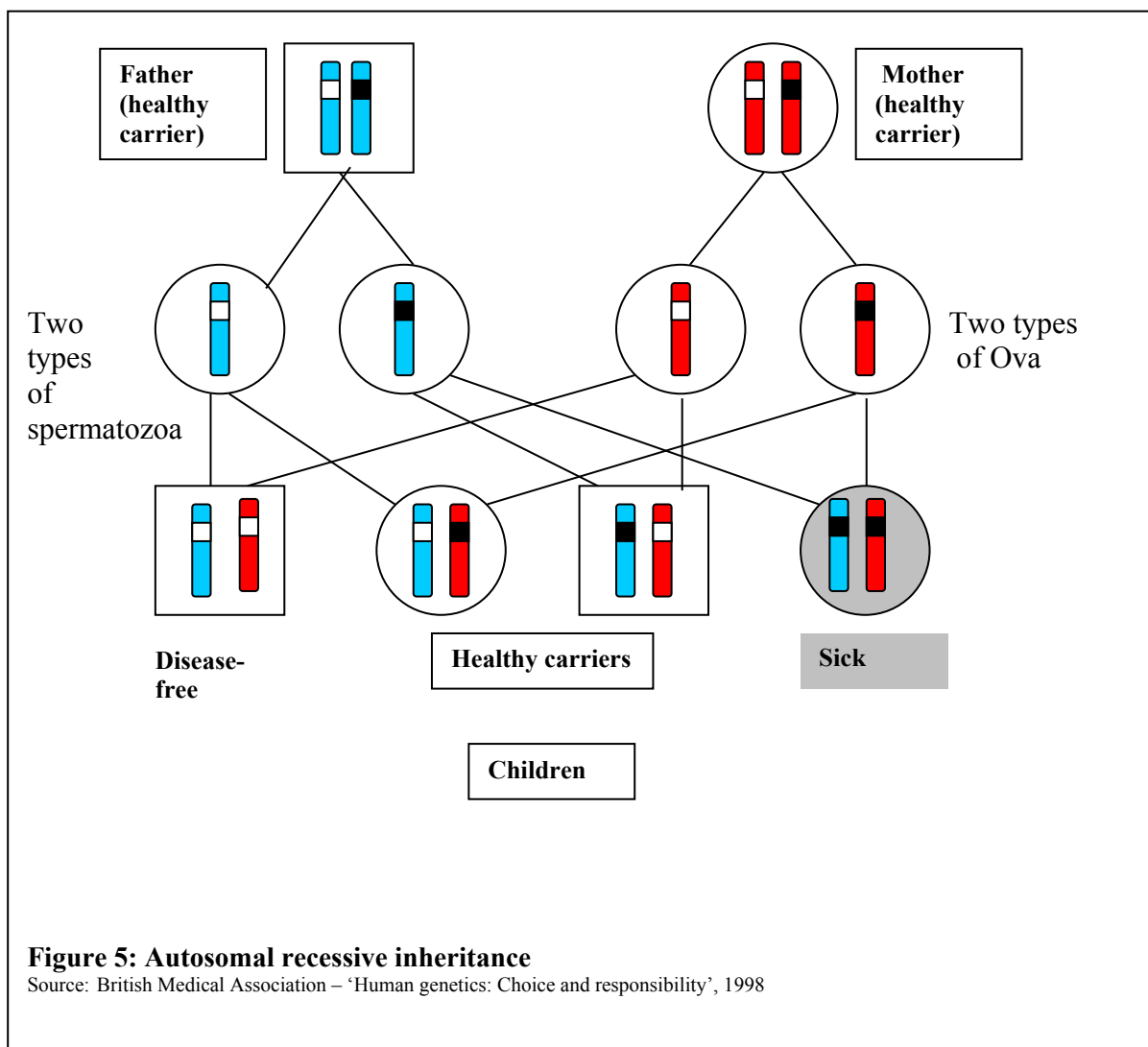


Figure 4: Autosomal dominant inheritance

Source: British Medical Association, 'Human genetics: Choice and responsibility', 1998

Autosomal recessive diseases

An example of a recessive disease is *cystic fibrosis*. To become ill, a child has to inherit two defective copies of the gene involved, since a normal gene will cancel out the defect in the other copy. Individuals who have one defective gene and one healthy gene are called 'carriers' and do not usually fall ill. If carriers have children by another carrier, the probability that a child will inherit two defective copies and consequently fall ill is 25%. However, the probability that the children will themselves become carriers is 50%, and the probability that they will inherit two healthy copies and hence escape the disease is 25% (Figure 5).



Autosomal X-linked diseases

An example of a disease in this category is *Duchenne muscular dystrophy*. In X-linked diseases the mutation occurs in genes located on the X chromosome. In women most of these diseases are recessive, and the healthy copy thus cancels out the defect. In general, therefore, the diseases affect males only because they have just one X chromosome, inherited from their mother. Females who inherit a copy of the defective gene will be healthy carriers and will not usually become ill, because their second X chromosome carries the normal gene (Figure 6).

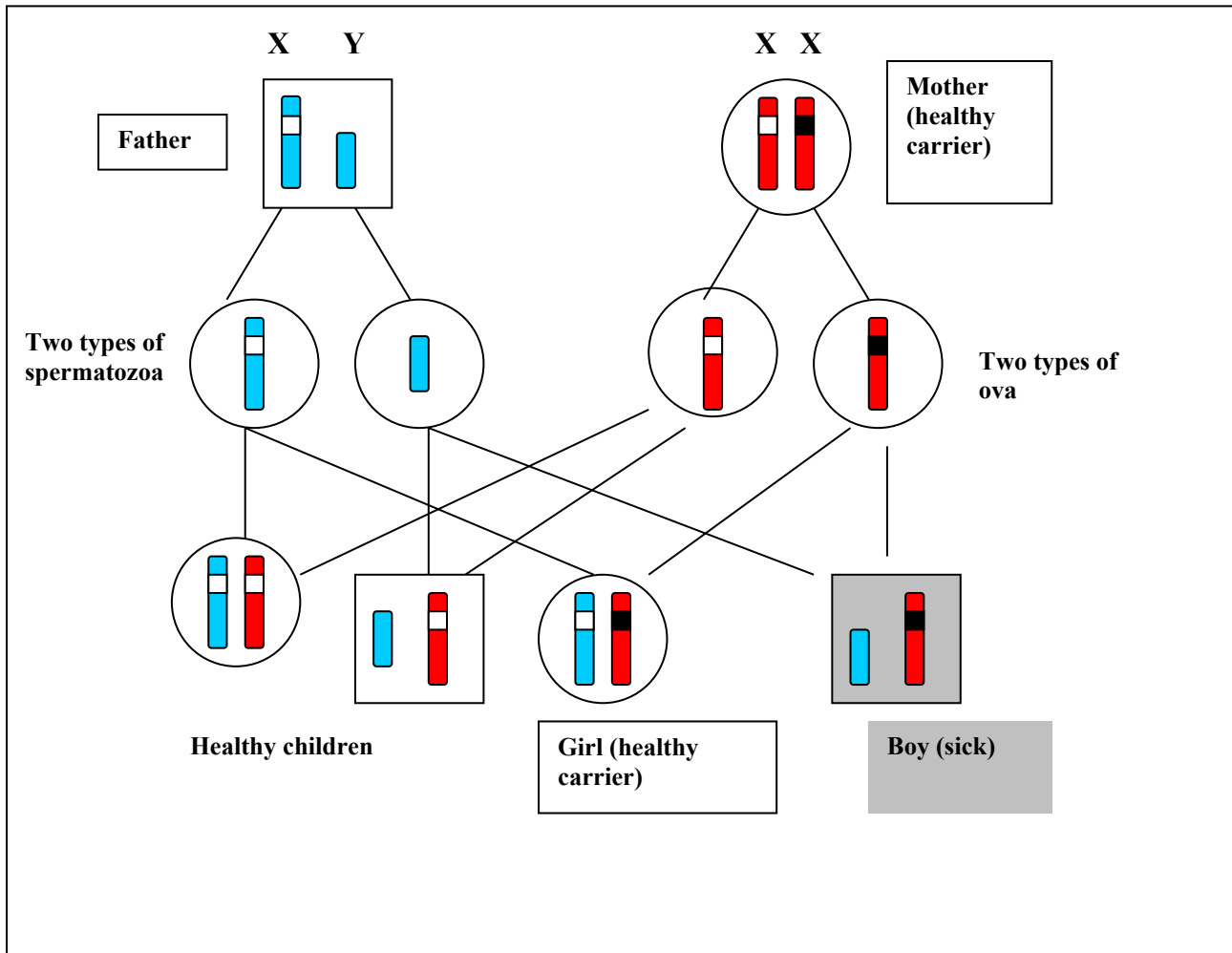


Figure 6: X-linked inheritance

Source: British Medical Association, 'Human genetics: Choice and responsibility', 1998

II.4. The function of genes

Genes are responsible for the cell functions used during an organism's lifetime. They do not, however, actively perform actions in the organism, but rather supply information for the production of **proteins**. Within a cell, proteins perform virtually all the tasks necessary for the cell to function. Among other functions, they can carry matter, give structure, communicate with other cells, and facilitate chemical reactions. The building blocks of proteins are **amino acids**, which are linked together to form long chains, that is to say, a protein. Just as different

organisms have different DNA sequences, so are the amino acids making up different proteins within the same organism configured in each instance in a different order (also called the amino acid sequence).

As already mentioned above, genes are regions on the chromosomes which code for proteins. It is important to note, however, that the coding regions within a gene (exons) are bounded by non-coding regions (introns) that do not supply information for the production of proteins. Not all DNA, then, codes for proteins and it seems in reality that much of it is superfluous and, according to our current understanding, has no discernible function.

The transfer of information from DNA (or a gene) to a protein is a complicated process involving several stages. Firstly, the genes are transcribed in the polynucleotides known as ribonucleic acid (RNA). RNA is very similar to DNA, the main difference being that the thymine base (T) is replaced by the uracil base (U). It does, however, contain all the information from the DNA sequence from which it has been transcribed. This process is termed DNA transcription. In any case, both the exons (coding regions) and the introns (non-coding regions) are copied. That is why, at the second stage, the introns are excised from the RNA in a process termed 'RNA splicing' (in which the RNA is cut up and rejoined), producing a shorter RNA molecule (called mRNA) containing only the coding regions of the gene. Finally, the mRNA molecule is translated into a protein by means of a special mechanism. The translation operates as follows: a specific sequence of three nucleotides (for instance 'AUG') codes for a given amino acid (for example AA1); another specific sequence of three nucleotides (for example 'CAG') codes for another given amino acid (for example AA2). Reading along the RNA sequence, the system knows exactly which amino acids must be added to the preceding acids to produce an amino acid chain or protein. The linear sequence of nucleotides in a gene thus determines the linear sequence of amino acids in a protein.

As a result of the Human Genome Project, the entire human genome sequence is now known. Surprisingly, human beings have far fewer genes than was previously predicted. The human genome consists of just 30 000 genes and not 100 000 as was believed in the past. In other words, we have only twice or three times as many genes as a fruit fly.

II.5. Consequences of the Human Genome Project

The Human Genome Project, the sequencing of all human DNA, and linear mapping of the genes on the chromosomes will have a significant impact on biomedical research and therapy and preventive diagnostics in general. A whole battery of new-generation concepts is emerging in the field of biomedicine, ranging from genetic screening to germinal gene therapies and targeted molecular drugs, which offer the promise of radical breakthroughs in health, prevention, diagnosis, and therapies. Over the past decade the advances in our knowledge of human genetics and developments in the diagnostic techniques using molecular biology have laid the foundations for a new branch of predictive medicine. To link genetic diseases back to their molecular causes is to widen the diagnostic and prevention options for treating those diseases with greater precision, in a more personalised way, and more effectively than they are treated at the present time.

The foreseeable economic advantages are likewise immense. However, the benefits for humankind, in terms of health, and the economic advantages, in terms of growth potential and

wealth and job creation, will be impossible to exploit to the full unless the prevailing conditions in Europe are right.

Developments are proceeding before our eyes at a furious pace that is challenging our ability to comprehend the full extent of what is happening and the consequences likely to ensue. A whole series of problems is bound to arise, some very old but with new dimensions, others unprecedented and highly complex, and the debate on these subjects is only just beginning. On the one hand, there are great hopes and expectations. At the same time however, grave anxieties are coming to the fore.

It is not yet clear how far (and when) biomedical research can be translated into therapy options likely to produce a statistically significant impact on human health¹. There are different opinions on that point. The most widely held view is that the clinical impact of the work now being done at the leading edge of biomedical research will be so colossal that the manner of practising medicine will be little short of revolutionised. Some academics, however, are more cautious and maintain that the applications in clinical practice, at least where therapy is concerned, amount for the time being more to promises than to achievements and, in any event, the extent of the revolution should not be overemphasised, because, for example, it will not have an appreciable impact on the way in which the most common diseases are diagnosed and treated, since the correlation between the genotype and the phenotype is in this case very slight and there is nothing to be gained by employing genetics on a massive scale².

Only the future course of research will determine who is right. What we have to do in the mean time is consider the problems that we must address and resolve in order to be able to deal as effectively as possible, in other words in a way that will benefit human health, with what scientific research is offering us. The current debate covers a very broad spectrum of topics which obviously cannot be discussed in detail in this document. However, the public rules most suitable to govern this area of biomedical research are undoubtedly one of the questions that the temporary committee will be seeking to answer.

Both the scientific community and the public at large are insisting that the sector has to supply clear and accurate information about its activities. This is the philosophy underlying the work of the high-level working party on the life sciences and the European Group on Ethics in Science and New Technologies, which has been set up within the Commission. Parliament's Temporary Committee on Human Genetics wishes to contribute to the debate.

III. A working method in support of an 'integrated approach' to promote a new relationship between science and society

As science and technology are forging ahead in the field of human genetics, the economic, financial, and commercial interests are growing to ever huger proportions, and fundamental values and principles of civil society are being called into question. The developments are such that researchers, political authorities, economic and industrial decision-making bodies, and citizens have to find new solutions to new problems. It is thus becoming apparent that science, technology, and society need to establish a new relationship.

¹ See paper by Prof. Demetrio Neri – temporary committee meeting of 26 April 2001.

² cf. for example N.A. Holtzman and T.M. Marteau, 'Will Genetics revolutionize Medicine?', *The New England Journal of Medicine*, vol. 343, No 2, 2000, pp. 141-144.

Human genetics in particular raises quite a few conflicts of interest, and the temporary committee has thought it best to adopt a kind of 'integrated approach' in order to obtain the views of those working in the different fields, each of which is tackling the same problems from its own perspective. The committee's working method is accordingly based on:

- hearings of experts,
- contact with the public via its Internet site¹,
- meetings with representatives of the national parliaments of the Member States and the applicant countries,
- discussion with representatives of civil society.

Other than at its first two meetings, at which the main speakers were two representatives of the European Group on Ethics in Science and New Technologies and the high-level working party on the life sciences² and three patients' association representatives, the committee has heard contributions from medical, legal, and ethics experts on the specific subjects dealt with in each instance, the aim being to gather the material needed to achieve a balanced view. The experts were chosen in the light of their specialist fields and, in particular, the need to strike a balance among the cases which they have been putting forward³. The meeting with representatives of the appropriate committees in the national parliaments of the Member States and the applicant countries⁴, and the meeting with civil society, have served only to complete and hence enhance the overall picture of a subject which, because it 'cuts across' divisions and boundaries, affects different walks of our society.

The responsibility for tackling the issues raised by human genetics thus falls to civil society, the national authorities, and in some cases the European Union. The Union can help to foster the debate now under way by seeking to understand the various cultural, national, and religious sensibilities. The 'integrated' working approach is consequently intended to promote an 'interactive dialogue' with end users and social forces – patients, ethics experts, institutions, and the public at large – to enable socially responsible decisions to be taken and secure the acceptance of public opinion.

The discussion must therefore be broadened out to encompass, on an equal footing, all sectors in which the implications are important. It is also vital for the Commission to cut across the divides in its approach because the various areas likely to be affected are linked in an interdependent relationship. The approach must of necessity involve the Research DG (Directorate-General), the Internal Market DG, and the Health and Social Affairs DG. In theory, the External Trade DG might likewise have a role to play because many of the questions which we are raising in Europe will have to be dealt with in the World Trade Organisation, in particular the key issue of intellectual property and also the safety and movement of research material, which is increasingly taking the form of products or parts of the human body (if only stem cells)⁵. The Telecommunications DG too should be involved simply because biotechnologies

¹ Site address: <http://www.europarl/genetics/default.htm>.

² See papers read at the temporary committee meetings of 30 January and 13 February 2001.

³ See attached work programme.

⁴ The proposal for a decision concerning the sixth framework programme includes an important provision entitling the applicant countries to play a full part in the programme activities by virtue of their associated country status (Article 6).

⁵ See paper read by Mrs Lenoir at the temporary committee meeting of 30 January 2001.

and genetics use the information technologies and robotics applications required for the purpose of genome sequencing. Finally, the departments responsible for human rights must have their say because the relevant provisions of the Charter of fundamental rights are very clear cut.

The ethical problem underlying the discussions on human genetics is this: how can the conflicts of interest be resolved? How can human health and hence a better quality of life, the starting-point for scientific advances in human genetics, be married with other aims such as the safety of patients and future generations?

The rapporteur regards the temporary committee's work as a means of fostering the debate in Europe, the ultimate goal being to reach a position that can be accepted by individuals with widely differing sensibilities and callings. It may be necessary to make concessions to deeply held personal beliefs when attempting to see what can be done in Europe, bearing in mind the prevailing pluralism which now lies at the foundations of Europe's development and is destined to become more marked once the forthcoming enlargement has been completed. The way to proceed is to set out a position which allows for this diversity rather than reproducing the various sensibilities expressed, for which the most appropriate place is national law. The Member States and the Union must seek to establish the conditions required for human genetics to prosper and determine when Europe should act. The committee should accordingly carry out its brief of identifying the legal, ethical, social, and economic consequences, without overstepping the Union's specific powers and responsibilities.

IV. Powers and responsibilities of the EU in the field of human genetics

The Union has no direct legislative powers where human genetics is concerned. None of the provisions of the Treaty refers explicitly to human genetics and new medical technologies. Under some articles, however, measures related to this field could be taken and indeed have been taken in the past. To put it more specifically, if a Community act is to be adopted to govern matters relating to human genetics or new medical technologies, its aim and substance must meet the criteria laid down in the Treaty article constituting its legal basis.

There are three areas in which the Community is empowered to act, namely:

- *public health* (Article 152 TEC)
- *research* (Articles 163 to 173 TEC, especially as regards funding of the research framework programme)

In both these cases the Community may act to encourage or fill the gaps in measures undertaken by the Member States;

- *the internal market* (Article 95 TEC¹, whereby the Community may act with a view to establishing the internal market and enabling it to operate and, without exceeding those limits, adopt measures affecting aspects of human genetics and new medical technologies).

Two directives are highly significant for the field concerned:

¹ The Court ruling of 5 October 2000 on advertising of tobacco products points out that Article 95 also applies where health is concerned, notwithstanding Article 152(4)(c).

- the October 1995 Directive 95/46/EC on the protection of individuals with regard to the processing of personal data and on the free movement of such data;
- the July 1998 Directive 98/44/EC on the legal protection of biotechnological inventions.

Provisions of the Treaty regarding public health

As far as public health is concerned, Article 152 TEC stipulates that Community action should complement national policies¹. The Community does not have exclusive responsibility for this area, but is called upon merely to '*encourage*' cooperation among the Member States and '*lend support*' to their action². Given that the Community's powers and responsibilities are complementary to those of the Member States, every form of Community action has to comply with the subsidiarity principle laid down in Article 5 TEC.

Article 152 allows incentive measures designed to protect and improve human health to be adopted under the codecision procedure. Harmonisation of national laws and regulations is, however, expressly prohibited. Article 152 also provides for the power, again under the codecision procedure, to set '*high standards of quality and safety of organs and substances of human origin, blood and blood derivatives*'. In this case the Treaty does not rule out the possibility of harmonisation. Nevertheless, the power in question is still one which stands in a complementary relationship to the powers of the Member States. The last paragraph of Article 152 limits its scope by stipulating that the measures concerned '*shall not affect national provisions on the donation or medical use of organs and blood*'.

In addition to the above measures to be taken under the codecision procedure, Article 152 states that the Council may adopt recommendations by a qualified majority without being required to consult Parliament.

Provisions of the Treaty on research

Title XVIII of the EC Treaty (Articles 163 to 173) deals with research and technological development. This is not an area falling within the Community's exclusive sphere of responsibility, and Community activities are thus intended to '*complement*' the activities carried out in the Member States. In accordance with Article 163, the Community must '*encourage*' undertakings, research centres, and universities in their research efforts and '*support*' cooperation among these bodies.

To that end, the Treaty calls for research framework programmes to be adopted under the codecision procedure. These programmes must be implemented by means of specific programmes adopted by the Council after consulting Parliament.

More specifically as regards human genetics, one of the key actions under the fifth framework programme³, adopted for the period from 1998 to 2002, is '*Research into genomes and diseases of genetic origin*', with reference to '*new technologies*', the object of which is to enable the

¹ As well as being covered by Article 152, which relates specifically to Community powers and responsibilities in the health sphere, the goal of health protection must also be taken into account under other Community policies such as consumer protection policy (Article 153(1)) or environmental policy (Article 174(1)).

² Opinion of the EP Legal Service on Community competences in the field of genetics – April 2001.

³ Decision No 182/1999/EC, OJ L 26, 1.2.1999, p. 46.

information contained in the genome to be exploited for the benefit of health, industry, and the environment in all parts of Europe.

The framework programme also covers *'the study of problems relating to biomedical ethics and bioethics'* and stipulates that *'No research activity which modifies or is intended to modify the genetic heritage of human beings by alteration of germ cells or acting at any other stage in embryonic development and which can make such alteration heritable will be carried out under the present framework programme'*.

Consequently, and even though the Community legislator has no direct exclusive power to adopt regulations or directives on human genetics, the Community can exercise its research responsibilities to lay down certain criteria to be observed for related activities to be financed under the framework programme.

The Commission has recently submitted its proposal for a decision on the 2002-2006 framework programme¹. The priority fields include research work based on human genome analysis to help develop new diagnostic tools.

Recital 11 of the proposal, which is to be adopted under the codecision procedure, states that research activities under the programme must be carried out in accordance with fundamental ethical principles, especially those set out in the Charter of fundamental rights.

The Charter of fundamental rights, indeed, prohibits eugenic practices, in particular those aiming at the selection of persons, and cloning of human beings for reproductive purposes. It is also forbidden under the Charter to make the human body and its parts as such a source of financial gain (see Article 3, 'Right to the integrity of the person').

Provisions of the Treaty on the internal market

In accordance with Article 95(1) TEC, measures may be adopted under the codecision procedure *'for the approximation of the provisions laid down by law, regulation or administrative action in Member States which have as their object the establishment and functioning of the internal market'*.

What is involved in this instance is a genuine power enabling the Community not just to encourage and complement action by the Member States, but also to legislate. Under this provision, regulations or directives can be adopted on matters covered by the remit of the Temporary Committee on Human Genetics and Other New Technologies in Modern Medicine, provided, of course, that they have some bearing on the operation of the internal market.

If the Community is to avail itself of the power provided for in Article 95, the purpose and substance of the act in question must indeed be *'the establishment and functioning of the internal market'*. Subject to that proviso, there is nothing to prevent the regulation or directive from dealing with matters relating, for example, to health.

¹ COM(2001) 94 of 21 February 2001.

However, as the Court of Justice has pointed out, Article 95 cannot be used to circumvent the ban on harmonisation laid down in Article 152(4)(c)¹. According to the Court, the measures referred to in Article 95(1) are intended to improve the conditions under which the internal market is established and operates. *‘To interpret this article to mean that it gives the Community legislator general competence to regulate the internal market would be not only contrary to the very wording of the provisions, but also incompatible with the principle sanctioned in Article 3 B of the EC Treaty (now Article 5) according to which the Community’s competences are empowering competencies’*.

It follows that, even though they may not relate to matters falling within the remit of the Temporary Committee on Human Genetics and Other New Technologies in Modern Medicine, acts adopted under Article 95 must be intended to make tangible improvements to the operating conditions of the internal market in a given sector. The discrepancies in the national provisions applicable must not create barriers to trade between Member States and distort competition, thereby impeding the operation of the internal market.

Some examples that might be mentioned in this connection are the Directive on *in vitro* diagnostic medical devices² and the Directive on medical devices incorporating stable derivatives of human blood or human plasma³, both of which were adopted under Article 95.

On the other hand, Directive 98/44/EC on the legal protection of biotechnological inventions⁴, also adopted under Article 95, is currently the subject of an action brought before the Court of Justice by the Netherlands, which, among other things, is challenging what it considers to be the wrong choice of legal basis.

In addition, in its opinion No 13 of 30 July 1999 the European Group on Ethics in Science and New Technologies (EGE), explored the *‘ethical issues of health care in the information society’*, citing, among other reference points, Directive 95/46/EC on data protection, again adopted under Article 95⁵. The EGE notes that there is as yet no specific European legislation on the protection of health-related personal data and recommends that a directive be *‘studied in order to take account of the implications of the computerisation of these data’*. Moreover, Article 21 of the Charter of fundamental rights, on non-discrimination, has banned discrimination on account of *‘genetic features’*.

¹ Judgment of 5 October 2000 in Case C-376/98: Germany v the EP and the Council, point 79.

² Directive 98/79/EC of the EP and of the Council of 27 October 1998, OJ L 331, 7.12.1998, p. 1.

³ Directive 2000/70/EC of the EP and of the Council of 16 November 2000, OJ L 313, 13.12.2000, p. 22.

⁴ OJ L 213, 30.7.1998, p. 13.

⁵ OJ L 281, 23.11.1995, p. 31.

V. International and European legal instruments

Many of the fundamental values and principles involved in human genetics are already recognised at world level. This fact does not mean that political authorities should not continue to consider the value of and possible need for new legal instruments to deal with new kinds of problems or call for international conventions and national legislation to be brought into greater synergy. The former, together with European legislation, are certain to have a significant impact on the governance decisions of the Union Member States.

The United Nations Educational, Scientific, and Cultural Organisation (Unesco), the World Health Organisation (WHO), the Council of Europe, and the European Union have various instruments to call upon. The Union, by adopting the Charter of fundamental rights, has taken a first step to lay down Europe-wide ethical guidelines. In general, what all the declarations have in common is a total commitment to respect the principles of human dignity, freedom of the individual, informed consent, and confidentiality in the application of human genetics to medical practice. The relevant articles of the main international legal instruments in force are listed on the following pages. Instead of listing them according to the international organisation in question, the rapporteur has thought fit to classify them on the basis of the criteria which, among other things, are discussed in this document¹, namely:

- the inviolability of human dignity
- freedom of research
- protection of public health
- non-discrimination on account of genetic features
- protection of personal data
- procedures performed on the human genome
- no financial gains
- intellectual property and patentability.

¹ For the text of the articles mentioned in the table below, see Annex II.

International and European legal instruments

Table of international and European legal texts on human genetics and the relevant aspects covered		RELEVANT ASPECTS							
		Respect for human dignity	Freedom of research	Protection of public health	Non-discrimination on account of genetic features	Protection of personal data	Procedures performed on the human genome	No financial gains	Intellectual property and patentability
United Nations and specialised agencies	United Nations Convention on Biological Diversity (1992)	/	/	/	/	Article 15(5)	/	/	Article 16(2)(3)(4)(5)
	Universal Declaration on the Human Genome – Unesco (1997)	Articles 1, 2, 10	Articles 12, 13, 17	Article 12(b)	Article 6	Articles 5(b), 7	Article 11	Article 4	/
	Resolution on the ethical, scientific, and social implications of cloning for human health – WHO (1998)	/	/	/	/	/	§1, §2	/	/
World Trade Organisation (WTO)	Agreement on Trade-Related Aspects of Intellectual Property Rights (1995)	/	/	/	/	/	/	/	Articles 7, 27(1)(2)(3)
Council of Europe (CE)	Convention on Human Rights and Biomedicine (1997)	Article 2	Articles 15, 18	Articles 3, 12	Article 11	Article 5	Article 13	Article 21	/
	Additional Protocol to the Convention on Human Rights and Biomedicine (1998)	/	/	/	/	/	Article 1	/	/

Table of international and European legal texts on human genetics and the relevant aspects covered		RELEVANT ASPECTS							
		Respect for human dignity	Freedom of research	Protection of public health	Non-discrimination account of genetic features	Protection of personal data	Procedures performed on the human genome	No financial gains	Intellectual property and patentability
European Union – primary legislation	Treaties establishing the EU (1997)	Article 6 TEU	Articles 163 to 173 TEC	Articles 95, 152 TEC	/	/	/	/	/
	EU Charter of fundamental rights (2000)	Article 1	Article 13	Article 35	Article 21	Article 8	Article 3	Article 3(2)	/
European Union – secondary legislation	Directive 95/46/EC the protection of individuals with regard to the processing of personal data and on the free movement of such data	/	/	/	/	Articles 7(a), 8	/	/	/
	Directive 98/44/EC on the legal protection of biotechnological inventions	/	/	/	/	/	/	/	Articles 5, 6
	Fifth Community framework programme for research, technological development and demonstration activities (1998 to 2002)	Article 7	Annex II, theme 1(b), note 1	/	/	/	/	/	/
	Council Decision (1999/167/EC) of 25 January 1999 adopting a specific programme for research, technological development and demonstration on quality of life and management of living resources (1998 to 2002)	/	/	/	/	/	Annex II, note 1	/	/

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VI. Work programme

Human genetics plays an important role in a number of diseases. If the genes were properly understood, new treatments could be developed, and medicines ‘designed’ to be used for specific cells in specific individuals. Genetic diagnosis is already used to determine whether a person has a predisposition to particular diseases. Gene therapy, in which a defective gene is replaced with a healthy one, is being developed; scientists are working to find a way of successfully introducing a correcting cell or cells.

The temporary committee’s work programme has been focusing on two aspects. On the one hand, the committee has been seeking to comprehend the potential medical applications of human genetics for the diagnosis and treatment of certain diseases. Secondly, it has been attempting to identify the consequences that might ensue from such applications, the use of genetic information, and the patentability of living matter.

VI.1. Genetic tests

Many tests have already been developed to identify or confirm rare genetic diseases. However, whereas until a few years ago there were only a handful of genetic tests for a small number of hereditary diseases, today, as a result of the impetus provided by academic and commercial laboratories, there are tests for cystic fibrosis, Huntington’s chorea, muscular dystrophy, and, moreover, a great many non-hereditary degenerative diseases – the symptoms of which can appear in youth or adulthood – such as, for example, diabetes, cancer, cardiovascular diseases, high blood pressure, and Alzheimer’s disease. Genetic tests give incontestable prognoses where some diseases are concerned but in many other cases reveal no more than a predisposition that can be influenced by external factors such as environment, diet, and lifestyle. Genetic tests can be carried out for various purposes:

- *postnatal diagnostics* is used to diagnose a disease, determine the probability that an infant will develop a given disease, the onset of which does not occur until later in life, and detect genetic alterations that increase the predisposition to some illnesses such as certain tumours and cardiovascular disorders;
- *antenatal diagnostics* is used to diagnose a genetic disease or condition in a foetus;
- *preimplant diagnostics*¹, an alternative to antenatal diagnosis, is used to diagnose a genetic disease or condition in an embryo before it is implanted in the uterus (it is an application of *in vitro* insemination).

¹ Preimplant genetic diagnostics

Embryonal chromosome analysis using the technique of **preimplant genetic diagnosis (PGD)** makes it possible to ensure that embryos will not be implanted if they have abnormal chromosomes and cannot survive. PGD enables selected, i.e. undeformed, embryos to be implanted and avoids the abortions that might otherwise follow a conventional antenatal diagnosis at an advanced stage of pregnancy (after the third month in the case of amniocentesis). It offers an alternative to the normal antenatal diagnosis methods, especially in cases where parents are at high risk of having a child with severe genetic diseases. It can be used to detect many single-gene disorders. Data and reports relating to the findings of PGD are compiled at world level. The PGD Consortium, a body which works in collaboration with the European Society of Human Reproduction and Embryology (ESHRE), published the most recent findings last summer. Over 200 babies have been born with the aid of this technique (see papers read by Professors Devroy and Hovatta at the temporary committee meeting of 27 March 2001).

PGD has undoubted advantages over conventional antenatal diagnostic techniques, in which diagnosis is carried

Part of the discussion has revolved around antenatal techniques, especially the effective methods for treating infertility (*in vitro* fertilisation (IVF)¹ and intracytoplasmic sperm injection)².

VI.1.1. Ethical and social implications of genetic tests

Principle of scientific freedom and patients' rights

The medical profession was the first to regulate itself by laying down a code of ethics. One of the foremost core values in doctors' established ethical tradition is freedom. There is also, however, a system of rules, that is to say a common scientific 'ethos' observed by scientists, which enshrines the independence of 'scientific truth' in relation to political, religious, and cultural ideologies. But can a scientist today simply invoke the principle of freedom and a sense of responsibility in order to operate within a scenario in which the prospects are as fascinating as they are disquieting? Scientists are morally implicated in the choices to be made by a wide range of unlike individuals. That is why it is necessary to pave the way for a debate to help interpret the great changes taking place in the biomedical sphere, assess the possibilities which they offer, and define the limits to be imposed on them. The principle of scientific freedom must consequently itself be based on key considerations essential for patients, for example:

- the voluntary and informed consent of the person undergoing tests,
- freedom and responsibility of patient choice in the face of social pressures,
- the priority of the rights of the individual over the rights of society,

out in about the third month of gestation, whereas PGD enables an eight-cell embryo to be analysed when it is as little as three days old. Conventional techniques require samples consisting of many cells, whereas in PGD the diagnosis can be confined to just a few (from one to three). Furthermore, the findings resulting from conventional techniques are not known until a couple of weeks after the tests, whereas the findings of PGD are available within about two days (see paper read by Prof. Devroy at the temporary committee meeting of 27 March 2001).

Merely from the above description of the technique it is plain to see that PGD entails different ethical implications from conventional diagnostic techniques for a couple who decide to have an abortion in the light of the diagnosis. PGD methods have prompted disquiet on account of the possibility that people might want 'made to measure' children with particular traits such as intelligence or a gift for music. However, leaving aside the possible objection that ethics has yet to address these questions, it is technically completely impossible to identify such characteristics in embryos (see paper read by Prof. Hovatta on 27 March 2001).

¹ In vitro fertilisation

The development of *in vitro* fertilisation (IVF) has marked a revolution for couples who want children but cannot have them in the normal way. In IVF, ova are removed from a woman's ovaries after hormone treatment, by means of an ultrasonically guided suction technique using a fine needle inserted through the vagina. The spermatozoa, prepared after being removed from the semen, are placed on culture plates together with the ova, and fertilisation is monitored in the laboratory. When the procedure produces more than one or two normally fertilised embryos of normal appearance, they cannot all be implanted in the uterus without risk of superfetation. The surplus embryos can be frozen to be used in a future infertility treatment, donated for research or to other childless couples, or discarded (see paper read by Prof. Hovatta on 27 March 2001).

² Intracytoplasmic sperm injection

The technique of intracytoplasmic sperm injection has brought about a significant change in the treatment of male infertility over the past ten years. The spermatozoon is injected directly under a microscope into the cytoplasm of an ovum, using a fine glass needle. Traditional ways of treating male infertility are confined to a few cases involving clear-cut problems linked to hormone production, and to reversible vasectomy. However,

- an individual's right to know/not to know¹.

Social consequences: a new doctor-patient relationship

Medical technological applications and genetic tests in particular have changed the way in which medicine is practised, creating new dilemmas every day, the implications of which are no longer merely individual and private, but also public and social. This applies especially to the concepts of health, sickness, and normality, and to the social roles of doctors and patients. Today's doctors are having to face quite unprecedented problems and decisions. It is not just their role which has changed, but also the role of patients, and new rights have consequently come into being. Respect for a sick person's wishes is firmly underpinned by the principle of freedom and self-determination.

Medicine is no longer regarded purely as a reaction to a disease (reactive medicine), but as a practice making it possible to act in advance and manage 'health capital' rationally. The new concept of medicine has to do with genetic information that does not affect an individual immediately, but rather can help to prevent probable or possible future diseases (predictive medicine). According to this revolutionary new definition of medicine, a patient is expected to absorb and utilise information about his or her genetic predisposition to a given disease and take decisions, even though the intention might not be to treat the potential disease as such².

The new definition of medicine implies that the role of a doctor has to change from one of a therapist to that of health counsellor and that, instead of being a suffering person, the position of a patient is one of a worried person anxious to cope with his or her health prognosis. It has consequently been said that the 'sick person-healthy person' pair of opposites has been expanded to include a third element, the 'worried' person.

Tests and genetic discrimination

The advantages of genetic tests apply essentially to a person's predisposition to contract a given disease and hence to the way of dealing with the disease before symptoms appear. The disadvantages of the tests lie in the fact that genetic information can be used to practise discrimination in various walks of life, often on the basis of mere probability but not absolute certainty. The question *who has the right to use* the information will become increasingly more crucial.

when childlessness is due to the infertility of the male partner, for whatever reason, the problem can now be treated by intracytoplasmic sperm injection if even just a few spermatozoa or immature postmeiotic sperm cells can be obtained from the semen or by aspiration or testicular biopsy (when patients have no spermatozoa in their semen). In Europe, the most attempts to use this form of treatment have been made in women in the Nordic countries. In Finland 3% and in Sweden 2% of all babies are born as a result of assisted reproduction. The difference between the two countries is due to the different systems of reimbursement. However, IVF and intracytoplasmic sperm injection are not just being used in the developed countries. There are now specially equipped clinics in all parts of the world. It has been estimated that some two million babies in the world have been born after IVF (see paper by Prof. Hovatta).

¹ The right to know means the right to be informed about one's genetic condition and receive reliable genetic information; the right not to know means the right not to be forced to undergo genetic tests or learn of one's genetic information, especially in cases where prior knowledge of a disease could provide a foretaste of suffering with no practical therapeutic advantages.

² See paper by Prof. Mauron – temporary committee meeting of 26 March 2001.

It is feared that insurance companies and employers might refuse to insure or employ people on account of genetic information. Access to such information needs to be discussed further to enable proper rules to be laid down.

Article 12 of the Council of Europe Convention on Human Rights and Biomedicine states that: ‘Tests which are predictive of genetic diseases or which serve either to identify the subject as a carrier of a gene responsible for a disease ... may be performed only for health purposes or for scientific research linked to health purposes, and subject to appropriate genetic counselling’. The CE Committee of Ministers is drawing up a protocol on human genetics with a view to enlarging on Articles 11 and 12 of the Convention¹. The protocol should deal in detail with matters relating to informed patient consent, the conditions for performing tests on persons under age, respect for privacy, the right to have access to test results, and the right not to be informed of findings. The EP could assist in this work by putting forward points to consider when drawing up the protocol.

It can easily be inferred from the points made above, and not just those points, that genetic tests may have a profound impact on people’s lives. They can increase their freedom and their ability to make choices with full knowledge of the facts, not least where having children is concerned. However, if the advantages of genetic testing are to be understood, three equally important conditions need to be satisfied:

- reliable tests available on the same basis to all,
- counselling that respects individual freedom,
- technology.

High standards for genetic tests thus appear to be a *sine qua non* because decisions having a crucial bearing on people’s lives are taken in the light of the results. Unless they are governed by clear-cut legislation, uncontrolled use of genetic tests could create a number of ethical problems. The rules ought perhaps to specify that genetic tests should be carried out only when the genetic condition that they serve to detect can be corrected by therapy or preventive treatment or when the genetic information obtained affects decisions to have children.

Questions raised

- Are antenatal diagnosis tests offered to a couple in a social context free of pressure?
- Can parents have antenatal examinations or must they have them? What results could entitle them to take corrective measures? What results could justify a decision not to give birth?
- Are there professional ‘genetic counsellors’ to assist those who agree to undergo genetic tests?
- Is there a danger that people might be relegated to a genetic ‘underclass’ and consequently denied proper health care and life assurance once they had been diagnosed with a predisposition to a disease occurring later in life?
- Under what conditions is an insurance company entitled to know the findings of genetic testing?
- Do employers, companies, universities, or schools have the right to select their employees or students on the basis of considerations linked to genetic code examination?

¹ See paper by Prof. Serrão – temporary committee meeting of 26 March 2001.

- Does a person have the right to divulge genetic information about another person? (If an individual is known to be a healthy carrier of a severe genetic disorder that would genetically endanger any offspring, do we have a duty to inform his or her partner? Furthermore, do we have a duty to prevent that person having children?)
- Does anyone have the right, in certain cases, to request that information about his or her genome be treated as confidential? If so, when?
- Given that it seems increasingly to be the case that genetic tests are available only to those who can afford them, should public health authorities cover all or part of the cost?
- Genetic tests on embryos before they are implanted in the uterus might reduce the risk of anomalies, but could they entail far-reaching social consequences (eugenics)¹?

VI.1.2. Legal and regulatory implications of genetic testing

Genetic diagnosis is a medical procedure that must invariably conform to the rules of ‘good clinical practice’. As the new biomedical developments progress, so must an international frame of reference, recognised at world level, for scientific and technological procedures, including guidelines on good laboratory, clinical, and industrial practice tailored to the latest biomedical trends, be validated and adopted throughout Europe in order guide and regulate them. Some first steps towards harmonisation of regulatory requirements have been taken, for instance where gene and cell therapy is concerned, since the European Agency for the Evaluation of Medicinal Products has drawn up guidelines for good practice. However, there is still no frame of reference and system of rules to govern new fields such as tissue engineering, artificial organs, and genetic testing².

The Directive adopted on clinical trials³, which lays down provisions for implementing ‘good clinical practice’ – defined as ‘an international ethical and scientific quality standard for designing, conducting, recording and reporting trials that involve the participation of human subjects’ – constitutes a first element of harmonised regulation of biomedical research and development.

Genetic testing is an example in point which shows how much regulation needs to be harmonised on the basis of quality assessment in order to provide a framework for biomedical research and development⁴. At present there are no common European rules and regulations to guarantee that the services provided will conform to a minimum standard. Genetic testing services are not covered by Council Regulation (EEC) No 2309/93 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use or Directive 98/79/EC on *in vitro* diagnostic medical devices⁵, which applies only to products to be marketed.

¹ See papers by Dr Haker and Mrs Quintavalle – temporary committee meeting of 27 March 2001.

² Commission note on ‘Human genetics’, Research DG, Directorate E (Policy aspects).

³ European Parliament and Council Directive on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use.

⁴ Report on the seminar entitled ‘*Genetic testing services: Quality Assurance and Need for Harmonisation in the EU*’, European Commission, Joint Research Centre (2000).

⁵ Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on *in vitro* diagnostic medical devices.

Genetic testing procedures are becoming increasingly common, since tests are carried out not only in specialised hospitals, but also in testing laboratories and to some extent are offered directly to patients. In Europe the number of laboratories performing genetic testing services is rising. Although genetics specialists and professional organisations have made many moves to promote quality assessment, genetic testing services are provided under widely varying conditions and systems of rules. The problems as regards consumer protection are highlighted by the results of a quality test conducted at 136 laboratories in 21 European countries and Australia involved in genetic testing for cystic fibrosis. In 35% of the laboratories the percentage of errors recorded in genetic tests would be considered unacceptable for the purposes of routine examinations¹.

Similarly, the European molecular genetics quality network² has recently published the results of a quality assessment programme relating to molecular diagnosis of Huntington's chorea. The programme has shown that there is some possibility of misdiagnosis by the laboratories offering this type of molecular diagnosis³.

Because research into genetic mutation is so complex, only a few laboratories are in a position to supply an appropriate test for certain diseases, whereas most European countries have at least one laboratory to deal with the more common diseases. It is thus highly unlikely that the costs of a laboratory test which a family might wish to have carried out will be reimbursable under the national health insurance scheme or by the hospital concerned. To avoid this difficulty, a network of European laboratories, covering the different diseases and genes, should be set up to meet the needs of European patients' families. The goal is one that cannot be attained by the Member States individually, but must be translated into reality at Community level⁴.

VI.2. Care approaches to genetic diseases: treatments (therapy and medicine)

VI.2.1. Gene therapy

Gene therapy is designed to correct anomalous gene function. It is termed somatic gene therapy when it is used on body cells (blood, organs, etc.) – the main applications are in oncology, cardiovascular medicine, and the treatment of genetic diseases – and the genes inserted will not be passed on to succeeding generations. It is termed germinal gene therapy when it is practised on reproductive cells (oocytes and spermatozoa) or embryos. In this case the change will be passed on to offspring.

VI.2.2. Genetic medicine

Unlike gene therapy, genetic medicine does not act upon or permanently alter cell functions⁵. Most of the new medicines are aimed at more easily reachable targets, generally proteins and enzymes on the surface of a cell or in its cytoplasm. They will be more efficacious but have

¹ European Commission, 4th FP, BIOMED 2, Dequeker and Cassiman, Eur. J. Hum. Genet., 1998, pp. 165-175.

² Supported by the Research DG, Directorate H, measurement and testing programme (SMT4-CT98-7515).

³ Loosekoot and others, Eur. J. Hum. Genet., 1999.

⁴ See paper by Prof. Mandel – temporary committee meeting of 26 March 2001.

⁵ See Commission note on 'Human Genetics', Research DG, Directorate E (Policy aspects).

less potent side effects and will act on the body in a much more selective way. Doses will be personalised on the basis of pharmacogenetic tests¹. Backed by knowledge of the patient's predispositions, these medicines will prevent the disease rather than curing the symptoms.

(a) Medicines obtained from transgenic animals

One way to produce human proteins for the new medicines is to breed 'transgenic animals', which carry human genes and therefore produce a protein, for instance in their milk, which can be used to treat humans. Many protein-producing transgenic animals have already been bred in various laboratories in all parts of the world. The animals used most often in the experiments are goats, along with sheep, pigs, and cattle. The problem with the use of animals, however, is that many of the animals treated fail to accept the modified gene and consequently do not express the human protein. Similarly, only some of a transgenic animal's offspring inherit the ability to produce the protein. That is why work is under way to clone transgenic animals so as to ensure that the only animals produced are those with the required qualities².

(b) Tissue and organ transplants

Internationally, organs for transplants are in permanently short supply. There is no reason to suppose that the public are becoming used to the idea of donating organs. If anything, the reverse is true. Taking organs from dead donors has posed the medical, ethical, and legal problem of establishing death and obtaining permission to remove the organs. The principle which appears to hold good where removal is concerned is that of presumed consent or assenting silence. In 1978 the Council of Europe called for the legislation governing organ removal and transplants to be harmonised. The World Health Organisation has followed suit. The legislative position, however, varies widely. The demand for organs rises as transplant technologies develop. At present 50 000 Europeans are on the waiting lists for new organs, and the lists grow 15% longer every year. That is why huge sums are being spent and immense efforts made to obtain organs by other means. Research is focusing on two areas in particular, namely *xenotransplantation and tissue and organ engineering, including the use of stem cells for therapeutic purposes*.

Xenotransplantation using transgenic animals

Xenotransplantation means the transplant of an animal organ into a human being. Because transplant waiting lists are so long, researchers have been endeavouring for years to find new sources of organs other than artificial organs. An attempt is being made to genetically engineer organs of transgenic pigs (with the proper genetic make-up) suitable for xenotransplantation into humans. However, there are two major problems to resolve. Firstly,

¹ See section on pharmacogenetics below.

² As regards genetic modification and cloning of (farm) animals, some scientists favour a 'NO, unless' approach. It is not considered ethically responsible to modify animals genetically with the aim of increasing (the efficiency of) animal production. However, when genetic modification and/or cloning offer *the only realistic possibility* for treating *patients suffering from incurable diseases for which there is as yet no (adequate) treatment*, they can, subject to certain conditions, be considered ethically acceptable (see paper by Prof. Jochensem – meeting of 26 April 2001).

immunological incompatibility is still a big obstacle in that it causes rejection of the pig's organs. From the epidemiological point of view, there could also be a risk of introducing viruses into the human body. Many people therefore believe that the way to remedy the shortage is to grow organs from human cells.

Use of stem cells for therapeutic purposes

The destruction of the tissue structure of an organ, associated with the death of the cells of which it is composed, is the root cause of most diseases affecting the population of the industrialised countries. A resolvent therapeutic approach aims to reconstruct the damaged tissue by transplanting new cells to replace those destroyed or altered by the illness. At clinical level this therapeutic strategy is based in most cases on the transplant of organs from a dead donor or, more rarely, one who is still alive¹. Unfortunately, this life-saving technique suffers from two fundamental limitations which make it impossible to apply to most of the patients who could benefit from it, namely the shortage of transplant organs and the need for continuous immunosuppression to prevent rejection of organs. The news that the use of human embryonal stem cells for experimental and therapeutic purposes has been liberalised by the British and US governments has attracted media attention and given rise to various discussions and controversies which have led to confusion between the concept of cloning for therapeutic purposes and the definition of stem cells in general.

The use of stem cells² for therapeutic purposes is becoming established as a potentially revolutionary new method for treating diseases and injuries³. The aim of the therapy is to develop differentiated cells or tissues to be transplanted into patients suffering from conditions such as diabetes, Alzheimer's disease, Parkinson's disease, coronary heart disease, and so forth, for which there are today no effective treatments or cures. Stem cells are present for the entire period of a person's growth, both in children and in adults. However, the proportion of stem cells and their ability to give rise to different types of specific cells decreases over time. Stem cells can be obtained from adult tissues, foetal tissues, cells from the inner mass of the blastocyst, embryos, or cloning by means of nuclear transfer.

One possible source of embryonal stem cells is 'surplus embryos', in other words those no longer required to treat infertility. Another possibility might be to isolate embryonal stem cells from embryos created by nuclear transfer (cloning for therapeutic purposes). These stem cells would have the advantage of being immunologically compatible with the patient. Foetal stem cells can be obtained from foetuses that have been aborted on account of genetic anomalies and from the blood contained in the umbilical cord at the moment of birth. Adult stem cells are isolated from certain tissues used for transplantation such as bone marrow, skin, and blood. One of the constraints associated with the use of adult stem cells is the difficulty of isolating the cells and their weak tendency to differentiate into individual types of cells (recent studies have shown that adult stem cells could have the same capacity to differentiate as other stem cells).

¹ Report of the Committee of Inquiry into the Use of Stem Cells for Therapeutic Purposes, Ministry of Health, Italy.

² For a definition of the different types of stem cells see the European Ethics Group's opinion No 15 of 14 November 2000.

³ See papers read at the temporary committee meeting of 26 April 2001.

One of the problems posed by stem cell transplants is immunological rejection by the recipient. Prevention strategies are based on stem cell banks from which to take a cell line matched with each recipient. In some cases, made to measure embryonal stem cells may also be produced by substituting the nucleus of a somatic cell in a donated ovum using a somatic cell taken from the recipient. The stem cells would have the same immunological structure as the recipient. The research into this procedure has, in essence, been taken into account in the recent changes to the law in the United Kingdom. At this point research has to demonstrate what is the real potential of stem cells, not just embryonal cells, but also those of other types. At all events, embryonal research offers unique prospects for exploring this promising medical field.

The problems regarding the use of the different types of stem cells (and possible differences in their therapeutic efficacy) and the obvious consequences for the quality of life are so substantial that they will greatly influence the current strategic options for State funding of research in most of the industrialised countries. Clearly, the decisions taken could significantly alter health policy in the next decades, and large-scale economic and human resources should therefore be invested in the area of stem cell biology, since its potential therapeutic applications are indeed of considerable interest and could bring about a veritable medical revolution which, in terms of its impact on human health, might even surpass the revolution entailed in the discovery of antibiotics. The ethical assessment to be undertaken relates to the purposes of and methods to be employed in a specific type of research, since the research in question is taking place against the background of a serious moral disagreement. It is widely agreed that the aims of stem cell research are beneficial, according as they do with one of the fundamental goals of medicine, namely to cure human beings as effectively as possible. The disagreement has to do with the fact that some cell lines are taken from embryos and with certain points related to derivation methods, but the purpose of this type of research should be borne in mind because awareness of the appreciable benefits likely to ensure could offer the most appropriate footing on which to reduce the extent of the moral disagreement.

Scientific problems

It is not easy to enable genes be expressed in a constant way once they have been transferred. It is also difficult to transfer genes to a sufficient number of target cells. A gene attaches itself wherever it happens to be, to any point in any chromosome. One of the risks is that it could inactivate a cancer-suppressing gene or activate an oncogene. And the process would not be reversible. A whole range of scientific questions must therefore be resolved before any clinical application can be employed:

- is there a special type of donor cell?
- by what mechanism are somatic cells reprogrammed?
- what mechanism comes into play to synchronise the functioning of a nucleus and the host cytoplasm?
- what are the signals for activating a newly formed embryo?
- what signals are required for the development of such embryos?
- will it be possible to stimulate stem cells to differentiate in the normal way while they are being cultured?
- will the tissue or cells generated be functional and healthy?
- will transplanted cells be able to migrate?

- what is the risk that these cells might turn into tumour cells¹?

(c) Pharmacogenetics

Pharmacogenetics studies how genetic differences influence the variable reactions of individual patients to drugs administered to them². The ultimate goal will be to devise a personalised therapy.

Today we are on the way to obtaining genetic profiles composed of what the jargon calls *snips* (single nucleotide polymorphisms) that will enable doctors to predict how a patient will react to a drug and hence decide whether or not to administer it and, if so, what should be the exact dose. In addition, it may eventually be possible to manufacture and administer made to measure drugs, entailing great benefits, first of all in terms of the therapeutic reaction and because suffering can be reduced and, secondly, in economic terms, both while drugs are being developed (pharmacological trial protocols will be completely transformed once the profiles have been developed) and when they are administered, since patients will not be given drugs that will do them no good and might even do them harm.

What is being described is not the outlook for the distant future. Today there is already a consortium of drug companies, university institutes, and private foundations³ which is completing a databank, accessible to everyone on the Internet, consisting of some 200 000 snips, a figure which will rise to approximately 800 000 within two years. Investment in the sector amounts to tens of millions of dollars, and, to illustrate the level of interest, the US National Institute of Health has recently launched a \$13 million pharmacogenetic project involving a form of public-private partnership⁴. Discussion is taking place because each side needs to overcome its distrust of the other: the private sector fears the bureaucratic inefficiency of public organisations, and public organisations think that the private sector is interested only in profit.

Genetic epidemiology databanks

In some Union Member States genetic epidemiology databanks, financed wholly or in part by public funds, are being planned or developed on a large scale. Provided that they are set up, run, and used in accordance with high ethical standards, these databanks could be valuable research tools that will enable European citizens to exploit the substantial advantages of genetic research, and they will attract further investment in European biomedical science. The potential for publicly funded genetic research databanks is consequently enormous. European health systems constitute a sizeable but underutilised resource that could afford opportunities for epidemiological research and supply studies on the diseases having the greatest impact on the quality of life for European citizens. The Union should therefore start to make a careful assessment of the opportunities being offered by genetics and the value of health-related computer databanks as a research resource.

Promising developments in this area could:

¹ See paper by Prof. Bedate – meeting of 26 April 2001.

² See papers by Prof. Neri and Mr Goodfellow – meeting of 26 April 2001.

³ Cf. A. Roses, 'Pharmacogenetics and Future Drug Development and Delivery', *The Lancet*, vol. 355, 2000, pp. 1358-61, and 'Pharmacogenetics and the Practice of Medicine', *Nature*, vol. 405, 2000, pp- 857-865.

⁴ Editorial, 'The Need for private-public partnerships', *Nature Medicine*, vol. 6, 2000, p. 481.

- provide an alternative to somatic gene therapy for the treatment of genetic diseases,
- improve the efficacy of drugs, since they could be prescribed taking into account individual genetic inheritance,
- enable new drugs to be developed,
- enable drug prescriptions to be personalised.

VI.2.3. Ethical and social implications

Research on embryos

Depending on the Member State concerned, policies towards research on embryos range from an absolute ban in Germany to laws which to some extent permit such research, subject to approval, as in the United Kingdom (see Annex III)¹. The basic argument revolves around the status of the embryo as a living organism with the rights and dignity of a living person. On the one hand, pro-lifers believe that life begins at the moment of conception. Others, however, consider this idea to be untenable because the cells have not yet differentiated and there are potential benefits for persons suffering from diseases. It is common knowledge that opinions are sharply divided about the moral lawfulness of experiments on embryos, the controversy being rooted in different ethically, philosophically, and/or religiously based views, each of which is recognised to be fully legitimate. Given the extent and intensity of the dispute, it is clear that neither the temporary committee or any other committee can undertake the task of settling a quarrel which has arisen on account of anthropological beliefs underpinned by philosophy and/or religion. Every view has its supporters, and it is understood that the mere fact that a given solution has secured a broad consensus does not make that solution more right than the others, nor does it invalidate the other positions. The use of surplus embryos, that is to say, those produced for the purposes of procreation but which, for various reasons, will not be implanted, raises the question whether some of them should be used for research that could result in significant benefits for humanity, especially bearing in mind that the alternative is to let them die. In the face of a dilemma, the best thing to do – apart from doing nothing, which is in any case a choice – is to weigh up the considerations at stake.

Nine Member States have ethics committees, and the others have machinery to deal with ethics. At Community level, the European Group on Ethics in Science and New Technologies has independent status and advises the Commission, the EP, and the Council, for the purposes of Community policies, on ethical values as they relate to scientific and technological developments. Decisions will probably – and rightly – continue to be taken at Member State level, whereas the EU will decide where and how it should direct its research and funding priorities in cases where the Treaty empowers it to act. In addition, proceeding from the premise that research should be expanded, it might be considered acceptable to attain a level of scientific knowledge making it possible to advance to the clinical trial stage. As far as principles are concerned, the consideration militating in favour of this solution might be the principle of beneficialness, which, albeit with different degrees of emphasis, is a common feature of the main moral doctrines, informs the ethics of biomedical research, and gives rise to the duties of responsibility for persons who are suffering. Whatever position

¹ See Annex III, 'Legislation of the Member States relating to research on embryos'.

emerges from the temporary committee, it must stem from a cautious attitude and team spirit seeking to avoid conflict as far as possible and to fully respect the different beliefs held.

Opinion of the European Group on Ethics in Science and New Technologies on stem cell research and use

In an opinion delivered in November 2000 the European Ethics Group stated its views on the ethical aspects of stem cell research and use¹. Interestingly, the matter was considered within a precise frame of reference, in other words from the point of view of Union research and health policy. The general approach proceeds from two considerations:

- the fundamental ethical principles, namely respect for human dignity, individual freedom, justice and beneficence, freedom of research, the proportionality principle, and the precautionary principle;
- pluralism and the variants of ‘European’ ethics: pluralism is inherent in the European Union. It reflects the richness of its traditions and entails an additional need for mutual respect and tolerance. Respect for the different moral, ethical, and cultural approaches is implicit in the ethical dimension of building a Europe-wide democratic society. From a legal perspective, respect for pluralism is in keeping with Article 22 of the Charter of fundamental rights and Article 6 TEU.

The European Ethics Group has recommended that:

- the time is not yet right to create embryos by means of somatic cell nuclear transfer (‘cloning for therapeutic purposes’) to meet the needs of cell therapy research, since there is a vast field of research still to be explored with the aid of other stocks of human stem cells, in other words those obtained from surplus embryos and foetal tissue and adult stem cells;
- a specific Community budget be drawn up to finance research using these alternative sources, in particular adult stem cells;
- steps be taken at European level to ensure that research findings are widely disseminated and not kept secret for commercial reasons (this is linked to the group’s statement that in countries where research on human embryos is permitted, all research activities should be authorised provided that they are subject to close public supervision by a central body – performing the same role as the Human Fertilisation and Embryology Authority in the United Kingdom – without detracting from complete transparency);
- a Community-funded ethical assessment of stem cell research be carried out before projects are launched and while they are being implemented.

Some bioethicists maintain that in the sphere of scientific research and biotechnological applications, any ethical uniformity is a vain hope. In other words, the divergences are ‘intrinsic’ and therefore immovable. The Member States cover a very broad spectrum where the key topics of bioethics are concerned². The rapporteur supports this view, but only in part. Even though it might not have been the desired result, a type of ‘European ethics’ already exists ‘in embryo’, having sprung from the ‘common sentiment’ deriving from the international and European legal sources. Some principles ought perhaps to be reconsidered

¹ See opinion No 15 on ethical aspects of human stem cell research and use (November 2000).

² See paper read by Prof. Caporale at the temporary committee meeting of 26 April 2001.

and adapted to the new developments. The common sentiment has produced an international consensus among politicians and scientists on the two conditions under which human genetic research and treatment may be carried out:

- it should not be permitted to apply gene therapies to ova and spermatozoa (the germ line), since the effects would be passed on to future generations. Treatment will be confined solely to somatic cells which act only on the person treated;
- it should be permitted to use the therapies only to cure serious diseases and not to improve normal human characteristics¹.

Questions raised

- Considering the value which every person attaches to the human embryo and the development of innovative therapies such as nuclear transfer techniques (therapeutic cloning), would it be possible or desirable to impose a single view?
- Having regard to the ‘subsidiarity principle’, what is the best area for collective action enabling citizens’ preferences to be taken into account more accurately?
- Because of the Union system and above all the powers and responsibilities, citizens, who enjoy freedom of movement, will be able to decide freely which body of legislation they wish to observe where bioethical questions are concerned. If standard laws were laid down throughout Union territory, would citizens eventually regard the EU as an intolerable limitation on their identity and not as an opportunity?
- Genuine federalism in the sphere of scientific research and its applications would make it possible to learn from what proved to be the ‘best practices’. Would this be sufficient to contain the looming possibility of out-and-out mass scientific and therapeutic tourism to non-Union countries where research was permitted?
- All technologies entail risks and benefits, but the ‘precautionary principle’ stipulates that theoretical risks should take precedence over proven or expected material benefits. In other words, precaution shifts the burden of proof from the regulator, who used to have to demonstrate that a new technology could cause some form of damage, to the innovator, who must now demonstrate that the new technology is not dangerous. Is this principle, which the European Ethics Group cites as one of the ethical foundations, right for human genetics? Or would it pose obstacles to biomedicine?
- The main argument put forward to challenge the idea that embryos should enjoy absolute protection in the first stages of their development is tolerance of abortion. Can the right to reject a pregnancy be compared, for reasons of principle, to the right of third parties to use embryos? Even allowing for the fact that termination of pregnancy is socially accepted, should it not be considered entirely justified to protect embryos in biomedical research from being exploited, that is to say, for commercial purposes²?
- In view of the technical problems to be resolved, can it be considered sufficient to declare a moratorium on clinical applications of human germ line therapy? Could a ‘stay of judgment’ constitute the ‘golden mean’?
- Is it right to believe in the duty to set standards for now and for all time, for present and future generations?

¹ Cf. the Council of Europe Convention on Human Rights and Biomedicine, the Unesco Declaration on the Human Genome, and the opinions of the European Ethics Group and the national ethics committees.

² See paper by Prof. Kollek – temporary committee meeting of 26 April 2001.

- Some scientists maintain that cloning for therapeutic purposes relies on biological and medical procedures necessary and sufficient to carry out cloning for reproductive purposes¹. If cloning were to be authorised for therapeutic purposes, would that mean that research into cloning for reproductive purposes, which, it is said, should be totally prohibited, would likewise be authorised without restrictions?

VI.3. Avenues to explore for Community action providing value added

What matters, therefore, is to weigh up the risk against the opportunities being opened up by science and to refrain from delaying the advent of useful technologies. Responsibility towards future generations applies not only to the responsibility for doing things, but also to the responsibility for not doing things that theoretically and in practice could be done. The debate on human genetics and its applications is taking shape haphazardly and often does not start until after a ‘product’ has become available. We must take up the challenge of:

- drawing up essential ethical guidelines, the substance of which should be such as to serve as a basis for general assessment of the development and use of human genetics and cover rules seeking to safeguard considerations such as: free and informed consent, assessment of risks in relation to benefits, protection of the health of persons involved in clinical trials, scientific assessment of stem cells for therapeutic uses, the anonymity of donors, management of stem cell banks and their confidentiality, a ban in trade in embryos, and import and export of stem cell products;
- establishing a framework for public discussion on the interpretation of the ethical guidelines with a view to launching a debate on the development and use of genetic engineering before it has been developed and applied on a large scale. Experience shows that interpretation of the guidelines cannot be a matter purely for those called upon to deal with specific cases, for example the authorities and scientists. In a democratic society the logical aim should be to ensure that the decision on the use of genetic information and genetic engineering is widely respected by all walks of society. It is therefore important for the discussion on the use of genetic engineering to be encompassed within a broader democratic public debate;
- encouraging integrated training and education and multilateral information and discussion activities. Multidisciplinary integrated education will meet the urgent need for dialogue among researchers, manufacturers, standard-setters, and social protagonists on new leading-edge technologies at the early stages of development and enable responsible choices to be made and backed up by policies providing support at the right time. Widening the information supplied to the public and the debate on the new developments in the biomedical field will help to consolidate responsible public acceptance.

The rules which society should draw up to govern (which does not mean obstructing or preventing) the changes taking place in the current biological revolution should seek to shape the future so as to avert the risk of having to endure it, whatever it might hold. Whereas fear and ignorance could give rise to counterproductive prohibitions, the inability to reach a ‘shared consensus’, stemming from genuine dialogue among the parties concerned, could

¹ See paper by Prof. Testard – temporary committee meeting of 26 April 2001.

result in a failure to lay down a single frame of reference and the impossibility of adopting public policies.

Especially where genetic tests are concerned, any discussion on the immense medical, legal, psychological, and ethical consequences of an incorrect test result raises questions such as:

- how to guarantee the quality and safety of genetic testing in Europe;
- how to afford equal access to information about the availability, usefulness, and limitations of genetic testing;
- how to ensure respect for the considerations, founded on freedom, which have to be taken into account in medical genetics (voluntary and informed consent, freedom from personal pressures or pressures exerted by society, fostering the ability to take independent decisions, priority of individual rights and interests over collective assets, the right to know and not to know);
- how to provide expert genetic counselling to prevent abuses occurring when genetic testing is incorporated into clinical practice;
- how to promote comprehensive training activities aimed at informing professionals and the public alike about the limitations as well as the risks and advantages of genetic testing, enlisting the assistance of public and private organisations, government sponsored or otherwise, and especially of national ethics committees, which must move closer to citizens and establish channels of communication using existing information technologies;
- how to ensure that society respects genetic differences under the necessary fair safeguard laws;
- how to set up a European laboratory network to cover rare diseases.

Especially where pharmacogenetics is concerned:

- if the outcome of the new biomedical research is to be turned to account in a safe, constructive, and responsible way, it will be essential to establish a harmonised regulatory framework, recognised throughout Europe, giving priority to the interests of the public, health, and research communities, and consisting of clear-cut rules to govern not just the development, but also trials and the approval of new biomedicines. The fact that there is a plethora of divergent, or at any rate not wholly consistent, national rules applying at every stage from development to the clinical trial is recognised to constitute a severe bottleneck making it difficult to develop and test new biomedicines on an EU-wide basis. If the opportunities are exploited to the full, Union citizens will be able to benefit from the significant health advantages of genetic research, and further investment will gravitate towards European science and the pharmaceutical industry, which are having to operate in an increasingly more competitive global context;
- if the public and private sectors work in greater synergy, the best results for everyone can be achieved where pharmacogenetics is concerned. Should that fail to happen, rigid or overcautious public rules may lead to a manifest loss of benefits.

VI.4 Economic implications of human genetics (diagnosis and therapy)

In the 1970s and 1980s countries such as the United Kingdom and the Netherlands regarded fledgling medical genetics as an independent specialist field acting as an interface between the new laboratory-based genetic technologies and their applications. The new specialist sector has adopted a family-oriented approach enabling parents to enjoy the benefits of a conscious

decision to have children and prevention tests for diseases developing late in life such as chronic Huntington's chorea. Clinics in the sector have specialised in the diagnosis of rare syndromes, bearing in mind that diagnosis is an essential prelude to careful counselling. In countries where the health care system calls directly on specialists to cope with genetic diseases, the machinery for dealing with such diseases has developed in a more piecemeal way, and laboratory services have sprung up alongside various university departments and general pathology and biochemistry units¹.

As investment in genetic diagnosis and counselling centres increases, Europe is likely to be faced with a dichotomy. In countries which have integrated genetics centres, investment in the sector will probably continue, whereas in countries with fewer facilities, genetics will develop in other fields. However, whatever form such developments might take, they will need to be pursued strenuously so as to enable the benefits of the Human Genome Project to translate into real improvements in health care. Approximately 6 500 phenotypes have been recognised, and genes are estimated to account for about a quarter of that number. All in all, single-gene disorders, chromosomal defects, and deformities due to genetic causes in the true sense will affect 1 person in 20 within 25 years. Genetic tests should mark an important step forward in the care of such people and their families.

In Europe, according to a reliable prediction, the genetics sector will grow rapidly over the next 10 to 15 years and become part of conventional medical practice, playing an increasingly greater role in diagnoses and prognoses affecting a person's health. Testing services could even be offered on a transnational or transcontinental basis, since there is no reason why tests should be carried out close to the source of the patient's sample. Some companies in the United States are already advertising genetic testing services for the public on the Internet. Provided that policies are adopted to bring to bear the appropriate regulation, a large competitive global market in genetic tests will come into being. If individual countries are to develop genetic testing in the sense of a service, it will be essential for them to perfect an all-round service capability of high quality measured in terms of reliability, processing capacity, response times, and accuracy.

As regards the financial outlay in the sector, known agreements in the period from 1996 to 2000 were worth a total of \$1 205 m, of which EU industries accounted for \$ 404 m, compared with \$636 m for US companies and \$127 m for Japanese companies. The European contribution to the sector is very significant, both as regards the substantial fund of basic knowledge (30% of publications on gene therapy in the world in the year 2000 originated from the Union) and in terms of industrial competitiveness. The European industry involved in gene therapy is of comparable size to its American counterpart in terms of the number of small and medium-sized enterprises (26 in the Union and 24 in North America in 2000) and large drugs companies (9 in the EU and 11 in the US) but appears to be lagging a little behind as regards the number of employees, the number of sponsored clinical trials, and the number of companies quoted on the Stock Exchange (4 as opposed to 8)².

¹ See paper by Prof. J. Burn – temporary committee meeting of 13 March 2001.

² Source: Studies on the socio-economic impact of biotechnology – Gene therapy in Europe: exploitation and commercial development – BIO4-98-0380, European Commission, Research DG.

The European researchers active in gene therapy are strongly oriented towards the market. Virtually all the new companies have been set up by academics and financed by venture capital and are creating new intellectual property, working in close contact with industry.

According to a survey conducted among university laboratories and gene research companies in Europe, 60% of university laboratories are working together actively with industry, and all the specialised companies are working together actively with university circles. 45% of the research carried out has resulted in applications for patients, and in a third of cases the licences in question have been sold to industry. The key figures relating to gene therapy in Europe are reproduced below.

VI.4.1. Situation of the European gene therapy sector¹

The changes which have occurred in the European gene therapy sector are summarised in table 1. All the available figures indicate that the sector has grown spectacularly in the last three and a half years. Attention should be drawn in particular to the increase in the number of clinical trials, companies which organise trials, and joint projects between companies, since this is a clear sign of the sector's maturity.

The changes which occurred during the same period in North America, however, have been much less dramatic (table 2). The 50% increase in the number of companies is due in part to the fact that gene therapy companies set up before 1996 have been identified as such. The only substantial increase was in the number of joint gene therapy projects involving US companies. Beneath this point lies one of the biggest changes in the sector, namely consolidation in which six companies have come to the fore. In Europe this trend is only just starting but seems certain to accelerate.

	1996	May 2000	Change (%)
Number of gene therapy companies	10	26	+160
Number of quoted companies	1	4	+300
Employees	299	735	+145
Number of companies organising trials	3	11	+270
Number of company-sponsored clinical trials	5	21	+320
Number of joint projects	3	39	+1200

Table 1. Changes in the European gene therapy sector (1996-2000)

	1996	May 2000	Change (%)
Number of gene therapy companies	16	24	+50
Number of quoted companies	8	8	0
Employees	911	1009	+10
Number of companies organising trials	14	16	+15
Number of joint projects	48	123	+150

Table 2. Changes in the North American gene therapy sector (1996-2000)

Despite the very rapid growth of the European industry and the consolidation of gene therapy companies in the US, the North American industry is still stronger and more advanced. This finding is true whether the yardstick applied is the number of employees, the number of companies quoted on the Stock Exchange, the number of companies which organise clinical trials, or the number of or amounts of money involved in joint projects (table 3). This applies in particular to product development in collaboration with certain US companies which organise the clinical trials at the final stages. In Europe only Transgene is in a position to do likewise.

	European industry	American industry	America/ Europe (%)
Number of gene therapy companies	26	24	-10
Number of quoted companies	4	8	+100
Employees	735	1009	+37
Number of companies organising trials	11	16	+45
Number of joint projects	39	123	+215

Table 3. Comparison of the strength and maturity of European gene therapy industries and their US counterparts – May 2000

As regards other companies involved in gene therapy, the number of large drug and biotechnology companies with a special interest in gene therapy is broadly comparable in Europe (9) and the US (11). In addition, the number of small and medium-sized biotechnology companies with significant gene therapy programmes is similar in the two continents.

In short, the European gene therapy sector has been transformed in the last three and a half years and moved much closer to its North American counterpart in terms of strength and maturity.

VI.4.2. National and European gene therapy research output

This section presents an overall picture of the scale and organisation of public sector gene therapy research in Europe, focusing in particular on publication output.

The details of the studies on gene therapy published in two periods, 1991 to 1995 (five years) and 1996 to 2000 (four years and four months), are set out in table 4¹.

¹ The information in this table is taken from Scientific Information's (ISI) Science Citation Index (SCI) and relates to publications in the individual countries containing the term 'gene therapy' in the title. The method used to some extent involves 'double entry bookkeeping', since some documents are published jointly by authors from different countries. ISI covers more than 3 500 of the world's leading scientific journals and publishes the OSCI, which contains data on the documents mentioned in the journals recognised by ISI. The English-speaking countries are represented most prominently, since most of the journals are in English. This source of information

Country	Documents on gene therapy 1991-1995	European total (%)	Documents on gene therapy 1996-2000	European total (%)	Change (%) in share of European total
Austria	3	0.8	9	0.9	+0.1
Belgium	2	0.5	25	2.6	+2.1
Denmark	9	2.4	10	1.1	-1.3
Finland	1	0.3	16	1.7	+1.4
France	100	26.4	194	20.4	-6.0
Germany	58	15.3	191	20.1	+4.8
Greece	0	0	4	0.4	+0.4
Ireland	0	0	1	0.1	+0.1
Italy	24	6.3	80	8.4	+2.1
Netherlands	28		33	3.5	-3.9
Norway	0	7.4	3	0.3	+0.3
Portugal	0	0	5	0.5	+0.5
Spain	3	0	18	1.9	+1.1
Sweden	2	0.8	20	2.1	+1.6
Switzerland	8	0.5	38	4.0	+1.9
United Kingdom	140	2.1	304	32.0	-5.3
European total	379	37.3	951 (+150%)	100	
World total	1465	100	3190 (+117%)		

Table 4. European gene therapy publication output (1991-1995) and (1996-2000)

The first point to note in table 4 is the huge increase in the total number of publications on gene therapy (117%) from the first period under review to the second. However, European publications have increased at an even faster rate (by 150%). Europe's share in the world total has thus risen from 26% to 30%, approaching its average share in the entire output of biomedical scientific publications. Given that world-wide publication output in the gene therapy sphere is dominated by the US, Europe appears to be catching up with the US.

Considerable changes have taken place within Europe. Firstly, the United Kingdom's and France's shares have fallen (by 5.3% and 6.3% respectively). However, the United Kingdom's share in the world total has remained virtually unchanged at 9.5%, whereas the French share has fallen slightly from 6.8% in 1991 to 1995 to 6.1% in 1996 to 2000. Denmark's and the Netherlands' shares have dropped more sharply.

Germany, which has traditionally been underrepresented in this sector, has accounted for the biggest and most significant change in the individual proportions of the European total. German scientists have increased their share in the European output from 15% to 20% and in the world output from 4% to 6%. These figures are probably due to the fact that Germany has been catching up and are more consistent with German strengths in biomedical research in general. Other countries which have recorded an improvement are Italy and Belgium.

VI.4.3. To what extent does gene therapy constitute an explicit priority in the national systems used to fund science?

Treating gene therapy as an express national priority or taking specific steps to promote the technology could be a means of enabling the Member States to develop scientific expertise in the gene therapy field. This is a prerequisite for subsequent commercial development and the

is nevertheless the best available measure of national publication output.

first factor that needs to be considered. The funding provided by each country is summarised in table 5, which also gives information on national gene therapy publication output and an assessment of the size of the scientific base as well as indicating whether countries have general biotechnology programmes.

All in all, 10 out of the 15 European countries considered have assigned a particular degree of priority to gene therapy or laid down public policies along the same lines. Six countries especially (Austria, Denmark, France, Germany, Sweden, and Switzerland) have chosen to treat gene therapy as a national priority, and four of them have drawn up national programmes to finance it. Three other countries (Belgium, Norway, and the United Kingdom) have funded gene therapy centres. It is interesting to note that in two of the countries which lay claim to substantial expertise in gene therapy (France and Italy), the main sources of public funding for gene therapy research are charitable associations and not government agencies.

Country	Percentage of European works quoted on gene therapy	Size of the national scientific base for gene therapy	Is gene therapy identified as a national priority sector?	National gene therapy (subprogramme)	Funding of gene therapy	Charitable associations as key financial backers of gene therapy	Specific national biotechnology programmes
Austria	1	Poor	Yes	Yes	Yes	-	-
Belgium	3	Modest	-	-	Yes	-	Yes
Denmark	1	Poor	Yes	-	-	-	Yes
Finland	2	Modest	-	-	-	-	Yes
France	20	Substantial	Yes	Yes	-	Yes	Yes
Germany	20	Substantial	Yes	-	-	-	Yes
Ireland	-	Very poor	-	-	-	-	Yes
Italy	8	Substantial	-	-	-	Yes	Yes
Netherlands	3	Modest	-	-	-	-	-
Norway	-	Very poor	-	-	Yes	-	Yes
Portugal	1	Modest	-	-	-	-	-
Spain	2	Modest	-	-	-	-	Yes
Sweden	2	Modest	Yes	Yes	-	-	-
Switzerland	4	Modest	Yes	Yes	-	-	Yes
United Kingdom	32	Substantial	-	(Yes)	Yes	-	-
TOTAL	100		6	4	4	2	10

Table 5. National science funding policies promoting the expansion of gene therapy

The figures in the table show that there is no simple relationship between the size of the scientific base – measured in terms of publication output – and the scale of funding policies. However, a few of the countries considered to be relatively weak in the gene therapy field have specific consolidated funding programmes designed to promote the technology. Denmark, Ireland, Portugal, and Spain are not pursuing any policies in this area, and although Austria does have a programme, it is something very modest. The one exception is Norway, which is currently investing substantially in the sector, an effort which began very recently.

In general, the strongest countries – France, Germany, Italy, Switzerland, and the United Kingdom – have specific national funding programmes or powerful national charitable organisations which are explicitly financing gene therapy as a matter of priority.

Although a scientific base of a given size tends at least to some extent to imply that specific measures are being taken to promote gene therapy, it is difficult to draw conclusive inferences as to the reasons. Many of the larger countries are strong in biotechnological research in general and can therefore be presumed to be equally strong in gene therapy, whether or not they provide specific funding. Furthermore, it is difficult to judge the value of policy because

many initiatives are relatively recent and may entail a considerable time-lag between the public investment and the emergence of scientific expertise in a given field.

What can be said, however, is that since the mid-1990s gene therapy has been treated as a much higher priority in the policies used to fund research in many European countries. This has probably served to channel higher amounts of funding into gene therapy research and to some extent explains why scientific output has increased in the last five years.

VI.4.4. Avenues to explore for possible recommendations to the Member States

Biotechnological research is tending increasingly to concentrate in a small number of large multinationals, and national, Community, and international public authorities should be called upon to:

- monitor the effects of such concentration, since they could have an impact on the public interest;
- safeguard the position of the smaller companies and non-profit-making organisations;
- strive to promote strong, independent publicly funded research focusing on areas offering little prospect of profit in the short or medium term which are being neglected by the private industries, for example treatments for diseases affecting the poor or children or which occur in the poorest countries or treatments for rare diseases;
- promote research into the risks of biotechnology and the ways of avoiding such risks;
- foster public-private partnerships.

VII. The use of genetic information

The availability of personal genetic information poses the risk of new forms of discrimination. The problems associated with genetic research raise questions linked to privacy, confidentiality of the data, and informed consent. The public at large have to be sure that genetic research is being conducted with sufficient safeguards to protect individual interests, and the interests of future generations, without obstructing legitimate medical research activities of benefit to society. It is feared that insurance companies or employers might use genetic data as an excuse for denying insurance cover or turning down a person for a job. Access to such information needs to be discussed further with a view to adopting the necessary legislation.

Genetic data are regarded as highly specific information. They can reveal important facts not just about the person examined, but also about the members of his or her family and, in the final analysis, have a great impact on individual lives and lifestyles, not least as regards decisions to have children. The legal framework for data protection covers matters such as confidentiality, anonymity, commercial exploitation, access to information, insurance, employers, and so forth. It might be necessary to update Directive 95/46/EC on the protection of individuals with regard to the processing of personal data and on the free movement of such data.

Political leaders need to ask how they can guarantee that genetic data will be protected. Is the regulation of DNA analysis a matter that can be resolved at national level? Or, in view of the single market, do certain principles need to be laid down at European level? It is highly likely that, following the lines of the 1995 Directive on data protection, European legislation will

need to be drawn up on the use of tests at the time of taking up employment or taking out insurance. Article 21 of the Charter of fundamental rights prohibits, among other forms of discrimination, discrimination on account of genetic features.

The medical risks facing an individual and his or her predisposition to diseases are being expressed in more scientific terms, but does that fact imply that the right of insurers to be acquainted with medical records should be restricted if genetic tests are carried out?

The EP recently stated its views in the resolution drawn up by Mr Purvis. '[The] use of and access to personal genetic information [should] be debated with a view to legislation, which should particularly focus on protecting the individual's personal integrity and on the requirement to obtain his consent ... Member States [should] protect individuals' right to genetic confidentiality and ensure that genetic profiling is used for purposes beneficial to individual patients and society as a whole; there should be an exception to this general principle of confidentiality where the genetic fingerprints held in DNA databases are used to identify and convict criminals'¹.

VIII. The patentability of living matter

In the European Union the patentability of the human genome has been the subject of heated debate since the mid-1980s. In 1998 the European Parliament and the Council, having noted that there was no Community law specifically to protect the processes and products of the new biotechnology sector, adopted Directive 98/44/EC on the legal protection of biotechnological inventions to define the limits within which 'biological material' and hence gene sequences could be patented in an attempt to settle the controversy².

VIII.1. Legislative frame of reference at Community level

There is as yet no Community legislation in force whereby an invention can be patented in all the Member States on the strength of a single application. However, when, in 1986, the Union cleared the way to complete the internal market, it opted to proceed by approximating the Member States' economic and monetary laws. It consequently became necessary, among other things, to provide for a Community instrument to protect the results of European inventions on the world market in the face of potential competitors, namely leading industrialised countries such as the US, Canada, and Japan. In its communication COM(1994) 219 the Commission pointed to some possible lines of action for the biotechnology sector, which had previously been set out in Jacques Delors's 1993 White Paper on growth, competitiveness, and employment, and to the need to remedy the shortcomings that had been found to exist in publicly and privately funded research and development (R. & D.) activities. It proposed to focus aid on some especially promising areas of R. & D. and involve small and medium-sized enterprises (SMEs) more widely with the twofold aim of:

¹ European Parliament resolution A4-0080/2001 on the future of the biotechnology industry.

² Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions.

- making firms in the Member States more aware of the importance of developing sectors (agriculture, medicine, foodstuffs, and environment) lending themselves to biotechnology applications, bearing in mind the beneficial economic and employment spin-offs;
- intensifying the discussion on ethical aspects, giving teeth to the existing legislation, with a view to supervising sectors in which the problems were more delicate on account of the direct impact on human health and the environment.

After issuing that first communication, the Commission began to draw up guiding instruments (recommendations) and legislative instruments (directives and regulations) to:

- boost and coordinate scientific consultation between and within the Member States' research programmes, since this was regarded as a crucially important factor (rapid access to scientific bases and availability of top-level personnel);
- encourage the Member States to promote the development of SMEs, given that they would play an essential role in the biotechnological sector;
- boost the expansion of 'science parks' (cooperation between SMEs and universities in agreement with local and regional authorities);
- improve the information about patents and make it accessible on a Community-wide basis;
- encourage R. & D. activities, enable businesses to be launched and expand, help set up advanced technology centres, and foster incentive-oriented tax arrangements;
- raise the profile of its existing advisory group (Group of Advisors on the Ethical Implications of Biotechnology in the Community context).

Later, in COM(1995) 688 and the first action plan for innovation in Europe, the Union, having noted that the innovation deficit had not been made good, maintained that a comprehensive approach had to be brought to bear on the problem, encompassing the technological aspects, training, expansion of venture capital, and the legal and administrative environment on its territory. It also highlighted the fact that there were too many national and regional disparities in the various fields and at the 1996 Florence European Council expressly declared that 'the fight for employment must remain the top priority for the Union and its Member States' and laid down a strategy to remedy the imperfections. It accordingly called 'on the Commission to draw up an action plan concerning the measures to be taken with regard to innovation'. The White Paper on growth, competitiveness, and employment acknowledged that modern biotechnology had the merit of being one of the sectors with the biggest growth and innovation potential precisely because the practical applications of biotechnological research could be of great interest to a very diverse range of sectors, namely health, industrial chemicals, foodstuffs and animal feed, agriculture, and environment. Moreover, future developments in biotechnology presuppose greater investment in the sectors supplying the services and products, thereby benefiting employment.

Since 1991, then, the Commission has recognised that biotechnology is a key field for the future development of Community competitiveness and will be an increasingly decisive factor which Community industries will have to take into account if they are to remain in the vanguard of innovative product development. Biotechnology requires the use of the most modern genetic engineering techniques, entailing repercussions on the different processes and products. It is therefore vital that such an innovative field should be encompassed within an appropriate regulatory framework so as to avert unforeseeable muddles. At world level, new markets are developing in the areas of information, environment, health, food, and culture, and demand for new products and services is emerging. Future jobs in Europe will depend on the capacity to innovate, and the capacity to innovate, especially in high-technology sectors,

will have a decisive role to play in maintaining competitiveness and employment in those sectors.

The only existing European legislation on industrial property rights has to date been administered by the Munich Patent Office, outside the rules of Community law, under the European Patent Convention, to which 20 contracting States have acceded and which has provided the model with which they have aligned their own legislation. Community legislation thus exists separately alongside the national laws based on the Convention¹.

VIII.2. Patented innovation as a driving force of research

Patents, which go hand in hand with and follow research, are, on the one hand, the most useful means afforded by industrial policy to secure a corresponding reward once the monopoly right over an invention has been recognised and, secondly, the most direct way of publicising existing innovative expertise and placing it at the disposal of experts in the fields concerned.

There have been many definitions of a patent, but it could perhaps be defined most aptly as an contract between an inventor and the community, represented by the State. The State undertakes to provide the means, first and foremost legal instruments, of safeguarding the right and hence the monopoly granted to the inventor, whereas the inventor supplies an example offered freely to the community to aid its progress. The State rewards the inventor by allowing him to exploit his patent exclusively for a given number of years (20 in the case of patents for inventions). The right accorded to the inventor takes the form of a monopoly on the manufacture, sale, and use of the invention, which, under that monopoly, may also be made over to others by means of licences, exclusive or otherwise, to use it, thus ensuring that the market is not denied the wherewithal for technological progress. Patents are also of considerable economic value because they are one of the most effective ways of encouraging scientific research by attracting human and capital resources. In the member countries of the WTO (World Trade Organisation) the number and importance of the patents awarded is used to measure technological development and competitive potential².

Patents are necessary in order to guarantee a profit for their holders and provide an incentive to investment. A new product costs between EUR 800 m and EUR 1 000 m to develop.

According to the European law in force, an invention must satisfy three basic conditions in order to be considered patentable:

1. the invention must be new;
2. it must involve an inventive step;
3. it must be suitable for industrial application.

¹ 'The Patentability of living organisms: science and ethics' (Forum on 'Trends in experimental and clinical medicine'), G. Morelli Gradi. The European Patent Convention, signed in Munich on 5 October 1973, enables a set of patents to be obtained on the basis of a single examination procedure. The patents become valid and take effect in the 20 contracting States once applications and translations have been filed in the respective languages. Thereafter, the patent is incorporated into the institutional legal systems of the individual States and consequently subject to the procedures laid down in the different national laws and the decisions of the appropriate courts.

² *Idem*.

As regards the possibility of patenting living matter, it is very important to make a clear distinction, which, moreover, exists in European law, between a ‘discovery’ and an ‘invention’, the former not being patentable. A discovery implies new knowledge, whereas an invention is a practical application of knowledge and reproducible in an identical form in every kind of industry, including agro-industry, in other words it lends itself to industrial application. US law, however, takes a somewhat different approach, which frequently does not clearly distinguish between inventions and discoveries, so that the term ‘invention’ can mean either one thing or the other. There is consequently a risk that some companies operating in the biotechnology sector, more often than not multinationals, to which exclusive rights have been granted under US law might use patents, even though the classic requirements might not be met, purely to prevent the information contained in them from being disseminated and used by other researchers to protect particular genes or gene sequences in the proper way. However, contrary to what happens in other sectors, biotechnological and biomedical innovations have to do with living organisms, and it thus appears to be an even more complex task to make the fundamental distinction between inventions and discoveries that would serve to determine when patent law was applicable and when it was not. Whereas, then, it is possible in the United States to patent both inventions and discoveries of things already existing in the natural environment, in the European countries only inventions can be patented.

VIII.3. Directive 98/44/EC on the legal protection of biotechnological inventions

Directive 98/44/EC provides clear guidelines as regards biotechnological products intended both for the medical and health sector and for the agricultural sector. It employs the basic concept of patent law also incorporated in the TRIPS Agreement on Trade-Related Aspects of Intellectual Property Rights¹, which states that inventions may not be patented if their practical applications would be contrary to *ordre public* or morality. The Directive, consisting of 18 articles and 56 recitals, was drawn up by the Commission not with a view to transforming existing patent law, but purely in order to:

- guarantee the free movement of patented biotechnological products by harmonising the national laws of the Member States;
- ensure compliance with the European Patent Convention (EPC), signed in Munich on 5 October 1973, the TRIPS Agreement (Trade-Related Aspects of Intellectual Property Rights), signed by the governments of the Member States at the GATT Uruguay Round, and the Rio de Janeiro Convention of 5 June 1992 on biodiversity.

It contains a set of definitions and interpreting rules intended to specify what is patentable or unpatentable and resolve problems connected with the definition of the patent system applied to the different biotechnological sectors in order to spell out the fundamental difference between a discovery and an invention, supplying the clarifications required for the products concerned to be properly protected. As well as technical provisions, it also covers points related to some extent to the ethical dimension of patenting of living matter and makes clarifications in line with Parliament’s proposals. The following in particular are expressly ruled out:

¹ TRIPS – Trade-Related Aspects of Intellectual Property Rights, signed in Marrakesh on 15 April 1994 following the GATT negotiations.

- patenting of the human body and elements thereof in the natural state (Article 5)¹;
- patenting of new ‘plant and animal varieties’ and ‘essentially biological processes for the production of plants or animals’ (Article 4);
- inventions ‘contrary to *ordre public* or morality’ (Article 6) may likewise not be patented, in keeping with Article 53 of the European Patent Convention (EPC), which has been incorporated in the corresponding provisions of the national laws of the Member States that have acceded to the Convention;
- Article 6 stipulates that ‘processes for cloning human beings’ or ‘modifying the germ line genetic identity of human beings’ and ‘uses of human embryos for industrial or commercial purposes’ may not be patented; a further ban is imposed on patenting of ‘processes for modifying the genetic identity of animals ... without any substantial benefit to man’ (it is permissible merely to use ‘animal models’ to research into new drugs that might be used to treat serious illnesses which are often fatal to humans, such as, for example, cancer, hepatitis, or Aids);
- the rights of farmers are also protected to the extent that they may replant patented seeds or use patented breeding stock on their own farms without having to pay expensive royalties to patent holders (Article 11);
- plant breeders are entitled to apply for a compulsory licence when they intend to use a patented plant to produce a new variety (Article 12);
- ‘every five years’ the Commission has to produce ‘a report on any problems encountered with regard to the relationship between this Directive and international agreements on the protection of human rights to which the Member States have acceded’. It must send that report to the EP and the Council (Article 16).

The articles referred to above establish the fundamental principles for improving and completing the scope of protection under existing patent law, purely as regards those points required to update the protection in line with the most recent and significant scientific developments. However, both the Commission and the Member States, and, indeed, European parliaments, are aware that the new legislation must lay down more exhaustive interpretation principles. That is why, in addition to the 18 substantive articles, as many as 56 recitals have been included to interpret the complex-subject matter so as to help examiners, who will be called upon to grant exclusive rights, and judges, who will be called upon to rule on the validity of those exclusive rights, to make consistent assessments. The Directive balances the right to inventions and ethical principles.

Recently, however, especially since the Community Directive was adopted, wide-ranging discussion has been focusing on the need to clarify the definition of the patentability criteria observed in US patenting systems, i.e. as opposed to the criteria laid down in the EU, especially where patenting of gene sequences is concerned. Under American law, for example, which interprets the concept far more sweepingly, patent protection may be granted if the ‘inventive find’ is simply new, not obvious, or useful, whereas the requirements under European legislation can be summed up in terms of newness, inventive steps, and industrial application.

¹ This ban is in line with Chapter VII, Article 21, of the Oviedo Convention of 14 April 1997 for the Protection of Human Rights and the Dignity of the Human Being with regard to the Application of Biology and Medicine (‘Convention on Human Rights and Biomedicine’), which states that ‘The human body and its parts shall not, as such, give rise to financial gain’. It is also consistent with the views expressed in opinion No 3 of 1 October 1993 by the Commission’s group of bioethics advisers, which maintained that the human body and its parts as such should not be marketed.

The European system thus observes more restrictive criteria for the purposes of granting an exclusive right, not least, and above all, to avoid confusion between a discovery and an invention. However, if human genome sequences are unpatentable, the risk is that hypothetical users of such products for commercial purposes might compel researchers to keep their research secret and refrain from availing themselves of patents. The EU, by contrast, is increasingly convinced that an appropriate legal instrument such as Directive 98/44/EC needs to be used, not least in the national law of the Member States, to enable information emanating from research laboratories to be brought to light.

Patents must serve to safeguard the financial interests of inventors and those working in the sector. That is why that which can be patented needs to be defined exactly. The award of excessively vague and sweeping patents could impede research and should be prohibited. The Community must continue to pursue these principles in the international negotiations on revision of the TRIPS Agreement (trade-related intellectual property rights).

VIII.4. Human genome

Mapping of the human genome, completed during the past year by the American company Celera Genomics and the Human Genome Project Group, has prompted heated discussion in the European Union about the patentability of human genes¹.

Genome sequencing, indeed, has sparked off an unprecedented race to the imminently expected 'genetic loot'². The ability to isolate, identify, and recombine genes makes it possible for the first time to tap a common stock of genes as a source of raw materials³, the economic exploitation of which would be encouraged especially by the possible award of patents. Global life science companies such as Novartis, Glaxo-Wellcome, SmithKline Beecham, and Du Pont have moved swiftly into action in order to exert influence and control over the new genetic trade⁴.

According to recent statistics, in the United States, Europe, and Japan patents have been granted or are awaiting approval in respect of 161 195 whole human genes or parts thereof, which control a very diverse range of human biological processes such as those of the heart, the brain, the bones, the blood, the immune system, and so on. To patent a gene is tantamount to securing the right to exploit any gene therapy or drug linked to the function of the DNA fragment for which the patent has been obtained. But how just is it that individual genes or

¹ 'Mappatura del genoma umana e brevettabilità delle sequenze geniche', Eleonora Palermo, Fondazione Basso, February 2001.

² In his book on the 'biotech century' Jeremy Rifkin describes genes as the new century's gold. The economic and political forces which control the earth's genetic resources will be in a position to wield enormous power over the future of the world economy, just as entry into the industrial age and control of fossil energies and precious metals helped to determine who dominated the world markets.

³ Genetic engineering techniques enable large biotechnology companies to locate, manipulate, and exploit genetic resources for specifically economic ends.

⁴ A typical sign of this trend was the bold decision in 1997 by Monsanto Corporation, a world leader in chemicals, to jettison its entire chemical operations and root its research, development, and marketing in biotechnology-based technologies and products. The global conglomerates have rapidly acquired fledgeling biotech companies and drug, medical, and health companies, concentrating immense power into their own hands. The pharmaceutical giants are buying stakes in and concluding research agreements with numerous companies working with the human genome.

portions thereof should constitute an asset on which one company has a monopoly? Above all, how just is it that a single company should be allowed to determine when and how to disseminate new knowledge that is bound to have a huge impact on the health of humanity as a whole? Given these questions, national and international legislators have to clarify the matter of patents and the ownership of genetic information in the light of the fundamental principles of democracy that must continue to guide humankind, even in the age of modern biomedical technologies.

VIII.5. Patentability of gene sequences

To address the problems posed by the patentability of genes and understand them more clearly, it is useful to refer to the specific provisions set out in Directive 98/44/EC on the legal protection of biotechnological inventions¹. The Directive was issued with a view to standardising the Member States' patent laws² and deals with the question of patentability of living matter by laying down a number of specific provisions concerning gene sequences³.

In accordance with Article 5⁴, mere knowledge of human gene sequences constitutes a discovery (a discovery is thus made every time a nucleotide sequence is isolated and its structure described, whether or not the knowledge is of any particular use). However, the knowledge assumes the proportions of an invention if it is specified that the DNA sequence concerned codes for a protein proven to be of use in the treatment of a given disease. Anything whose usefulness is not specified falls short of the precise requirement of suitability for industrial application⁵, as laid down in Article 5(3). Mere knowledge of a new enzyme and the gene sequence that codes for it, as such and with no indication of the exact function

¹ Official Journal of the European Communities, No 90, 16 November 1998.

² Article 3 of Directive 98/44/EC stipulates that '*inventions which are **new**, which involve **an inventive step** and which are susceptible of **industrial application** shall be patentable even if they concern a product consisting of or containing **biological material** or a process by means of which biological material is produced, processed or used. **Biological material which is isolated from its natural environment or produced by means of a technical process may be the subject of an invention even if it previously occurred in nature***'.

³ In a paper he read in the Bari University Faculty of Law, Jean-Pierre Clavier of the University of Nantes maintained that the Directive was important on two counts. The first reason was that Italian patent law dated back to a period, the late 1970s, when the prerequisites for technologies centring on living beings were only just beginning to be established and was therefore naturally intended to cover only inventions of a mechanical or chemical nature, thus posing fairly considerable difficulties of interpretation for the legal experts called upon to deal with inventions linked to the biotechnologies and biomedicine. Secondly, the subject-matter covered had a very important ethical dimension, especially in view of the fundamental questions as to the real dangers entailed in the spread of the new life technologies, for example, cloning, eugenics, impoverishment of the gene pool, etc.

⁴ Article 5 states that '*... The human body, at the various stages of its formation and development, and the simple discovery of one of its elements, including the sequence or partial sequence of a gene, cannot constitute patentable inventions.*

... An element isolated from the human body or otherwise produced by means of a technical process, including the sequence or partial sequence of a gene may constitute a patentable invention, even if the structure of that element is identical to that of a natural element.

... The industrial application of a sequence or partial sequence of a gene must be disclosed in the patent application'.

⁵ Some people will naturally criticise Article 5 of the Directive because the only possible inference to be drawn from its interpretation, notwithstanding paragraph 1, is that genes are patentable as such because, by definition, any gene or gene sequence can be discovered only by means of a procedure to identify, isolate, purify, characterise, and replicate it.

whereby the gene codes, is consequently and in every case a discovery that can be freely used to produce possible future inventions¹.

As regards the patentability of gene sequences allowed under Article 5(2) and (3) and the recitals setting out the interpretation of those paragraphs (20 to 25), it can therefore be inferred from the Directive is that the concept of discovery loses its pejorative connotation for patentability purposes only when it is associated with an industrial application².

To complete the picture, under Article 6 of the Directive inventions may not be patented if their commercial exploitation would be contrary to *ordre public* or morality. Exploitation of an invention cannot in itself be deemed contrary to *ordre public* or morality just because it is prohibited by a law or regulation. Processes for cloning human beings or modifying their germ line genetic identity or the use of human embryos for industrial or commercial purposes are expressly considered unpatentable.

The deadline imposed on the governments of the Member States for transposition of the Directive was 30 July 2000. Only a few have complied to date (Ireland, Finland, Denmark, and the United Kingdom), whereas adoption by the parliaments of the other countries is being held up, despite the fact that, only three years ago, the governments serving in the Council (27 November 1997) called enthusiastically for the Directive to be endorsed. The most controversial subject has proved to be and still is the possible patentability of human genes.

The doubts which are prompting this reluctance are many and varied and relate to:

- the possibility of regarding human genes as inventions rather than discoveries;
- all are unanimously agreed that DNA sequences, as they occur in the natural state, should be considered discoveries. But why should the fact of discovering a particular function associated with a given protein be considered an invention, and why should the use of that protein be patentable?
- the criteria for assessing newness and usefulness where genes are concerned;
- ethical prohibitions applying to the possible patentability of parts of the human genome;
- doubts about the future of medical research in a situation in which it would be necessary to pay royalties in order to gain access to information about human DNA and, in particular, misgivings about the implications which might ensue for the development of new drugs and treatments.

VIII.6. Arguments for and against the patentability of genes

There are a number of arguments in favour of the patentability of genes and a number of arguments against.

It is said that patentability is justified because:

¹ The discovery of an enzyme and its structure may enable that enzyme to be produced in a purified form or on an industrial scale and thereafter used to treat a disease. *The isolated and purified enzyme is a new object* of use to industry. The same reasoning applies to gene sequences. Once a sequence has been established, it can be isolated or synthesised and transferred to other organisms: the isolated gene is thus a new object and can be defined as an invention.

² Scoperte ed Invenzione alla luce della direttiva 98/44/EC – Giorgio Floridia.

- researchers would be rewarded for their work as a result of patents and could invest the proceeds generated by exploitation of their patents in their future research;
- investment in research would consequently be encouraged if a right of commercial exploitation were granted to an inventor, who, subject to given conditions, would be entitled to enjoy a monopoly over a period not exceeding 20 years, assuming that the right has not lapsed beforehand. Having obtained the right, the inventor would undertake to describe his innovation in exhaustive detail. Only those elements of the innovation that could legitimately be so covered would be covered by the right, that is to say, competitors would be forbidden to produce, use, or sell the patented invention without the inventor's consent or a licence to use it;
- as regards biotechnological products in the health sector, the patent right would serve to encourage medical research and development;
- it would be possible to avoid expensive and useless overlapping of efforts seeking to achieve the same results;
- research would be directed into unexplored new areas;
- it would be less necessary to resort to industrial secrecy, and all researchers would have access to the new invention (without infringing the patent right).

However, many arguments have been put forward in support of the idea that human genes should be unpatentable:

- owing to the high cost of using the information to which they relate, the award of patents could impede diagnostic and therapeutic research (gene therapy and predictive medicine), creating a system in which genes would be exploited on a monopoly basis¹;
- even if the industries interested in the research were willing to pay them, the high royalties accorded to the holders of patents for gene sequences would eventually be passed on to consumers, thus making the products resulting from the research more expensive and difficult to obtain;
- the only kind of medical development which patents would accelerate would be that linked to research into diagnostic and therapeutic tools offering the prospect of substantial profit. By contrast, all research activity would cease in fields that did not hold out the promise of the desired profit margins, in which nobody would want to invest²;
- if patents were awarded for genes, future generations would come to perceive life as an invention pure and simple, in which the boundaries between the sacred and the profane, intrinsic value and utilitarian value, would be erased, reducing life itself to the rank of an object without any unique or essential quality to distinguish it from a basically mechanical system³;
- genomic data should be brought rapidly into the public domain, since only in that way will research be able to proceed normally at international level⁴;

¹ The award of patents entails nothing short of privatisation of the human body, which is thus shared out in the form of intellectual property among commercial enterprises. The patent awarded by the European Patent Office to a US company called Biocyte is a symptomatic case. Under this patent the company owns all the blood cells originating from a new-born baby's umbilical cord, which are used for many therapeutic purposes. The patent is so sweeping that the company can prevent any individual or institute from using any blood cell extracted from the umbilical cord if he or it is unwilling to pay the royalties.

² 'Orphan drugs' are a case in point.

³ It was in these words in particular that a coalition of over 200 adherents of the Protestant, Catholic, Jewish, Muslim, Buddhist, and Hindu religions declared its opposition in 1995 to the award of patents for genes, human or otherwise.

⁴ This attitude is also strongly supported in the 1997 Unesco Universal Declaration on the Human Genome,

- if new data on genomic sequences could be patented before there were an opportunity to ascertain what products or clearly defined applications might result from them, a wealth of information would be ‘confiscated’ by a minority of dominant companies, which would consolidate their position by applying for patents;
- some people certainly believe that the patentability of genes might induce medicine, spurred by the pharmaceutical laboratories¹, to adopt an exclusively genetic approach to diseases. The important work in the field of genomics must not cause physiology to be regarded as wholly linked to genes and the appreciable effects due to the environment to be underestimated.

How can the principle of freedom of research be reconciled with certain ethical values?

Article 13 of the Charter of fundamental rights states that ‘The arts and scientific research shall be free of constraint’. Freedom of access to knowledge and freedom of research should go hand in hand. The former becomes a matter of acute importance when the subject under consideration is decoding of the genome of living organisms and, above all, access to the findings of work connected with human genome sequencing. That principle was reaffirmed in the ‘Clinton-Blair’ statement. The rule that the fruit of a labour of invention can be protected but the product of a discovery must remain in the public domain is basically clear. Europe must explicitly assert its firm commitment to the above principle and do its utmost to ensure that it is observed in the best possible way. The conditions governing its application to the life sciences must, however, be spelt out and translated into reality in line with developments in knowledge and technologies. This can be done by employing the existing procedures for revising legal acts².

The European Group on Ethics in Science and New Technologies will be delivering an opinion on patents in September. It may hold an exchange of views with the temporary committee.

IX. The sixth research framework programme³

Genomics as the first priority of the sixth framework programme

Genomics is the first priority set out in the proposal for a decision on the sixth framework programme. ‘The activities in this area are intended to help Europe exploit, by means of an integrated research effort, breakthroughs achieved in decoding the genomes of living

which maintains that genes as such are not patentable, because they belong to humanity’s common heritage. In a joint statement issued on 14 March 2000 the then US President Bill Clinton and the British Prime Minister Tony Blair spoke out in favour of free access to data relating to the human genome and called on scientists to put them in the public domain. The effectiveness of this plea, however, appears somewhat dubious because only two days later the American Patent and Trade Mark Office (USPTO) maintained that US patent policy had not been altered one jot by the statement. Indeed, Q. Todd Dickinson of the USPTO publically stated that genes and genomic inventions which were patentable the week before were still patentable at the present time under the same procedures.

¹ Pharmaceutical laboratories view the reductionist ‘one disease – one gene – one medicine’ approach as a wonderful source of profit.

² See papers read at the temporary committee meeting of 31 May 2001 – Dr Freire, Dr Alexander, Dr Gugerell, and Prof. Mattei.

³ Proposal for a decision of the EP and of the Council concerning the multiannual framework programme 2002-2006 of the European Community for research, technological development and demonstration activities, COM(2001) 94.

organisms, more particularly for the benefit of public health and citizens and to increase the competitiveness of the European biotechnology industry'¹.

Article 7 of the Decision concerning the fifth framework programme states that 'All research activities conducted pursuant to the fifth framework programme shall be carried out in compliance with fundamental ethical principles, including animal welfare requirements, in conformity with Community law'. The ethical aspects of increasing in knowledge, technological advances, therefore need to be taken into account, and research activities conducted without infringing fundamental ethical principles and the protection of privacy.

Article 3 of the proposal concerning the sixth framework stipulates that 'All the research activities carried out under the framework programme 2002-2006 must be carried out in compliance with fundamental ethical principles'.

Under the current fifth research framework programme certain types of research may not be financed, for essentially ethical reasons. This applies to research into cloning techniques (for reproductive or therapeutic purposes) or relating to germinal line therapy or modification of the germ line. The Commission has developed a procedure for the purposes of the research framework programme for assessing particular types of research from the ethical point of view².

Citizens and governance in the European knowledge society

¹ **Genomics and biotechnology for health – Justification of the effort and European added value:** 'Post-genomic' research based on analysis of the human genome and genomes of model (animal, plant and microbial) organisms, will culminate in numerous applications in various sectors, and notably in the development of new diagnostic tools and new treatments capable of helping to combat diseases that are not at present under control, offering major potential markets.

However, this work requires considerable and sustained financial outlay. In the United States, public and private spending on post-genomic research is rising steadily and significantly: nearly 2 billion dollars of public-sector funding per annum, essentially managed by the NIH (the total budget for which will increase by 14.4% in 2001) and twice as much industrial funding.

Europe's spending on research is at present much lower and less coherent. The launching of publicly funded research programmes on post-genome research in several Member States is a big step in the right direction. All in all, however, the efforts made are inadequate and dispersed.

European industry also spends much less on research than US industry does: 70% of genomics companies are located in the United States and a substantial and increasing proportion of European private-sector investment is made in that country.

To enable the EU to improve its position in this area and benefit fully from the economic and social spin-offs of the expected developments, it is necessary both to increase investment significantly and integrate the research activities conducted in Europe within a coherent effort.

Actions envisaged: The Community activities carried out to this end will address the following aspects:

- Fundamental knowledge and basic tools for functional genomics: gene expression and proteomics; structural genomics; comparative genomics and population genetics; bioinformatics;
- Application of knowledge and technologies in the field of genomics and biotechnology for health: technological platforms for the development of new diagnostic, prevention and therapeutic tools; support for innovative research in genomics start-up companies;
- Application of medical genomics knowledge and technologies in the following fields: combating cancer, degenerative diseases of the nervous system, cardiovascular diseases and rare diseases; combating resistance to drugs; studying human development, the brain and the ageing process.

A broader approach will be pursued with regard to combating the three poverty-linked infectious diseases (Aids, malaria and tuberculosis) which have priority in terms of disease control at EU and international level.

² Ethical review under the quality of life programme, European Commission, Research DG, January 2000.

The relationship between science and society has taken a paradoxical turn, since it is finding expression on the one hand in high expectations and, on the other, a degree of hostility. How can the two be reconciled? The debate has given rise to a number of questions about the ethical and social consequences of progress in knowledge and technology and the conditions under which the fundamental decisions are taken (or not taken). Research policy must be based on principles determined in the light of specific goals.

The Commission has spelt out the issues in a recent working document that raises the problems underlying the relationship between science, society, and citizens¹, which are prompting anxieties among citizens and political decision-makers. How can research policies be founded on the real aims of society? How can risks be managed? How is it possible to allow both for the ethical implications of technological progress and for the imperative of freedom of research and access to knowledge? How can the dialogue between science and society be intensified?

The Heads of State or Government have decided to establish a 'European research area', a crucial point to address when considering the procedures for what Community jargon terms 'governance' for Europe, which relates to the new forms of participation in public life on the various tiers of power and decision-making, in other words the new forms of organisation of government and administration of the *res publica* based on interaction between the traditional public authorities and civil society.

Steps to be taken:

- contacts between the ethics committees established at national and European level need to be placed on a more organised footing;
- research on the ethics of science needs to be coordinated more closely;
- the criteria for ethical assessment of research projects need to be standardised to a greater extent;
- the legislative activities of the Council of Europe and the Union need to move closer together.

If any progress is to be achieved, strengths will have to be pooled, and the Member States must work in close collaboration with one another and with the Union. The sixth research framework programme is due to be adopted by the end of the first half of 2002. The programme is based on a new approach confined to priority research areas in which Union action can bring the greatest measure of value added to national policies.

X. Conclusions: what should be the role of the Union?

The points below, relating to the matters discussed above, summarise some avenues to explore to help foster discussion with and among all those active in the field and with civil society on Union action seeking to provide genuine value added in relation to the national policies on human genetics, which might even be put forward as a European model in the international context.

Information policy

¹ Science, society, and citizens in Europe, European Commission, working document SEC(2000) 1973.

- Public debate should be intensified and encompass public consultation on human genetics involving patients and their families, industry, investors, ethics experts, and the public at large. The Commission launched a public debate on human genetics by holding a conference on 6 and 7 November 2000 entitled ‘Genetics and Europe’s future’, in collaboration with the high-level working party on the life sciences. The EP will be holding a large conference on 9 and 10 July, to be attended by civil society.

Legal and regulatory framework

- The European Ethics Group should be asked for its opinion on human genetics and genetic testing in particular¹;
- Union-wide ethical guidelines should be laid down on human genetics and implemented in close collaboration with the European Ethics Group and the high-level working party on the life sciences, taking into account the work being carried out in the Council of Europe to draw up the protocol on human genetics;
- An EU regulatory framework should be laid down to govern the development, trials, and approval of new biomedicines, including genetic testing;
- A climate should be established to help foster innovation regarding the genome, for example by facilitating access to venture capital and promoting entrepreneurship and technology transfer.

Financial support for research

- Cooperation among university researchers, doctors, the biotechnologies, entrepreneurs, and industry in general should be supported with a view to identifying the role of genome data and developing new medical treatments;
- Support should be granted to prenormative research relating to human genetics, including, for example, quality assessment standards and quality guarantees for genetic testing;
- Standard-setters should be enabled to play an active role at the right time, and, to that end, forums established to consider new biomedical developments;
- Centralised information and/or common material systems should be set up, one example being registration of data on new biomedicines, including clinical trial data and information on subsequent approval (for instance comments on adverse reactions), comparison with pharmacogenetic data (correlating genetic specificity with individual reactions to drugs), patient databanks, or central tissue banks;
- Support should be granted for research into the ethical, social, legal and economic issues associated with human genetics;
- Support should be provided with a view to moving towards a new consensus on life science applications by popularising the life sciences in the media and increasing public understanding;
- Multidisciplinary training and education should be promoted. Increased education and training in advanced technologies (such as pharmacogenetics, biocomputing, and nano-biotechnologies) and integrated biomedical research/development/management education and training programmes, based on international cooperation between universities and

¹ The European group has published several opinions on human genetics and genetic engineering (for example opinions No 4 on gene therapy, No 6 on antenatal diagnosis, No 8 on patenting inventions concerning elements of human origin, and No 15 on the ethical aspects of human stem cell research and use).

industry, will afford opportunities for universities, industry, and society as genotypic analysis, diagnosis, and therapy become increasingly more integrated.

ANNEXES

Annex I

Work programme of the temporary committee¹

CONSTITUENT MEETING

16 January 2001, Strasbourg

Topic: Election of Committee Bureau and Draftsman

HEARING OF EXPERTS²

30 January 2001, morning, Brussels

Topic: **Activities of the European Group on Ethics (EGE) and the High Level Group of Life Sciences (HLGLS)**

- Mr Derek BURKE, Member of HLGLS
- Mrs Noëlle LENOIR, President of EGE

13 February 2001, afternoon, Strasbourg

Topic: **Patients and Patient Organisations**

- Mr Luca COSCIONI (Representative of the Italian Association of lateral amiotrofical sclerosis)
- Mr Stephan KRUIP (Spokesman of the German adult cystic fibrosis patients association)
- Mr Robert MEADOWCROFT (Director of Policy, Research and Information, UK Parkinson's Disease Society)

13 March 2001, afternoon, Strasbourg

Topic: **Mapping and Sequencing the Human Genome (including the uses of population genetics)**

- Prof. John BURN (Clinical Director, Institute for Human Genetics, University of Newcastle, United Kingdom)
- Prof. Gert-Jan VAN OMMEN (Chair of Human and Clinical Genetics Department, Leiden University, the Netherlands)

26 March 2001, afternoon, Brussels

Topic: **Postnatal Genetic Testing (scientific, medical, ethical, legal and psychological aspects)**

- Prof. Jean-Louis MANDEL (IGMBC, France)
- Prof. Alexandre MAURON (Research Unit on Bioethics, University of Geneva)
- Prof. Daniel SERRAO (National Council on Ethics and Human Sciences, Portugal)

27 March 2001, morning, Brussels

Topic: **Prenatal Genetic Testing and Assisted Reproduction (scientific, medical, ethical, legal and psychological aspects)**

- Prof. Paul DEVROEY (Centre for Reproductive Medicine, Université Libre de Bruxelles)

¹ As agreed by the coordinators on 15 March 2001.

² Authorised by EP Bureau, decision of 1 March 2001.

- Prof. Joep GERAEDTS (European Society of Human Reproduction and Embryology, Maastricht)
- Dr. Hille HAKER (Centre of Ethics in the Sciences, University of Tübingen, Germany)
- Prof. Outi HOVATTA (Karolinska Institutet, Stockholm)
- Countess Joséphine QUINTAVALLE (Director of Comment on Reproductive Ethics, London)

26 April 2001, morning and afternoon, Brussels

Topic: **Genetics and Medicine**

Part 1: Research involving Embryos and Cloning (scientific, ethical, social, medical, legal and psychological aspects)

- Prof. Carlos Alonso BEDATE (Centre of Molecular Biology, University of Madrid, Spain)
- Prof. Cinzia CAPORALE (Prof. of Bioethics and Education in Environment, Sienna, Italy)
- Prof. Regine KOLLEK (Research Unit on Technology Assessment of Modern Biotechnology in Medicine, University of Hamburg, Germany)
- Dr Anne McLAREN (Research at the Wellcome CRC Institute of Cambridge, Member of the GEE)
- Dr Jacques TESTART (National Institute of Health and Medical Research, INSERM, France)

Topic: **Genetics and Medicine**

Part 2: The Use of Genetics in Medicine (scientific, ethical, economic, legal, social, medical and psychological aspects)

- Peter GOODFELLOW (Research Director, GlaxoSmithKline pharmaceuticals, Hertfordshire, UK)
- Prof. H. JOCHEMSEN (Advisory Board Member of the Centre for Bioethics and Human Dignity, Trinity International University, Bannockburn, USA)
- Prof. Peter KRIZAN (Chairman of the Slovak Society of Medical Genetics)
- Prof. Demetrio NERI (Prof. of Bioethics, University of Messina, Italy)

15 May 2001, afternoon, Strasbourg

Topic: **The Use of Genetic Information**

- Prof. Lars REUTER (Centre of Bioethics, University of Aarhus, Denmark)

31 May 2001, afternoon, 14.30 – 18.00, Brussels

Topic: **Patentability**

- Daniel ALEXANDER (Barrister, London)
- Maria FREIRE (National Institute of Health, Office of Technology Transfer, Rockville, MD, USA)
- Christian GUGERELL (European Patent Office, Munich)
- Jean-François MATTEI (Docteur ès Sciences, Prof. de pédiatrie et de génétique médicale, France)

18 June 2001, afternoon and 19 June 2001, morning, Brussels

Topic: Round Table with Representatives of the Corresponding Committees of the Parliaments of the EU Member States and Candidate Countries

9 July 2001, afternoon and 10 July 2001, morning, Brussels

International and European legal instruments

Inviolability of human dignity

Universal Declaration on the Human Genome and Human Rights (Unesco – United Nations Educational, Scientific, and Cultural Organisation) (1997)

Article 1 - Human Dignity and Human Genome

The human genome underlies the fundamental utility of all members of the human family as well as the recognition of their inherent dignity and diversity. In a symbolic sense, it is the heritage of humanity.

Article 2 - Human Dignity and Human Genome

§a) Everyone has a right to respect for their dignity and for their rights regardless of their genetic characteristics. §b) That dignity makes it imperative not to reduce individuals to their genetic characteristics and to respect their uniqueness and diversity.

Article 10 - Research on the Human Genome

No research or research application concerning the human genome, in particular in the fields of biology, genetics and medicine, should prevail over respect for the human rights, fundamental freedom and human dignity of individuals or, where applicable, of groups of people.

Council of Europe Convention on Human Rights and Biomedicine¹ (1997)

Article 2 - Primacy of the human being

The interests and welfare of the human being shall prevail over the sole interest of society and science.

Treaty establishing the European Union (1997)

Article 6(1)

The Union is founded on the principles of liberty, democracy, respect for human rights and fundamental freedoms, and the rule of law, principles which are common to the Member States.

Charter of fundamental rights of the European Union (2000)

Article 1 – Human dignity

Human dignity is inviolable. It must be respected and protected.

¹ As at September 2000, the following Member States had ratified the Convention: Denmark, Greece, and Spain. Finland, France, Italy, Luxembourg, Portugal, and Sweden had merely signed the Convention, but not yet ratified it. Austria, Belgium, Ireland, and the United Kingdom had not signed it.

Decision No 182/1999/EC of the European Parliament and of the Council concerning the fifth framework programme of the European Community for research, technological development and demonstration activities (1998 to 2002)

Article 7

All research activities conducted pursuant to the fifth framework programme shall be carried out in compliance with fundamental ethical principles, including animal welfare requirements, in conformity with Community law.

Freedom of research

Universal Declaration on the Human Genome and Human Rights (Unesco – United Nations Educational, Scientific, and Cultural Organisation) (1997)

Article 12 - Research on Human Genome

§ a). Benefits from advances in biology, genetics and medicine, concerning the human genome, shall be made available to all, with due regard for the dignity and human rights of each individual.

§ b). Freedom of research, which is necessary for the progress of knowledge, is part of the freedom of thought. The applications of research, including applications in biology, genetics and medicine, concerning the human genome, shall seek to offer relief from suffering and improve the health of individuals and humankind as a whole.

Article 13¹ - Conditions for the exercise of scientific activities

The responsibilities inherent in the activities of the researchers (...) in carrying out their research as well as in the presentation and utilisation of their findings should be subject of particular attention in the framework of research on the human genome, because of its ethical and social implications. Public and private science policy makers also have particular responsibilities in this respect.

Article 17 - Solidarity and International Cooperation

States should respect and promote the practice of solidarity towards individuals, families and population groups who are particularly vulnerable to or affected by disease or disability of a genetic character. They should foster, *inter alia*, research on the identification, prevention and treatment of genetically based and genetically influenced diseases, in particular rare as well as endemic diseases which affect large numbers of the world's population.

Council of Europe Convention on Human Rights and Biomedicine (1997)

Article 15 - Scientific research: general rule

Scientific research in the field of biology and medicine shall be carried out freely and subject to the provisions of this Convention and the other legal provisions ensuring the protection of the human being.

Article 18 - Research on embryos in vitro²

§1. Where the law allows research on embryos *in vitro*, it shall ensure adequate protection of the embryo.

§2. The creation of human embryos for research purposes is prohibited.

¹ The European Group on Ethics in Science and New Technologies to the European Commission, Press Dossier, Adoption of an opinion on Ethical Aspects of Human Stem Cell Research and Use, Paris, 14 November 2000, p. 4.

² The European Group on Ethics in Science and New Technologies to the European Commission, Press Dossier, Adoption of an opinion on Ethical Aspects of Human Stem Cell Research and Use, Paris, 14 November 2000, p. 12.

Treaty establishing the European Community (1997)

Title XVIII – Research and technological development

In particular:

Article 163(1): The Community shall have the objective of strengthening the scientific and technological bases of Community industry and encouraging it to become more competitive at international level, while promoting all the research activities deemed necessary by virtue of other Chapters of this Treaty.

Article 164: In pursuing these objectives, the Community shall carry out the following activities, complementing the activities carried out in the Member States: ...

Article 166(1): A multiannual framework programme, setting out all the activities of the Community, shall be adopted by the Council, acting in accordance with the procedure referred to in Article 251 after consulting the Economic and Social Committee.

Charter of fundamental rights of the European Union (2000)

Article 13 – Freedom of the arts and sciences

The arts and scientific research shall be free of constraint. Academic freedom shall be respected.

Protection of public health

Universal Declaration on the Human Genome and Human Rights (Unesco – United Nations Educational, Scientific, and Cultural Organisation) (1997)

Article 12(b) - Research on the Human Genome

Freedom of research, which is necessary for the progress of knowledge, is part of the freedom of thought. The applications of research, including applications in biology, genetics and medicine, concerning the human genome, shall seek to offer relief from suffering and improve the health of individuals and humankind as a whole.

Council of Europe Convention on Human Rights and Biomedicine (1997)

Article 3 - Equitable access to health care

Parties, taking into account health needs and available resources, shall take appropriate measures with a view to providing, within their jurisdiction, equitable access to health care of appropriate quality.

Article 12 - Predictive genetic tests

Tests which are predictive of genetic diseases or which serve either to identify the subject as a carrier of a gene responsible for a disease or to detect a genetic predisposition or susceptibility to a disease may be performed only for health purposes or for scientific research linked to health purposes, and subject to appropriate genetic counselling.

Treaty establishing the European Community (1997)

Article 95 – Approximation of laws

1. ... The Council shall, acting in accordance with the procedure referred to in Article 251 and after consulting the Economic and Social Committee, adopt the measures for the approximation of the provisions laid down by law, regulation or administrative action in Member States which have as their object the establishment and functioning of the internal market.

Article 152 – Public health

1. A high level of human health protection shall be ensured in the definition and implementation of all Community policies and activities.

Community action, which shall complement national policies, shall be directed towards improving public health, preventing human illness and diseases, and obviating sources of danger to human health. Such action shall cover the fight against the major health scourges, by promoting research into their causes, their transmission and their prevention, as well as health information and education.

The Community shall complement the Member States' action in reducing drugs-related health damage, including information and prevention.

2. The Community shall encourage cooperation between the Member States in the areas referred to in this Article and, if necessary, lend support to their action.

4. The Council, acting in accordance with the procedure referred to in Article 251 and after consulting the Economic and Social Committee and the Committee of the Regions, shall contribute to

the achievement of the objectives referred to in this Article through adopting:

- (a) measures setting high standards of quality and safety of organs and substances of human origin, blood and blood derivatives; these measures shall not prevent any Member State from maintaining or introducing more stringent protective measures;

5. Community action in the field of public health shall fully respect the responsibilities of the Member States for the organisation and delivery of health services and medical care. In particular, measures referred to in paragraph 4(a) shall not affect national provisions on the donation or medical use of organs and blood.

Charter of fundamental rights of the European Union (2000)

Article 35 – Health care

Everyone has the right of access to preventive health care and the right to benefit from medical treatment under the conditions established by national laws and practices. A high level of human health protection shall be ensured in the definition and implementation of all Union policies and activities.

Non-discrimination on account of genetic features

Universal Declaration on the Human Genome and Human Rights (Unesco – United Nations Educational, Scientific, and Cultural Organisation) (1997)

Article 6 - Protection against discrimination

No one shall be subjected to discrimination based on genetic characteristics that is intended to infringe or has the effect of infringing human rights, fundamental freedoms and human dignity.

Council of Europe Convention on Human Rights and Biomedicine (1997)

Article 11 - Non-discrimination

Any form of discrimination against a person on grounds of his or her genetic heritage is prohibited.

Charter of fundamental rights of the European Union (2000)

Article 21 – Non-discrimination

1. Any discrimination based on any ground such as sex, race, colour, ethnic or social origin, genetic features ... shall be prohibited.

Protection of personal data

United Nations Convention on Biological Diversity (1992)

Article 15(5) - Access to genetic resources

Access to genetic resources shall be subject to prior informed consent of the Contracting Party providing such resources, unless otherwise determined by the Party.

Universal Declaration on the Human Genome and Human Rights (Unesco – United Nations Educational, Scientific, and Cultural Organisation) (1997)

Article 5(b) - Rights of the person concerned

In all cases, the prior, free, and informed consent of the person concerned shall be obtained. If the latter is not in a position to consent, consent or authorization shall be obtained in the manner prescribed by law, guided by the person's best interest.

Article 7 - Confidentiality of genetic data

Genetic data associated with an identifiable person and stored or processed for the purpose of research or any other purpose must be held confidential in the conditions set by law.

Council of Europe Convention on Human Rights and Biomedicine (1997)

Article 5 - Consent: general rule

An intervention on the health field may only be carried out after the person concerned has given free and informed consent to it.

This person shall beforehand be given appropriate information as to the purpose and nature of the intervention as well as on its consequences and risks.

The person concerned may freely withdraw consent at any time.

Charter of fundamental rights of the European Union (2000)

Article 8 – Protection of personal data

1. Everyone has the right to the protection of personal data concerning him or her.
2. Such data must be processed fairly for specified purposes and on the basis of the consent of the person concerned or some other legitimate basis laid down by law. Everyone has the right of access to data which has been collected concerning him or her, and the right to have it rectified.

Directive 95/46/EC on the protection of individuals with regard to the processing of personal data and on the free movement of such data

Article 7 – Criteria for making data processing legitimate

Member States shall provide that personal data may be processed only if:

- (a) the data subject has unambiguously given his consent;

Article 8(1) and (2)(a) – Special categories of processing

1. Member States shall prohibit the processing of personal data revealing racial or ethnic origin, political opinions, religious or philosophical beliefs, trade-union membership, and the processing of data concerning health or sex life.

2. Paragraph 1 shall not apply where:

- (a) the data subject has given his explicit consent to the processing of those data, except where the laws of the Member State provide that the prohibition referred to in paragraph 1 may not be lifted by the data subject's giving his consent;

Procedures performed on the human genome

Universal Declaration on the Human Genome and Human Rights (Unesco – United Nations Educational, Scientific, and Cultural Organisation) (1997)

Practices which are contrary to human dignity, such as reproductive cloning of human beings, shall not be permitted. States and competent international organizations are invited to cooperate in identifying such practices and in taking, at national or international level, the necessary measures to ensure that the principles laid down in this Declaration are respected.

World Health Organisation resolution on the ethical, scientific, and social implications of cloning for human health (1998)

Prohibition of cloning for replication of human beings

The Fifty-first World Health Assembly:

§1. reaffirms that cloning for replication of human individuals is ethically unacceptable and contrary to human dignity and integrity;

§2. urges Member States to foster continued and informed debate on these issues and to take appropriate steps, including legal and juridical measures, to prohibit cloning for the purpose of replicating human individuals.

Council of Europe Convention on Human Rights and Biomedicine (1997)

Article 13 - Intervention on human genome

An intervention seeking to modify the human genome may only be undertaken for preventive, diagnostic or therapeutic purposes and only if its aim is not to introduce any modification in the genome of any descendants.

Additional Protocol to the Council of Europe Convention on Human Rights and Biomedicine (1998)¹

Article(1) - Prohibition of reproductive cloning

Any intervention seeking to create a human being genetically identical to another human being, whether living or dead is prohibited.

Charter of fundamental rights of the European Union (2000)

Article 3(2) – Right to the integrity of the person

In the fields of medicine and biology, the following must be respected in particular:

- the free and informed consent of the person concerned, according to the procedures laid down by law,
- the prohibition of eugenic practices, in particular those aiming at the selection of persons,
- ...
- the prohibition of the reproductive cloning of human beings.

¹ As at September 2000 Greece and Spain had ratified the Protocol. Denmark, Finland, France, Italy, Luxembourg, the Netherlands, Portugal, and Sweden had signed it, but not yet ratified it. Austria, Belgium, Ireland, and the United Kingdom had not yet signed it.

No financial gains

Universal Declaration on the Human Genome and Human Rights (Unesco – United Nations Educational, Scientific, and Cultural Organisation) (1997)

Article 4 - Prohibition of financial gains

The human genome in its natural state shall not give rise to financial gains.

Council of Europe Convention on Human Rights and Biomedicine (1997)

Article 21 - Prohibition of financial gains

The human body and its parts shall not, as such, give rise to financial gain.

Charter of fundamental rights of the European Union (2000)

Article 3(2) – Right to the integrity of the person

In the fields of medicine and biology, the following must be respected in particular:

...

- the prohibition on making the human body and its parts as such a source of financial gain,

...

Intellectual property and patentability of living matter

United Nations Convention on Biological Diversity (1992)

Article 16(2)(3)(4)(5) - Access to and transfer of technology

§2. Access to and transfer of technology referred to in paragraph 1 above to developing countries shall be provided and/or facilitated under fair and most favourable terms, including on concessional and preferential terms where mutually agreed, and, where necessary, in accordance with the financial mechanism established by Articles 20 and 21. In the case of technology subject to patents and other intellectual property rights, such access and transfer shall be provided on terms which recognize and are consistent with the adequate and effective protection of intellectual property rights.

§3. Each Contracting Party shall take legislative, administrative or policy measures, as appropriate, with the aim that Contracting Parties, in particular those that are developing countries, which provide genetic resources are provided access to and transfer of technology which makes use of those resources, on mutually agreed terms, including technology protected by patents and other intellectual property rights, where necessary, through the provisions of Articles 20 and 21 and in accordance with international law and consistent with paragraphs 4 and 5 below.

§4. Each Contracting Party shall take legislative, administrative or policy measures, as appropriate, with the aim that the private sector facilitates access to, joint development and transfer of technology referred to in paragraph 1 above for the benefit of both governmental institutions and the private sector of developing countries and in this regard shall abide by the obligations included in paragraphs 1, 2 and 3 above.

§5. The Contracting Parties, recognizing that patents and other intellectual property rights may have an influence on the implementation of this Convention, shall cooperate in this regard subject to national legislation and international law in order to ensure that such rights are supportive of and do not run counter to its objectives.

World Trade Organisation (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (1995)

Article 7 - Objectives

The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations.

Article 27 - Patentable Subject Matter

§1. Subject to the provisions of paragraphs 2 and 3, patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application.¹ (...) Patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced.

§2. Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect *ordre public* or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their law.

§3(a). Members may also exclude from patentability diagnostic, therapeutic and surgical methods for the

¹For the purposes of this Article, the terms 'inventive step' and 'capable of industrial application' may be deemed by a Member to be synonymous with the terms 'non-obvious' and 'useful' respectively.

treatment of humans or animals (...).

Directive 98/44/EC on the legal protection of biotechnological inventions

Article 5

1. The human body, at the various stages of its formation and development, and the simple discovery of one of its elements, including the sequence or partial sequence of a gene, cannot constitute patentable inventions.
2. An element isolated from the human body or otherwise produced by means of a technical process, including the sequence or partial sequence of a gene, may constitute a patentable invention, even if the structure of that element is identical to that of a natural element.
3. The industrial application of a sequence or a partial sequence of a gene must be disclosed in the patent application.

Article 6

1. Inventions shall be considered unpatentable where their commercial exploitation would be contrary to *ordre public* or morality; however, exploitation shall not be deemed to be so contrary merely because it is prohibited by law or regulation.
2. On the basis of paragraph 1, the following, in particular, shall be considered unpatentable:
 - (a) processes for cloning human beings;
 - (b) processes for modifying the germ line genetic identity of human beings;
 - (c) uses of human embryos for industrial or commercial purposes;
 - (d) processes for modifying the genetic identity of animals which are likely to cause them suffering without any substantial medical benefit to man or animal, and also animals resulting from such processes.

Other relevant provisions of the Treaty establishing the European Community (1997)

Article 5 – Subsidiarity principle

In areas which do not fall within its exclusive competence, the Community shall take action, in accordance with the principle of subsidiarity, only if and insofar as the objectives of the proposed action cannot be sufficiently achieved by the Member States and can therefore, by reason of the scale or effects of the proposed action, be better achieved by the Community.

Any action by the Community shall not go beyond what is necessary to achieve the objectives of this Treaty.

Further relevant European secondary legislation

Directive 98/79/EC on *in vitro* diagnostic medical devices

Article 1(4)

For the purposes of this Directive, the removal, collection and use of tissues, cells and substances of human origin shall be governed, in relation to ethics, by the principles laid down in the Convention of the Council of Europe for the protection of human rights and dignity of the human being with regard to the application of biology and medicine and by any Member States (*sic*) regulations on this matter.

(As far as diagnosis is concerned, the key considerations are the confidentiality of information connected with privacy and the principle of non-discrimination on account of men's and women's family genetic characteristics.)

Decision No 182/1999/EC of the European Parliament and of the Council of 22 December 1998 concerning the fifth framework programme of the European Community for research, technological development and demonstration activities (1998 to 2002)

Annex, section II, Scientific and technological objectives – point VI(b): research into genomes and diseases of genetic origin, footnote 1

... No research activity which modifies or is intended to modify the genetic heritage of human beings by alteration of germ cells or by acting at any other stage in embryonic development and which can make such an alteration heritable will be carried out under the present framework programme. In the same way, no research activity, understood in the sense of the term 'cloning', will be conducted with the aim of replacing a germ or embryo cell nucleus with that of the cell of any individual, a cell from an embryo or a cell coming from a late stage of development to the human embryo. ...

Council Decision 1999/167/EC of 25 January 1999 adopting a specific programme for research, technological development and demonstration on quality of life and management of living resources (1998 to 2002)

Annex II, The general outlines, the scientific and technological objectives and the priorities – point vi(b): Research into genomes and diseases of genetic origin, footnote 1

... In the same way, no research activity, understood in the sense of the term 'cloning', with the aim of replacing a germ or embryo cell nucleus with that of the cell of any individual, a cell from an embryo or a cell coming from a later stage of development to the human embryo, will be supported.

Legislation of the Member States relating to research on embryos¹

Country	Law	Research	Time-limits	Freezing	Research conditions and aims	Other restrictions	Bioethics committees
Austria	On reproductive medicine (1992)	Prohibited	-	One year	Embryo donation is prohibited	Conditions for carrying out reproductive medicine: stable heterosexual relationship; aim: procreation; procedure: implantation of one oocyte only	-
Belgium	No specific legislation, but IVF centres are governed by a 1999 royal decree. A number of bills are currently being discussed in the Senate Bioethics Committee	Permitted subject to the approval of the local bioethics committee.	-	-	At an IVF centre having an arrangement with the State health service; necessary to obtain the approval of the bioethics committee of the institute concerned (university etc.)	-	Every institution (university etc.) allowed to carry out research has a decentralised ethics committee; role: to approve research protocols
Denmark	No 460 (1997) on assisted reproduction	Permitted subject to certain conditions	14 days (excluding freezing time)	One year with the couple's consent	Conditions: with the permission of a regional ethics committee; aim: to improve IVF/pre-implant diagnosis techniques	Fusion of genetically different embryos or parts thereof is prohibited. Ova used for research may not be transferred to the uterus.	National ethics committee for health and research (advisory role)

¹ The information set out in the table has been taken from the following bibliographic sources:

- 1) European Commission, Directorate-General for Science, Research, and Development, *Societal, medical and ethical implications of cloning*, Proceedings of a workshop held at the Royal Society, London, 24 and 25 November 1997, 1998
- 2) European Group on Ethics in Science and New Technologies to the European Commission (EGE), *Adoption of an opinion on ethical aspects of human stem cell research and use*, Paris, 14 November 2000, revised edition January 2001
- 3) European Parliament, DG III (Information and Public Relations), Press Monitoring and Rapid Response Unit, *Fact sheet on the Temporary Committee on Human Genetics and Other New Technologies in Modern Medicine*, Brussels, 21 February 2001
- 4) Scientific and technological options assessment (STOA), Directorate-General for Research, Directorate A, Industry, Research and Energy Division, *The ethical implications of research involving human embryos, Final study*, Working document for the STOA panel, Luxembourg, July 2000, PE 289.665/Fin. St.
- 5) Sénat, Service des affaires européennes, Division des Études de législation comparée, Les documents de travail du Sénat, *Les instances nationales de Bioéthique*, série législation comparée, n. LC 89, avril 2001.

Country	Law	Research	Time-limits	Freezing	Research conditions and aims	Other restrictions	Bioethics committees
Finland	Medical Research Act (1999)	Permitted subject to certain conditions	14 days from conception	15 years (must be destroyed thereafter)	Conditions: research may be carried out only by agencies authorised by the National Authority for Medical and Legal Affairs with the prior consent of the parents	It is forbidden to create embryos purely for research. Research on foetuses may not be carried out unless the pregnant woman gives her permission in writing; research to modify the germ line is prohibited (unless it can prevent/cure a serious disease)	The National Authority for Medical and Legal Affairs authorises research conducted by specialised agencies only
France	Law No. 94-654 (1994); Decree No 97-613 (1997). A bill authorising research on embryos will be debated in 2001	Permitted subject to certain conditions	7 days	5 years; within that time the couple may donate the embryo to another couple wishing to have a child	Conditions: must be of direct use to the embryo or reproductive medicine; the man's or woman's written consent is required; an independent commission must give its authorisation	The following are prohibited: cloning, creation of chimeras and embryos purely for research, and modification of the germ line	National Advisory Ethics Committee for Biological and Health Sciences (1983): has opposed Directive 98/44/EC on patentability and protested against its transposition
Germany	On the protection of embryos (1992)	Permitted only if the embryo benefits	-	Prohibited	Research on embryos for non-therapeutic purposes is prohibited	The afore-mentioned law expressly prohibits human cloning. Embryos may not be destroyed, and it is an offence to fertilise an oocyte not intended for a pregnancy; it is forbidden to separate and use totipotent embryonal cells for research and diagnosis. It is hoped that Parliament will debate the matter	Federal Medical Association's Central Ethics Committee (delivers opinions)

Country	Law	Research	Time-limits	Freezing	Research conditions and aims	Other restrictions	Bioethics committees
Greece	No regulations on research on embryos; the matter is covered in a declaration by the General Health Council (1988)	Permitted subject to certain conditions	14 days from conception	-	Conditions: research requires the approval of the appropriate ethics committee	Cloning is expressly prohibited	There are ethics committees
Ireland	The matter is governed by the eighth amendment to the 1983 Constitutional Act	Prohibited	-	-	-	-	-
Italy	Research on embryos is not regulated by law; a 1997 Health Ministry order prohibits cloning procedures	-	-	-	-	-	National Bioethics Committee (set up within the Prime Minister's Office, performs an advisory role by delivering opinions). A ministerial committee drew up a report in 2000 on the use of stem cells for therapeutic purposes: supports therapeutic cloning and research on embryos
Luxembourg	No regulation. 1999 bill on IVF	-	-	-	-	-	
Netherlands	No regulation. 2000 bill on human gametes and embryos	Research protocols have to be approved by the Central Committee on Research on Human Subjects, whose opinions are based on a 1995 memorandum ruling out research on embryos for therapeutic purposes	-	-	-	A bill on the use of sperm, oocytes, and embryos (for purposes other than pregnancy) was tabled in Parliament by the Government in September 2000	

Country	Law	Research	Time-limits	Freezing	Research conditions and aims	Other restrictions	Bioethics committees
Portugal	No regulation (a bill was adopted in Parliament but vetoed by the President in 1999)	-	-	-	-	-	The National Ethics Committee for Life Sciences (independent consultative body) published a report in 1995
Spain	On assisted reproduction techniques (1988). Human cloning is prohibited	Permitted subject to certain conditions	14 days with the parents' consent	5 years	The research must be for diagnostic or therapeutic purposes; research for non-therapeutic purposes may be carried out only on inviable embryos and when it cannot be conducted on animals	-	-
Sweden	On <i>in vitro</i> fertilisation (1988): law on measures to be taken with regard to research or treatment using fertilised human ova (1991)	Permitted subject to certain conditions	14 days from fertilisation	-	Once the research has been completed, embryos must be destroyed; it is forbidden to implant an embryo into the uterus for research purposes	Research seeking to genetically modify an embryo is prohibited	-
United Kingdom	Human Fertilisation and Embryology Act (1990)	Permitted subject to certain conditions	14 days	5 years; 10 years with consent	Conditions: licence awarded by the Human Fertilisation and Embryology Authority	Research for non-therapeutic purposes must help to improve techniques for the treatment of sterility, increase understanding of the causes of congenital diseases and miscarriage, improve contraceptive systems, or develop systems for identifying anomalous genes or chromosomes prior to implantation in the uterus	Human Fertilisation and Embryology Authority (independent public body which supervises research on embryos and IVF techniques and authorises research into therapeutic cloning)

EU texts on human genetics: a chronology

20 July 1988

Proposal for a Council decision adopting a specific research programme in the field of health: Predictive Medicine: Human Genome Analysis (1989-1991)
/* COM(1988) 424 – SYN 146 */ (*Official Journal C* 27, 2.2.1989, p. 6)

19 December 1988

Rothley report (Committee on Legal Affairs and Citizens' Rights) on the ethical and legal problems of genetic engineering. (A2-327/88)

30 January 1989

Haerlin report (Committee on Energy, Research and Technology) on Predictive Medicine: Human Genome Analysis (A2-0370/88)

30 January 1989

Casini report (Committee on Legal Affairs and Citizens' Rights) on artificial insemination 'in vivo' and 'in vitro' (A2-372/88)

15 February 1989

Legislative resolution (Cooperation procedure – first reading) embodying the opinion of the European Parliament on the proposal from the Commission to the Council for a decision adopting a Specific Research and Technological Development Programme in the field of Health: Predictive Medicine: Human Genome Analysis (1989-1991) (*Official Journal C* 69, 20.3.1989, p. 95)

16 March 1989

EP resolution on artificial insemination 'in vivo' and 'in vitro' (*Official Journal C* 96, 17.4.1989, p. 171) called for the number of embryos to be limited to what can be successfully implanted and for the prohibition of any experimentation outside the womb. It stated that embryos should not be cryopreserved under any circumstances for a period in excess of three years.

16 March 1989

EP resolution on the ethical and legal problems of genetic engineering (*Official Journal C* 96, 17.4.1989, p. 165) called for legislation prohibiting any gene transfer to human germ line cells and defining the legal status of the human embryo in order to provide unequivocal protection of genetic identity. It stated that the zygote needed protection and must not be subject to arbitrary experimentation, that it should be a criminal offence to keep embryos alive with a view to removing tissues or organs as the need arose and that human cloning should be a criminal offence. It stated that research on human embryos would be justified only 'if [its possible applications] are of direct and otherwise unattainable benefit in terms of the welfare of the child concerned and its mother and respect the physical and mental integrity of the woman.'

16 April 1990

Decision (Cooperation procedure: second reading) on the common position drawn up by the Council with a view to the adoption of a decision on a Specific Research and Technological development programme in the field of Health: Human Genome Analysis (1990-1991)
Official Journal C 149, 18.6.1990, p. 80

11 June 1990

Re-examined proposal for a Council decision adopting a Specific Research and Technological Development Programme in the field of Health: Human Genome Analysis (1990-1991)
/* COM(1990) 251 – SYN 146 */

29 June 1990

Council Decision 90/395/EEC adopting a specific Research and Technological Development Programme in the field of Health: Human Genome Analysis (1990 to 1991) (*Official Journal L 196, 26.7.1990, p. 8*). Objectives included: the use and improvement of new biotechnologies in the study of the human genome for a better understanding of the mechanisms of genetic functions as well as the prevention and treatment of human diseases; drawing up an integrated approach to the medical, ethical, social and legal aspects of possible applications of results to ensure that they were not misused; establishing a set of bioethical principles to be followed for future developments. The alteration of germ cells at any stage of embryo development with the aim of modifying human genetic characteristics in a hereditary manner was excluded.

28 October 1993

EP resolution on the cloning of the human embryo (*Official Journal, C 315, 22.11.1993, p. 224*)

1 March 1995

Decision on the joint text approved by the Conciliation Committee for a European Parliament and Council Directive on the legal protection of biotechnological inventions (C4-0042/95 – 94/0159(COD) rejected by the EP by 240 votes against, 188 for and 23 abstentions. (*Official Journal C 68, 20.3.1995, p. 26*)

24 October 1995

Directive 95/46/EC of the European Parliament and of the Council on the protection of individuals with regard to the processing of personal data and on the free movement of such data
(*Official Journal L 281, 23.11.1995, pp. 31-50*)

13 December 1995

Commission adopted a new proposal for a directive on the protection of biotechnological inventions.

28 February 1997

Commission requested an opinion from its Group of Advisers on the Ethical Implications of Biotechnology (GAEIB) on the ethical implications of cloning techniques, in particular animal cloning, and their potential impact on human beings.

12 March 1997

EP resolution B4-0209 on the cloning of human beings, (*Official Journal C 115, 14.4.1997, p. 92*). In response to the ethical issues surrounding cloning and the alarm caused by the production of a sheep cloned from an adult cell, the resolution urged Member States to ban the cloning of human beings and urged the Commission to report any research carried out in this field and on the legal framework in the Member States. Proposals concerning the establishment of an EU Ethics Committee to monitor developments in the area of gene technology were also requested.

30 April 1997

Proposal for a Parliament and Council decision regarding the Fifth Framework Programme of the European Community for Research, Technological Development and Demonstration Activities (1998-2002) – Article 6 concerning compliance with fundamental ethical principles.

6 June 1997

EP resolution on the mandate of the European Commission's Group of Advisers on the Ethical Implications of Biotechnology (GAEIB) reaffirming its belief that it was essential to establish ethical standards, based on respect for human dignity, in the areas of biology, biotechnology and medicine, and that such standards should apply, if possible, globally and afford a high level of protection. The Commission was asked to bring forward proposals to guarantee Parliament's involvement in ethical questions relating to biotechnology. (*Official Journal C 200, 30.6.1997, p. 258*)

16-17 June 1997

Declaration by the European Council in Amsterdam on banning the cloning of human beings, requesting that the Council and Commission confirm this by amending the directive on the legal protection of biotechnological inventions (*Official Journal C 222, 21.7.1997, p. 17*)

16 July 1997

Parliament adopted amendments to the Commission proposal for the directive on legal protection for biotechnological inventions.

15 January 1998

EP resolution B4-0050/98 on the cloning of human beings (*Official Journal C 34, 2.2.1998, p. 164*) called on Member States to sign and ratify the Council of Europe 'Convention on the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine' (Bioethics Convention) and its additional protocol prohibiting human cloning. The EU Member States and the UN were also requested to take all the necessary steps to bring about a legally binding ban on the cloning of human beings.

10 June 1998

Proposal for a Council decision concerning a Specific Programme for Research, Technological Development and Demonstration on Quality of Life and Management of Living Resources – footnote 8 on ethical requirements.

6 July 1998

Directive 98/44/EC of the European Parliament and the Council on the legal protection of biotechnological inventions stipulated what was and was not patentable in the area of living organisms, together with the precise significance of the intellectual property rights conferred by a patent. It cited patenting as being out of the question for all processes resulting from research on embryos that were not of direct benefit, inventions based on modification of the genetic identity of human germ line cells and cloning processes for the purposes of human reproduction.

11 September 1998

Commission requested the opinion of the EGE on Amendment 36 by the European Parliament, which proposed to exclude from Community funding research projects that ‘result in the destruction of human embryos’ in the context of deciding on the Fifth Framework Programme.

22 December 1998

Decision No 182/1999/EC of the European Parliament and of the Council concerning the Fifth Framework Programme of the European Community for Research, Technological Development and Demonstration Activities (1998 to 2002) (*Official Journal L 26, 1.2.1999, pp. 1-33*)

25 January 1999

Council Decision 1999/167/EC adopting a Specific Programme for Research, Technological Development and Demonstration on Quality of Life and Management of Living Resources, 1998-2002. (*Official Journal L 64, 12.3.1999, pp. 1-19*) stated that ‘no research activity which modifies or is intended to modify the genetic heritage of human beings by alteration of germ cells or by acting at any other stage in embryonic development and which can make such alteration hereditary will be supported under the present framework programme. In the same way, no research activity understood in the sense of the term “cloning”, with the aim of replacing a germ or embryo cell nucleus with that of the cell of any individual, a cell from an embryo or a cell coming from a later stage of development to the human embryo, will be supported.’

30 March 2000

EP resolution B5-0288 on the decision by the European Patent Office with regard to patent No EP 695 351 granted on 8 December 1999 objected to the University of Edinburgh being granted a patent which could be used to cover the cloning of human beings. It called for this patent to be revoked and for the swift incorporation of Directive 98/44/EC on the legal protection of biotechnological inventions into national law.

6 September 2000

Commissioner for research, Philippe Busquin, addressed the EP during a debate on human cloning in which he highlighted the importance of shared ethical values through Europe and 'Commission plans to adopt initiatives such as strengthening the links between ethics committees across Europe and the exchange of good practice in the ethical assessment of research projects.' He also reiterated Mr Prodi's hopes that there could be an enlightened debate in close cooperation with the EP on the value of research into human embryo stem cells and their therapeutic application within a legal and ethical framework.

7 September 2000

EP rejected a joint motion for a resolution on the cloning of human embryos for therapeutic ends.

7 September 2000

EP resolution B5-0710 on human cloning emphasised the need to respect human dignity and human life, called on the UK Government to review its position on human embryo cloning and repeated calls for each Member State to enact binding legislation prohibiting all research into human cloning and to provide for criminal penalties. It stated that any temporary committee set up by the EP on human genetics should take previous resolutions into account and examine questions on which the EP had not yet expressed a clear position.

7 September 2000

Conference of Presidents discussed the powers, composition and term of office of the Temporary Committee on Human Genetics (temporary committee responsible for considering the ethical and legal issues raised by new developments in human genetic engineering).

19 October 2000

Letter from Mr Behrend (Secretary-General of the Green/ALE Group), forwarding a proposal drawn up by the political group coordinators concerning the powers and responsibilities, membership and terms of reference of the Temporary Committee on Human Genetics and Other New Technologies in Modern Medicine. (PE 296.482)

13 December 2000

EP decision to set up a Temporary Committee on Human Genetics and Other New Technologies in Modern Medicine (B5-0898/2000)

16 January 2001

First meeting of the Temporary Committee on Human Genetics and other New Technologies in Modern Medicine.

29-30 January 2001

Temporary Committee on Human Genetics and other New Technologies in Modern Medicine hearing with experts Professor Derek Burke, member of the Life Sciences High Level Group, and Ms Noelle Lenoir, chair of the Commission's European Group on Ethics.

Human genetics: a chronology¹

1952

The first successful cloning experiment in vertebrate animals, frogs, was reported.

1971

James Watson (winner, with Francis Crick and Maurice Wilkins, of the 1962 Nobel Prize for Medicine for discovering the structure of DNA) wrote an essay for *Atlantic Monthly* called ‘Moving towards clonal man’ – in it he warned that human clones were coming and society was unprepared.

1978

The first baby conceived by ‘*in vitro*’ fertilisation outside the mother’s body is born in the United Kingdom. No specific regulations in existence concerning human embryo research.

24 September 1986

Recommendation 1046 of the Parliamentary Assembly of the Council of Europe on the use of human embryos is adopted, forbidding ‘the creation of identical human beings by cloning or any other methods’.

21 October 1988

An initial proposal for a directive on the protection of biotechnological inventions is adopted by the Commission.

2 February 1989

Council of Europe Parliamentary Assembly Recommendation 1100 on the use of human embryos and fetuses in scientific research to the effect that the Committee of Ministers should provide a framework of principles from which national laws or regulations could be developed in as universal and uniform a manner as possible and encourage Member States to increase the level of public information and understanding concerning biomedicine and human reproduction.

20 November 1991

A Group of Advisers on the Ethical Implications of Biotechnology (GAEIB) is set up by the Commission, composed initially of six experts – later expanded to nine – in various fields and from different countries.

14 April 1994

Council of Europe Parliamentary Assembly Recommendation 1240 on the protection and patentability of material of human origin, asking the Committee of Ministers adopt the text of the Bioethics Convention, thereby providing Europe with a reference to fundamental moral principles in the field of bioethics, and to initiate preparation of a protocol to the draft convention setting limits to the application of the genetic manipulation of human beings.

¹ Fact sheet on the Temporary Committee on Human Genetics and Other New Technologies in Modern Medicine: EP Directorate-General for Information (DG III).

5 July 1996

Birth of a cloned lamb in the UK by the transfer of a nucleus from an adult sheep.

19 November 1996

Council of Europe Parliamentary Assembly Opinion No 184 for the Protection of Human Rights and the Dignity of the Human Being with regard to the Application of Biology and Medicine (Bioethics Convention) is adopted by the Committee of Ministers. DIR/JUR(96)14.

4 April 1997

The Bioethics Convention is signed. Article 13 implicitly forbids the cloning of human beings.

14 May 1997

50th World Health Assembly meeting in Geneva adopts a resolution affirming that the use of cloning for the replication of human beings is ethically unacceptable and contrary to human dignity and morality. The Director-General was requested to inform Member States in order to foster a public debate on the issues.

28 May 1997

GEAIB submits opinion No 9 to the Commission on the ethical aspects of cloning techniques in which it states that ‘particular attention should be paid to the need to preserve genetic diversity ... any attempt to produce a genetically identical human individual by nuclear substitution from a human adult or child cell (“reproductive cloning”) should be prohibited ... The European Community should clearly express its condemnation of human reproductive cloning ... in the relevant texts and regulations in preparation.’ It calls for a distinction between cloning and embryo splitting, and therapeutic and reproductive cloning.

16 July 1997

Steering Committee on Bioethics (CDBI) gives opinion to the Council of Europe Parliamentary Assembly on the draft additional protocol to the Bioethics Convention on the prohibition of the cloning of human beings. ‘Considering the purpose of the Convention on Human Rights and Biomedicine, in particular the principle mentioned in Article 1 aiming to protect the dignity and identity of all human beings, the CDBI is of the opinion that specific binding provisions should be adopted within the Council of Europe to prohibit any intervention seeking to create a human being genetically identical to another human being, whether living or dead’.

31 July 1997

Expiry of the mandate of the GAEIB.

23 September 1997

Council of Europe Parliamentary Assembly Opinion No 202 recommending the rapid adoption of the draft additional protocol to the Convention on Human Rights and Biomedicine on the prohibition of the cloning of human beings.

10 –11 October 1997

Final Declaration adopted by the Second Summit of the Council of Europe, in which the Heads of State or Government undertook to prohibit all use of cloning techniques aimed at creating genetically identical human beings and instructed the Committee of Ministers to adopt an additional protocol to the Bioethics Convention.

6 November 1997

Council of Europe adopts the Additional Protocol to the Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine, on the Prohibition of Cloning of Human Beings.

11 November 1997

Universal Declaration on the Human Genome and Human Rights and a resolution for its implementation adopted by the General Conference of the United Nations Educational, Scientific, and Cultural Organisation (Unesco). Article 5b stated the need for prior free and informed consent for research and treatment. Article 6 stated that no one should be subject to discrimination based on genetic characteristics. Article 11 asserted that practices contrary to human dignity such as reproductive cloning should not be permitted.

11 December 1997

The GAEIB issues Opinion No 10 on the ethical aspects of the 5th Framework Research Programme. Article 2(3) stated that the Commission should ensure that an ethical assessment is made of the research projects submitted to it, that the analysis of ethical questions on controversial research issues such as gene therapy (excluded from the Framework Programme) should be undertaken and studies should take place on interaction between research development and society. It recommended that the Commission set up an information system concerning all the related legal and ethical data at international and national levels, which should be regularly updated.

16 December 1997

The European Group on Ethics in Science and New Technologies (EGE) replaces the GAEIB. The EGE, essentially similar to national ethics committees, is independent, multicultural and multidisciplinary and therefore able to deliver opinions entirely free of outside influence.

12 January 1998

The additional protocol to the Bioethics Convention relating to the prohibition of cloning of human beings is signed.

7 May 1998

Executive Board of Unesco established the International Bioethics Committee

23 November 1998

Opinion No 12 of the European Group on Ethics in Science and New Technologies (EGE) considers that, according to the ethical dimension of the Community's Fifth Framework Programme, respect for pluralism of cultures and ethical approaches in Europe, which is reflected by the extreme diversity of national regulations, should not *a priori* exclude European financial support for human embryo research carried out in countries where it is permitted, but that this funding should be granted only under strict conditions. This type of research is forbidden by law, notably in Germany, Austria and Ireland. In France research projects that ultimately lead to the destruction of the embryo are prohibited. However, studies which do not interfere with the integrity of the embryo are permitted. In Denmark, the United Kingdom, Spain and Sweden human embryo research is allowed by law under certain conditions. Laws concerning this issue are at the preparatory stage in the Netherlands, Belgium and Finland.

8 December 1998

Joint report in the UK by the Human Genetics Advisory Commission and the Human Fertility and Embryology Association recommending that human cloning be banned but that the 1990 Human Fertility and Embryology Act be altered for therapeutic purposes.

9 December 1998

United Nations General Assembly Resolution 53/152 endorsed the Declaration on the Human Genome and Human Rights. It stated that it was *convinced* of the need to develop international rules and a life sciences ethic at national and international levels. It invited governments to establish independent, multidisciplinary and pluralist ethics committees, notably in conjunction with the International Bioethics Committee, with a view to promoting exchanges of experience.

3 February 2000

Report of the EGE on the Charter of fundamental rights in relation to new technology, emphasising the serious risk of the instrumentalisation of human beings through genetic manipulation. This is deemed ethically unacceptable but it is acknowledged that it could become a reality at a time when human power over life is increasing considerably.

June 2000

UK Department of Health Report from the Chief Medical Officer's Expert Group reviewing the potential of developments in stem cell research and cell nuclear replacement to benefit human health. The report concludes that the great potential to relieve suffering and treat disease means that research is warranted across the whole range of possible sources of stem cells in the first instance, including embryos. Provided that the need to use embryos created by cell nuclear replacement is clearly demonstrated on a case-by-case basis with proper consent of the donors and under the regulatory control of the Human Fertilisation and Embryology Authority, the Expert Group is willing to support it and concludes that the potential benefit of discovering the mechanism for reprogramming adult cells and thereby providing compatible tissue for treatment justifies this transitional research involving the

creation of embryos by cell nuclear replacement.

14 November 2000

Opinion No 15 of the EGE attached to the Commission, 'Ethical Aspects of Human Stem Cell Research and Use', recommending that a specific Community budget for research on alternative sources, especially adult stem cells, be provided and an ethical assessment of research on stem cells financed by Community appropriations be carried out before the launching of a project and also when monitoring its implementation.

7 December 2000

The Charter of fundamental rights is proclaimed at the European Summit in Nice. Under Article 3 of Chapter 1 on dignity the reproductive cloning of human beings is prohibited.

17 December 2000

British MPs vote in favour of allowing scientists to harvest special stem cells for early-stage embryos in order to grow skin and organ tissue for research. This vote is passed as an amendment to the 1990 Human Fertilisation and Embryology Act, which allows 14-day-old embryos left over from IVF treatment to be used for research on infertility only.

11 January 2001

Scientists at the Oregon Regional Primate Research Centre in the United States produce the first genetically modified monkey.

22 January 2001

Members of the House of Lords approve government plans to allow the cloning of human embryos for research purposes. They also decide that a select committee should begin an inquiry into the implications of the decision.