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

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DRAFT REPORT

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

Part 1: Motion for a resolution

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

Rapporteur: Francesco Fiori

CONTENTS

	Page
PROCEDURAL PAGE.....	4
MOTION FOR A RESOLUTION.....	5
Published separately:	
Explanatory statement.....	Part 2: A5-0000/2001

PROCEDURAL PAGE

At the sitting of 13 December 2000 Parliament 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 meeting(s) of

At the latter/last meeting it adopted the motion for a resolution by ... votes to ..., with ... abstention(s)/unanimously.

The following were present for the vote: ... chairman/acting chairman; ... and ..., vice-chairman/vice-chairmen; ..., rapporteur; ..., ... (for ...), ... (for ... pursuant to Rule 153(2)), ... and

The explanatory statement is published separately in part 2 of the report.

The report was tabled on

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

MOTION FOR A RESOLUTION

European Parliament resolution on the social, legal, ethical, and economic 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 medicine,

having regard to the following Community legal instruments:

- 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 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 data¹,
- Directive 98/44/EC on the legal protection of biotechnological inventions²,
- 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)³,
- 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)⁴,
- 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) and the proposals for decisions concerning the specific programmes (COM(2001) 279),
- the European Parliament resolution of 7 September 2000 on human cloning,

having regard to the following international legal instruments:

- 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,

¹ OJ L 281, 23.11.1995, p. 31.

² OJ L 213, 30.7.1998, p. 13.

³ OJ L 26, 1.2.1999, p. 1.

⁴ OJ L 64, 12.3.1999, p. 1.

- 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 November 1998,
- 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 Edinburgh in October 2000,
- 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 and Use’,
- 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 the report of the Temporary Committee on Human Genetics and Other New Technologies in Modern Medicine (A5-..../2001),

As regards genomic research

- A. whereas knowledge of the human genome marks the beginning of real understanding of the way in which the human body functions and interacts with the environment; whereas such understanding could eventually make it possible to diagnose, prevent, and treat diseases much more accurately, by a far more personalised approach, and much more effectively than is at present the case; whereas the foreseeable economic advantages are immense; whereas, however, the benefits to humankind, in terms of health, and the economic advantages for the Union will be impossible to exploit to the full unless Europe creates the right general conditions,
- B. whereas in the context described above, there is a perceived need for integrated approaches; 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, 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 interactive dialogue with end-users and social players – patients, ethics experts, investors, institutions, and the public at large – leading to socially responsible decisions and to secure the acceptance of public opinion,

As regards the common ethical principles

- C. whereas the indispensable principle of respect for human dignity needs to be reconciled with the principle of freedom of research, since both are unanimously recognised at international level and have been reaffirmed more recently in the European Union Charter of fundamental rights,
- D. whereas over the course of its history the Union has developed an inbuilt cultural, ethical, and religious pluralism that reflects the richness of its traditions and imposes an additional requirement of mutual respect and tolerance, implicit in the ethical dimension of European society; and whereas from the legal point of view, respect for the above values is consistent with Article 22 of the Charter of fundamental rights and Article 6 of the TEU,
- E. whereas the United Nations Educational, Scientific, and Cultural Organisation (Unesco), the World Health Organisation (WHO), the Council of Europe, and the European Union itself have provided themselves with various instruments that take account of fundamental ethical principles such as 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), freedom of research, protection of public health, and non-discrimination on the grounds of genetic features,
- F. whereas there is an international consensus 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 should 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,
- G. whereas in the Charter of fundamental rights the EU has taken a decisive step 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 as such a source of financial gain, ... [and] the prohibition of the reproductive cloning of human beings’,

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

- H. whereas it is recognised that the Member States and the Union need to work together to establish conditions enabling human genetics to assume its due importance and must determine the cases in which European action would be appropriate,
- I. whereas the Treaty on European Union does not contain any provisions referring

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.

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),

- J. whereas the rules that the Union should draw up to govern 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; whereas the inability to achieve a ‘shared consensus’, stemming from genuine dialogue among the parties concerned, could result in a failure to lay down a single frame of reference and the impossibility of adopting public policies,

As regards the work of the temporary committee

- K. whereas in keeping with the brief conferred on it, the Temporary Committee on Human Genetics has been focusing chiefly on two areas, namely diagnosis (genetic testing) and therapy (cure and treatments) on the one hand and, secondly, financing of research under the sixth framework programme and the patentability of products and processes derived from biological materials,

As regards genetic tests

- L. whereas a growing number of laboratories in Europe are offering genetic testing services and whereas genetic testing practices are becoming increasingly more frequent, following a trend that is bound to gather pace,
- M. whereas there are at present no common European rules or regulations to guarantee that genetic testing 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 devices¹, which applies only to products to be marketed,
- N. 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,

¹ Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on *in vitro* diagnostic medical devices.

As regards biomedicines

- O. 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 is recognised to pose a severe limitation that makes it difficult to develop and test new biomedicines on an EU-wide scale¹,
- P. 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 regards stem cells

- Q. whereas the use of stem cells for therapeutic purposes is becoming established as a potentially revolutionary 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, and so forth, for which there are today no effective treatments or cures,
- R. whereas stem cells are present for the entire duration of an individual’s development, both in children and in adults; whereas, however, the proportion of stem cells and their ability to give rise to different types of specific cells decreases over time; whereas 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,

As regards the sixth research framework programme

- S. whereas genomics and biotechnology for health is one of the ‘priority thematic areas of research’ set out in the proposal for a decision concerning the sixth framework programme,

As regards the use of genetic data

- T. whereas the spread of genetic tests will increasingly fuel the momentum of the shift towards a form of social organisation strongly characterised by genetic classification and control criteria, as is being demonstrated by the numerous proposals for genetic databanks; whereas genetic data are viewed as highly specific information; whereas they can 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,

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.

U. whereas the possibility of obtaining personal genetic information entails the risk of new forms of discrimination, raising problems related to privacy, the confidentiality of data, and informed consent,

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

V. 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 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,

W. whereas Directive 98/44/EC provides a guideline as to what is at present deemed contrary to public morality and hence unpatentable; and whereas discussion has recently been taking place to determine that which should be considered patentable and that which should not,

X. 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; whereas it is permitted in the United States to patent both inventions and discoveries of things already existing in the natural environment; whereas in the European countries, however, only inventions may be patented,

Y. whereas under the above-mentioned Directive it is expressly forbidden to patent:

- the human body and its 'elements' in the natural state (Article 5);
- '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',

As regards an 'integrated working method'

1. To prevent the debate on human genetics and its applications from taking shape in a random fashion and, more often than not, lagging behind the scientific developments under way, without detracting from the pluralism of the ethical attitudes represented in Europe, considers it necessary to take the following action:

- (a) essential ethical principles must be emphasised, including, for example, those set out in the Union Charter of fundamental rights, 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 hence influence the future trend regarding the laws on that subject;
- (b) public debate needs to be launched on the use of genetic engineering before it is applied on a large scale;
- (c) researchers, business circles, standard-setters, 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;

As regards the legal context

- 2. Maintains that science and research must be free;
- 3. Maintains that there are limits to the above freedom on account of the need to protect the dignity of the individual and the fundamental rights of every human being, and that the outcome of biomedical research should be such as to benefit humankind as a whole and future generations;
- 4. Considers that ‘governing’ the changes taking place in the current biological revolution is a task to be undertaken by legislators, whether operating at national and/or European level;
- 5. 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);

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

I. Human genetics: diagnosis and therapy

Genetic tests

- 6. Notes that genetic diagnosis is a medical procedure that must invariably conform to the rules of what is termed ‘good clinical practice’; genetic testing can enable individuals to take independent decisions and 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, the forms of testing offered (tests must be accurate, and equal access to testing services afforded to all), the context (explanations and counselling without encroaching on personal self-determination), and technology may become equally important factors; high standards of genetic testing are thus a *sine qua non*, given that decisions having a crucial bearing on a person’s life are taken in the light of the results;

7. 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;
8. Believes, furthermore, that the rules governing this area ought to state clearly that genetic testing should be used only for medical 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;
9. Notes that genetic testing will in many cases be used for predictive purposes and that any discussion on the enormous medical, legal, psychological, and ethical implications of inaccurate findings raises the need to determine a legal and regulatory framework 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;
 - (c) ensure compliance with essential values in medical genetics, proceeding from the premiss 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 must have the right to know and not to know);
 - (d) provide expert 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 genetic differences under the necessary fair safeguard laws prohibiting every form of discrimination against persons suffering from the conditions concerned;
 - (g) set up social services to help meet the human and economic costs incurred when a person suffers from a given physical or mental condition (support for parents, access to education, and job opportunities);
 - (h) set up a European laboratory network to cover rare diseases;
10. Calls, therefore, on the Commission to take the necessary steps as described above with a view to filling the current regulatory vacuum;

Pharmacogenetics

11. Believes that one key area is the potential for personalised therapy, the aim of which would be to prepare and administer made-to-measure drugs to match genetic profiles identified by means of what the jargon terms snips (single nucleotide polymorphisms), enabling doctors to predict how a patient would react to a drug and consequently to decide whether or not to administer it and, if the case were to arise, what exact dose to give;
12. Recognises that pharmacogenetics could offer great benefits, first of all as a form of therapy that could help reduce suffering 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;
13. 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; 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;
14. 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;
15. 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 clear-cut rules to govern not only the development, but also testing and approval of new biomedicines;

II. Use of personal data related to genome analysis

16. Points out that under Articles 8 and 21 of the Charter of fundamental rights, discrimination on account of genetic features, as well as on other grounds, is prohibited and that ‘Everyone has the right to the protection of personal data concerning him or her’; notes in addition that under Articles 11 and 12 of the European Convention on Human Rights and Biomedicine, predictive genetic tests may be performed ‘only for health purposes or for scientific research linked to health purposes, and subject to appropriate genetic counselling’, and that ‘Any form of discrimination against a person on grounds of his or her genetic heritage is prohibited’;
17. Maintains that the public at large needs to be sure that genetic research is being conducted with sufficient safeguards to protect the interests of individuals and future generations as well as enabling legitimate medical research activities to be pursued for the benefit of society;

18. 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 on protection of the inviolability of the person and the requirement to obtain an individual's consent for the purpose of protecting his or her health (or medical research), ruling out any other purposes such as those connected with assessment of his or her suitability from the point of view of an employment relationship or insurance contract;
19. 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;
20. 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 biological 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 prevent the emergence of disturbing 'genetic normality' parameters;
21. 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);
22. 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 be restricted to the utmost degree, even more severely than in the past, since assessments on that basis disregard the decisive relationship with proteins and environment and therefore produce distorted images of the person in question; if it were to become more difficult 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 fundamental right to health;
23. Maintains, 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 in addition that insurers cannot ask to be informed about the genetic data of which an insured person knows;

24. 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; 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;
25. Calls for a legally binding ban on the selection of workers on the basis of genetic criteria and mass genetic testing for the purposes of medical check-ups, the aim being to avert the danger of a society in which the 'unemployable' would emerge alongside the 'uninsurable' and selection policies would predominate;
26. 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; 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;
27. 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, prevent the existing drug licensing rules from being circumvented, and ensure that individual access does not make nonsense of the increasingly recognised need for genetic counselling;
28. 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 and society as a whole; exceptions to this general principle of confidentiality should be permissible in cases where genetic fingerprints stored in DNA databanks are to be used to identify and apprehend criminals¹;

III. Patentability of processes and products derived from biological material

29. 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;

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

30. Notes that Directive 98/44/EC, on the legal protection of biotechnological inventions, is currently being transposed in the Member States' legislative systems and four countries have transposed it to date¹; and draws attention to the difficulties inherent in implementing the Directive;
31. Recognises, notwithstanding the difficulties of interpreting the Directive and especially Article 5(1) and (2), that there has to be a legal framework and harmonisation in this area; points out, however, that in such a sensitive field, in which the need to safeguard knowledge and disseminate research findings has to be reconciled with the outright economic imperatives dictated by commercial suppliers, some clarifications ought to be made to the interpretation of unpatentability of the human body, given that 'elements isolated from the ... body' may, by contrast, be patented;
32. Maintains that, as regards the possibility of patenting biological material, it is vital to make a clear distinction, which, moreover, already exists in European law, between a 'discovery' and an 'invention' to the effect that the former is not patentable; United States law is different to the extent that the term 'invention' is often indistinguishable from a 'discovery';
33. Points out that if an invention is to be considered patentable under the European law in force, it must be involve an inventive step and lend itself to industrial application;
34. Notes that the Commission is required 'every five years' to produce 'a report on any problems encountered with regard to the relationship between ... Directive [98/44/EEC] and international agreements on the protection of human rights to which the Member States have acceded' and 'annually' to publish '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 to ensure that it submits the first annual report without delay and points to the importance of implementing the Directive and, in particular, dealing with the difficulties of interpretation raised by Member States;
35. Calls in this connection for a forum to be set up to discuss and assess the provisions of the above Directive; the purpose of the forum, taking into account scientific progress, should be to oversee the implementation of a Europe-wide legal philosophy and at the same time encourage all parties concerned to develop a common vision of the possibilities and limitations of the Directive;

IV. The sixth research framework programme

Guidelines for an ethical frame of reference

36. 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;

¹ Denmark, Ireland, Finland, and the United Kingdom.

37. 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 set out in the Union Charter of fundamental rights and relevant international conventions such as the Declaration of Helsinki, as adopted in Edinburgh in October 2000, the Council of Europe Convention on Human Rights and Biomedicine, signed in Oviedo on 4 April 1997, and the Additional Protocol prohibiting cloning of human beings, signed in Paris on 12 January 1998, the Universal Declaration on the Human Genome and Human Rights adopted by Unesco, and World Health Organisation (WHO) resolutions on the above and related subjects,
 - (b) the laws of the Member States;
38. Endorses the opinion of the European Ethics Group on ethical aspects of stem cell research, which makes the following recommendations:
- (a) it is too early for the time being to create embryos by means of somatic cell nuclear transfer (therapeutic cloning) to meet the needs of cell therapy research, because a vast field of research has still to be explored using other strains of human stem cells;
 - (b) a Community budget should be drawn up to finance research using these alternative sources, in particular adult stem cells;
 - (c) steps should be taken at European level to ensure that research findings are disseminated widely and not kept secret for commercial reasons;
 - (d) 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;
39. 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;
40. Recommends that no Community funding be granted for:
- (a) the creation of human embryos from donated gametes solely for research purposes;
 - (b) the creation of human embryos by means of somatic cell nuclear transfer (therapeutic cloning);
41. Maintains that human cloning for reproductive purposes must be prohibited;

Recommendations to the Union Member States regarding genomic research funding

42. Acknowledges that, given the pluralism obtaining in Europe, it is up to each Member State to prohibit or authorise embryo research but maintains that, if such research is authorised, respect for human dignity implies that rules must be laid down to avert the risk of arbitrary experimentation and exploitation of the human embryo;

43. Maintains that research on ‘surplus’ human embryos (embryos created for use in the treatment of infertility in order to increase the success rate of IVF but no longer needed) should be financed if, and only if, it is subject, in the country where it is authorised, to strict public supervision by a central body; this rule should apply whether the research in question is publicly or privately funded;
44. Notes that biotechnological research is tending to concentrate increasingly in a small number of large multinationals and believes that national, Community, and international public authorities should be called upon to:
- (a) monitor the effects of such concentration, given that they could have an impact on the public interest;
 - (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 poor or children or which occur in the poorest countries or treatments for rare diseases;
 - (d) promote research into the risks of biotechnology and the ways of avoiding such risks;
 - (e) foster public-private partnerships;

Measures to be pursued using Community genomic research funding

45. 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 in the proposal for a decision concerning the sixth research framework programme, on the understanding that a distinction should be made in the above priority area according to its two component research fields, each of which should be identified under its own heading;
 - (b) support cooperation among academic researchers, doctors, biotechnologists, entrepreneurs, and industry in general aimed at identifying the functions of genome data and developing new medical treatments;
 - (c) support prenormative research in the field of human genetics, including for example 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 new biomedical developments;
 - (e) set up centralised information and/or common material systems, employing procedures such as registration of data on new biomedicines, including clinical trial data and information connected with the subsequent approval stage (for instance notes

on adverse reactions), comparison with pharmacogenetic 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 into the ethical, social, legal, and economic aspects of human genetics;
- (g) support initiatives seeking to foster a new consensus on life science applications (such as, for example, the high-level working party on life sciences), by popularising the life sciences in the media and increasing public understanding;
- (h) 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;

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

46. 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;
47. 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, including public consultation, by involving patients 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;
48. Considers that, in order to take the action referred to above and be able to keep up with the extremely fast-moving scientific developments and, as far as possible, make provision in advance for the necessary public policy rules, a permanent forum needs to be set up, in collaboration with the other EU institutions, to deal with human genetics and

developments in new medical technologies;

49. Believes that such a forum would not only make it possible to monitor developments, but would also help to channel information towards the public and foster 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 one representative each from the Commission and Council, could meet twice a year for the purpose of reviewing research investment and taking action on such ethical, legal, economic, and social problems as might periodically arise;
50. 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.