The World of Biotech:

A Review of Biotechnology and Human Genetics Policy in Selected International Agencies, Business Organisations and States (EU, UK, Australia and the USA).

Commissioned by The Working Group on Women, Health and the New Genetics
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THE CORPORATE WORLD

Biotechnology is a booming business. In the international biotech industry, the largest market segment is human health therapeutics. Altogether, it accounts for about 69 per cent of biotechnology assets world-wide. The world market for products derived through modern biotechnology in 1992 was estimated at $10 billion in sales and is expected to reach $100-305 billion by the year 2000-2005. In 1996, the majority of European bioscience companies (44 per cent) were involved in health care, while the percentage of companies involved in the agro-bio, environmental or food processing sectors amounted to 16 per cent. In this same year the total US biotechnology product market was estimated at $10.1 billion in sales.

See "The Economic Aspects of Biotechnologies Related to Human Health -- Part I: Biotechnology And Medical Innovation: Socio-Economic Assessment Of The Technology, The Potential And The Products" published by Organisation for Economic Co-operation and Development (OECD) in 1998 at http://www.oecd.org/dsti/sti/s_t/biotech/act/reports.htm.

For the latest on biotech in the OECD, see the latest edition of Policy Brief: Modern Biotechnology and the OECD at http://www.oecd.org/publications/Pol_brief/.

For a primer on the business side of biotech, see the 1999 report published by PriceWaterhouseCoopers entitled "The Impact of Genomics on the Pharmaceutical Industry: A Pharmaceutical Group White Paper" at http://www.pwcglobal.com/gx/eng/about/ind/pham/pdf/PwC_pharma_genomics.pdg.

Organisation For Economic Co-Operation And Development (OECD)

The Organisation for Economic Co-operation and Development has been called a think tank, monitoring agency, rich man's club, an un-academic university. It has elements of all, but none of these characterisations captures the essence of the OECD. The OECD groups 29 member countries in an organisation that, most importantly, provides governments a setting in which to discuss, develop and perfect economic and social policy. Members compare experiences, seek answers to common problems and work to co-ordinate domestic and international policies that increasingly are to form a web of common practice across nations. Members' exchanges may lead to agreements to act in a formal way - for example, by establishing legally-binding codes for free flow of capital and services, agreements to crack down on bribery or to end subsidies for shipbuilding. But more often, their discussion makes for work within their own governments on the spectrum of public policy and clarifies the impact of national policies on the international community. And it offers a chance to reflect and exchange perspectives with other countries similar to their own.

The OECD is a club of like-minded countries. It is a rich club. OECD countries produce two thirds of the world's goods and services. Membership is limited only by a country's commitment to a market economy and a pluralistic democracy. The core of original members has expanded from Europe and North America to include Japan, Australia, New Zealand, Finland, Mexico, the Czech Republic, Hungary, Poland and Korea. And there are many more contacts with the rest of the world through programmes with countries in the former Soviet bloc, Asia, Latin America - contacts

which, in some cases, may lead to membership.

Exchanges between OECD governments flow from information and analysis provided by a Secretariat in Paris. Parts of the OECD Secretariat collect data, monitor trends, analyse and forecast economic developments, while others research social changes or evolving patterns in trade, environment, agriculture, technology, taxation and more. This work, in areas that mirror the policy-making structures in ministries of governments, is done in close consultation with policy-makers who will use the analysis, and it underpins discussion by member countries when they meet in specialised committees of the OECD. Much of the research and analysis is published. See http://www.oecd.org/about/general/index.htm.

> Pursuant to Article 1 of the Convention signed in Paris on 14th December 1960, and which came into force on 30th September 1961, the Organisation for Economic Co-operation and Development (OECD) shall promote policies designed: to achieve the highest sustainable economic growth and employment and a rising standard of living in Member countries, while maintaining financial stability, and thus contribute to the development of the world economy; to contribute to sound economic expansion in Member as well as non-member countries in the process of economic development; and to contribute to the expansion of world trade on a multilateral, non-discriminatory basis in accordance with international obligations.
>
> The original Member countries of the OECD are Austria, Belgium, Canada, Denmark, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, the Netherlands, Norway, Portugal, Spain, Sweden, Switzerland, Turkey, the United Kingdom and the United States. The following countries became Members subsequently through accession at the dates indicated hereafter: Japan (28th April 1964), Finland (28th January 1969), Australia (7th June 1971), New Zealand (29th May 1973), Mexico (18th May 1994), the Czech Republic (21st December 1995), Hungary (7th May 1996), Poland (22nd November 1996) and the Republic of Korea (12th December 1996). The Commission of the European Communities takes part in the work of the OECD (Article 13 of the OECD Convention).

The OECD is now undertaking a project looking at the harmonisation of different aspects of genetic testing. The Austrian government offered to host an OECD workshop to be held in Vienna, 23-25 February 2000 for future research. See the 15 November 1999 edition of "OECD Biotechnology Update: Internal Co-ordination Group for Biotechnology" by OECD at http://www.oecd.org/ehs/ehsmono/Newsletter4.pdf.

The OECD published a background paper "Intellectual Property Practices in the Field of Biotechnology" on 1 February 1999 at http://appli1.oecd.org/olis/1998doc.nsf/LinkTo/td-tc-wp(98)15-final.

The OECD also published another report in 1996 called "Intellectual Property, Technology Transfer and Genetic Resources: An OECD Survey of Current Practices and Policies" at http://www.oecd.org/dsti/sti/s_t/biotech/index.htm.

International Chamber of Commerce (ICC)

The International Chamber of Commerce (ICC) published two documents on biotechnology and intellectual property. The ICC claims to represent thousands of companies in 130 countries and has the highest consultative status with UN.
See: http://www.iccwbo.org/home/intro_icc/introducing_icc.asp (Tab 3).

The ICC published "Trade Related Aspects of Intellectual Property Rights (TRIPS) and the Biodiversity Convention: What Conflicts?" on 28 June 1999.
See: http://www.iccwbo.org/home/statements_rules/statements/1999/trips_and_cbd.asp (Tab 4).

The ICC also published "Biotechnology Patents in the European Union" on 23 October 1997.
See: http://www.iccwbo.org/home/statements_rules/statements/1997/biotechnology.asp (Tab 5).

INTERNATIONAL AGENCIES

UNESCO & IBC

UNESCO, United Nations Educational, Scientific and Cultural Organization.

UNESCO's constitution was adopted by the London Conference in November 1945, and entered into effect on the 4th of November 1946 when 20 states had deposited instruments of acceptance. It currently has 188 Member States (as of 19 October 1999).

The main objective of UNESCO is to contribute to peace and security in the world by promoting collaboration among nations through education, science, culture and communication in order to further universal respect for justice, for the rule of law and for the human rights and fundamental freedoms which are affirmed for the peoples of the world, without distinction of race, sex, language or religion, by the Charter of the United Nations. To fulfill its mandate, UNESCO performs five principal functions:

1. Prospective Studies : what forms of education, science, culture and communication for tomorrow's world?
2. The advancement, transfer and sharing of knowledge : relying primarily on research, training and teaching activities.
3. Standard-setting action : the preparation and adoption of international instruments and statutory recommendations.
4. Expertise : provided to Member States for their development policies and projects in the form of "technical co-operation".
5. Exchange of specialized information among nations.

UNESCO formed a permanent Committee, the International Bioethics Committee (IBC) to

> …promote reflection on the ethical and legal issues raised by research in the life sciences and their applications, as well as encourage the exchange of ideas and information, particularly through education. It shall also co-operate with the international governmental and non-governmental organizations concerned by the issues raised in the field of bioethics as well as with the national and regional bioethics committees and similar bodies.

For IBC Statutes, see http://www.unesco.org/ibc/uk/presentation/statutes.html (Tab 8). The Web page was last updated on 7 May 1998.

In November 1997, the Universal Declaration on the Human Genome and Human Rights was adopted by the UNESCO.

The Declaration is located at http://www.unesco.org/ibc/uk/genome/projet/index.html (Tab 6). Also see Mechanism for "Monitoring the Future Universal Declaration on the Human Genome and Human Rights" issued by IBC of UNESCO on 3 October 1996 at http://www.unesco.org/ibc/uk/genome/mecanisme/index.html (Tab 7).

World Health Organisation (WHO)

Founded in 1948, the World Health Organization (WHO) leads the world alliance for Health for All. WHO has four main functions:

1. to give worldwide guidance in the field of health;
2. to set global standards for health;
3. to cooperate with governments in strengthening national health programmes;
4. to develop and transfer appropriate health technology, information and standards.

The WHO definition of health: "Health is a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity."
See: http://www.who.org/aboutwho/en/rapid.htm.

A great number of international committees, commissions and advisory groups and many reports and guidelines have been produced on specific biomedical issues. In dealing with ethics, WHO has said it will not duplicate what has been done or is being done in existing national or regional forums. WHO's involvement in ethics will be directly derived from its global mission, its inclusive vision of health, and its responsibility for coordinating international health action.

Cutting across specific health issues and disciplines, WHO's main aim is to enhance the integration of ethics in overall public health policies and practices as well as in international health cooperation. WHO said perhaps the most pressing reason for this is to promote greater equity in access and use of health services by all individuals and in all countries. WHO said it will contribute to coordinating national and regional approaches, identifying gaps and workable solutions, and promoting harmonization of standards and practices at a global level.

The Human Genetics Programme (HGN) is a separate programme in WHO which develops genetic approaches to the control of the most common hereditary diseases and those with a genetic predisposition. HGN covers different subjects in response to various genetic questions which face WHO. HGN has continued the further strengthening of community approaches to the control of genetic diseases, as well as developing a network of international collaborating programmes. In cooperation with various nongovernmental and other international organizations, HGN now covers different fields of medical genetics including monogenic diseases (thalassaemias and sickle cell disorder, cystic fibrosis, haemochromatosis, haemophilia, neurofibromatosis, phenylketonuria), congenital disorders (monitoring of congenital malformations), some common diseases with a genetic predisposition (cardiovascular diseases, familial hyperholesterolaemia, mental disorders), new genetic technology (monitoring of human genome research, ethical aspects of genetic service delivery) and education and training aimed at communities and health professionals (guidelines, education materials). For information on the HGN at WHO, please see http://www.who.int/ncd/hgn/infogen.htm (Tab 9).

In 1998, the HGN issued a set of guidelines that espouse ideas similar to the UNESCO's Declaration. The HGN states as follows:

> Genetics teaches that there is no such thing as a "superior" or "inferior" genome; humankind depends for its richness and its survival on the interaction of its complex genetic diversity with the environment. Genetic data should only be used to the advantage of members of a

family or ethnic group, and never to stigmatize or discriminate against them. The medical application of genetic knowledge must be carried out with due regard to the general principles of medical ethics; doing good to individuals and families, not doing harm, offering autonomy of choice after information is given, and facilitating personal and social justice. Genetic services for the prevention, diagnosis and treatment of disease should be available to all, without regard to ability to pay, and should be provided first to those whose needs are greatest.

There shall be no compulsory genetic testing of adult individuals or populations. Every test shall be offered in such a way that individuals and families are free to refuse or accept according to their wishes and moral beliefs. All testing should be preceded by adequate information about the purpose and possible outcomes of the test and potential choices that may arise. Children shall only be tested when it is for the purpose of better medical care, as in the case of newborn screening when early treatment will be of benefit to the child. Prenatal diagnosis should be offered to those who need it, but there must be no pressure on couples to accept such testing, nor to use the results of the test to compel either continuing or terminating a pregnancy when the fetus is affected with a genetic disorder. Decisions in the context of reproduction should rest with those being tested, not with physicians or the government.

The woman should be an important decision-maker in all matters related to reproduction. Prenatal diagnosis should be done only to give parents and physicians information about the health of the fetus; its use for paternity testing, except in cases of rape or incest, or for gender selection, apart from sex-linked disorders, is not acceptable.

Genetic data should be treated as confidential at all times. Genetic data should only be used to advantage and empower an individual or family, and for better treatment or prevention of disease. Data relevant to health care should be collected and kept by medical geneticists in secure confidential files. Genetic data should not be given out to insurance companies, employers, schools or governments, other than after the full informed consent of the person tested. In some countries it may be possible, or necessary, to protect both confidentiality and non-discrimination through legal means.

Genetic counselling is the provision of accurate, full and unbiased information in a caring, professional relationship that offers guidance, but allows individuals and families to come to their own decisions. Counselling is essential before any genetic testing is carried out, and should continue afterwards if the results entail choices for the person and family tested. Genetic counselling should be available to all, and should be as non-directive as possible.

Education about genetics for the public and health care professionals is of paramount importance. Genetics is playing an increasingly important part in medical practice, and many people are concerned about possible abuse of this new knowledge. It is important that education about genetic principles relevant to human health be emphasized appropriately for all people in all cultures.

For more on the above detailed framework, please see “Proposed International Guidelines on Ethical Issues in Medical Genetics and Genetic Services” at

http://www.who.int/ncd/hgn/hgnethic.htm (Tab 10).

Human Genome Organisation (HUGO)

The Human Genome Organisation (HUGO) is the international organisation of scientists involved in the Human Genome Project (HGP), the global initiative to map and sequence the human genome. HUGO was established in 1989 by a group of the world's leading genome scientists to promote international collaboration within the project. HUGO carries out a complex coordinating role within the HGP. HUGO activities range from support of data collation for constructing genetic and physical maps of the human genome to the organisation of workshops to promote the consideration of a wide range of ethical, legal, social and intellectual property issues. HUGO fosters the exchange of data and biomaterials, encourages the spreading and sharing of technologies, provides information and advice on aspects of human genome programmes and serves as a coordinating agency for building relationships between various governmental funding agencies and the genome community. HUGO provides an interface between the HGP and the many groups and organisations interested or involved in the human genome initiative. HUGO currently has over 1000 members representing over 50 countries. HUGO maintains three regional offices, HUGO Americas, HUGO Europe and HUGO Pacific, which carry out the administrative duties of the organisation. On HUGO's mission, see http://ash.gene.ucl.ac.uk/hugo/index.shtml (Tab 11).

In February 1998, HUGO Ethics Committee issued a statement called "Statement on DNA Sampling Control and Access." In the statement, the committee maintains that respect for free and informed consent and choice as well as for privacy and confidentiality in the collection, storage and use of human DNA are the cornerstones of ethical conduct in research. It reiterates the importance of recognizing that the pursuit of scientific knowledge is essential to human progress and to the relief of human suffering. This pursuit must adhere to international norms of human rights. In the context of research involving human beings, the acceptance and upholding of human dignity and freedom require prior ethical review.
See http://ash.gene.ucl.ac.uk/hugo/sampling.html (Tab 12).

In January 1999, the HUGO published a report entitled "The Future Directions of Human Genome Research in Europe: Florence Strategy Meeting in 23-6 January 1999."
See http://europa.eu.int/comm/dg12/biomed/florence-hgr-rep.pdf (Tab 13).

EUROPEAN UNION

European Commission

The Commission's job is to ensure that the European Union can attain its goal of an ever-closer union of its members. One of the principal tasks here is to secure the free movement of goods, services, capital and persons throughout the territory of the Union. The Commission must also ensure that the benefits of integration are balanced between countries and regions, between business and consumers and between different categories of citizens. The Commission initiates Community policy and represents the general interest of the European Union. The Commission acts as the guardian of the EU treaties to ensure that European legislation is applied correctly. As the Union's executive body, the Commission manages policies and negotiates international trade and cooperation agreements. Although it has the right of initiative, the Commission does not take the main decisions on EU policies and priorities. This is the responsibility of the Council of the European Union, whose members are ministers from member governments, and (in most cases) of the European Parliament as well. Please see http://europa.eu.int/comm/role_en.htm#1.

In a survey published in February 1999, the European Commission said the areas of particular importance in biotechnology development include scientific research and intellectual property. But the Commission didn't include ethics on the list of priorities even though the survey reflected greater social than economic concerns among European scientists and funding agencies. The Commission said a urgent need is for the development of a clear European directive on intellectual property designed to ensure rapid accessibility to information while protecting inventors' rights in the case of industrial exploitation. The survey covered Belgium, Denmark, France, Germany, Iceland, Sweden and the U.K. The survey includes sections of research on ethical, legal, and social implications (ELSI) issues in genetics on the following countries: Austria, Belgium, Denmark, Finland, France, Germany, Iceland, Ireland, Italy, Netherlands, Norway, Portugal, Spain, Sweden and the U.K.
See "Survey on the Current Status of "Genomes" Research in the European Union" at http://europa.eu.int/comm/dg12/biomed/genomes-book.pdf (Tab 14).

For a synopsis of the latest Ernst & Young report on the biotech industry in Europe, go to "EuroBiotech99" at http://www.ey.com/global/gcr.nsf/International/EuroBiotech99 (Tab 15).

The European Group on Ethics in Science and New Technologies of the European Commission was formed in 1998 to advise the European Community. So far the multi-disciplinary group hasn't directly addressed issues related to human genetics but it has offered opinions on human tissues banking and human embryo research. Information about the Group is available at http://www.europa.eu.int/comm/secretariat_general/sgc/ethics/en/intro_en.htm (Tab 18).

For the two Opinions, go to
http://www.europa.eu.int/comm/secretariat_general/sgc/ethics/en/opinions.htm.

Council of Europe

The Council of Europe is an international organisation based in the French city of Strasbourg. Its main role is to strengthen democracy, human rights and the rule of law throughout its member states. The defence and promotion of these fundamental values is no longer simply an internal matter for governments but has become a shared and collective responsibility of all the countries concerned. The Council of Europe is also active in enhancing Europe's cultural heritage in all its diversity. Finally, it acts as forum for examining a whole range of social problems, such as social exclusion, intolerance, the integration of migrants, the threat to private life posed by new technology, bioethical issues, terrorism, drug trafficking and criminal activities. The Council of Europe was established by 10 countries in the wake of the Second World War, with the signing of its Statute in London on 5 May 1949. For the first forty years of its life it remained a west European institution. In this regard, its history reflects that of the continent as a whole. At the end of this period, which was marked by the return to the European democratic fold of a number of countries which had formerly had authoritarian regimes, the institution numbered 23 members. It had established a significant body of standards and co-operation agreements. At a time of great stability in Europe, its political role remained fairly modest.

Since 1989, the Council of Europe has become the main political focus for co-operation with the countries of central and eastern Europe, as and when these have opted for a democratic form of government. It now has 41 members. It was given an increased role by the Vienna summit in October 1993, where the member states recognised how important it was for security and stability in Europe that all its countries should accept the principles of democracy, human rights and the rule of law. Under that general concern for democratic security, the Council of Europe has laid down a series of common principles governing the protection of national minorities, actively supported the democratic transition process and strengthened its machinery for monitoring its members' respect for their undertakings. The Strasbourg Summit of October 1997 fixed new priorities for co-operative efforts which will now benefit some 800 million Europeans. Fostering social cohesion and protecting citizen security more effectively are two of the main emphases. Others include promoting human rights - the establishment of a single, permanent Court on 1 November 1998 will be an important part of this - strengthening democracy and responding to the major cultural and educational challenges which Europe faces today.
See http://www.coe.fr/eng/present/about.htm.

The Council of Europe expressed its intent to prohibit genetic discrimination in a convention treaty on 4 April 1997 and to prohibit cloning in a follow-up protocol on 1 December 1998. Under the Convention, genetic testing should only be used for health purposes and genome modification should only be done for preventive, diagnostic or therapeutic purposes rather than sex selection of children. But as of today, the U.S., the U.K. and Australia haven’t signed on.

Please see “Summary of Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine (ETS No. 164)” at http://www.coe.fr/eng/legaltxt/164e.htm (Tab 16) and “Additional Protocol ETS NO. 168 to the Treaty ETS No. 164” at http://www.coe.fr/eng/legaltxt/168e.htm (Tab 17).

EuropaBio

EuropaBio represents 47 corporate members operating globally and 12 national associations (totalling up to 700 SMEs) involved in research and development, testing, manufacturing and distribution of biotechnology products.

EuropaBio, the voice of European bioindustries, aims to be a promoting force for biotechnology and to present its proposals to industry, politicians, regulators, NGOs, and the public at large. For more on the EuropaBio's positions, see http://www.europa-bio.be/publications/pg001.html (Tab 22).

The industry grade group EuropaBio said there should not be any more weakening of the existing directive on patent protection in Europe because that any weakening is likely to hurt the biotechnology industry in Europe. Please see the 17 March 1999 report of the forum for European Bioindustry Coordination's views on "The Directive on the Legal Protection of Biotechnological Inventions" at http://www.europa-bio.be/publications/patent02.htm (Tab 19). Corporate Watch, an non-profit group that campaigns against corporate abuses of power, claimed that the directive would allow companies to patent human biological materials without obtaining informed consent to whom the materials belong. Please see "The Proposed EU "Biotech" Patent Directive" at http://www.igc.org/trac/corner/worldnews/other/other117.html (Tab 20).

The "Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions" of the European Parliament is located at http://europa.eu.int/eur-lex/en/lif/dat/1998/en_398L0044.html (Tab 21).

Article 5.1 of the Directive 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. But Article 5.2 states that 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. Article 5.3 states that the industrial application of a sequence or a partial sequence of a gene must be disclosed in the patent application.

The EuropaBio does agree that informed consent should be required for genetic testing and human subject research, and cloning should be prohibited to be used to product human beings.

UNITED KINGDOM (UK)

In economic terms, the pharmaceutical industry is one of the most important in the UK. It contributes approximately 0.6% to total GDP and 3% of manufacturing GDP (almost £4.5 billion). It is among the UK's largest exporting sectors with exports in 1998 of £5.9 billion and a positive balance of trade of £2.4 billion. Please see "Genome Valley: The Economic Potential and Strategic Importance of Biotechnology in the UK Report" published by Department of Trade and Industry of the U.K. government in December 1999 at http://www.dti.gov.uk/genomevalley (Tab 23).

In the 1999 industry report, the government showed that it is very keen in cooperating with the biotechnology industry in general. The report indicated that the U.K. biotechnology ranks first in Europe, and but it is under threats from other European countries that provide more incentives. The report said the government understands that the industry wants a balanced regulatory regime that encourages industry innovation while at the same time ensuring public and environmental safety. For more on the biotech business in the U.K., please see "Industrial Markets for UK Biotechnology - Trends and Issues" published by the British industry trade group BioIndustry Association on 2 March 1999 at http://www.bioindustry.org/whatsnew/9903/001.html (Tab 24).

Human Genetics Commission

Based on a regulatory review conducted in 1999, the U.K. government decided to set up the Human Genetics Commission (HGC) to replace existing genetics regulatory bodies to eliminate overlaps and enhance efficiency. The HGC is supposed to spearhead the strategic development of biotechnology in the U.K. A main mandate of the HGC is to advice government ministers on ELSI issues. For background on HGC, see http://www.hgc.gov.uk/about_origin.htm (Tab 25).

The establishment of HGC reflected surveys that the public did not understand current regulatory and advisory arrangements and they considered such arrangements do not properly reflect ethical questions and stakeholders views. Please see "The Advisory and Regulatory Framework for Biotechnology: Report from the Government's Review" published by the Office of Science and Technology and the Cabinet Office of the U.K. government in May 1999 at http://www.dti.gov.uk/ost/rmay99/Bioreprt.pdf.

Advisory Committee on Genetic Testing

In 1998, the Advisory Committee on Genetic Testing (now absorbed by HGC) said it assumes that where an individual is able to give consent this will always be obtained before testing is undertaken. Consent should only be sought after the individual has been given information. The committee took the view that presymptomatic genetic testing of children for disorders not currently influenced by therapy is unjustifiable in the context of research. Please see "Advisory Committee on Genetic Testing: Advice to Research Ethics Committees" published in October 1998 at http://www.doh.gov.uk/genetics/recrev3.htm.

Human Genetics Advisory Committee: On Genetic Testing

In 1997, the Human Genetics Advisory Committee (now absorbed into HGC) said that it did not consider that a permanent ban on the use of genetic tests in insurance would be appropriate. The committee concluded that a requirement to disclose results of specific genetic tests as a condition of purchasing a specific type of insurance product would only be acceptable when a quantifiable association between a given pattern of test results and events actuarially relevant for a specific insurance product had been established. The committee did say that there is widespread concern that the perceived threat of discrimination by insurers, but it couldn't gather enough evidence to prove the concern one way or another.
See "The Implications of Genetic Testing for Insurance" published in December 1997 at http://www.dti.gov.uk/hgac/papers/paperg1.htm (Tab 26).

Also in 1997, the Human Genetics Advisory Committee concluded that the use of genetic test results to exclude people from employment or advancement on the grounds that they have a predisposition to future ill health would be unacceptable.

See "The Implications of Genetic Testing for Employment" published in July 1997 at http://www.dti.gov.uk/hgac/papers/paperg1.htm (Tab 27).

Human Genetics Advisory Committee: On Cloning

On 8 December 1998, the Human Genetics Advisory Commission (now absorbed by HGC) stated that cloning should be banned and the supposed ban received public support in consultation.

See "Consultation Rejects Human Reproductive Cloning" at
http://www.dti.gov.uk/hgac/press/press_n.htm (Tab 28).

The consultation report is entitled "Cloning Issues in Reproduction
(http://www.dti.gov.uk/hgac/papers/paperd1.htm).

The Report concluded that the Human Fertilisation and Embryology Act 1990 has proved effective in dealing with new developments relating to human cloning. It recommends that these safeguards be recognised as wholly adequate to forbid human reproductive cloning in the UK. However, it suggests that the Government might wish to consider the possibility of introducing legislation that would explicitly ban human reproductive cloning regardless of the technique used, so that the full ban would not depend upon the decision of a statutory body but would itself be enshrined in statute.

A latest background report on cloning entitled "Human 'Cloning': A Discussion Paper for the World Medical Association" was published by the British Medical Association in October 1999.
See http://web.bma.org.uk/public/ethics.nsf/webpagesvw/Cloning (Tab 29).

Nuffield Council of Bioethics

The Nuffield Council on Bioethics is an independent body established by the Trustees of the Nuffield Foundation in 1991. The Council is funded jointly by the Nuffield Foundation, The Wellcome Trust and the Medical Research Council. Current members of the Council include clinicians, educators, lawyers, nurses, philosophers, scientists and theologians. See http://www.nuffieldfoundation.org/bioethics/index.html.

Human Subject Testing and Research

In September 1998, the Nuffield Council on Bioethics made the following recommendations as follows:

> Predictive genetic testing should be strongly discouraged for children unable to give consent unless there are implications for clinical intervention in childhood. The NCB recommended that children should not be tested for carrier status for mental, or indeed other, disorders until they are competent to make their own decisions.
>
> Non-therapeutic research involving people lacking the capacity to consent to participation on their own behalf should be considered ethically acceptable, subject to strict safeguards. Written consent for participation should be the general rule. Any proposed payment for participation in research should always be carefully considered by research ethics committees and by grant-giving bodies.
>
> People making reproductive decisions in the light of a family history of a mental disorder should have access to genetic counselling. The duty of physicians to discuss and disclose any possible increase in risk revealed by genetic tests for conditions other than that under investigation be considered equivalent to the duty to do so for non-genetic types of information.
>
> The confidential nature of genetic information should be maintained. It can conceive of exceptional circumstances in which, in the absence of the consent of the individual, disclosure to close family members might be justified, if there are serious implications for them. Such decisions should be judged on a case by case basis.

For more details, please see “Mental Disorders and Genetics” at http://www.nuffieldfoundation.org/bioethics/publication/pub0006741.html. Also see the April 1995 report of “Human Tissue: Ethical and Legal Issues” at http://www.nuffieldfoundation.org/bioethics/publication/humantissue/rep0013057.html(Tab 30).

AUSTRALIA

According to "an industry-focused report" jointly produced by Ernst & Young and the Commonwealth Department of Industry, Science & Resources (ISR), Australia has approximately 120 core biotechnology companies in mid-1999. Of these, 20 are companies publicly listed on a stock exchange and 100 are privately held or publicly held unlisted companies. For more on the Ernst & Young report that was published on 1 September 1999, see "Australian Biotechnology Report 1999" at http://www.ey.com.au.

Biotechnology Australia

The Australian government launched two biotechnology initiatives in 1999. First, the government created Biotechnology Australia (BA) to help develop the country's biotechnology industry. BA reports to a Council of five ministers and will operate from within the ISR. Second, the government created an oversight agency called The Office of the Gene Technology Regulator, which operates from within the Department of Health and Aged Care portfolio and is intended to be overseen by both Commonwealth and State Ministers. The Federal Government has committed $17.5 million to fund these two agencies and other related measures in the 1999 Budget. For more, see "Biotechnology: A Framework for the Future" published by BA in May 1999 at http://www.isr.gov.au/ba/framework.html (Tab 31).

In a 1999 discussion paper, BA said that commercialization of biomedical research is a central challenge in Australia, more public research funding is crucial and the public acceptance of biotechnology is the key. For more on investment in biotechnology in Australia, see "Developing Australia's Biotechnology Future: Discussion Paper" published by BA on 2 September 1999 at http://www.isr.gov.au/ba/Reports/reports.html. Extracts of the report on investment in biotechnology by other countries are placed at Tab 32.

Biotechnology Australia: On Investment

The BA discussion paper said adequate and effective funding of public and private sector research will be essential if Australia is to compete with the rest of the world through the development of new biotechnologies. Australian government expenditure on biotechnology is estimated at approximately $200 million to $250 million per annum. The BA discussion paper said Australia's key competitor countries invest substantially more in this area. As with many areas of technology, Australia has made a significant public sector investment in research but lags internationally in the size of the private sector contribution. The BA discussion paper said that Australia has few large locally based pharmaceutical companies, most of which are subsidiaries of multinational companies, that can invest the $100 million to $200 million needed to finance the highly risky process of commercialising a research breakthrough. However, Australian biotechnology companies and research centres have demonstrated their ability to establish agreements with international partners for research commercialisation.

The BA discussion paper said commercial returns to public and private investment in research and development are likely to be modest unless development can progress to proof of concept and

product trial stages. Key issues are the effective management of intellectual property and funding of early stage development. A feature of biotechnology in the medical sector has been the formation of alliances between multinational biopharmaceutical companies and small innovative biotechnology companies and research organizations.

The Ernst & Young report, which was cited in section 5.0, said that the current Australian taxation system is noncompetitive in comparison to other major countries, particularly in the areas of capital gains tax. Because of this perception, Australian biotechnology has been missing out on investment from overseas, despite the availability of a number of concessions and grants for such ventures. Tax reforms of a capital gains tax cap of about 10% and a company income tax cap of about 30% are under consideration. The Australian Biotechnology Association, an industry organization, issued a statement on 29 September 1999 to support tax reforms. See "Australian Biotechnology Association Strongly Supports Government Capital Gains Tax System Overhaul" at http://www.aba.asn.au (Tab 33).

The Ernst & Young report also said that the patent system in Australia is very well suited for protection of biotechnology inventions, because the Australian Patents Act does not include any firm definition of what constitutes a patentable invention. In 1976, Australia was the first country to grant a valid patent for a living organism. A legislation that came into effect in January 1999 provides for an extension of term of up to five years for pharmaceutical substances for human use.

Biotechnology Australia: On Public Opinion

The Ernst & Young report said that the Australians were mixed about the advent of biotechnology. Over the period from February 1999 to the end of July 1999, coverage of biotechnology in the print, television and radio media grew dramatically with exposure in July almost doubling that of February 12 . There was also a shift in the amount of negative publicity. In February 40 per cent of the total media coverage was rated as negative and in July this negative sentiment rose to 54.4 per cent. However there was also an increase of 50% in positive articles about biotechnology in the period Feb-July 1999.

However, a December 1999 public opinion survey commissioned by BA said that most participants remained suspicious of biotechnology and genetic engineering. The main motivation for this technology was seen as increasing the profits of multinational corporations. A few participants noted the social and health benefits that could arise from biotechnology, such as a reduced use of pesticides and chemicals and the production of food to assist third world countries. Cynicism, however, was more prevalent than the perceived benefits with most participants considering that private enterprise directs the development of these applications and is only driven by financial returns. Please see "Public Attitudes Towards Biotechnology" at http://www.isr.gov.au/ba/Reports/reports.html.

National Health and Medical Research Council: Human Research

The National Health and Medical Research Council (NHMRC) consolidates within a single national organisation the often independent functions of research funding and development of

advice. One of its strengths is that it brings together and draws upon the resources of all components of the health system, including governments, medical practitioners, nurses and allied health professionals, researchers, teaching and research institutions, public and private program managers, service administrators, community health organisations, social health researchers and consumers. The functions of the NHMRC come from the statutory obligations conferred by the National Health and Medical Research Council Act 1992. The Act sets down four statutory obligations on the directions taken by NHMRC. These obligations are:

1. to raise the standard of individual and public health throughout Australia;
2. to foster the development of consistent health standards between the various States and Territories;
3. to foster medical research and training and public health research and training throughout Australia; and
4. to foster consideration of ethical issues relating to health.

The Council comprises nominees of Commonwealth, State and Territory health authorities, professional and scientific colleges and associations, unions, universities, business, consumer groups, welfare organisations, conservation groups and the Aboriginal and Torres Strait Islander Commission. See http://www.health.gov.au/nhmrc/about.htm.

In 1999, the NHMRC stressed the importance of obtaining informed consent in human subject genetic research. The Australian Health Ethics Committee (AHEC), a principal committee of the National Health and Medical Research Council (NHMRC) of the government, was appointed in December 1997 with part of its mandate to work on human subject research issues. For more on the AHEC program information last updated in June 1998, please see "The Australian Health Ethics Work Program" at http://www.health.gov.au/nhmrc/ethics/workprog.htm (Tab 34).

In a 1999 statement, the AHEC made the following recommendations:

> Before research is undertaken, whether involving individuals or collectivities, the consent of the participants must be obtained, except in specific circumstances. The ethical and legal requirements of consent have two aspects: the provision of information and the capacity to make a voluntary choice.
>
> So as to conform with ethical and legal requirements, obtaining consent for research involving human should involve: (a) provision to participants, at their level of comprehension, of information about the purpose, methods, demands, risks, inconveniences, discomforts, and possible outcomes of the research (including the likelihood and form of publication of research results); and (b) the exercise of a voluntary choice to participate.
>
> Where a participant lacks competence to consent, a person with lawful authority to decide for that participant must be provided with that information and exercise that choice. However, it is ethically acceptable to conduct certain types of research without obtaining consent from participants in some circumstances, for example, the use of de-identified data in epidemiological research, observational research in public places, or the use of anonymous surveys.

> A participant must be free at any time to withdraw consent to further involvement in the research. If any consequences may arise from such withdrawal, advice must be given to participants about these before consent to involvement in the research is obtained. A person may refuse to participate in a research project and need give no reasons nor justification for that decision. Where consent to participate is required, research must be so designed that each participant's consent is clearly established, whether by a signed form, return of a survey, recorded agreement for interview or other sufficient means.
>
> In some circumstances and some communities, consent is not only a matter of individual agreement, but involves other properly interested parties, such as formally constituted bodies of various kinds, collectivities or community elders. In such cases the researcher needs to obtain the consent of all properly interested parties before beginning the research. The consent of a person to participate in research must not be subject to any coercion, or to any inducement or influence which could impair its voluntary character.

For more on the above framework, see "National Statement on Ethical Conduct in Research Involving Humans" published by NHMRC on 28 June 1999 at http://www.health.gov.au/nhmrc/ethics/statemen.htm.

The extracts at Tab 35 are about privacy. Also see "Guidelines for Ethical Review of Research Proposals for Human Somatic Cell Gene Therapy and Related Therapies" published by NHMRC on 8 November 1999 at http://www.health.gov.au/nhmrc/publicat/synopses/e38syn.htm (Tab 36).

The NHMRC issued "Draft Guidelines under Section 95 of the Privacy Act 1988" on 13 July 1999. The Guidelines stressed the weighting of the benefits of research without consent and public interests in determining whether any privacy breach is allowed. The guidelines also ask for the consideration of alternative research method that will not breach the privacy of the subjects or will minimize the breach. See http://www.health.gov.au/nhmrc/ethics/priv2syn.htm.

Also see "Guidelines for Genetic Registers and Associated Genetic Material" published by NHMRC on 8 November 1999 at http://www.health.gov.au/nhmrc/publicat/synopses/e14syn.htm (Tab 37).

National Health and Medical Research Council: On Cloning

The NHMRC has already issued guidelines which prohibit human experimentation with the intent to produce two or more genetically identical individuals (or human cloning). Consequently, no NHMRC funding is made available for research involving the cloning of human beings. The cloning of individual human beings is prohibited by State legislation in Victoria, South Australia and Western Australia and is prohibited by National Health and Medical Research Council guidelines. The NHMRC said that legislation should be introduced in the remaining States and Territories to regulate human embryo research and to prohibit research on human embryos except as it is permitted in the NHMRC's ethical guidelines. See "Scientific, Ethical and Regulatory Considerations Relevant to Cloning of Human Beings" published by NHMRC on 16 December 1998 at http://www.health.gov.au/nhmrc/ethics/clonelnk.htm (Tab 38).

Australian Academy of Science

The Academy was founded in 1954 by Australian Fellows of the Royal Society of London with the distinguished physicist Sir Mark Oliphant as founding President. It was granted a Royal Charter establishing the Academy as an independent body but with government endorsement. The Academy's Constitution was modelled on that of the Royal Society of London. It receives government grants towards its activities but has no statutory obligation to government. The objects of the Academy are to promote science through a range of activities. It has defined five major program areas. They are:

1. recognition of outstanding contributions to science;
2. education and public awareness;
3. science policy international relations; and
4. science and industry.

The Fellowship of the Academy is made up of about 300 of Australia's top scientists, distinguished in the physical and biological sciences and their applications. Please see http://www.science.org.au/academy/academy.htm.

In a 1999 report, the Australian Academy of Science (AAS) regarded that human reproductive cloning to be unethical on safety grounds alone, whereas therapeutic cloning for tissue repair and research would be defined as an important issues for public debate. Legislation is an imperfect vehicle for responding to the rapid changes in scientific procedures and techniques and to less rapid changes in public opinion. The AAS floated the idea of formulating a set of national uniform regulations that could better react to rapid changes.

See "Therapeutic Cloning for Tissue Repair: Report from a Forum Held on 16 September 1999." Extracts of the report at Tab 39 includes some information on situations in the U.K. and the U.S.

The AAS made the following three recommendations with respect to existing and any proposed regulatory and legislative arrangements regarding human reproductive and therapeutic cloning in a report published on 4 February 1999.

1. The AAS considers that reproductive cloning to produce human fetuses is unethical and unsafe and should be prohibited. However, human cells, whether derived from cloning techniques, from ES cell lines, or from primordial germ cells should not be precluded from use in approved research activities in cellular and developmental biology;
2. The AAS strongly supports the recommendation of the AHEC that the Minister for Health and Aged Care should encourage and promote informed community discussion on the potential therapeutic benefits and possible risks of the development of cloning techniques;
3. If Australia is to capitalise on its undoubted strength in medical research, it is important that research on human therapeutic cloning is not inhibited by withholding federal research funds or prevented by unduly restrictive legislation in some States.

See "On Human Cloning: A Position Statement" at http://www.science.org.au/academy/media/contents.htm (Tab 40). The extracts include some

information on cloning status in other countries.

Australian Medical Association

The Australian Medical Association is an independent organisation which represents more than 23,000 doctors, whether salaried or in private practice, whether general practitioners, specialists, teachers and researchers or young doctors. It also represents the public face of Australian medicine. It is the vehicle through which doctors fulfil their obligations to the community as advocates for those with neither power nor influence. The AMA is an agent of change, a voice of reason and an independent leader of societal values. The AMA has a federal structure, with branches in each state and territory which focus primarily on state matters, and a Canberra-based federal body which deals with national issues. See http://domino.ama.com.au/DIR0103/WhosWho.nsf/cb4834a4ac5a2ba24a2564b00048928c/1caa3bb0d5700f604a25673c00418e71?OpenDocument.

The Australian Medical Association said it supports the prohibition of the cloning of human beings. But human genetic tissue can be used for processes involving cloning techniques with approval by an institutional ethics committee. For more, see "Australian Medical Association Position Statement on Genetic Issues" last updated in July 1999 at http://domino.ama.com.au/DIR0103/Position.nsf/b327c9ef331587e04a25651c001e0cee/6e2328bf42de13a34a2566560022d4b8?OpenDocument (Tab 41).

UNITED STATES OF AMERICA (USA)

Internationally, the U.S. is widely recognized as the country with the most mature biotech industry though it is still in an infant stage. According to an October 1999 report by the U.S. Congress, the prominence is believed to be driven by the federally-sponsored medical research carried out by the National Institutes of Health (NIH) and other government agencies as well as the research of about 1,300 U.S. biotech companies. In 1998, the industry generated revenues of about $19 billion, spent $10 billion on research and development and employed about 150,000 highly-skilled workers. Most biotech companies are fairly small, with two-thirds of firms having fewer than 135 employees. In 1998 alone, the Food and Drug Administration (FDA) approved 30 new biotech drugs and nine new biologics, two of which are aimed at combating breast cancer. For more on the background of the U.S. biotech industry in congressional testimonies, please see "Putting a Human Face on Biotechnology: A Report on the Joint Economic Committee's Biotechnology Summit" published by the Joint Economic Committee of the U.S. Congress at http://www.senate.gov/~jec/bio_report.htm.

ELSI

Begun formally in 1990, the U.S. Human Genome Project is a 13-year effort coordinated by the U.S. Department of Energy and the National Institutes of Health. The project originally was planned to last 15 years, but rapid technological advances have accelerated the expected completion date to 2003. Project goals are to:

1. identify all the approximate 100,000 genes in human DNA;
2. determine the sequences of the 3 billion chemical bases that make up human DNA;
3. store this information in databases;
4. develop tools for data analysis;
5. address the ethical, legal, and social issues (ELSI) that may arise from the project.

Please see http://www.ornl.gov/hgmis/about.html.

The U.S. Department of Energy (DOE) and NIH have devoted 3% to 5% of their annual Human Genome Project (HGP) budgets to studies of the project's ethical, legal, and social implications (ELSI) since the outset of the HGP. Focusing on privacy concerns, some proposed legislation has attempted to establish a legal framework of fair practices for health information and to regulate its access, disclosure, and use. A draft bill (Genetic Privacy Act), drawn up in 1995 by George Annas of the Boston University School of Public Health to assist legislators, proposed that access to information in genetic data banks should be regulated during sample collection and when it is stored, disclosed and used. Several state lawmakers used language and concepts from this draft bill in drawing up proposals for legislation in their own states. For the review entitled "DOE ELSI Program Emphasizes Education, Privacy: A Retrospective (1990-1999)," please go to http://www.ornl.gov/TechResources/Human_Genome/resource/elsiprog.html (Tab 42). The review was published in July 1999. For the Genetic Privacy Act and accompanied commentary published on 28 February 1995, please go to http://www.bumc.bu.edu/www/sph/lw/gpa/PrivacyA.Zip (Tab 43).

ELSI Questions

In the past decade, the ELSI of the HGP asked the following set of questions:

1. Who should have access and how will it be used?
2. Who owns and controls it?
3. How does the information affect an individual and society's perceptions of that individual?
4. Should testing be performed when no treatment is available?
5. Should parents have the right to have their minor children tested for adult-onset diseases?
6. Are genetic tests reliable and interpretable by the medical community?
7. Do healthcare personnel properly counsel parents about the risks and limitations of genetic technology?
8. How reliable and useful is fetal genetic testing?
9. What is normal and what is a disability or disorder, and who decides?
10. Are disabilities diseases? Do they need to be cured or prevented?
11. Does searching for a cure demean the lives of individuals presently affected by disabilities?
12. What safety and ethical questions does this raise?
13. If this became common practice, how would it affect the diversity of the gene pool?
14. Who will have access to these expensive technologies?
15. Who will pay for their use?
16. How will genetic tests be evaluated and regulated for accuracy, reliability and utility?
17. Who owns genes and other pieces of DNA?
18. Do someone's genes make them behave in a particular way? Can people always control their behavior?
19. What is considered acceptable diversity?

For more on the ELSI issues, please go to http://www.ornl.gov/TechResources/Human_Genome/resource/elsi.html (Tab 44). For more about the ELSI program, please see http://www.nhgri.nih.gov/ELSI/aboutels.html (Tab 45).

ELSI on Genetic Testing

The Joint Working Group of NIH and DOE on ELSI teamed up with the National Action Plan on Breast Cancer to make recommendations on genetic discrimination in employment in 1996 and genetic discrimination in insurance in 1995. In general, no genetic information of an individual should be released without informed consent of the individual. Under the 1996 recommendations, employers should be prohibited from making hiring and firing decisions simply based on genetic information of job applicants and employees. Employers might ask about the genetic information of job applicants only after conditional offers are made. Under the 1995 recommendations, insurers should be prohibited from asking for and using genetic information of the policy applicants and policy holders to make underwriting decisions.

See http://www.nhgri.nih.gov/Policy_and_public_affairs/Legislation/legelsi.html (Tab 46).

ELSI: Revised Goals

In 1998, the Ethical, Legal and Social Implications Research Planning and Evaluation Group (ERPEG) of the National Human Genome Research Institute and the DOE set the ELSI agenda for

1998-2003. The agenda has five themes:

1. Issues surrounding the completion of the human DNA sequence and the study of human genetic variation;
2. Issues raised by the integration of genetic technologies and information into health care and public health activities;
3. Issues raised by the integration of knowledge about genomics and gene-environment interactions into non-clinical settings;
4. Ways in which new genetic knowledge may interact with a variety of philosophical, theological, and ethical perspectives; and
5. Ways of how socioeconomic factors and concepts of race and ethnicity influence the use and interpretation of genetic information, the utilization of genetic services, and the development of policy.

For more on the goals and related research questions and education activities for 1998-2003 of the U.S. Human Genome Project, please go to http://www.nhgri.nih.gov/98plan/elsi/ (Tab 47). For more about the ERPEG, please see http://www.nhgri.nih.gov/About_NHGRI/Der/Elsi/erpeg.html (Tab 48).

Secretary's Advisory Committee on Genetic Testing (SACGT)

Secretary of Health and Human Services Donna Shalala chartered the Secretary's Advisory Committee on Genetic Testing (SACGT) in June 1998 in response to recommendations of two working groups commissioned jointly by the National Institutes of Health (NIH) and the Department of Energy (DOE) for the Human Genome Project. The groups were the Task Force on Genetic Testing and the Joint NIH/DOE Committee to Evaluate the Ethical, Legal, and Social Implications Program of the Human Genome Project. These groups identified the need for broad-based public policy development to help the Nation address the benefits and challenges of genetic knowledge and genetic testing. The Secretary assigned the management of the SACGT to the Director, NIH. The SACGT will advise the government about all aspects of the development and use of genetic tests, including the complex medical, ethical, legal, and social issues raised by genetic testing. Among the general issues that the Committee may take up include: the development of guidelines, including criteria regarding the risks and benefits of genetic testing, to assist Institutional Review Boards in reviewing genetic testing protocols in both academic and commercial settings; the adequacy of regulatory oversight of genetic tests; provisions for assuring the quality of genetic testing laboratories; the need for mechanisms to track the introduction of genetic tests to enable accuracy and clinical effectiveness over time to be evaluated; and safeguarding the privacy and confidentiality of genetic information and preventing discrimination and stigmatization based on genetic information. Procedurally, recommendations made by the Committee will be submitted to the Secretary through the Assistant Secretary for Health.

The SACGT at NIH has launched a public consultation on oversight of genetic tests between 1 December 1999 and 31 January 2000. The committee considers that no single agency or organization will be able to address all the issues raised by genetic tests. Instead, the combined expertise of entities including NIH and FDA and others may be needed. The consultation addressed the following five issues:

1. What criteria should be used to assess the benefits and risks of genetic tests?
2. How can the criteria for assessing the benefits and risks of genetic tests be used to differentiate categories of tests? What are the categories and what kind of mechanism could be used to assign tests to the different categories?
3. What process should be used to collect, evaluate, and disseminate data on single tests or groups of tests in each category?
4. What are the options for oversight of genetic tests and the advantages and disadvantages of each option?
5. What is an appropriate level of oversight for each category of genetic test?

In the consultation paper, the SACGT said that genetic testing is clinically available for more than 300 diseases or conditions in more than 200 laboratories in the United States. In addition, investigators are exploring the development of tests for an additional 325 diseases or conditions. A recent survey of genetic testing laboratories found that over a recent three-year period, the total number of genetic tests performed increased by at least 30 percent each year, rising from 97,518 in 1994 to 175,314 in 1996. Most of the tests are conducted for diagnostic, carrier, and presymptomatic purposes for rare genetic disorders. Recently, tests have been developed to detect mutations for about 25 more common, complex conditions—such as breast, ovarian, and colon cancer—whose effects generally do not appear until later in life. These tests are currently used for presymptomatic purposes in individuals with a family history of the disorder. Although the tests could be used for predictive purposes, they are not recommended for this purpose because more must be learned about the significance of the mutation in someone without a family history of the disease. The consultation paper contains recent and quite thorough background on genetic testing.

Please see http://www4.od.nih.gov/oba/sacgt.htm (Tab 49). For the press announcement of the consultation, please see http://www4.od.nih.gov/oba/pr121599.htm (Tab 50).

National Bioethics Advisory Commission (NBAC): Research

First created in 1995 via an presidential executive order, NBAC was formed to provide advice and make recommendations to the National Science and Technology Council and to other appropriate government entities regarding the following matters:

1. the appropriateness of departmental, agency, or other governmental programs, policies, assignments, missions, guidelines, and regulations as they relate to bioethical issues arising from research on human biology and behavior; and applications, including the clinical applications, of that research;
2. NBAC shall identify broad principles to govern the ethical conduct of research, citing specific projects only as illustrations for such principles;
3. NBAC shall not be responsible for the review and approval of specific projects;
4. In addition to responding to requests for advice and recommendations from the National Science and Technology Council, NBAC also may accept suggestions of issues for consideration from both the Congress and the public. NBAC also may identify other bioethical issues for the purpose of providing advice and recommendations, subject to the approval of the National Science and Technology Council. Please see http://bioethics.gov/about/eo12975.htm.

In a new Charter approved on 20 October 1999, the NBAC is mandated to provide advice and make recommendations to the National Science and Technology Council, chaired by the President, other appropriate entities and the public on bioethical issues arising from research on human biology and behavior and applications of that research. As a first priority, the Commission will direct its attention to consideration of the protection of the rights and welfare of human research subjects and issues in the management and use of genetics information including but not limited to human gene patenting. The Commission shall consider four criteria in establishing priority for its activities:

1. The public health or public policy urgency of the bioethical issue;
2. The relation of the bioethical issue to the goals for Federal investment in science and technology;
3. The absence of another body able to deliberate fruitfully on the bioethical issue; and
4. The extent of interest in the issue across the government.

But the NBAC ordinarily will not deliberate on a bioethical issue of interest to just one department or agency. For more, please see http://bioethics.gov/about/nbacchart.pdf.

NBAC on Informed Consent

With respect to informed consent and capacity issues, the NBAC recommends that no person who has the capacity for consent may be enrolled in a study without his or her informed consent. In addition, NBAC recommends that a subject's objection to participation should be heeded even if he or she is confused or is incompetent. Properly interpreted and modestly modified, present federal regulations can protect subjects' rights and interests and at the same time permit well-designed research to go forward using materials already in storage as well as those newly collected by investigators and others.

Please see the 9 December 1999 testimony of Eric J. Cassell, a member of the NBAC and Clinical Professor of Public Health Cornell University Medical College Before the Subcommittee on Criminal Justice, Drug Policy, and Human Resources Committee on Government Reform U.S. House of Representatives at http://bioethics.gov/cassell.pdf.

Please see "Research Involving Human Biological Materials: Ethical Issues and Policy Guidance Volume I" published by NBAC in August 1999 at http://bioethics.gov/hbm_exec.pdf (Tab 51).

For more please see "Ethical Issues in Human Stem Cell Research: Executive Summary" published in September 1999 by NBAC at http://bioethics.gov/execsumm.pdf.

Oversight by NBAC

According to the Director of Office of Science and Technology Policy in the Executive Office of the President, one of the driving forces behind the 1995 establishment of NBAC was the desire to accelerate progress towards the goal of ensuring adequate oversight of human subject research. The Department of Health and Human Services, and within that department, the NIH, have taken several actions to strengthen their oversight capability of human subject research and forestall situations in which subjects could potentially be harmed. Other agencies including the Department of Veteran Affairs and the Department of Justice have also made changes and instituted policies

and procedures that address their role in overseeing human subject research.

While there has been increased attention paid to this area, the director said he thinks it is increasingly clear that a comprehensive examination is in order. He said he would expect that such a study would include: an assessment of the adequacy of the current federal system of protections; a review of the relevant statutes and regulations, with particular attention to the effectiveness of the Common Rule and its applicability to the full range of government sponsored research activities involving human subjects; and an examination of the strengths and the weaknesses of the infrastructure responsible for ensuring the entire system's integrity. The most important component of this task is to provide detailed recommendations for changes necessary to ensure that our ethics are as good as our science. It took ten long years to promulgate the Common Rule in 1991. Yet even at that time additional work was recognized to be needed to be done.

Please see the 22 October 1999 remarks by the Director of Office of Science and Technology Policy in Executive Office of the President at http://bioethics.gov/neallane.pdf.

The Federal Policy for the Protection of Human Subjects (45 CFR 46 or the "Common Rule," as it is sometimes called) is a set of regulations that was adopted independently by 17 federal agencies that conduct, support, or otherwise regulate human subjects research; the FDA also adopted certain provisions of the Common Rule and is governed by additional regulations that apply to research on products in its regulatory purview. As implied by its title, the Common Rule is designed to make uniform the human subjects protection system in all relevant federal departments and agencies. The NIH Office for Protection from Research Risks (OPRR) has taken the lead within the federal government in working to make human subjects protections across agencies consistent.

NBAC on Cloning

In a June 1997 report, the NBAC concluded that it is morally unacceptable for anyone in the public or private sector, whether in a research or clinical setting, to attempt to create a child using somatic cell nuclear transfer cloning. American tradition has been to avoid prohibiting or regulating personal activities, absent a compelling reason related to effects on others or society as a whole. Where the individual actions are expressions of fundamental rights, such as the right to free speech or the right to privacy, the reasons for limitation must be compelling, and the limitations made as minimal as possible.

Please see "Cloning Human Beings" at http://bioethics.gov/pubs/cloning1/executive.pdf (Tab 52).

Two commissioned papers released in June 1997 may be useful, though part of their content might be out of dated. They are "The Current and Future Legal Status of Cloning" at http://bioethics.gov/pubs/cloning2/cc6.pdf and "Cloning: An International Comparative Overview" at http://bioethics.gov/pubs/cloning2/cc7.pdf.

American Medical Association (AMA)

Founded over 150 years ago, AMA's strategic agenda remains rooted in our historic commitment to

standards, ethics, excellence in medical education and practice, and advocacy on behalf of the medical profession and the patients it serves.

AMA's work includes the development and promotion of standards in medical practice, research, and education; strong advocacy agenda on behalf of patients and physicians; and the commitment to providing accurate, timely information and discourse on matters important to the health of America. The AMA strives to serve as the voice of the American medical profession. Being that voice is our mission. Please see http://www.ama-assn.org/about/wedo.htm.

In a December 1996 report, the Council on Ethical and Judicial Affairs of the AMA said that current ethical and legal standards Council reaffirms its opinion on ethical issues in carrier screening, which requires that patient decisions regarding testing be voluntary and based on informed consent. In addition, the Council maintains that genetic information should not be disclosed to a third party without the explicit informed consent of the screened individual.

See the December 1996 report of "Principles of Genetic Carrier Testing" at http://www.ama-assn.org/ethic/report76b.pdf.

Also see the Policy Finder at http://www.ama-assn.org for policies entitled Multiplex Genetic Testing, Insurance Companies and Genetic Information, Genetic Testing of Children, Ethical Issues in Carrier Screening of Genetic Disorders, Genetic Counseling, Genetic Testing by Employers (Tab 53).

AMA on Cloning

The AMA did not say that cloning should be banned. In a June 1999 report, the AMA's Council on Ethical and Judicial Affairs said that current ethical and legal standards hold that under no circumstances should human cloning occur without an individual's permission. But the AMA also said that current ethical and legal standards hold that a human clone would be entitled to the same rights, freedoms, and protections as every other individual in society. The fact that a human clone's nuclear genes would derive from a single individual rather than two parents would not change his or her moral standing.

See "The Ethics of Human Cloning" at http://www.ama-assn.org/ethic/report98.pdf (Tab 54). Please also see AMA policy "Genetic Engineering" at http://www.ama-assn.org (Tab 55).

AMA on Patents

In a December 1997 report, the Council on Ethical and Judicial Affairs of the AMA said that an outright ban on patenting of genomic material is unlikely and may be unwise and it made the following four recommendations:

1. Patents on processes such as gene sequencing do not raise the same ethical problems as patents on the substances themselves and are thus preferable;
2. Substance patents on purified proteins present fewer ethical problems than patents on genes or DNA sequences and are thus preferable.
3. Patent descriptions should be carefully constructed to ensure that the patent holder does not limit the use of a naturally occurring form of the substance in question. This includes

patents on proteins, genes, and genetic sequences.
4. One of the goals of genetic research is to achieve better medical treatments and technologies. Granting patent protection should not hinder this goal. Individuals or entities holding patients on genetic material should not allow patents to languish and should negotiate and structure licensing agreements in such a way as to encourage the development of better medical technology.

For more on the report, please see http://www.ama-assn.org/ethic/report82b.pdf. For a policy derived from the report, see "Patenting the Human Genome" at http://www.ama-assn.org (Tab 56).

American Medical Women's Association (AMWA)

The American Medical Women's Association (AMWA) is an organization of 10,000 women physicians and medical students dedicated to serving as the unique voice for women's health and the advancement of women in medicine.

AMWA was founded in 1915, at a time when women physicians were an under-represented minority. As of 1996, 21% of all practicing physicians are women.

As women in medicine increase in numbers, new problems and issues arise that were not anticipated. Other medical organizations are starting to recognize these problems and are looking at ways to address them. AMWA has been doing this for over 80 years.

Some of the women's health issues AMWA has worked to improve include smoking prevention and cessation, osteoporosis, violence against women, heart disease, gender equity, breast cancer, and reproductive health. AMWA has worked to improve the financing mechanisms for medical students and for gender equity in medical education. Association members have testified before Congress on many of these issues. AMWA's policy agenda includes a focus on tobacco control and prevention, reproductive health, affirmative action, and managed care. Please see http://www.amwa-doc.org/abouta.html.

In November 1995, the AMWA issued a position statement on genetic testing for breast and ovarian cancer susceptibility. The AMWA urged the enactment of legislation to protect the individual at the state and federal levels to address the multiplicity of issues that will emerge as a result of genetic testing outside of the research setting. Such legislation should be designed to:

1. require counseling for patients submitting to genetic testing both before and after testing;
2. require confidentiality for those individuals or organizations holding genetic information so that the information cannot be released without the expressed written consent of the individual to whom the results belong;
3. provide health and life insurance coverage to individuals who consent to genetic testing under research protocol conditions;
4. prohibit both health and life insurers to deny, limit, or otherwise control the coverage, eligibility, continuation, enrollment, or contribution requirements of individuals based on genetic testing information, or requests for genetic services;
5. prohibit both health and life insurers to establish differential rates or premium payments

based on genetic information or an individual's request for genetic services;
6. prohibit employers or employment agencies from discriminating against an individual because of genetic testing results;
7. prohibit any agencies, organizations, or individuals from requiring an individual to submit to genetic testing or to disclose or collect results of testing; and
8. prohibit minors or individuals deemed incompetent for submission to genetic testing for breast and/or ovarian cancer susceptibility.

Please see http://www.amwa-doc.org/publications/Position_Papers/genetictesting.htm (Tab 57).

Biotechnology Industry Organization (BIO)

According to a December 1998 report by Ernst & Young, the BIO represents more than 800 biotechnology companies, academic institutions and state biotechnology centers in 46 states and more than 26 nations. BIO members are involved in the research and development of healthcare, agricultural and industrial and henvironmental biotechnology products. The BIO maintains ongoing relationships with the White House, Congress and key regulatory agencies such as the FDA, the Environmental Protection Agency, the NIH and the United States Department of Agriculture to protect and promote the responsible use of this technology and its growing applications and uses.

See "Biotech 99: Bridging the Gap" at
http://www.ey.com/global/vault.nsf/International/Biotech99:BridgingTheGap/$file/biotech99.pdf.

The BIO's legislative Priorities for the 106th Congress illustrates the organization's agenda. The BIO wants more patent protection, near absolute research freedom, no privacy protection that hinder biotech research, more research funding, more investment incentive, little trade barrier, minimized tort liability and no price control on biotech research products. For more on the wish list, please see http://www.bio.org/govt/priority106.html (Tab 58).

BIO on Genetic Testing

On the surface, the BIO argues against the misuse of genetic testing. But at the same time, it views at least some of the ways in preventing such discrimination skeptically. The BIO said that it is committed to the socially responsible use of biotechnology to research treatments for diseases. It said it believes in the need for regulation and insists that the technology being developing health care, agricultural, industrial and environmental products be used to benefit patients and other consumers of biotechnology. The BIO said that people should have the option of using diagnostic or predictive tests that can help them to recognize early warning signs of disease and to seek proper treatment. This option would be jeopardized if genetic information were used to discriminate unfairly. Therefore, the BIO said it supports the call for national legislation to prohibit discrimination using predictive genetic information in health insurance.

The BIO said that genetic information should not be addressed separately in privacy legislation because genetic information cannot be scientifically or practically separated from other medical information. The BIO recognized that even a simple fact like gender is genetic information. The

BIO said that it believes in and abide by the existing regulations put in place by the FDA and the NIH to protect the safety of medical research participants and the confidentiality of information generated about them. For more on the BIO's statement of principles on bioethics, please go to http://www.bio.org/bioethics/overview.html (Tab 59). Please also see the BIO's current record on ethics at http://www.bio.org/govt/ethics.html (Tab 60).

Moreover, the BIO recommends state privacy legislation to be crafted to protect individual privacy yet not obstruct medical research. The BIO said it is concerned that many of the legislative initiatives currently being considered contain provisions that would impede medical research. The BIO said privacy legislation that is improperly drafted could significantly undermine medical research. For instance, it could increase the cost and complexity of locating projects in particular states with burdensome laws. More importantly, it could dash the hopes of patients whose lives depend on access to innovative treatments.
See http://www.bio.org/laws/state10.html (Tab 61).

BIO on Human Subject Research

In a 7 December 1999 report, the BIO said the tragic death of a patient in the University of Pennsylvania clinical trial has led to a re-examination of the roles of the FDA and the NIH. The biotech industry's willingness to provide adverse event data to the NIH is contingent upon an agreement between NIH and the industry on how the data will be used. NIH would be responsible for ensuring that patient privacy rights are protected and that trade secret data remains confidential. How will NIH carry out that mission? What patient data will become public? How will the NIH ensure that confidential commercial and financial information from companies will not be disclosed? How will the NIH use this data to complement the oversight role of the FDA?

See "Oversight of Gene Therapy: A Position Paper of the Biotechnology Industry Organization" at http://www.bio.org/issues/genetherapy_120799.html (Tab 62).

See "NIH Guidelines for Research Involving Recombinant DNA Molecules: Requirements for Reporting Serious Adverse Events: Request for Institutional Review" issued on 23 November 1999 by Office of Recombinant DNA Activities of the NIH at http://www.grants.nih.gov/grants/policy/recombinentdnaguidelines.htm (Tab 63).

For AMA's policy on gene therapy, please see http://www.ama-assn.org (Tab 64).

BIO on Cloning

In 1999, the BIO said there is no need for a rush to legislate; pending bills regarding human cloning would inadvertently ban vital biomedical research for treatment of disease. The BIO said it opposes the cloning of human beings. However, biomedical research on human genes, tissues and cells must be protected from overly broad definitions and imprecise legislative language to ensure the development of tomorrow's treatments and cures. For more on the BIO's position on cloning last updated on 24 September 1999, go to http://www.bio.org/bioethics/cloning_paper1.html (Tab 65).

BIO on Patents

According to the Joint Economic Report of the U.S. Congress, the biotech industry has for years been asking for patent reform, only to get bills passed in the House and have them not acted upon in the Senate. The industry wants to ensure that the new 20-year GATT patent term does not end up shortening the terms of patents when the government causes delays in the issuance of a patent. In 1999, the House passed the American Inventors Protection Act by a vote of 376 to 43. The industry hopes that the Senate will act quickly as well.

The BIO said it advocates strong intellectual property protection for biotechnology inventions. For this reason, the organization opposes any legislation, regulatory change by the Patent and Trademark Office (PTO) or judicial effort that would shorten the length of a patent or limit the scope and protections a patent affords. See the BIO's statement on its current legislative concerns http://www.bio.org/govt/legislative_issues.html (Tab 66).

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