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COMMUNICATION

The changing landscape of European and international regulation on embryonic stem cell research

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Abstract Legislation in individual member states of the European Union on human embryonic stem cell (hESC) research is as divergent as the different cultural, ethical, and religious views on the issue. On the occasion of the public launch of the European Human Embryonic Stem Cell Registry (hESCreg: www.hescreg.eu), a two-day symposium was held on 18 and 19 January 2008 in Berlin to offer participants an overview of state-of-the-art hESC research and legislation throughout Europe and in selected regions of the world. Thirty leading scientists from Europe as well as from the United States, Japan, and Australia reported on a range of aspects related to research on hESC and reviewed the key elements of the newly established hESCreg database of hESC lines. In this article we summarize and complete the information on the current status of international hESC regulation.

hESCreg reflects European and international pluralism

The European Human Embryonic Stem Cell Registry (hESCreg) is an online database that provides a comprehensive source of information on all human embryonic stem cell (hESC) lines that have been derived within the European Union (EU) and beyond (Borstlap, 2008; Sipp, 2008). It provides scientists and the public at large with optimal and free access to several lines of information on hESC. Providers of hESC lines are being registered to provide detailed characteristics of the cell lines derived. Research groups and stem cell banks can register to provide information on their research projects. The minimum registration criteria encompass information on the origin of the cell line and its availability, its consented and traceable procurement, and genetic information, as well as differentiation potential and analysis of pluripotent marker expression. Additional information includes details on culture conditions, further hESC markers, and derivation information as well as regulatory and ethical information (Borstlap and Kurtz, 2008; Borstlap et al., 2008).

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As of December 2008 hESCreg has registered 217 cell lines derived in the EU and Europe-associated countries (see Table 2) and 302 hESC lines derived outside Europe. Some 49 additional lines are being registered through the U.K. Stem Cell Bank as well as 8 lines through the U.S. National Stem Cell Bank (at WiCell).

Differing views in the individual EU member states are reflected in a multitude of national legislations on stem cell research (Bosch, 2005). Legislation usually applies to procurement of embryos for research, preimplantation genetic diagnostic techniques (PGD), and research on and derivation of hESC lines from (a) supernumerary "IVF" embryos, i.e., human embryos created for medically assisted fertilization (IVF) that are no longer intended for clinical use, and (b) embryos created for research, i.e., human embryos created by IVF with donated gametes and not intended to induce pregnancy. Creation of embryos by somatic cell nuclear transfer (SCNT) is referred to here as "therapeutic cloning."

Ethical guidelines in Europe

Despite the divergent hESC legislation in Europe, the ethical concern in Europe is unifying. European countries in which hESC research is allowed carry out experiments in accordance with the following fundamental ethical principles and human rights laws of the European Union: (1) personal protection rights (protection of human life), (2) political rights (e.g., no inappropriate state intervention), and (3) social and economic rights. Research on hESC in Europe, therefore, meets a number of basic rules and requirements: scientific necessity and high-ranking research objectives, urgency, social desirability, and primacy of personal well-being and interests of the individual over the sole interests of science and society. Furthermore, in countries where research on hESC lines is allowed, it may be carried out on hESC lines only if deemed necessary, if there are no valid alternatives, and if the work is nonredundant.

hESC research and legislation in selected European and Europe-associated countries

By 2001, only a few member states such as Great Britain, Belgium, and Sweden had enacted specific laws on the use of embryos for research, but by 2008 around 16 EU and Europe-associated countries have introduced legislation to regulate stem cell research. While many countries in Europe are moving to enable stem cell research using embryo-derived stem cells through new legislation, the situation regarding the specific nature of regulation across Europe is still quite complex (Table 1, Fig. 1).

The following sections describe the legal situation in the EU and Europe-associated countries that are members of the European human embryonic stem cell registry (see Table 2) and from which delegates were provided with information on hESC research legislation during the hESCreg launch symposium. The subsequent sections present the legal situation in the United States and in the Asian-Pacific countries.

Belgium

In Belgium the Law on Research on Embryos *in vitro* from 2003 (Loi relatif à la recherche sur les embryons in vitro: http://www.eshre.com/emc.asp?pageId=751) forbids the creation of embryos for medical research unless the objective of the project cannot be achieved using supernumerary IVF embryos. Research on supernumerary embryos is acceptable if (a) it concerns research in the area of fertility, sterility, organ and tissue transplantation, or prevention or treatment of diseases; (b) the research is based on the latest research methodologies; (c) the research is conducted at an accredited facility at a university clinic for reproductive medicine or medical genetics; (d) the research is supervised by a specialized physician or a scientist with necessary qualifications; (e) the age of the embryo is not greater than 14 days; and (f) the local ethics committee has approved. Therapeutic cloning for medical research is allowed, reproductive cloning is

Table 1 Regulatory variations for embryonic stem cell research in the EU and Europe-associated countries

Regulatory position on human embryonic stem cell research	Countries
hESC research permitted • Derivation of new hESC lines from supernumerary IVF embryos permitted • Therapeutic cloning permitted	Belgium, the Czech Republic, Finland, Israel, Portugal, Spain, Sweden, United Kingdom (the Czech Republic, Finland, and Portugal neither prohibit nor allow therapeutic cloning by law)
hESC research permitted • Derivation of new hESC lines from supernumerary IVF embryos permitted • Therapeutic cloning prohibited	Denmark, France, Hungary, the Netherlands, Norway, Switzerland
hESC research permitted only with imported hESC lines • Derivation of new hESC lines from supernumerary IVF embryos prohibited • Therapeutic cloning prohibited	Germany, Italy (there is no specific law covering existing hESC lines in Italy)

For a geographical overview please see Fig. 1.

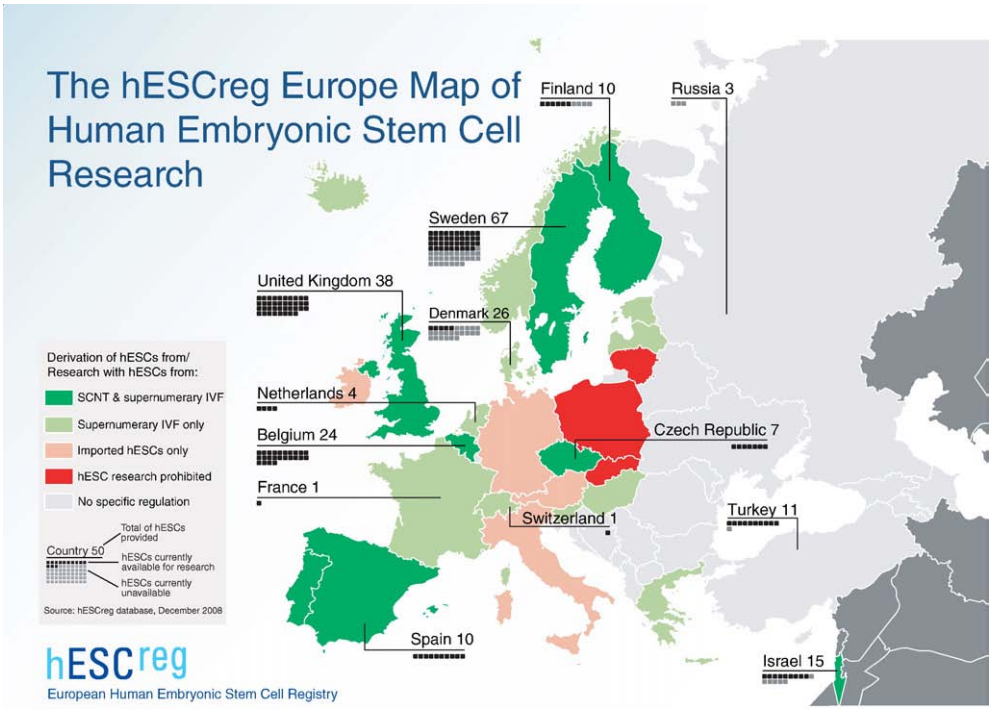

Figure 1 The status of hESC research legislation throughout the EU and Europe-associated countries. The four colors represent the four positions on hESC research in Europe: green, hESC research and derivation of hESC lines from supernumerary IVF embryos permitted (dark green, therapeutic cloning permitted; light green, therapeutic cloning prohibited); orange, hESC research permitted only with imported hESC lines—hESC derivation and SCNT prohibited; red, prohibition of any hESC research; grey, no hESC-specific legislation in place.

forbidden. It is forbidden to use embryos, gametes, or embryonic stem cells for commercial purposes. The procurement of and research on hESC from supernumerary IVF embryos are allowed (Pennings, 2007). Major active research sites are the Vrije Universiteit in Brussels and the Université Libre de Bruxelles.

The Czech Republic

In the Czech Republic, hESC research is allowed by the Act on Research on Human Embryonic Stem Cells (Zákon 227/2006: http://www.eshre.com/emc.asp?pageId=998) from 2006 only if the research (a) brings about important knowledge applicable to the development of new or improved diagnostics, prevention, or therapeutics in humans; (b) cannot be solved by using animal models; and (c) is ethically acceptable. PGD is permitted, although not yet treated by the law. Therapeutic cloning for research purposes as well as for the development of new therapies is not explicitly prohibited by law and is subject to case-by-case decisions of the respective institutional ethical bodies. In contrast, the Czech act clearly prohibits any manipulation that could lead to the creation of a new human individual, the so-called reproductive cloning. hESC may be derived from supernumerary IVF embryos. hESC lines on which research is performed must be listed in the Czech central registry, which is open to the public. Two institutions, one in Brno (Masaryk University) and one in Prague (Institute of Experimental Medicine Academy of Sciences of the Czech Republic), with around six research groups are involved in hESC research.

Denmark

In Denmark research is allowed on embryos if it can lead to the improvement of IVF or PGD methods and the obtainment of important new knowledge applicable to therapies for human diseases. This is covered by the Act of Artificial Fertilization from 1997 (Lov nr. 460 om kunstig befrugtning som ændret ved: https://www.retsinformation.dk/Forms/R0710.aspx?id=84963), which was updated in 2006 (Lov nr. 535 om kunstig befrugtning som ændret ved: https://www.retsinformation.dk/Forms/R0710.aspx?id=10291). Embryo research can be conducted within 14 days of embryo development after fertilization. From 2003 on, hESC can be procured from supernumerary IVF or PGD embryos. The Danish law prohibits cloning procedures. Major research centers are the Ciconia Aarhus Privathospital Højbjerg, the University of Copenhagen, and the University of Southern Denmark at Odense.

France

In France the Bioethics Law (Loi no. 2004-800 relative à la bioéthique: http://www.legifrance.gouv.fr/affichSarde.do?reprise=true&page=1&idSarde=SARDOBJT000007108472&ordre=null&g=ls) was last reviewed in 2004. Every 5 years the law is revised by the French parliament, so the next time will be in 2009. The decree of February 2006 complemented the Bioethics Law. Embryo research is allowed (a) if the proposed research is expected to result in significant therapeutic gains and no other efficient alternative method is available; (b) if

the embryos used have been created *in vitro* for reproductive issues and failed to be suitable for that purpose; (c) if both parents have given written consent; (d) if the research protocol has been specifically approved by the ministries responsible for research and health (competent authority: Agence de la Biomedicine); and (e) if the embryo is destroyed within 7 days after fertilization. Both therapeutic cloning and reproductive cloning are prohibited. Contraventions to the reproductive cloning ban carry a penalty of up to 30 years imprisonment and a fine of up to €7,500,000. The procurement of hESC lines is allowed from supernumerary IVF embryos as well as from those that have been identified as unsuitable for implantation following preimplantation diagnosis. The first French hESC line was derived in October 2007 from such a PGD embryo carrying a monosomy 21 and a trisomy 1 (http://ist.inserm.fr/basispresse/CPS/CPS2007anglais/23october2007.pdf). To achieve the greatest possible transparency the embryos and hESC lines used are registered. Currently hESC research is authorized in around 34 authorized laboratories.

Finland

The Medical Research Act (Laki lääketieteellisestä tutkimuksesta: http://www.finlex.fi/fi/laki/ajantasa/1999/19990488) from 1999 forbids the production of embryos for research purposes in Finland. However, embryos created by therapeutic cloning might not be considered embryos by law ("living group of cells resulting from fertilization") and could possibly be procured. The research on such embryos is allowed only for 14 days after fertilization, after which the embryo has to be destroyed. Donated gametes have to be used within 10 years. Gametes and ovarian tissue for the patient's own use can be stored in liquid nitrogen for an unlimited period of time. There are no restrictions on research with PGD embryos, nor on the procurement of and research on hESC that have been derived from supernumerary PGD or IVF embryos. Reproductive cloning and the production of chimeras are prohibited by law. Research centers are at the University of Helsinki, the University of Tampere, the University of Turku, the University of Kuopio, and the University of Oulu.

Germany

In April 2008, Germany amended its Stem Cell Act (Stammzellgesetz: http://www.bmj.bund.de/enid/77e71f1a0cb444ca3eabd0cff43559fd,33d0e45f7472636964092d0933303334/Menschenrechte/Bioethik_xb.html), which generally forbids any use of hESC, but also grants certain exceptions to the law. Researchers wishing to import or use hESC must submit an application for license on a case-by-case basis. Imported hESC lines must be derived from supernumerary embryos from

Table 2 EU and Europe-associated countries that are members of the European Human Embryonic Stem Cell Registry (hESCreg) and that have hESC-specific legislation in place

Country	No. of hESC [a]	Law/year
Belgium	24	Law on Research on Embryos *in vitro* (Loi relatif à la recherché sur les embryons *in vitro*)/2003
Czech Republic	7	Act on Research on Human Embryonic Stem Cells (Zákon 227/2006)/2006
Denmark	26	Act on Artificial Fertilization (Lov nr. 460 om kunstig befrugtning som ændret ved/1997, Lov nr. 427/2003, Lov nr. 69/2004, Lov nr. 240/2004, Lov nr. 535/2006
France	1	Bioethics Law (Loi no. 2004-800 relative à la bioéthique)/2004, Decree No. 2006-126
Finland	10	Medical Research Act (Laki lääketieteellisestä tutkimuksesta)/1999
Germany	hESC derivation prohibited	Stem Cell Law (Stammzellgesetz StZG)/2008
Hungary	hESC derivation not allowed	Health Care Act (CLIV/1997)
Israel	15	Prohibition of Genetic Intervention Act (Human Cloning and Genetic Modification of Reproductive Cells)/1999, modified 2004
Italy	hESC derivation not allowed	Law on Medically Assisted Reproduction (Norme in materia di procreazione medicalmente assistita)/2004
Netherlands	4	Embryo Act/2002; phase 2/2007
Norway	n.d.	Biotechnological Act (Lov om humanmedisinsk bruk av bioteknologi)/2007
Portugal	n.d.	Law on Medically Assisted Procreation (Procriação medicamente assistida)/2006; Opinion on Human Cloning (Parecer sobre clonagem humana)/2006
Spain	10	Law on Biomedical Research (Ley de Investigación Biomedical)/2007
Sweden	67	Act on Stem Cell Research (Lag om åtgärder i forsknings-eller behandlingssyfte med ägg från människa)/1991, with changes in 2006 (Lag om genetisk integritet m.m.)
Switzerland	1	Stem Cell Research Act (Stammzellengesetz)/2005
United Kingdom	38	Human Fertilization and Embryology Act/1990; Human Fertilization and Embryology Bill/2001 and 2008 (still under parliamentary review)

n.d., not determined.
[a] Number of hESC lines derived that are registered in hESCreg as of December 2008.

in vitro fertilization procedures and must have been produced before 1 May 2007; they may not have been obtained following PGD and the procurement of the cell lines must have been compliant with the respective national legislation. Thirtyfour licenses have been issued by the competent licensing authority, the Robert-Koch Institute Berlin, in accordance with the Central Ethics Committee for Stem Cell Research. More than twenty research groups are active in hESC research.

Hungary

In Hungary, embryos cannot be created for research purposes. Only embryos created in assisted reproductive procedures can be used for research on the basis of the decision of the Hungarian Reproduction Commission and as regards the Health Care Act (CLIV/1997: www2.ohchr.org/english/bodies/cescr/docs/E.C.12.HUN.3-Annex10.pdf). Embryos on which experiments were carried out cannot be implanted into the human body and cannot be kept alive for more than 14 days. For the unique purpose of investigating on the probable illness of the child to be born, separation of the cells of the embryo is allowed. hESC derivation is not allowed. With special permission from the Hungarian Reproductive Council, which regulates all hESC work in Hungary, the import of hESC is permitted. Licenses that were given so far are few and up until now (as of December 2008) only one research group is actively working with hESC lines.

Israel

Israel takes third place worldwide as regards publications of research teams that have utilized hESC in research experiments (Löser et al., 2008). In general, the public opinion in Israel has been in favor of research on hESC. According to Jewish law human life begins 40 days after the fusion of egg and sperm cells and only when the embryo is within the mother's womb. With the view of the great therapeutic potential of hESC the religious leaders in Israel support hESC research. After thorough moral discussions at the Israeli House of Parliament, the Prohibition of Genetic Intervention Act (Human Cloning and Genetic Modification of Reproductive Cells: http://www.bibliojuridica.org/libros/5/2292/59.pdf) from 1999, modified in 2004, allows therapeutic cloning and the derivation of hESC lines from supernumerary IVF embryos. Reproductive cloning is prohibited. Preimplantation genetic diagnosis is allowed in Israel. There is an Israeli society for stem cell research (the Israel Stem Cell Society) and a governmentally funded consortium of industrial and academic partners for the development of cell therapy (the Israeli Consortium for Cell Therapy, "Bereshith"). Active hESC research laboratories are at the Hadassah University Hospital Jerusalem, the Israel Institute of Technology Haifa, the Hebrew University of Jerusalem, and other institutions.

Italy

In Italy the Law on Medically Assisted Reproduction (Norme in materia di procreazione medicalmente assistita: http://assemblealegislativa.regione.emilia-romagna.it/wcm/biblioteca/apub/pbib/dossier/index/2005/procreazione_assistita/normativa/legge_19febbraio_04.htm) from 2005 prohibits the creation of embryos not only for research purposes but also for experimentation. Clinical and basic research is allowed when it is aimed at improving therapy and diagnosis and protecting the health and development of the embryo itself. Research on hESC is allowed only if alternative methodologies are not available. As in Germany hESC lines must be imported from other countries. Any cloning procedures are prohibited.

The Netherlands

The Embryo Act (Embryowet: http://www.minvws.nl/en/folders/ibe/2002/introduction-embryo-act.asp) from 2002 bans the creation of embryos for research purposes and stem cell procurement in the Netherlands. The derivation of hESC from supernumerary IVF embryos is possible if there are no alternatives to embryonic stem cells for the purpose of the research. To carry out hESC derivation or PGD each case must be approved by the Central Committee for Research Involving Human Subjects. As of 2008, two licenses to derive lines have been granted (to the universities of Utrecht and Groningen) and only the AZM, a teaching hospital from the University of Maastricht, has been allowed to perform PGD. Therapeutic cloning and the creation of chimeras are permanently prohibited. This situation is unlikely to change until 2012.

Norway

Since the review of the Biotechnology Act from 2007 (Lov om humanmedisinsk bruk av bioteknologi m.m.—bioteknologiloven: http://www.lovdata.no/all/nl-20031205-100.html), research on supernumerary embryos and PGD in Norway has been allowed. The government has decided not to issue licenses for PGD to Norwegian clinics. Patients can apply to the Preimplantation Genetics Board (a new board appointed by the government). If the board accepts the application, the couple may be treated abroad and the expenses will be covered by the health service. Stem cell procurement from supernumerary IVF embryos for medical and biological research and education is allowed as well. Cloning (therapeutic) and the use of techniques aimed at the production of genetically identical individuals are prohibited. The act will be reviewed every 4 years and amendments are expected in June 2011.

Portugal

In Portugal the Law on Medically Assisted Procreation (Lei no. 32/2006 Procriação medicamente assistida: http://www.dre.pt/pdfgratis/2006/07/14300.pdf) from 2006 prohibits the creation of embryos for research but allows research on supernumerary IVF embryos or those with severe genetic disorders. It is also permissive if the envisaged project will benefit humankind and aims at prevention, diagnosis, or therapy as well as the perfection of medically assisted reproduction techniques. Embryos that have not been created through the fertilization of a human oocyte by a human sperm, a condition that includes therapeutic cloning techniques, might be allowed but only for research purposes. Law 32/2006 does not regulate therapeutic cloning. The National Council of Ethics for the Life Sciences supports the idea of

therapeutic cloning because of the potential therapeutic benefits for human beings (Opinion on Human Cloning/2006 (http://www.cnecv.gov.pt/cnecv/pt/Pareceres/), which has no legal implication). However, it recommends that research should rather be focused on techniques that do not involve nuclear somatic transfer and on somatic cell reprogramming research. Reproductive cloning is prohibited. PGD is allowed.

Spain

While the Law on Biomedical Research from 2007 (Ley 14/2007 de Investigación Biomédica: http://noticias.juridicas.com/base_datos/Admin/l14-2007.html) in Spain prohibits the creation of embryos for research purposes, it allows the production of hESC for research or therapy using all the currently available technologies such as therapeutic cloning, reprogramming of somatic cells, and any other future technique (Article 33 of the BMR Act). There is a nonprofit national stem cell bank (BNLC) with branches in three separate locations—Granada, Barcelona, and Valencia—with the aim of guaranteeing availability and exchange of hESC lines. Ten Spanish stem cell lines have been completely characterized with respect to morphological, phenotypic, microbiological, virological, molecular, and functional markers *in vitro* and *in vivo* by two research centers, the Center of Regenerative Medicine in Barcelona and the Principe Felipe Centro de Investigacion in Valencia.

Sweden

As early as 1991 the act concerning research on fertilized eggs (Lag om åtgärder i forsknings-eller behandlingssyfte med ägg från människa: http://www.notisum.se/rnp/sls/fakta/a9910115.htm) in Sweden allowed research on embryos in the first 14 days after fertilization (with most recent amendments in 2006, Lag om genetisk integritet m.m.). Since 2005 the Swedish Act on Embryo Research has permitted the creation of embryos also by means of therapeutic cloning for medical research and stem cell procurement. It also permits the donation of egg cells for research purposes. PGD and research on embryos up to 14 days are allowed. At least three centers are active in hESC research and derivation of hESC lines. Cellartis AB in Gothenborg has derived 37 hESC lines, the Karolinska Institute in Stockholm, 30. Another research institute is the Stem Cell Center Lund. It has been reported that the first xeno-free hESC line in the world was derived in Sweden in 2006 (Ellerström et al., 2006).

Switzerland

The Stem Cell Research Act (Stammzellenforschungsgesetz: http://www.bag.admin.ch/themen/medizin/03301/03361/03410/index.html?lang=fr) of Switzerland, which went into force in 2005, prohibits the creation of embryos for research. hESC may be obtained from supernumerary IVF embryos, donated by informed consent, until the seventh day of their development. hESC lines obtained from supernumerary IVF embryos may also be imported from abroad for research purposes and are subject to approval by the Federal Office of Public Health. Imported hESC can be used for research if obtained in the respective country according to the Swiss legislation. Ethically approved research projects involving ESC are required. The cloning of human germ cells and embryos is prohibited by law. PGD is not yet allowed but a law project is in preparation. Research laboratories working on ESC are in Geneva, Basel, and Bern (see also the Swiss Stem Cell network: www.sscn.unige.ch).

The United Kingdom

In the United Kingdom the 2001 amendment to the Human Fertilisation and Embryology Act (http://www.parliament.the-stationery-office.co.uk/pa/ld200708/ldbills/006/08006.i-iv.html), which became law in 1990, legalizes the creation of embryos for medical research, including therapeutic cloning and the derivation of hESC lines. PGD is allowed. In the HFE bill that updates the HFE Act from 2008, as of December 2008, the definition of an embryo now includes embryos created by cloning and other processes. Furthermore, it includes the permission for creation of interspecies embryos for research. In addition to Sheffield, London, Edinburgh, Newcastle, Manchester, Nottingham, and Cambridge, there are 13 more geographic hESC research centers and a central UK Stem Cell Bank at the National Institute for Biological Standards and Control, South Mimms (www.ukstemcellbank.org).

hESC research and legislation in the United States

Eleven states, namely California, Connecticut, Illinois, Maryland, Massachusetts, New Jersey, New York, Rhode Island, Wisconsin, Iowa, and Missouri support hESC research. The first nine of these states supportive of hESC research have come together to form the Interstate Alliance on Stem Cell Research with the aim of improving scientific exchange, coordination, and collaboration in the field. Several other states ban or restrict hESC research. The common guidelines in the supportive states are: (1) ethical and scientific oversight, (2) voluntary and informed consent, (3) donors are not paid/reimbursed, and (4) transparency and public reporting. These standards are influenced by the National Academy of Sciences. In the United States, no federal funding is available for the manufacture of new hESC or research into human embryonic stem cells that were produced after 9 August 2001. It is possible to apply for funding for the manufacture of pluripotent stem cells and research into human embryonic stem cells with a production date prior to 9 August 2001. In addition to the 21 NIH-registered available cell lines, a further 17 cell lines may be obtained from Harvard University and 4 from Stanford University (personal communication, S. Stayn, Stanford University, Stanford, CA, USA, at hESCreg launch symposium, Berlin, January 2008).

hESC research and legislation in the Asia-Pacific region

The research centers in the Stem Cell Network of the Asia-Pacific region (SNAP) are located in Australia, China, India, Japan, Singapore, South Korea, and Taiwan (see Table 3). SNAP was established in October 2007. Its aims are to promote research into hESC in the region, to improve international collaboration, and to offer exchange programs

Table 3 hESC research in the Asia-Pacific region

Country	Major hESC research centers
Australia	Australia Stem Cell Centre and Monash University
China	CAS (Beijing, Shanghai, Guangzhou)
India	National Stem Cell Center (under development, Bangalore)
Japan	RIKEN CDB, national and private universities (Kyoto, Tokyo, Keio)
Singapore	A*STAR (IMCB, IMB), NUS
South Korea	National Stem Cell Center, Seoul National University
Taiwan	Academia Sinica, National Yang Ming University

The countries listed form the Stem Cell Network of the Asia-Pacific Region (SNAP; personal communication, D. Sipp, hESCreg launch symposium, Berlin, January 2008).

to young researchers. With the exception of Australia, each of these countries has its own stem cell bank. To date, clinical-grade stem cell lines are claimed to have been produced by researchers in Singapore. Chinese researchers are thought to have produced the highest number of stem cell lines; the exact status of these lines is, however, unverified. As of February 2008 scientists in the Asia-Pacific region are thought to have produced a total of more than 215 hESC (personal communication, D. Sipp, RIKEN Center for Developmental Biology, Japan, at hESCreg launch symposium, Berlin, January 2008). Of that number already 10 have been proposed as clinical grade. In the countries of the Asia-Pacific region researchers receive generous state funding. Religious, political, or cultural limitations on hESC research are practically nonexistent. However, many regions do not have research and clinical governance traditions in the European or North American mode, and efforts to coordinate international collaboration and consistency are developing (e.g., International Stem Cell Forum initiatives on stem cell characterization and stem cell banking: www.stemcell-forum.org).

Conclusion

Since there is no single universally accepted view on the ethical, legal, and moral status of the embryo as such, nor on the use of hESC lines derived thereof, one of the registry's tasks is to reflect European and international pluralism adequately and provide appropriate methods of safeguarding high standards in relation to ethical concerns and transparency in research. Eventually this may prevent the unnecessary development of new cell lines, avoid the duplication of research work, and consolidate Europe's position in the field. hESCreg is already the most comprehensive registry of its kind worldwide and will contribute to strengthening the role of the European Union in embryonic stem cell research at the international level. Consequently, the European Commission has issued hESCreg with the mandate to act as the central reference for all funding decisions on proposed hESC research projects within the Commission's Seventh Framework Programme of the European Community for Research, Technological Development and Demonstration Activities (2007–2013). The registry is actively engaged in the societal discourse on research into human embryonic stem cells, a debate with direct impact on the next Framework Programme after 2013.

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