32 Biotechnology Law Report 349
Number 6, 2013

DOI: 10.1089/blr.2013.9865

New President, New Human Embryonic Stem Cell Research Policy: Comparative International Perspectives and Embryonic Stem Cell Research Laws in France*

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ABSTRACT

This article provides an overview of French legislative history, Parliamentary debates, and recent amendments in hESC research policy, as well as additional comparisons with laws across the European Union. Unlike policy discussions in the U.S., French dialogue on hESC research generally rejects the arbitrary division between the status of the embryo and hESCs, recognizing that hESC research necessarily requires the destruction of human embryos. Accordingly, French discourse debates the competing interests of science with secular ethical and civic considerations relating to the symbolic status of the embryo and society's duty to moderate what constitutes appropriate boundaries on research. Parliament recently amended France's hESC research laws to explicitly permit hESC research, signaling the beginning of reform efforts under President Hollande's new power structure, but the inclusion of secular moral considerations in the policy debate will likely restrain the extent of any future changes.

INTRODUCTION

During his presidential campaign, French President Francois Hollande promised to transform the life sciences and push Parliament to reform human embryonic stem cell (hESC) research policies.[1] Up until recently, French law prohibited hESC research and research using embryos on principle but provided an exception permitting research under an approved set of conditions.[2] As in many other countries, including the United States, laws regulating hESC research are the subject of an ideological and political struggle, and each shift in power provides an opportunity to sway policy. During the summer of 2012, the French Senate began debating a bill to amend the 2011 law and explicitly permit hESC research through a licensing system, among other proposed provisions,[3] and in August 2013, the Senate and National Assembly adopted law number 2013-715, permitting human embryonic stem cell research by authorization rather than exemption.[3a] In contrast

*This publication was supported by a grant from the Richard M. Fairbanks Foundation to the Indiana University Center for Bioethics. Its contents are solely the responsibility of the author and do not reflect the official views of the Indiana University Center for Bioethics.

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[1]Butler D. Q&A The French election: a question of science. Nature 2012;484:298; *see also Francois Hollande Wants to Allow Research on Embryonic Stem Cells*, Ouest France Online (February 22, 2012); *available at* http://presidentielle2012.ouest-france.fr/actualite/hollande-veut-autoriser-la-recherche-sur-les-cellules-souches-embryonnaires-22-02-2012-359 (last visited July 31, 2012).

[2]Research on Embryos and Embryonic Stem Cells. Code of Public Health. Articles L2151-1 - L2151-8. (2011).

[3]Proposed Legislation to Amend Act No. 2011-814 of 7 July 2011 Concerning Bioethics Under Certain Conditions by Allowing Research on Embryos and Embryonic Stem Cells, Senate Bill 576 (hereinafter S. 576) (2011–2012).

[3a]Law No. 2013-715: http://www.legifrance.gouv.fr/affichTexte.do;jsessionid=8DE166F34A25D1129E06625D904FE6B8.tpdjo14v_2?cidTexte=JORFTEXT000027811435&categorieLien=id

Bill and legislative history: http://www.senat.fr/dossier-legislatif/ppl11-576.html

to the ideological U.S. debates, the majority of French discourse rejects the arbitrary division between the status of the embryo and that of hESCs, recognizing that hESC research necessarily requires the destruction of human embryos. Accordingly, French policy discussions debate the competing interests of science with secular ethical and civic considerations relating to the symbolic status of the embryo and society's duty to moderate what constitutes appropriate boundaries for research. Although this particular law is likely only the beginning of reform efforts under a new power structure, the process of policymaking in France reveres the social contract between ethics and science, tempering the extent of any legal reform.

LEGAL HISTORY AND OVERVIEW OF hESC RESEARCH LAW IN FRANCE

In 1994, France adopted comprehensive bioethics legislation, which banned both the creation of embryos for research and experimentation on embryos.[4] In 2004, Parliament passed a revised law that upheld the general ban on embryo and hESC research but created an exception to permit hESC research using surplus embryos created for *in vitro* fertilization, subject to approval of the Biomedicine Agency and the satisfaction of several conditions.[5] Back in 2004, then-Minister of Health Phillipe Douste-Blazy stated that protecting human embryos was an explicit goal of the Civil Code.[6] In 2010, the Senate proposed amendments that would change the classification of permissible research from ban-with-an-exception to explicit permission under conditional authorization.[7] In 2011, the National Assembly rejected the Senate amendments and voted to uphold the prohibition with the exception provision of the 2004 law.[8] The legal prohibition allowing research through an exception procedure governed hESC research until President Hollande signed law 2013-715 creating an authorization system. Currently, there are approximately 30 groups and 40 projects in France that are carrying out research using whole embryos or cell lines derived from surplus IVF embryos.[9]

RELEVANT PROVISIONS OF FRENCH PUBLIC HEALTH CODE GOVERNING hESC RESEARCH

The French Public Health Code provides a set of detailed laws governing hESC research, specifically designed to signify a balance between secular moral considerations and scientific freedom.[10] The following set of laws by principle prohibit certain categories of research, but allow some hESC research via authorization (prior to the 2013 amendment, this portion of the law detailed the exception that permitted hESC research) and protocol approval.

Articles L2151-1 to L2151-8 outline regulations relating to research on embryos and embryonic stem cells.[11] The French Public Health Code prohibits therapeutic cloning to create embryos, using therapeutically cloned embryos for research, creating embryos for research purposes (including deriving stem cell lines), and creation of transgenic or chimeric embryos.[12] Article L2151-3 specifically prohibits the commercialization of embryos.[13]

Despite these general restrictions, Article L2151-5 sets out criteria under which researchers can submit their research protocol to the Biomedicine Agency for a research exception.[14] The researcher must show: (1) the scientific relevance of the project; (2)

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[4]Butler D. France mulls embryo research reform. Nature 2011; 469:277.

[5]*Id.*

[6]Brahic C. France allows stem cell work. Scientist (July 15, 2004); *available at* http://classic.the-scientist.com/news/20040715/01/ (last visited July 31, 2012).

[7]Butler, *supra* n. 4; *see* Notice Number 112: Ethical Reflection in Research on Human Embryos, National Consultative Ethics Committee for Life Sciences and Health (October 21, 2010)(herein after CCNE 112); available at www.ccne-ethique.fr/docs/AVIS_112.pdf (last visited July 31, 2012).

[8]*France Set to Uphold Curbs on Embryonic Stem Cell Research*, Reuters (May 26, 2011); *available at* www.reuters.com/article/2011/05/26/us-france-embryo-idUSTRE74P38220110526 (last visited July 31, 2012).

[9]Butler, *supra* n. 4.

[10]*See* Gregor Becker and Anna Grabinski, "Ethics and Law in Regenerative Medicine: A Legal and Ethical Outline on Regenerative Medicine" in France, Germany, and Poland, *in Regenerative Medicine: From Protocol to Patient*, at 971-975 (Gustav Steinhoff, ed., 2011)(discussing key points of the French Public Health Code relating to hESC research); The Witherspoon Council on Ethics and the Integrity of Science, *The Stem Cell Debates: Lessons for Science and Politics*, 34 The New Atlantis (Winter 2012) at 132–133 (hereinafter The Stem Cell Debates)(*see* Appendix E: Overview of International Human Embryonic Stem Cell Laws discussing French law as well as an overview of other international law pertaining to hESC research, including a number of European Union member countries).

[11]Research on Embryos and Embryonic Stem Cells. Code of Public Health. Articles L2151-1 - L2151-8. (2011).

[12]*Id.*

[13]Research on Embryos and Embryonic Stem Cells. Code of Public Health. Article L2151-3. (2004); *but see* Notice Number 93: Commercialization of Human Stem Cells and Other Cell Lines, National Consultative Ethics Committee for Life Sciences and Health (November 17, 2006); *available at* www.ccne-ethique.fr/docs/fr/avis093.pdf (last visited July 31, 2012).

[14]Research on Embryos and Embryonic Stem Cells. Code of Public Health. Article L2151-5. (2011).

the research is likely to allow major medical advances; (3) the result cannot be achieved with research that does not use human embryos, embryonic stem cells, or stem cell lines; and (4) the research project and conditions of the protocol reflect the ethical principles for research on embryos and embryonic stem cell lines.[15] This section also notes that despite this research exception, alternatives that do not use human embryos should be promoted.[16]

Researchers may use surplus IVF embryos that are no longer engaged in a parental project, where both parents provide written informed consent, which is revocable until the research begins.[17] Researchers also may use imported stem cells for research purposes subject to the Biomedicine Agency's approval.[18] The researcher submits the protocol to the Agency for approval, demonstrating how the protocol will satisfy each requirement listed above. The Biomedicine Agency and its advisory committee then submit its decision to the Minister of Health and Research. The Minister of Health and Research has additional authority: the Minister can find the protocol does not satisfy the Code's requirements and prohibit or suspend the approval, or, alternatively, the Minister can request that the Agency reconsider a refusal if the protocol would be in the interest of public health or scientific research.[19] Should the research protocol violate the Code's requirements, the Agency shall suspend the authorization.[20]

CHANGES UNDER PRESIDENT HOLLANDE

This widely debated issue recently surfaced again on the forefront of French politics. During President Francois Hollande's campaign, the Socialist Party social democrat staked a portion of his campaign on life sciences reform for the country, promising he would urge Parliament to amend the law to explicitly authorize hESC research.[21] Hollande stated that this change would allow France to "catch up" with other countries' progress; that he sees "no compelling reason otherwise," because stem cells are not embryos; and that he finds it imperative to put an end to a policy he describes as hypocritical.[22] In June 2012, the Senate heard the first discussion of Bill 576, which embodied Hollande's promises to shift the policy from exception to authorization.[23] After Parliamentary debate, President Hollande signed the amendment permitting hESC research via authorization rather than exception in August 2013.[3a]

Senators led by Jacques Mezard (European Social and Democratic Rally) introduced Senate Bill 576, which advocated several substantial changes to the 2011 law. Most notably, Senator Mezard proposed adopting a licensing system to oversee and approve the research process, which would explicitly permit research in this area.[24] This framework represents a significant shift, both removing hESC research from a legal category of a closely regulated exception, as well as changing the symbolic categorization of hESC research. In addition to this paradigm shift, Senator Mezard sought to expand research liberty by removing the current parental informed consent requirement.[25] Rather than informing parents of the potential nature of research involving their donated embryos, Senator Mezard proposed a blanket consent system where parents consent for their surplus embryos to be used for research generally. However, advocacy for blanket consent in this contentious area of research is undoubtedly problematic, given the controversial nature of some research projects—especially if cell lines are exported to a country with vastly different regulations that permit research (such as creating chimeric or hybrid entities or cloning) which the parents may not have envisioned or approved had they known of them.

This specific law likely is only the beginning of discussions aimed at shifting French policy to a more-lenient system favoring research interests. Similar to the politics of policymaking in the U.S. following President Barack Obama's election, Hollande will spearhead an ideological rotation of the hESC research climate with the end of a socially conservative administration. Both President Hollande and Senator Mezard, similar to Obama in Executive Order 13505, maintain that the previous exception policy caused the country to "fall behind" research in this area because the conservative policy constituted a cumbersome barrier to efficient research progress and did not represent scientific reality.[26] As in the U.S., these statements rally support for a specific research agenda, but also have unfortunately influenced reporting by a number of mainstream media outlets, at best infusing articles with bias, and at worst, offering

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[15] *Id.*
[16] *Id.*
[17] *Id.*
[18] Research on Embryos and Embryonic Stem Cells. CODE OF PUBLIC HEALTH. Article L2151-7. (2011).
[19] *Id.*
[20] *Id.*
[21] *See supra* note 1.
[22] *Id.*
[23] S. 576, *supra* n. 3.
[24] *Id.*
[25] *Id.*
[26] *Id.*; *see also The Stem Cell Debates*, *supra* n. 10, Appendix D at 120–122 (discussing the shift from President Bush's hESC research policy to President Obama's policy and the substance of Executive Order 13505).

false and misleading facts.[27] For example, both U.S. and British media incorrectly classified the French hESC exception policy as one of the strictest across Europe, definitively equate hESC research with life-saving research (which suggests effective therapies are imminent or currently exist), and argue that reservations about this research, or opposition to it, arise solely from irrational religious dogma.[28] These assertions perpetuate public misunderstanding and prevent an honest discussion of competing policy considerations.[29] Unlike the U.S., French discussion and policymaking largely recognize that *secular* moral considerations must shape the policymaking process and should not be summarily dismissed.

AUTHORIZATION

Proponents for an authorization and licensing system, as set forth in law number 2013-715, echoed commonly utilized arguments favoring the regulated, but unhindered, progression of hESC research. There are a number of entities (including the National Institutes of Health and Medical Research, the Institute for Stem Cell Therapy and Exploration of Monogenetic Diseases, and the International Society for Stem Cell Research) and individual researchers interested in reforming the French Public Health Code to, at a minimum, provide an explicit licensed allowance for research relating to embryos and embryonic cell lines.[30] The Parliamentary Office for Science and Technology Assessment (OPECST), the State Council, and the Biomedicine Agency have each issued reports prior to 2013 amendment supporting the legislative adoption of an explicit licensed research allowance, ranging from changing the language of the statute from exception to authorization while protecting the *status quo* level of oversight (State Council) to adopting a system more favorable to research interests (OPECST).[31]

This authorization constituency argued that the 2011 law was "retrograde," "unduly restrictive," "absurd," and "hypocritical."[32] Media have emphasized the importance of competing in a global market to find new therapies, and Senator Mezard reiterated concerns that OPECST initially raised in 2006. According to OPECST, France is "lagging behind" in a "worrisome manner" because the 2011 policy did not appropriately reflect balancing the rights of researchers with the principle of respect for potential human life.[33] OPECST and individual researchers argued that research via exception stigmatized scientists, causing their work to suffer.[34] Furthermore, the lack of research progress, combined with researchers' tarnished image, denigrated France's global image, which hindered both research efforts and economic profitability arising (in part) from pharmaceutical partnerships. OPECST advocates easing regulation relating to hESC research to stimulate development in this area, including amending the Public Health Code to permit therapeutic cloning to produce more embryos for research purposes.[35]

STATUS OF EMBRYO

As in the U.S., policy disagreement relating to the goals and appropriate balance to be struck by the law is partially reducible to belief about the status of the embryo. Unlike the U.S., however, only a minority of scientists and interested parties in France maintain the legal fiction we continue to perpetuate in the U.S. between embryos and stem cells.[36] In 1999, U.S. Department of Health and Human Services legal counsel Harriet Rabb issued her infamous memorandum to interpret the Dickey-Wicker Amendment, declaring that its prohibition against providing federal funding to create embryos for research purposes and perform research in which an embryo was destroyed or discarded did not apply to hESC research because

[27] *France Set to Uphold Curbs on Embryonic Stem Cell Research,* Reuters (May 26, 2011); *available at* www.reuters.com/article/2011/05/26/us-france-embryo-idUSTRE74P38220110526 (last visited July 31, 2012); Tamara Cohen, *Euro Judges Outlaw Life-Saving Embryo Stem Cell Research as Immoral*, UK Daily Mail Online (October 19, 2011); *available at* www.dailymail.co.uk/news/article-2050467/Euro-judges-outlaw-life-saving-embryo-stem-cell-research-immoral.html 9 (last visited July 31, 2012); Tom Heneghan, *France to Renew Tight Limits on Stem Cells, IVF*, Reuters (February 9, 2011); *available at* http://in.reuters.com/article/2011/02/08/idINIndia-54748520110208 (last visited July 31, 2012); Helen Briggs, *European Court Ruling 'Threatens Stem Cell Work,'* BBC News (October 18, 2001); *available at* www.bbc.co.uk/news/health-15350723 (last visited July 31, 2012).

[28] *Id.*

[29] *Id.*

[30] Butler, *supra* n. 4.

[31] Alain Claeys, Research on the Operation of Human Cells, Report No. 3498 National Assembly No. 101; Senate Consultable on the National Assembly and Senate Sites, Parliamentary Office for Science and Technology Assessment (December 2006); S. 576, *supra* n. 3.

[32] Sandrine Cabut, *Research on Embryonic Stem Cell Research Divides*, Le Figaro Online (February 2, 2011); Heneghan, *supra* n. 27; Cohen, *supra* n. 27.

[33] Claeys, *supra* n. 31; Jean-Yves Le Deaut, The Place of Biotechnologies in France and in Europe, Report No. 2046 National Assembly No. 158 Senate Consultable on the National Assembly and Senate Sites, Parliamentary Office for Science and Technology Assessment (January 2005).

[34] Cabut, *supra* n. 32; *see generally supra* n. 27.

[35] Claeys, *supra* n. 31.

[36] Olivier Pourquie, *Embryonic Stem Cells Are Not Embryos!* Les Echos Voyage Online (April 21, 2011); *available at* http://lecercle.lesechos.fr/economie-societe/recherche-innovation/221134670/cellules-souches-embryonnaires-sont-embryons (last visited July 31, 2012).

hESC research simply relies on the products of that destruction.[37] Imposing this bizarre segmentation amounts to "linguistic jiu-jitsu," according to dissenting D.C. District Court Judge Karen Henderson in *Sherley v. Sebelius*. Rather than adopting this distinction, the French State Council asserts that hESC research necessarily involves the destruction of embryos, and the law must not treat embryos as mere research materials.[38] Notably, even eminent geneticist and President of the University of Paris–Descartes, Professor Axel Kahn, who views hESC research as "legitimate and necessary," admits that research using embryos has parallels to human subjects research because embryos are required to carry out hESC research.[39]

France's National Consultative Ethics Committee (CCNE) advises the government on topics in the life sciences and health and has set forth opinions directly relating to hESC research. Notice Number 112: Ethical Reflection in Research on Human Embryos contains a lengthy discussion relating to the moral status of embryos and an explanation of the law's history, function, and rationale. The CCNE presumes moral regard for the embryo and its derivations, referring to an embryo as a "potential human" deserving of a form of moral status, and states that it is society's medical and social responsibility to see that law and research practices respect the first stage of human life. The CCNE adopts the position that this form of moral status exists independently of the embryo's enrollment in a parental project: that moral regard and respect constitutes an inviolable principle.[40] The CCNE finds the destruction of embryos problematic, but regards using surplus IVF embryos for research purposes as the lesser of two evils because France does not limit the number of embryos that can be created to an implantable number, as do countries such as Italy.[41] According to CCNE, the previous law that permitted research via exception rather than via a statutory authorization signified Parliament's intention to uphold human dignity and the respect for human life, but CCNE nonetheless suggested in its 2010 report that the complexities of the law could be better reflected in a conditional authorization.[42]

Notably, public dialogue in France incorporates secular moral considerations into the discussion on the status of embryos and the corresponding implications for hESC research. Favoring the legal status quo (or opposition to hESC research altogether) is not necessarily based on religious ideology, but rather on a moral framework that *a priori* assumes the following: research using hESC cannot be divided from the process of obtaining the stem cells (rejection of Harriet Rabb's infamous bright line); the embryo reflects or is a potential human in the making and therefore warrants dignity and respect; and society must balance these needs with potential advances in scientific knowledge. The CCNE discusses these considerations at length with authority and legitimacy and assumes the necessity for ethical discussion in the public discourse, which is often lost in U.S. rhetoric and media coverage, where the media and politicians have mischaracterized and distorted secular moral considerations.[43]

In the Winter 2012 edition of *The New Atlantis*, the Witherspoon Council published a lengthy report, "The Stem Cell Debates: Lessons for Science and Politics," which identified and corrected widely accepted misrepresentations relating to the factual progression of hESC research policy in the U.S., as well as the general connection between science and ethics.[44] The Witherspoon Council delicately disentangled the mistaken notion that moral reticence to explicitly authorize (or provide federal funding in the U.S.) for hESC research means opposing science generally, blocking regenerative medicine's therapeutic promises, or inappropriately politicizes the scientific process. Rather, The Witherspoon Council asserts that the progression of science is tethered by public perception of morality, and these restrictions provide positive limitations to shape public policy. Other scholars, such as Robert George and Eric Cohen, have also recognized the significance of this social contract between science and ethics, maintaining that when reasonable people differ on morally charged issues such as structuring the law relating to hESC research, society must collectively assess the thorny moral and civic questions about "the proper uses, ambitions and limits of science."[45]

EXCEPTION

Although CCNE proposed an additional compromise between exception and authorization, during the legislative debate, National Assembly members emphasized the symbolic value of the statute's structure and maintained that the legal status of exception held significant value. In Report No. 3111 to the

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[37]*See* The Stem Cell Debates, *supra* n. 10, Appendix D at 116.
[38]*Id*. at 124; Jean Leonetti, No. 3111, Report Done on Behalf of the Special Committee to Review the Bill Relating to Bioethics No. 2911, National Assembly (January 26, 2011).
[39]Cabut, *supra* n. 32.
[40]CCNE 112, *supra* n. 7 at 13.
[41]*Id.* at 52.
[42]*Id.* at 35, 56; The Stem Cell Debates, *supra* n. 10, Appendix E at 135.
[43]*Id.*
[44]*Id.*
[45]Robert George and Eric Cohen, *The President Politicizes Stem-Cell Research*, The Wall Street Journal Online (March 20, 2009); *available a*t http://online.wsj.com/article/SB123664280083277765.html (last visited July 31, 2012).

National Assembly following the Senate's proposal in 2011 to provide an authorization, Member Jean Leonetti (Union for a Popular Movement) articulated the connection between the status of the embryo and the importance of a research exception in the statute.[46] Member Leonetti acknowledged the Biomedicine Agency and OPECST's position advocating authorization and a licensing scheme but asserted that that a licensing scheme would allow the law to treat embryos as a thing—research material—rather than an undefinable entity. This amounts to a vital distinction, according to Member Leonetti, because the status of the embryo itself cannot be defined in a society where positions at each end of the spectrum are irreconcilable.[47] Indeed, French law treats the embryo as neither a full person with vested human rights nor an object within the property law system but adopts a third category reflective of the "complex riddle of human potential."[48] The State Council has commented on this legal and practical debate as well, stating that "the embryo is a potential human life and not a thing; it cannot be treated as mere research material."[49] Thus, the extensive ongoing debate serves as a reminder of the exceptional status of such research.[50] According to the Report, these exceptions permit scientists to push the boundaries of science and ethics to work toward developing revolutionary new therapies, but Parliament should not write these "transgressions" into the law.[51] Member Leonetti's reasoning pragmatically considers the frequency with which biotechnology outpaces the law and researchers creatively circumvent regulations designed to account for competing concerns.

The Report also discusses how legislative history and the structure of the 2011 law deliberately classified hESC research as exceptional.[52] When it was amended in 2011, the law required research applicants to show that the research is likely to result in major medical progress and that such research cannot be conducted without using hESCs.[53] In other words, the applicant must show that the substantial potential scientific value and the necessity of hESCs to the research agenda outweigh the competing principles relating to respect for a developing entity. The State Council has emphasized the connection between respecting the symbolic value of embryos and the law's structure, stating that "one can harm it in principle only for compelling reasons and [if it is] duly justified."[54] Thus, both elements of the previous exception system constituted restrictive conditions reflecting a desire to maintain rigorous legal control over the status and use of hESCs for research.[55]

PROHIBITION WITHOUT EXCEPTION

Although the majority of the French public approves of a closely regulated system permitting some hESC research, a portion of the public, some research organizations, and several legislators conclude that upholding a principle of respect for human life from its beginning (guaranteed by French law) or potential human life requires pursuing alternate research agendas and definitively precludes hESC research.[56] Back in 2004, when Parliament passed the research exception to permit and regulate hESC research, media reports and National Assembly members warned against a "revolution" of "general indifference," arguing that the law regards embryos as mere objects for research and inappropriately destroys this category of beings' inviolable right to dignity.[57] In a speech during the discussion of the 2011 amendments, former Senator Anne-Marie Payet (Centrist Union) asserted that if the law treats embryos as "a category of beings" rather than as mundane objects to use for research, recognition of this legal status would preclude treating them with a contingent right to dignity depending on whether parents use them for IVF and would prevent justifying their destruction to create hESCs.[58]

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[46]Leonetti, *supra* n.38.
[47]*Id.* at 8.
[48]*Id.* at 6–7, 9.
[49]*Id.* at 9.
[50]*Id.* at 10.
[51]*Id.* at 11.
[52]*Id.* at 19.
[53]*See* Research on Embryos and Embryonic Stem Cells. Code of Public Health. Article L2151-5. (2011).
[54]Leonetti, *supra* n. 38, at 9.
[55]*Id.* at 19.
[56]George Gaskell *et al*., Europeans and Biotechnology in 2010, prepared for the European Commission Directorate General for Research (October 2010); *available at* http://ec.europa.eu/research/science-society/document_library/pdf_06/europeans-biotechnology-in-2010_en.pdf (last visited July 31, 2012); Press Release: Bioethics Bill in Final Phase: The Mobilization of the Majority in Extremis Has Not Broken Anesthesia on Fundamental Points, Jerome Lejeune Foundation; *available at* www.fondationlejeune.org/index.php?option=com_content&task=view&id=268 (last visited July 31, 2012); Press Release: The New Law Marks the Dehumanization Bioethics A Battle for 2012, Jerome Lejeune Foundation; *available at* www.fondationlejeune.org/index.php?option=com_content&task=view&id=320 (last visited June 5, 2012); Anne-Marie Payet, *Bioethics: Shadow of Slavery*, Liberte Politique Online (April 8, 2011); *available at* www.libertepolitique.com/L-information/Le-fil-d-actualite/Bioethique-l-ombre-de-l-esclavage-par-Anne-Marie-Payet (last visited July 31, 2012).
[57]*Id.*; Aude Dugast, *France Legalizes The Commodification of the Embryo*, Liberte Politique Online (April 8, 2011); *available at* www.libertepolitique.com/L-information/Le-fil-d-actualite/Bioethique-l-ombre-de-l-esclavage-par-Anne-Marie-Payet (last visited July 31, 2012); The Foundation, Jerome Lejeune Foundation, available at http://www.fondationlejeune.org/index.php?option=com_content&task=view&id=273&Itemid=177 (last visited July 31, 2012).
[58]Payet, *supra* note 56.

Importantly, many opponents of hESC research emphasize that their commitment to upholding what they view as vital moral principles co-exists with their dedication to medical research and the progress of science.[59] However, this prohibition constituency asserts that the law's blind promotion of science inappropriately replaces ethical questions with a myopic charge to promote research for its own sake, aligned with the notion that more research is synonymous with progress, gaining global competitive advantage, and obtaining lucrative economic benefits.[60] According to this constituency, science does not exist in a vacuum and does not represent a hierarchical trump card to gain international recognition or boost the nation's life sciences economy but must be modulated by competing ethical and civic considerations.

Indeed, pure science alone may dictate exercising caution when considering research using embryos as raw materials and potential clinical therapies using hESCs.[61] An issue rarely discussed in major newspapers and bioethics circles, hESCs used in therapy pose the intrinsic risk of developing into teratomas—tumors that can contain components such as hair, teeth, bones, and portions of organs and nervous system tissue.[62] In addition to navigating the clinical and ethical considerations of managing inappropriate differentiation of implanted cells, teratomas provide a physical mirror to the ethical debate relating to the status of the embryo and hESC research.[63] That is, teratomas constitute a concrete manifestation that hESCs, by their inherent nature, develop into unpredictable masses when injected for therapy—masses that are neither ordinary cell masses, nor developing humans, but which form growing entities with portions of distinctly human-looking characteristics.

COMPARISON AND LESSONS FROM EUROPEAN POLICIES

European countries, including European Union Member States, span a policy range reflecting disparate starting assumptions relating to the embryo's moral status and hierarchy of social values.[64] For example, Lithuania, Slovakia, and Poland have strict prohibitions against the creation of embryos for research purposes or cloning embryos for research purposes, structure their laws in a manner that classifies the embryo as a potential research subject (the research must benefit the embryo), and contain provisions for legal violations set forth in the penal and/or medical ethics code.[65] Media often refer to the restrictions in Western Europe in Italy and Germany when comparing hESC research policies.[66] Italy has a ban on research on embryos, including using embryos to derive stem cell lines; prohibits creating embryos for research purposes; and contains penal provisions for violation.[67] Germany bans the importation, utilization, and derivation of stem cells in the country, but permits the importation of stem cell lines created from surplus IVF embryos before 2008, subject to a set of conditions, ethical research guidelines, and penal provisions for violation.[68] On the other end of the spectrum, the United Kingdom permits using surplus IVF embryos for research, creating embryos for research purposes by IVF or cloning, and the creation of hybrid and chimeric embryos.[69] However, note that even in counties, such as the UK, with the least-restrictive research policies, the law often still contains a provision that prohibits research on embryos that are older than 14 days, which time period signifies a change in the legal status of the embryo.[70] Unlike many media characterizations, French law—both the 2011 law permitting research via exception and the current law permitting research via authorization—could be classified as a moderate approach to regulating hESC research compared with other European countries.[71]

The European Union has set forth its position relating to research on embryos in the 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 (also referred to as Oviedo Convention).

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[59] *Id.*; *Call for a Civic Bioethics*, Le Figaro Online (November 3, 2010); *available at* www.lefigaro.fr/flash-actu/2010/11/03/97001-20101103FILWWW00582-appel-pour-une-bioethique-citoyenne.php (last visited July 31, 2012).

[60] *See* The Stem Cell Debates, *supra* n. 10; George & Cohen, *supra* n. 45; *see generally supra* n. 56.

[61] Although both hESCs and iPS can potentially form teratomas, only hESCs have the intrinsic capacity without additional manipulation of cellular function to develop in this manner. *See* CTGTAC Meeting #45 Cellular Therapies Derived From Human Embryonic Stem Cells—Considerations for Pre-Clinical Safety Testing and Patient Monitoring Briefing Document, US Food and Drug Administration (April 10, 2008); Monya Baker, *Tumors Spark Stem Cell Review*, Nature News Online (February 17, 2009); *available at* www.nature.com/news/2009/090217/full/457941a.html (last visited July 31, 2012).

[62] *Id.*

[63] H-W Denker, *Potentiality of Embryonic Stem Cells: an Ethical Problem Even With Alternative Stem Cell Sources*, 32 Journal of Medical Ethics 665 (2006).

[64] *See* The Stem Cell Debates, *supra* n. 10, Appendix E; Stephen Latham, *Between Public Opinion and Public Policy: Human Embryonic Stem Cell Research and Path Dependency*, 37 Journal of Law, Medicine & Ethics 800 (2009)(discussing how the history of political institutions and past policies shape policy development rather than the law reflecting public debate).

[65] The Stem Cell Debates, *supra* n. 10, Appendix E at 136–8.

[66] *Id.* at 133–5.

[67] *Id.* at 135. Italy limits to only three the number of IVF embryos which can be created during the IVF process, and requires that all embryos created shall be implanted, which eliminates surplus embryos.

[68] *Id.* at 133.

[69] *Id.* at 139.

[70] *Id.* at 139.

[71] *See supra* n. 27.

Article 18 governs research on embryos and states: (1) where the law allows research on embryos *in vitro*, it shall ensure adequate protection of the embryo; and (2) the creation of human embryos for research purposes is prohibited.[72] The Oviedo Convention also set forth the principle that "the interests and welfare of the human being shall prevail over the sole interest of society or science" and requires each signatory country to enact laws to give effect to the Convention's provisions.[73] French Minister for European Affairs, Member Jean Leonetti, ratified the Convention, and it went into force in April 2012. The European Union began providing funding for research using hESCs in 2002, but it does not fund research for the derivation of hESCs (similar to U.S. HHS legal counsel Harriet Rabb's distinction).[74] The European Union's policy guidance states that the EU will finance research on both hESCs and adult stem cells, depending on the scientific proposal and the legal framework of the Member State(s) involved.[75] Additionally, EU policy guidance sets forth the precautionary principle, which requires projects to conduct a careful assessment of predictable risks and potential benefits at the outset, establish proportionality between these, and implement appropriate safety measures.[76]

The EU's framework reflects the impossibility of international compromise where each principled constituency cannot agree on the starting premise. The UK policy regards embryos as research material to create innovative therapies, including experimenting with inventive models of cloning and hybrid entities, while some eastern Member States legally classify the embryo as a person or developing person and accordingly prohibit hESC research because it instrumentalizes and destroys the embryos for the sake of research. This policy construction principle means that if the majority of French society accepts a set of starting premises, any future amendments will likely not depart significantly from a strictly regulated model that recognizes and attempts to balance two opposing interests: a need to protect developing life, and a desire for research innovation.

CONCLUSION

Although Parliament recently reformed the hESC research laws to explicitly permit research through authorizations, majority assumptions relating to the symbolic and legal status of the embryo will likely tether future legal changes to a system that closely regulates and permits hESC. Unlike the U.S. and EU policy, the majority of French policymakers refuse to accept the absurd legal fiction that divides the processes of research in a manner that too conveniently ignores the source of research materials and the intricately connected ethical, clinical, and civic considerations. Rather, French debate openly grapples with this quandary and discusses at length the meaning of the embryo, how to appropriately accord it legal significance, and how to balance society's competing desire to benefit from potential therapeutic discoveries down the pipeline. As Leonetti articulated during the 2011 Parliamentary debate on this topic, there are indeed many compelling reasons for the current policy structure because it represents a vital reminder of the special nature of this research and the responsibility we have as a society to engage in policymaking that integrates secular moral and civic questions into the debate about the appropriate limitations and uses of science.

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[72]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, European Commission of the European Union; *available at* http://conventions.coe.int/Treaty/en/Treaties/html/164.htm

[73]The first clause is significant because several EU countries laws classify or refer to embryos as human beings, and if not, as humans in the making deserving of respect, which would influence how these countries interpret the Convention.

[74]The Stem Cell Debates, *supra* n. 10, Appendix E at 132.

[75]Policy Issues: Ethics in EU Research, European Commission of the European Union; *available at* http://ec.europa.eu/research/health/policy-issues-ethics_en.html (last visited July 31, 2012).

[76]*Id.*