THE PUBLIC COMMUNICATION AND BIOPOLITICS OF HUMAN EMBRYONIC STEM CELL RESEARCH IN THE UNITED STATES AND THE EUROPEAN UNION

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ABSTRACT

This dissertation uses the methods of interpretive social science to explore the multidimensional nature of the stem cell controversy, its competing epistemologies, and types of resolution and policy closure that have been sought in the United States and the European Union. It provides a comparative perspective on the social dynamics of public involvement in stem cell research and evaluates efforts by governments and bioethics advisory bodies to integrate dialogue and deliberation in science policy and decision making. The analysis highlights the agenda-setting and framing roles of the print and electronic news media in the public discourse over stem cells and human cloning, including their ability to validate conflicting knowledge claims about stem cell science and frame uncertainty about its clinical promise. I argue that stem cell policy debates are deeply embedded in particular socio-political and cultural contexts, and therefore regulatory responses to the societal challenges arising from this biomedical innovation have largely been shaped by non-epistemic factors (considerations external to science and its epistemologies). In the US, the issue of human embryonic stem cell research was right from the outset framed in terms of the contentious politics of abortion, became caught up in America's culture wars, and the funding policy debate revived salient political themes of earlier controversies over abortion and fetal transplantation research. By contrast, efforts by EU policymakers to develop a framework for the ethical governance of stem cell technologies and their applications in regenerative medicine were intertwined with fundamental questions of EU federalism, common European cultural values, and the traditional consensus-oriented politics. I claim that in both cases the moral and policy

dilemma was brought to a conclusion by non-epistemic procedural closure. By sealing off the debate through legislative and administrative procedures, policymakers have failed to achieve a morally justifiable resolution of the issues central to the stem cell controversy either through the method of consensus closure or on the basis of epistemic (knowledge-based) factors.

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AHRA	Canada Assisted Human Reproduction Act of 2004
ART	Assisted reproductive technology
ASC	Adult stem cell
CAMR	Coalition for the Advancement of Medical Research
DefCon	Campaign to Defend the Constitution
DG RTD	European Commission Directorate General for Research
DHEW	US Department of Health, Education and Welfare
DHHS	US Department of Health and Human Services
ELSI	Ethical, legal and social issues
EGE	European Group on Ethics in Science and New Technologies
EG cell	Embryonic germ cell
ESC	Embryonic stem cell
FP6	Sixth EU Framework Program for Research and Technological Development (2002-2006)
FP7	Seventh EU Framework Program for Research and Technological Development (2007-2013)
HERP	NIH Human Embryo Research Panel
hESC	Human embryonic stem cell
HFEA	Human Embryology and Fertilization Authority
HSC	Hematopoietic stem cell
ICM	Inner cell mass of the human blastocyst

IVF	In-vitro fertilization
iPS cells	Induced pluripotent stem cells
NAS	US National Academy of Sciences
NBAC	National Bioethics Advisory Commission
NIH	National Institutes of Health
Oct3/4, Sox2, c-Myc, Klf4	Key transcription factors used for the production of pluripotent stem cells
PCBE	President's Council on Bioethics
PEST	Public engagement with science and technology
PUS	Public understanding of science
p53, p16INK4a	Tumor suppressing proteins
SCNT	Somatic cell nuclear transfer (also known as therapeutic cloning or cloning for research purposes)
SSC	Somatic stem cell

CHAPTER 1

INTRODUCTION

Human embryonic stem cell (hESC) research has become one of the most controversial areas of contemporary biomedicine and has sparked a global ethical controversy over the ontological status of the human embryo and the morality of the creation and use of embryos for research. There is widespread consensus within the scientific community that this research holds immense promise for the development of novel, cell-based therapies for diabetes, multiple sclerosis, Alzheimer's disease, Parkinson's disease, spinal cord injuries and other life-threatening conditions (Bongso & Richards, 2004; Mimeaults, Hauke, & Batra, 2007; Strode, 2002). Nevertheless, it is expected that the transition from promising research results to the general use of stem-cell therapies in clinical practice will require substantial investment in research and lengthy clinical trials (Braude et al., 2005; Coutts & Kierstead, 2008; Daley, Goodell, & Snyder, 2003). While stem cell advocates have often exaggerated the prospects for immediate clinical impact, most researchers in the field have expressed cautious optimism. As the renowned expert in stem cell science George Daley points out, "Just as small-molecule pharmaceuticals revolutionized medicine in the last century, cellular therapeutics are destined to emerge as a major modality for treating the degenerative diseases of an aging population, but it may take the better part of this century to get it right" (2002, p. 611). Although there is serious concern about the safety of new hESC-based treatments, such therapies are directly marketed to patients via the internet by privately operated clinics across the world, such as Beike Biotech in China, ACT in

Turks and Caicos, and Emcell in Ukraine (Lau et al., 2008). In most countries with advanced biotech industries the development of stem-cell technology has generated contentious public and parliamentary debates over the ethical regulation of biomedical research involving human embryos. More importantly, the stem cell controversy has revived perennial philosophical debates over human nature, the moral and legal status of pre-nascent life, the boundaries of human longevity, and our proper moral stance towards nature.

The prominence of religiously informed moral arguments in stem cell debates worldwide has also coincided with recent reconsiderations of the sociological thesis of secularization (Bruce 1992, 2002; Joas, 2008) and the emergence of a new sociology of religion in the "post-secular world society" (Habermas, 2006, 2008b). Stem cell policy debates, especially in the United States and in some catholic regions of Europe, have provided yet another visible manifestation of the increasing public influence of religious traditions both globally and within national public spheres. Habermas (2008b) has claimed that challenges to the secularization paradigm, which had long ago predicted the waning of religion in the political arena and public life of modern societies, are by no means limited to regional conflicts that have unleashed violence innate in major world religions. Rather, the dissonance between religious and secular worldviews is reflected in value conflicts on scientific and social issues that have entered the public spheres of Western pluralistic societies. In recent years, divisive moral arguments over the legalization of abortion and voluntary euthanasia, the ethical issues of reproductive medicine, animal protection and climate change have intensified and there are indications

that political regulation by the state is needed to resolve these societal conflicts (Habermas, 2008b). Since religion can help citizens articulate convincing moral intuitions on some of these biomedical issues, Habermas (2006) has argued that we should not exclude religious perspectives as a legitimate background for contributions to an open public debate. Their significance in political and policy decisions, however, is largely contingent on the translation of religious arguments into a generally accessible language which requires the shared effort of religious and non-religious citizens.

In the public discourse the value and meaning of human embryonic stem (hES) cells have extended beyond their status as experimental biological objects and they have become contested categories in the domains of bioeconomy, politics, religion and law. Stem cells and lines are precious commodities in a fast expanding global market for human tissue, political objects subjected to intense scrutiny and regulation, sacred objects with metaphysical qualities and dignity, and legal objects that are subject to patent protection (Ganchoff, 2004). Human embryonic stem cells are imagined as repositories of multiple meanings that occupy intersecting social worlds. As such, they have entered the category of "boundary objects"—scientific objects that are "both plastic enough to adapt to local needs and the constraints of the several parties employing them, yet robust enough to maintain a common identity across sites; they are weakly structured in common use, and become strongly structured in individual site use" (Star & Griesemer, 1989, p. 393). These new living entities, along with other ambiguous products of clinical biotechnology, genetic engineering and xenotransplantation, resist disambiguation and defy categorizations that have long been considered foundational in the ordering of

societies; they have called into question "the fundamental divisions between nature and culture, moral and immoral, safe and risky, god-given and human-made" (Jasanoff, 2005, p. 26).

Located at the intersection of the complex interdisciplinary fields of science and technology studies (STS) and social and political thought (SPT), this dissertation aims to compare the political and policy contexts for stem cell innovation in the United States and the European Union, the two leaders in the emerging regenerative medicine. My analysis of the stem cell controversy focuses on how the biopolitics of stem cells has become the subject of contentious public and political debates and has generated extensive public involvement in techno-science policy and decision making. The development of stem cell research and regenerative medicine in both political entities currently takes place in heavily contested and/or regulated settings, as there are strong ethical objections against the morality and permissibility of research that involves destruction of human embryos, but also a vast array of problems arising from the global bioeconomy. The stem cell controversy has made visible deep tensions between science and society, with public communication campaigns on both sides of the Atlantic constructing stem cell technologies as a type of scientific innovation that entails difficult philosophical, ethical, legal and social dilemmas for democratic societies. The biopolitics of hESC research has presented unexpected regulatory challenges for governments and policymakers as public contestations have transcended narrow policy considerations regarding the ethical governance of different stem cell derivation techniques. Rather, the scope of the public discourse surrounding stem cell technologies has extended to intricate

questions of how the rapidly expanding biotechnology sector impinges on personal and social identities, communities, and life forms. It is not surprising that efforts to resolve the stem cell controversy have become inextricably bound up with political attempts to ensure the deployment of human biotechnologies for the common good. Political mobilizations around the issue of "stem cells" have subsequently implicated rather diverse social groups and representatives of civil society—scientists, academics, patients, patient rights' advocates, religious communities and churches, biotech corporations, politicians, radical activists, celebrities, and lay persons who have often ventured into the public sphere to question policy decisions and develop legislative initiatives.

While stem cell debates have revived some salient political themes of earlier controversies over abortion and fetal transplantation research, there are also significant differences in rhetorics, tactics of organization, participation strategies and political interventions that have given rise to claims about stem cell research exceptionalism. My analysis of the public engagement with stem cell policy and ethics in a comparative US-EU context aims to highlight such convergences and divergences. I argue that an attempt to historicize and contextualize emerging practices of public involvement with stem cell science can help us achieve a better understanding of the multi-dimensional nature of this controversy, its competing epistemologies and patterns of closure that have occurred in different political and cultural contexts. Public involvement is by no means a simple, one-dimensional process that can be easily understood and evaluated; neither is there one single mechanism for enabling and enacting effective participation of citizens in policy decisions and other public affairs. When looking at communicative interactions between

science and society around the biopolitics of stem cells, it is important to recognize that *public participation* or *public engagement* (with the two terms often used interchangeably in the scholarly literature) is a rather contested analytical category which designates different communication practices, deliberative processes, dialogue events and multiple framings of public contestations emerging around science and technology issues. There have been different attempts to develop a typology of public engagement activity and mechanisms and to define key terms in the public participation domains. Conceptual issues in public participation research have been considered by Rowe and Frewer (2005) who have defined "public participation" as "the practice of involving members of the public in the agenda setting, decision-making, and policy-forming activities of organizations/institutions responsible for policy development" (p. 254). This definition, albeit too broad, makes it possible to distinguish participatory models of governance from more traditional forms in which policy making authority is delegated to elected representatives without the requirement for public input. At the same time, it does not clearly indicate in what ways and at what levels of participation lay people may be implicated. While in some situations the public may be involved by simply being a passive recipient of information from regulatory bodies, in other cases policy makers may intentionally seek public input in a variety of ways, ranging from public opinion research projects to the inclusion of public representatives in the decision-making process (i.e., lay persons participating in deliberations of advisory bodies). Therefore, Rowe and Frewer (2005) argue that earlier distinctions between communication and participation do not suffice to categorize the plethora of public involvement situations and suggest a typology

of public engagement activity based on the directionality of information flows. They use public engagement as an overarching term for public communication, public consultation and public participation. There are respectively three types of engagement mechanisms—communication, consultation and participation—that enable these forms of public engagement. Figure 1 presents a more detailed outline of this typology of public engagement activity from an information flow perspective. In public communication, information is conveyed from the sponsors of the initiative (i.e., a policy-setting organization) to the general public and there is no public involvement per se, as there are no mechanisms to record and evaluate feedback. Public consultation is characterized by an inverse directionality of information flow, from the public to the sponsor, and yet there is no formal dialogue but rather the public's opinions on the issue are simply conveyed to the sponsor. Public participation is a more dialogical activity as both the sponsor and members of the public are open to negotiation and possibly changing their positions. This type of engagement activity can contribute to "maximizing the relevant information from the maximum number of all relevant sources and transferring it (with minimal information loss) to the other parties, with the efficient processing of that information by the receivers (the sponsors and participants) and the *combining* of it into an accurate composite" (Rowe & Frewer, 2005, p. 263).

A different typology of science-society communication interactions has been proposed to distinguish between participatory activities which aim to directly influence policy outcomes and other forms of public engagement with science and technology that are not policy-related (Davies et al., 2009; Davies, 2009). The second type includes

"dialogues" and "dialogue events" hosted by organizations which have no direct involvement in the policy process and scientific governance such as scientific communities, science centers and museums. Innovative public engagement mechanisms developed by these organizations exemplify the growing tendency towards participatory activities in the field of scientific communication, with institutional responses indicating that dialogue has become a key practice for effective communication between scientific institutions and the public. The emphasis on dialogue also signifies a departure from the traditional deficit model of science communication and the much criticized public understanding of science (PUS) paradigm (Davies et al. 2009). Rather, it is believed that concurrent with the growing number of recent public controversies and dialogical activities in the domains of biotechnology, health and the environment in the UK and elsewhere is a deliberative or dialogic turn in science policy (Irwin & Michael, 2003; Rowe & Frewer, 2005; Davies, 2009). Although public involvement retains its discursive fluidity and is essentially contested, the concept has been used as a generic term that covers diverse activities and emerging practices of deliberation, consultation and dialogue, with some scholars using the terms "public engagement" and "dialogue" interchangeably (Davies, 2009).

My inquiry into the public engagement with hESC research aims to evaluate to the extent to which governments and policymakers have sought to integrate dialogue and deliberation in the science policy-making process. I focus on communicative interactions between citizens, interest groups, regulatory and advisory bodies, and the media at different levels and in a variety of formats. First, I look at how the news media have

influenced the public communication of stem cell science and ethics. Mass media, together with the general education system, presently constitute the primary source of health and science information for the public (Garrett & Bird, 2000; Geller, Bernhardt, & Holtzman, 2002). The news media can significantly influence the ways in which scientific controversies are negotiated and resolved in the public domain through their ability to act as gatekeepers and filter the information they convey to the audience. Furthermore, McCombs and Shaw (1972) have established that the main effect of news media is agenda-setting—although media organizations cannot tell people what to think, they can still influence people what to think about by highlighting certain issues for public debate and excluding others from coverage. There are also normative expectations associated with the ability of different news media, i.e. newspapers, radio, television, and online news, to serve as "watchdogs" of government behavior and activity and act in the public interest. My analysis is premised on the assumption that mass media play an active role in shaping and constructing scientific controversies, rather than simply reporting scientific facts and discoveries, and that their important position in the public domain is heightened by their ability to open up controversial scientific and technological innovations for public criticism. Print, broadcast and Internet-based media in the US and the EU member states have used specific framings of the ethical, legal and social implications (ELSI) of stem cell technologies and regenerative medicine to instigate societal responses and influence policy outcomes. The news media have become an important factor in the evolution of the stem cell controversy not only by validating knowledge claims and ethical perspectives around the politics of potentiality, but also by

shaping public judgments about policy decisions (Nisbet, Brossard, & Kroepsch, 2003; Kitzinger & Williams, 2005; Döring & Zinken, 2005). While they traditionally provide a forum for debating science policy within which controversial health and medical issues have been defined and played out (Miller, Kitzinger, & Williams, 1998), media representations of the stem cell controversy have given legitimacy to conflicting utopian narratives and dystopian predictions about the societal impact of biomedical science (Kitzinger & Williams, 2005). These narratives have also evoked powerful bio-fantasies (Petersen, 2001) by combining traditional ways of claiming scientific authority with more emotive discourses and appeals.

Secondly, I intend to demonstrate how attempts to resolve the stem cell controversy have become intricately related to more overarching political and ethical concerns about the regulation of human biotechnologies for the public good. I examine public debates over what policy oversight would best ensure the ethical development of stem cell technologies and regenerative medicine. Such negotiations have taken place in diverse forums of public communication and consultation: public relations campaigns by interest groups and citizens' associations, political debates in the US Congress and the EU Parliament, and deliberations of expert advisory bodies such as the US National Bioethics Advisory Commission (NBAC), the President's Council of Bioethics (PCBE), the European Group on Ethics in Science and New Technologies (EGE), and the European Expert Group on Science and Governance appointed by the European Commission Directorate General for Research (DG RTD). I also aim to compare modes of deliberations adopted by national bioethics advisory bodies in the US and the EU, and

how their recommendations have outlined different frameworks for ethical and policy decision-making regarding hESC research.

Why Stem Cell Policy in a Comparative Perspective

Recent debates on the nature and the future development of the European Union have drawn parallels to American federalism and have generated a significant body of scholarly work comparing the US and EU institutions, policies, and developmental trajectories (Menon & Schain, 2006; Sbragia, 2006; Howse & Nicolaidis, 2001; Fabbrini, 2005). Despite their comparative orientation, many early theorists of European integration have consistently emphasized the EC/EU exceptionalism and, as a result, have failed to recognize the potential benefits of comparison with other federal systems, especially the United States (Menon & Schain, 2006). While there seems to be "a consensus in defining the EU as a *supranational polity* pursuing the project of *post-national democracy*" (Fabbrini, 2005, p. 3), it is argued that a comparative perspective on the EU institutional structure vis-à-vis that of the US could challenge prevailing notions of a European uniqueness. Fabbrini (2005) points out that the EU is unique only in comparison with the European nation-states; however, its formation and functioning as a democratic polity that is compound, rather than unified, closely resembles the American federal experience. There are both structural and functional reasons for a comparative analysis of the two systems. Similarities between the US and the EU are visible in their characteristics of a compound republic, that is, the presence of a mixed system territorially organized around a plurality of centers of authority (Fabbrini, 2005). In a nutshell, the EU is presently characterized by the coexistence of governance

(supranational level) and government (national level). It is also based on a vertical or supranational federalization and a horizontal multiple separation of powers. A similar sort of fragmented sovereignty could be observed in the vertical and horizontal separation of powers in the American federal system. Unlike other models of democracy, the purpose of such double separation of power elaborated in Philadelphia in 1787 was to prevent the formation or identification of a political majority (Fabbrini, 2005). Although there are clearly many differences between the two systems, the institutional context and the functional logic of the EU and the US are similar since the decision-making process is by no means limited to a single authority or level of government (Fabbrini, 2005). Nonetheless, this institutional convergence between the EU and the US appears rather surprising given the significant disparities in historical development and nation-state building processes between the European states and America that are highlighted in a cross-national comparison (Fabbrini, 2005).

Regardless of the growing literature on comparative federalism, scholars have indicated some deficiencies in comparative research on highly complex federal systems such as the US and the EU (Menon & Schain, 2006). Problems for comparativists arise from the apparent dissimilarities of these two federal political systems; each system has been viewed as a product of unique historical circumstances that have driven the development of particular federal compromises. Scholars in the field have claimed that comparative EU-US scholarship could be counterproductive, as researchers often slip into general characterizations, rather than focus on complicated aspects of the two polities that make the subject so intriguing (Menon & Schain, 2006). By contrast, Sbragia

(2006) has argued that a comparison of the US and the EU can be productive if we consider the wide dispersal of power in their federal systems that make them unique in comparison with any other political system. Both the US and the EU stand in stark contrast to all other advanced industrial democracies in their ability to deliberately avoid institutional concentration of political power. As she points out, "the dispersal of power is so striking in both systems and shapes the policymaking to such a degree that these two systems would be situated in the same box of whatever matrix one cares to construct" (Sbragia, 2006, p. 16).

Menon and Schain (2006) have claimed that comparative research efforts could provide valuable empirical contributions to the significant body of scholarship on federalism since they allow scholars to indentify "variance among single variables that operate within each system," are essential in developing and testing theoretical propositions, and can help generate new theoretical insight (p. 3). They have also observed that examination of specific public policies in a comparative European-American perspective can shed light on key questions of federalism such as tensions between territorial diversity and advantages of centralization, special problems of democratic legitimacy that stem from blurred divisions of national and local decision-making, and problems with "democratic deficit" experienced by federal systems. Case studies on a variety of social and political issues "examine policy as an outcome of a political process embedded in a federal framework" (Menon & Schain, 2006, p. 10) and, therefore, provide important insight into the complex dynamics of the federal process in a comparative US-EU context. In addition, comparative policy analyses that scrutinize the

policy-making process and review impacts of policy outcomes in each case can help us develop a broader understanding of how the efficiency of centralized policy-making is complicated by its implementation in decentralized administrative environments.

Tensions in federal systems of government are often manifested in conflicts between national government and subnational governments over aspects of economic policy and social regulation. Federalism scholars in the United States have indicated increasing disagreements between the federal government and state governments in the period between 2001 and 2008 due to the Bush administration's conservative policy preferences and attempts to gain control over policy administration (Mintrom, 2008). Disagreements have occurred over policies in the areas of education, welfare and homeland security, but also as a result of the administration's effort to re-centralize oversight of environmental policy (Mintrom, 2008). State activism has also emerged around the issue of stem cell research, with state-level policy initiatives in response to the federal government's failure to establish comprehensive national regulation of this controversial scientific innovation. During his two terms, President Bush focused exclusively on restricting federal funding for research to the already existing hESC lines, rather than developing a national regulatory framework. This lack of regulatory oversight at the national level has undermined federalism by prompting states to assume a leadership role in the funding and regulation of stem cell research (Mintrom, 2008). The politics of stem cell research in the US and different state policies after the federal funding restrictions in 2001, but also as a result of the widely-anticipated shift in policy under the Obama administration, will be examined in greater detail in Chapter 6.

Similarly, policy debates on stem cell research in the EU have become linked to the issue of federalism, but also to key questions about European cultural values and the role of citizenship as essential to the politics of twenty-first century Europe. My comparative analysis of the stem cell policies in the Unites States and the European Union therefore has a two-fold objective: (1) It compares and contrasts specific policy outcomes; and (2) It considers the larger issue of how their institutional responses to ethical challenges raised by stem cell technologies and regenerative medicine are shaped by their divergent political cultures and institutional development as federal states. My effort to contextualize the policy making processes is informed by the notion of both knowledge and policy as culturally embedded, and also by the understanding that comparative studies of science policy should by no means be limited to analyses of how successful different nations or political systems are in implementing particular policy goals. As suggested by Jasanoff (2005), "rather than prescribing decontextualized best practices for an imagined global administrative elite, comparison should be seen as a means of investigating the interactions between science and politics, with far-reaching implications for governance in advanced industrial democracies" (p. 15). This new type of comparative analysis, she claims, has shifted the focus away from static categories of political actors, interests and institutions towards a more dynamic notion of political culture and its key role in constituting the civic epistemologies of modern nation states. Therefore, Jasanoff (2005) proposes a rather broad definition of political culture as "the systematic means by which a political community makes binding collective choices" and suggests that it "encompasses institutionally sanctioned modes of action, such as

litigiousness in the United States, but also the myriad unwritten codes and practices with which a polity supplements its formal methods of assuring accountability and legitimacy in political decision making" (p 21). This use of the term allows an analytical reflection beyond formal politics and decision making (i.e., the state) onto less apparent strategies of legitimation and social practices that shape the governance of science and technology.

I argue that Christian religious ideas and values have played a key role in the US stem cell debate and have subsequently determined policy outcomes, especially between 2001 and 2008. By contrast, during this time period, most EU member states have adopted stem cell policies that are more consistent with the democratic values of secularism, religious pluralism, and scientific freedom. My analysis aims to show how the public debates on stem cell research in the US and the EU exemplify the two divergent socio-political trends that had shaped the development of these political entities. As Habermas (2006) has noted, while the trend towards social modernization in Europe, particularly after World War II, has gone along with an increasing wave of secularization, the unfolding of political modernity in America has coincided with the political revitalization of a strong religious consciousness. This tendency towards increasing religiosity has become highly visible in American public discourse over the last few decades, a time when religious traditionalism had been established as a strong predictor of political behavior. Given the profound influence of religiously informed moral arguments in the American public sphere, it is by no means surprising that the Christian Right and bio-conservatives have succeeded in setting a strong public agenda on most issues concerning the politics of life, with abortion, euthanasia and hESC

research reaching the top of the political agenda on Capitol Hill and the White House. Politics and religious conservatism became even more tightly linked during the two presidencies of George W. Bush. In the field of bioethics, the shift to conservative ideologies and values was exemplified by the President's Council on Bioethics (PCBE), an advisory body within the executive branch, which did not hesitate to adopt a narrow, embryo-centric approach to current bioethical issues, rather than a conceptually richer approach and diversity in perspective that would be more appropriate for this type of presidential commission (Annas, 2005). Under the political pressure of the Religious Right, in 2001, the Bush administration implemented a restrictive federal funding policy, which became not only unpopular, but also triggered an increase in embryo research through state-level programs (Reynolds, 2008). The policy has left the United States without a comprehensive legal and ethical oversight at the federal level of the development of stem cell technologies and other controversial biomedical research such as cloning, pre-implantation genetic diagnostics, and the creation of animal-human chimeras for stem cell research. Different research and ethical standards apply to the public and private sectors, as well as at the state and federal levels, and there is no unified national strategy for the development of stem cell medicine within an ethically regulated environment (Reynolds, 2008). Rather, at the federal level, the issue of hES cells has been framed in terms of the embryo's contested moral status, thus precluding a substantive public debate on the potential medical benefits and the broader ethical issues created by this research. A change in policy direction was initiated by President Barack Obama on March 9, 2009 with the signing of *The Stem Cell Executive Order and*

Scientific Integrity Presidential Memorandum which put an end to the eight-year ban on federal funding for research on new hESC lines (*The White House Press Room*, 2009). The reversal of Bush stem-cell policy had been long expected by the scientific community and stem cell advocates; however, the new federal policy has failed to address the key issue of what types of hESC research and derivation techniques will be supported with tax payers' money. While commentators expected that Obama would limit the federal funding to research that utilizes stem cells derived from discarded IVF embryos, his order delegated to the National Institutes of Health the authority to decide, within 120 days, whether funding will be allocated for research on hESC lines from more contentious sources such as cloning and embryos produced solely for research (Stein, 2009). Likewise, it is yet to be seen whether the present administration will address the broader policy dilemma in regulating human biotechnologies faced by the US: a largely unregulated private sector, different ethical standards in federally funded and private research facilities, the Biotech lobby propaganda, and strong opposition against hESC research as one of the defining issues in America's relentless culture wars.

By contrast, the current policies governing hESC research in the EU have reflected a more balanced approach at the supranational level to the issue of protection and respect owed to embryos used for research, which was carefully weighed against the moral imperative to develop new medical treatments that could potentially save the lives of EU citizens with degenerative diseases. Although European Community funding was allocated for research on hES cells obtained from supernumerary IVF pre-implantation embryos (in member-states where permitted), no EU financial support for research using

therapeutic cloning to create embryos was allowed. Despite religious divisions, differences in national policies of member states, and considerable opposition by the Vatican, the European Commission has established strict ethical guidelines for public funding of research on both adult and embryonic stem cells that reflect the position that this biomedical innovation is a compelling public good. Policy decisions have also been influenced by the EU's 2000 Lisbon agenda, which focused on scientific research and technology development as a way to build the most competitive global knowledge-based economy by 2010 (Wynne et al., 2007), and also as by traditional notions of "consensus politics." Nonetheless, EU member states have responded to the controversy with different ethical and policy assessments of what type of regulatory approach will best serve the public interest. For example, while the stem cell policy debate in Germany has revived old anxieties about Nazi science and unethical human experimentation in the context of the rebuilding of German identity in the aftermath of two world wars, biotech countries like the UK, Sweden, and Belgium have elevated the development of hESC research and regenerative medicine to the top of their national agendas. It is worth exploring how political culture has played out in EU debates and has shaped policy decisions regarding hESC research. Therefore, my dissertation strives to understand the intricate relationship between universal ethical values, cultural specificities, and regulatory regimes that apply to human biotechnologies and to deconstruct dominant themes in framing the biopolitics of stem cells. This perspective can also help us gain better insight into the complicated public responses to stem cell technologies and their impact on the political life of communities, nations and federal states.

The next sections of this chapter provide background information on the controversy over hESC research and examine ethical and political considerations in the US and EU policy debates. The chapter concludes by outlining the methodology and structure of the dissertation research.

Defining the Public Interest

The main premise of this dissertation is that the stem cell controversy raises important challenges for *a democratic politics of communication*. Public deliberations on the ethics of hESC research have been characterized by political polarization and partisan rhetorics. The ethical objections against research on hES cells have revolved around their derivation from human embryos at the blastocyst stage of development (from the fourth or fifth day of embryogenesis to the moment of implantation in the uterus). Much of the embryo politics involved in the stem cell controversy has its deeper roots in the earlier abortion debate and the rise of the pro-life movement in the 1960s and the 1970s (Holland, Lebacqz, & Zoloth, 2002). As a result, the public interest in stem cell innovation has been repeatedly debated in relation to a fundamental political, moral and legal question: "Do we destroy a potential human being when a blastocyst is used in hESC research?" Public deliberations on the embryo's highly contested status have reflected a deep moral divide in contemporary pluralistic societies. On the one hand, stem cell activists have repeatedly questioned the validity of both religious and secular beliefs in the moral equivalence between blastocysts and born people (Sandel, 2004; Kaplan, 2007). In mass media and popular discourses the issue has consistently been framed in terms of the intense conflict between religious traditionalism and scientific freedom,

conservative bioethics and the scientific community (Maienschein, 2003b). On the other hand, opponents of embryo research have claimed that stem cell activists had undermined a rational public discussion on biological issues by dismissing arguments about the ontological status of human embryo as fundamentally religious and thus beyond the scope of a legitimate public debate (Shields, 2007). It was argued that stem cell advocates had taken advantage of people's suffering and had manipulated the public opinion through the effective use of propaganda techniques, impassioned rhetorics and appeal to human emotions (Shields, 2007). In the US, the two camps have framed the issue in accordance with their preferred outcome and have waged nationwide lobbying and public relations campaigns. They have offered competing views of what constitutes a responsible governance of the stem cell technologies.

The stem cell wars have become a good case study to evaluate the legitimacy of religious-based values in public debates over science policies, as well as the complexities of public communication of scientific controversies in contemporary multicultural and pluralistic societies. Religion has played an important role in stem cell debates worldwide and therefore appropriate consideration should be given to the significant differences between the major religious traditions on the issue of moral respect and legal protection owed to embryos and fetuses (Walters, 2004; Waters & Cole-Turner, 2003). Religious perspectives on the ethics of hESC research have significantly shaped public attitudes and influenced the present regulatory regimes not only in the US, but also in EU member states with predominantly Roman Catholic populations, such as Ireland, Italy, Poland, Austria, Slovakia, Malta, and Lithuania. The stem cell controversy, however, was not

solely based on the embryo's highly contested moral status; it also involved public anxieties and misconceptions about stem cell science. While hESC research has become the subject of theological and ethical debates and its implications for humanity have been widely debated, the topic is still about science and the production of fundamental knowledge in scientific fields such as developmental biology and embryology. Scholars have claimed that both academic and public discussions need to be properly informed by accurate scientific knowledge on the issue (Jones, 2004; Finlay, 2004).

A substantive public debate on hESC research should consider the ethical issues within their larger scientific, political, social, cultural, and legal contexts and address the difficult normative questions arising from new developments in biomedicine. It should also involve efforts at developing strategies to promote civic engagement with science policy and increase public knowledge about stem cell technologies. Stem cell research has quickly developed into an important interdisciplinary field of inquiry, especially as innovations in regenerative medicine have become the target of global corporate interests, political agendas of governments and interest groups, and citizens' activism. It is the ultimate goal of this dissertation to provide critical reflection on how contemporary biopolitics affects collective decision-making in democratic societies. This objective will be accomplished by addressing, in light of the stem cell controversy, the philosophical and political question of how new developments in biomedicine challenge the communicative processes of public opinion and will formation in the democratic public sphere. I also examine how the issue of hES cells has been extended to metaphysical and normative questions over traditional notions of personhood, human nature and the status

of the human in the world (Habermas, 2003; Sandel, 2007) and has been linked to ethical critiques of post-humanism (Fukuyama, 2002).

At the close of the twentieth century, many predicted that we were entering "the age of biological control" (Wilmut, Campbell & Tudge, 2000). With the growing power of biotechnology to produce novel forms of life and transform our own biology, it has become necessary to exercise greater political control over biomedical research that could have negative consequences for future generations (Cole-Turner, 2001; Fukuyama, 2002). We are presently witnessing epistemological shifts in contemporary life sciences that have uprooted conventional understandings of what constitutes "human nature" and have forced scholars to reconsider concepts of living organisms, species, individual, community, and race. Rose (2007b) has argued that the most visible mutations of contemporary biopolitics were the molecularization, optimization and subjectification of technologies of life, as well as the emergence of bioeconomy and biocapital. Advances in the life sciences and biomedicine, such as the human genome project, cloning, genetic testing, somatic gene therapy, germline gene modification, and pre-implantation genetic diagnosis, have also generated technologies of biopower in the form of risk politics. These new "economies of vitality" were "fuelled not merely by the commercial interests of biotech companies, but also by parental desires for a perfect child in an age of manipulated consumerism and reproductive choice" (Rose, 2001, p. 2). Contemporary biomedical knowledge systems have become an integral part of the neo-liberal tendency towards the privatization of health risks. Subsequently, questions concerning the regulation of human biotechnologies and biomedical research have spawned heated

scholarly debates and have triggered political mobilization and action. Some have viewed that the ideological shift towards individual choice and autonomy that has taken place within our highly medicalized, neoliberal societies as concurrent with a reductionist social agenda. In his philosophical critique of liberal eugenics, Habermas (2003) has warned against the resurgence of genetic determinism and scientific racism which would eliminate those considered biologically abnormal. By contrast, analyses of genetic governmentality have shifted the focus away from the preoccupation with problems of reductionism, reproduction and repression in an attempt to achieve a better understanding of the relationship between the government of risks and the development of technologies of the self (Lemke, 2004; Novas & Rose, 2000). Genetic reductionism was seen as a truth program that functioned in the context of power strategies and political rationalities. As Lemke (2004) has pointed out, "Rather than being viewed in terms of objective fate, genes today are increasingly seen to represent subjective potential: they refer to the supremacy of the consumer, who aims at profitable optimization of individual human capital and personal quality of life" (p. 551). Biopolitics as subjectification has produced medical subjectivities that are oriented towards the norms of personal responsibility, risk aversion, and informed decision making (Novas & Rose, 2000).

Stem cell research has arguably become the most prominent issue in the highly contested, molecularized biopolitics of the twenty-first century. In both Europe and America, extensive publicity has been given to this biomedical innovation, its ethical implications and the future of regenerative medicine. Stem cell activists have tended to emphasize potential benefits for society, e.g. the promise of regenerative medicine to

radically transform global tissue economies and optimize healthcare systems, while overlooking the significant risks associated with clinical translation of stem cell therapies. Currently, these potential adverse effects of stem cell transplants vary from tumorigenesis to immunological complications and problems associated with phenotype transformations of transplanted ESCs such as dedifferentiation or excess proliferation. Nonetheless, some scientists believe that we are on the brink of a new revolution in biomedicine, with stem cell therapies having the potential to transform the twenty-first century medicine in a manner similar to the small molecule drugs in the twentieth century.

In their book *Tissue Economies: Blood, Organs, and Cell Lines in Late Capitalism*, Waldby and Mitchell (2007) observe that the public interest in the development of stem cell technologies and regenerative medicine arises from their potential to provide solutions to two arduous biopolitical problems faced by the nation-state. The first issue is the difficulty of encouraging organ and tissue donations. The existing organ donation and procurement regimes are inefficient and remain plagued by systemic problems, with an ever-growing demand far outstripping the supply of available organs. The unlimited capacities of hESCs to generate various types of body tissues promise, at least in theory, to resolve this problem. In this context, hESC research is clearly viewed as a pure public good, while "the stem cells are imagined as an unlimited resource, the precise opposite of individual organs" (Waldby & Mitchell, 2007, p. 63). The second biopolitical problem concerns the changing demographics of the industrialized Western nations. Aging populations currently present a number of economic, social and policy challenges to governments. Regenerative medicine and stem

cell technologies have the potential to develop treatments for chronic and degenerative conditions associated with aging that place significant burden on national healthcare systems. Therefore, significant biovalue—a concept introduced by Waldby (2002) to designate the relationship between the promotion of health, the production of capital and the question of ethics in the use of human tissue in stem cell research—has been assigned to the hESC tissue, as it is believed that the science of "stem cells" has finally provided the fast growing biotech industries with an easy shortcut to the prolongation of life. Recent research has shown that aging processes in the human body are correlated to the diminishing capacity of stem cells for self-renewal, which is caused by DNA damage and changes in their supporting niches (Sharpless & DePinho, 2007). Decline in the replicative function of certain stem cell types as age progresses could also be induced by mechanisms that protect against cancer development, such as senescence and apoptosis, which depend on telomere shortening and the tumor suppressing proteins p53 and p16INK4a (Sharpless & DePinho, 2007). Finding connections between this decreased regenerative capacity of stem cells and mammalian ageing clearly advances a "stem-cell hypothesis" for medical conditions commonly associated with aging such as frailty, atherosclerosis, and type 2 diabetes.

Most nation-states with advanced biotech industries have carried out parliamentary debates on the ethical regulation of hESC research and funded efforts to advance stem cell innovation. The stem cell debates in the US and the EU have largely focused on the issue of regulation and funding for this biomedical research. There are profound disagreements in these multicultural, pluralistic societies on whether public

funding should be allocated for research that some constituencies believe to be at least ethically objectionable. While opponents of embryo research have advocated prohibitions of public funding, research activists on both sides of the Atlantic have contended that private investments would not provide the best opportunity for realizing the therapeutic potential of hESC research. The US National Academies Committee on the Biological and Biomedical Application of Stem Cell Research in 2001 has emphasized the crucial role public funding had played and would continue to play in generating and optimizing scientific advances in biomedicine (*Stem Cells and Regenerative Medicine*, 2002). First of all, conducting basic biomedical research is the key to the development of new medical treatments. Such research involves a systematic approach that can help scientists achieve a better understanding of essential aspects of phenomena and produce new fundamental knowledge in their respective fields (*Stem Cells and Regenerative Medicine*, 2002). In the United States and elsewhere, basic research in biomedicine and the life sciences has traditionally been the domain of public funding. Despite the growing investments of private pharmaceutical and biotechnological companies in overall biomedical research in recent years, the National Institutes of Health (NIH), a federal agency under the umbrella of the Department of Health and Human Services, is still the largest sponsor of basic biomedical research that produces fundamental knowledge, with an annual budget of $29.4 billion in 2007. By comparison, basic research comprised a small percentage of all private sectors pharmaceutical R&D, with only 14 percent in the 1990s and, as illustrated by the 2001 Report of the National Research Council, with pharmaceuticals being the main area of concentration (*Stem Cells and Regenerative*

Medicine, 2002). Basic research is often removed from commercial applications and, therefore, it is unlikely that it would be vigorously pursued by private companies that are oriented towards fast returns of R&D investments and satisfying profits for their stakeholders.

Science, technology and engineering innovation in the EU is presently funded though the Seventh Framework Program (FP7) of the European Commission, which will allocate approximately 73 billion euro for a seven year period (2007-2013) in four specific program areas: cooperation, ideas, people and capacities (FP7, 2008). Health research is one of the priority areas under FP7, with an emphasis on translational research (e.g., the translation of basic discoveries to clinical application), the development of new therapies, methods for health promotion and effective diagnostics, as well as sustainable healthcare systems (FP7, 2008). In most EU member states, public funding is indispensable for the production of fundamental knowledge in the field of biosciences and biomedicine which is a necessary precondition for the development of new biomedical treatments. The European Commission has acknowledged the importance of public investment in health care and biomedical research by heavily investing in cooperation projects for basic and translational research between EU research networks and national health institutions (FP7, 2008).

Science policy advisory bodies, such as the US National Research Council, have indicated that restrictions on public funding for hESC research would limit the number of scholars engaged with basic research in the field of stem cell biology (*Stem Cells and Regenerative Medicine*, 2002). Most stem cell scientists work in academic institutions

and laboratories that are funded with federal funds. While these academic researchers may in principle accept funding from private organizations, conducting research that is subject to federal restrictions in NIH-funded facilities entails significant risks, including revoking the scientist's individual funding, and may also jeopardize the funding of the institution as a whole (*Stem Cells and Regenerative Medicine*, 2002). Another negative consequence of federally imposed funding restrictions is that the development of stem cell innovation will be confined to only a few avenues of research (*Stem Cells and Regenerative Medicine*, 2002). Such constraints will inevitably diminish the rate of discoveries and knowledge development and will adversely affect translational research (i.e., the transition from basic research to actual clinical applications). By contrast, public funding in any scientific field greatly increases the rate of discovery and knowledge production through the encouragement of a broad range of diverse research activities (*Stem Cells and Regenerative Medicine*, 2002). Publicly funded biomedical research also facilitates open exchange and access to data, experimental methods, and technologies within the scientific community. Finally, one of the strongest arguments in favor of the governments' involvement in and financial support for hESC research is the need to provide appropriate ethical oversight of controversial biomedical research (*Stem Cells and Regenerative Medicine*, 2002). Therefore, the 2001 report released by the US National Academies Committee on the Biological and Biomedical Application of Stem Cell Research concluded that public funding, combined with established standards of open scientific exchange, peer-review, and public oversight, would constitute the most

efficient and responsible way to realize the potential of stem cells for regenerative medicine (*Stem Cells and Regenerative Medicine*, 2002).

Despite the sound argumentation of science and public policy advisory bodies in America and Europe, determining what policies will best ensure the deployment of stem cell technologies for the common good continues to be a real challenge in stem cell debates. Ethical and religious critiques of hESC research arise from framing the controversy around some fundamental questions that society has grappled with over the centuries. Similar to scientific controversies involving human reproduction, such as abortion, pre-implantation genetic diagnosis, and inheritable genetic modification, experiments with hESCs have revived perennial philosophical debates over the definition of human life and the moral status of the human embryo. The public understanding of the stem cell controversy, as Jane Maienschein (2003a) points out in her article on the role of language in the stem cell debate, was further complicated by discrepancies between the public use of language and the complex terminology adopted by scientific communities. Such discrepancies have traditionally been a source of confusion in public debates on issues related to science, technology and innovation. As the stem cell controversy has unfolded, the public use of biological concepts pertaining to hESC research has contradicted conceptual paradigms in developmental biology (Maienschein, 2003a). Subsequently, most public debates over the morality of embryo research have overlooked conceptual differences between the terms "embryo" and "pre-embryo" outlined by embryologists and have failed to consider how the focus on "embryo" had been shifting historically in science and research (Maienschein, 2003a). Scholars have also observed

that bioethical discourses on stem cell research could be particularly confusing to lay persons, as only few experts are familiar with the complex scientific, philosophical, and theological debates over the beginnings of human life (Nisbet 2004b; Scott, 2006). Political debates and public communication campaigns in America and elsewhere have often reduced these complexities to irreconcilable polar-opposite positions by framing the controversy in terms of an irresolvable conflict between morality and science, religion and secular bioethics, pro-lifers and pro-choice positions. This has led to a significant bifurcation of opinions on whether hESC research constitutes a pure public good that is worthy of government funding and protection, with advocates emphasizing the potential health benefits for the community and our moral obligation to pursue life-saving biomedical research in response to their opponents' criticism of controversial technologies used in stem cell studies such as embryo destruction and cloning.

Rhetorical Challenges in the Stem Cell Debate

The ethical and policy issues pertaining to hESC research have deeply affected the democratic politics of communication in America, but also in EU member states with strong social movements against abortion and embryo research. An interesting twist in the almost decade-long debate was the contention of some right-wing US intellectuals that the contemporary public sphere had failed to produce a legitimate public discourse on this thorny bioethical issue. In his 2006 article "Bioethical politics," Jon Shields (2006) argued that the Secular Left in America had undermined a rational public discussion on biological issues by dismissing arguments about the ontological status of the human embryo as fundamentally religious and thus beyond the scope of a legitimate

public debate. Furthermore, in an article published in *Social Science and Modern Society*, Shields (2007) claimed that proponents of hESC research in America had won overwhelming public support not with rational, substantive arguments, but rather with persuasive images of human suffering, impassioned rhetorics and strong emotional appeals. Although research advocates sincerely believe that embryos are not human beings, they—similarly to the pro-choice supporters—have failed to articulate convincing philosophical arguments that establish a morally significant dividing line between the zygote and the person. Shields (2007) has also alleged that conservative intellectuals had offered well-reasoned defenses of the full moral respect and protection owed to the early embryo, as well as a sound ethical justification for restrictions on hESC research. Nonetheless, the Right has found it difficult to persuade the public of the validity of their arguments since they were unable to provide compelling sentimental evidence confirming the human nature of the early embryo. Unlike the pro-life activists who could take great advantage of shocking pictures of human fetuses with crushed skulls and broken bodies, opponents of hESC research could hardly build their case on visual representations of blastocysts from which pluripotent stem cells are derived. The embryo at this stage does not possess any anthropomorphic characteristics, but rather looks like a simple cluster of cells. People tend to be less compassionate about the destruction of blastocysts in research than to the suffering of those dying of Parkinson's, Alzheimer's, type-1 diabetes or other degenerative diseases. Shields (2007) has concluded that, regardless of the strong philosophical arguments against embryo research that had been offered by opponents of hESC research, the Left would eventually prevail in the stem cell fight due to its

sentimental advantage. Their emotional appeals have also resonated well with utilitarian claims about the potential medical benefits from this research.

Arguments by Shields (2007) and other commentators (Lawler, 2007; Kaye, 2007; Levin & Cohen, 2007) that persuasive communication campaigns and media hype, rather than rational arguments and evidence-based reasoning, have shaped public attitudes and activism are by no means unique to the stem cell debate. In their critiques of the right-to-life movement, pro-choice supporters expressed similar concerns about how the politics of images which provoke visceral responses could affect the rationality of deliberative public engagement processes. Abortion-rights activists in the US have used a line of argumentation similar to Shields' claims in order to reflect on the persuasive nature of shocking, graphic images in Jack and Barbara Willke's *Handbook of Abortion* (1971) which had played an instrumental role in the mobilization of several generations of pro-life citizens. Debates on highly contested social and medical issues such as abortion and research on stem cells involve conflicting normative claims and ideologies, with both sides in the dispute deploying scientific theories and concepts as a resource in their social struggles. This raises doubts of whether such controversies are purely rational debates, with only one defensible position on the issues under consideration and whether they could be negotiated, resolved, or terminated simply through the use of evidence-based reasoning, rather than evaluating competing moral claims to rationality made by participants in the debate. While the position defended by Shields has some ancillary merits, his argument is poorly substantiated and overlooks the political realities and conflicting epistemologies of the stem cell controversy as it has unfolded in the US.

Although both sides have framed the issue as a moral matter according to their preferred policy outcomes, the religious Right and pro-life groups have played a key role in the politicization of public bioethics on all institutional levels by framing the stem cell debate around the contested politics of abortion. During the Bush presidency, conservative bioethicists on the President's Council of Bioethics (PCBE) have consistently provided intellectual ammunition for the Right on controversial bioethical issues that range from abortion and embryo research to the right-to-die debate. Right-wing intellectuals such as Leon Kass, Wesley J. Smith, Gilbert Meilaender, Robert P. George, Eric Cohen, and William Kristol have heavily relied on emotional appeals to make the case against "embryonic stem cells" and have capitalized on the power of rhetoric to provide ethical justification for the Bush stem cell policy announced in his televised address to the nation on August 9, 2001. They have utilized dystopian visions to claim that hESC research not only involves the destruction of nascent human life, but is yet another step toward the creation of a post human race in a biotech-dominated "Brave New World" of designer babies, human clones, and fetal farming (Bush, 2001; Kass, 2001, 2002, 2003; Smith, 2004). Aldous Huxley's *Brave New World* (1932), the famous dystopian tale of how advances in biotechnology and genetic engineering have brought into existence a society of dehumanized benevolent dictatorship and pharmacological hedonism, has served as a common reference point for critics of stem cell technologies and has provided validation for the administration's regulatory approach.

In order to stifle a substantive and inclusive debate on the public interest in the development of stem cell technologies, the Right has relied on the rather emotional

appeal that public support for hESC research would only ensure that the culture of death becomes deeply entrenched in American society. Their opposition against the use of human embryos in research is grounded on the much contested belief that full personhood begins at conception and therefore embryos are morally equivalent to born humans. Right-wing organizations such as the Family Research Council, Concerned Women for America, Christian Coalition for America, the U.S. Council of Catholic Bishops, and the American Life League, among many others, have been relentless in spreading misconceptions about the science of embryonic stem cells. Their activists have made outrageous statements that public funding for hESC research will increase the rate of abortions and that stem cell scientists encourage women to have abortions so that they can conduct experiments on late-stage fetuses. Anti-stem cell advertisements commissioned by pro-life groups have incorrectly defined the pluripotent stem cells derived from blastocysts as synonymous to "human embryos" and "babies." An example of such propaganda campaigns is a TV commercial sponsored by NoStemCell.com which claims that "stem cells" are "are tiniest of human beings harvested from human embryos" and that the microscopic cell lines grown on Petri dishes used in stem cell research are "babies" that will be subjected to cruel experimentation (Sky Soft Consulting, n.d.). Christian Fundamentalist leaders like Reverend Pat Robertson, Reverend Jerry Falwell and James Dobson have opposed stem cell research using similar rhetorical strategies and pseudoscientific notions. In 2006, when the Congress passed its first bill to increase federal funding for hESC research, the Campaign to Defend the Constitution (DefCon), an online grass-roots movement to combat threats to American democracy posed by

Christian fundamentalism, published full-page advertisements in *New York Times* in May and June criticizing the President and the Religious Right for holding the stem cell legislation "hostage" and "imposing its will on all Americans, through limits on a woman's right to privacy, a steady assault on gay and lesbian rights" and "the march to teach creationism as science" (Figure 2). The May ad was more specific, as it included photos of the three conservative religious leaders beneath the headline "Meet America's Most Influential Stem Cell Scientists." It also quoted Falwell's references to embryonic stem cell research as "dangerous and unethical," Dobson's claim that it compares to Nazi human experimentations and Pat Robertson's statements that "before long, we'll be harvesting body parts from fully formed people" and that "once you begin this...utilitarian use of cells, then everything is up for grabs" (Figure 3). Stem cell advocates have also consistently targeted the hypocrisy of Bush's stem cell morality in numerous cartoons and spoof ads, posted online or in various print media (Figure 4).

While Shields (2007) rightfully highlights the power of rhetorics in politically effective communication, his defense of the conservative position is dismissive of some strong arguments against the "equal moral status view" articulated in the stem cell debate that have helped mobilize public support for this biomedical innovation. The first compelling ethical defense of public investment in stem cell technologies stems from the so-called "research imperative" (Callahan, 2007). This is the view that we have moral obligation to pursue biomedical research that can save human lives and ease the suffering of millions of people with degenerative diseases, and that this obligation outweighs the respect and protection owed to pre-implantation embryos. From this perspective, the

central bioethical issue for policy makers becomes how to weigh the moral worth and respect owed to embryonic forms of life against the lives of those that can be saved by advancements in hESC research. Stem cell advocates have raised at least two compelling logical arguments that cast doubt on the Religious Right's unproblematic acceptance of the moral equivalence between embryos and people. The first objection concerns the belief that all embryos have the potential to develop into human life. In reality, almost half of the pre-implantation embryos never become human life. The embryo can become a person only if it is placed in a woman's uterus and provided that it implants. Therefore, many believe that the embryo's adherence to the uterine wall of the mother constitutes a pivotal moment in realizing its potential to develop into a human being. ESCs are usually derived from donated unused embryos which were created during in vitro fertilization. Such embryos, which are routinely discarded or kept in frozen storage for many years by IVF clinics, are a pure potential since it is unlikely that they will ever be implanted into a woman's womb and become human beings. The second argument in favor of hESC research has resonated even more powerfully with the American public. While right-wing bioethicists and pro-lifers claim that the destruction of the pre-implantation embryo is morally wrong, they disregard the fact that it is a common occurrence in the process of sexual procreation (Caplan, 2007). In reality, the rate of early pregnancy loss remains high, and approximately half of all fertilized eggs either do not implant or are simply lost. People view the natural loss of embryos as an event that is by no means morally and religiously equivalent to the tragic death of an infant (Sandel, 2005). Embryo destruction is a daily practice at the IVF fertility clinics. Stem cell advocates have accused President

Bush and his supporters in hypocrisy for accepting the destruction of surplus embryos in IVF labs, while, at the same time, opposing such destruction in medical research that could potentially save lives. If opponents of embryo research are consistent in their belief in the full moral respect owed to pre-implantation embryo, it only makes sense that they should strongly oppose the "test-tube" baby technology (Kaplan, 2007). Sandel (2005) has also argued that defending "the full moral status view" would inevitably entail support for a total ban on destruction of human embryos in research, not just restrictions on federal funding. It is these well-reasoned arguments that had won the "battle over stem cells," secured strong bipartisan support for the Stem Cell Enhancement Act of 2007 (S.5) in the US Congress, and mobilized voters to organize ballot initiatives and pass constitutional amendments in California, Missouri, and Michigan.

In his book *Life's Dominion: An argument about abortion, euthanasia, and individual freedom*, Ronald Dworkin (1994) has argued that we need to distinguish between the public rhetoric in which people frame their opinions and their actual opinions, and that it is not always possible to find out what exactly lay persons think by simply focusing on the high rhetoric of the abortion debate. When people are asked to express their views on the issue in a general way, they tend to "use the strident and heated rhetoric that leaders of various interests groups have made prominent, whether or not it fits their actual instinct and convictions (Dworkin, 1994, p. 20). In reality, people often make decisions about abortions that are clearly at odds with the pro-life rhetoric in which they express their position. When lay persons use emotionally charged descriptions of abortion such as "murder" or "homicide" and express the notion that the fetus is a person

from the moment of conception, Dworkin (1994) argues, they often do so because they hold the detached, not the derivative view, that is, they condemn the act of deliberately terminating pregnancy "not because they think a fetus has rights and interests but just to emphasize the depth of their feeling that abortion is wrong because it is the deliberate destruction of the life of a human organism" (p. 21). I believe that these considerations about the independent emotive power of rhetoric should be taken into account when evaluating public discourses surrounding stem cell research, particularly if we strive to achieve a historical reflection on convergences between the public rhetoric of the abortion debate and framings of the stem cell controversy around the intricate questions of what sort of entity the embryo is and when personhood begins.

Methodology and Chapter Outline

The comparative account of the politics and public engagement with hESC research in the US and the EU offered by this dissertation utilizes the methods of the interpretive social sciences to elucidate some far-reaching socio-political and ethical implications of what has been described as the "new biomedical revolutions" in the life sciences, biomedicine and biotechnology. I engage in textual analysis of theoretical perspectives and empirical studies in disciplines such as science and technology studies, sociology, political science, communication theory, media studies, philosophy, and bioethics that have examined the impact of these new developments for democratic theory and practice. Although I undertake a qualitative analysis of policy and political developments primarily in the field of stem cells research, I also want to illustrate how the stem cell controversy has become a reference point for larger and more salient

debates over the appropriate limits of biomedical research and innovation. The politics of biotechnology has occupied the center stage of public and political arenas over the past ten years and contested developments have called into question fundamental democratic values such as individuality, privacy, freedom, equality and solidarity. Advances in the fast-growing field of biomedical engineering have also posed immense ethical challenges for humanity, with the technology making the generation of novel biological entities, as well as human germline genetic modification, a foreseeable future. As Nikolas Rose (2007) has pointed out, the intersection of human reproductive technologies and stem cell engineering has led to the appearance of a whole set of liminal entities such as "stem cells and stem cell lines, the embryonic stem cell clusters, containing cells from all three germ layers, termed "embryiod bodies," which can be induced to differentiate into various types of tissue or to express particular enzymes" (p. 49). The nature of such new biological entities, their legal status and the legitimacy of practices that generate them are highly contested; they also incite critical discussions about how paradigm shifts in the biosciences have redefined our knowledge practices, legal categories, political concepts, and personal identities.

The next two chapters set out to examine entanglements of science, religion and ethics that have shaped public discourses on hESC research. I argue that the stem cell debate constitutes a "scientific controversy with a heavy political and ethical overlay" (Engelhardt & Caplan, 1987) and that scientific disputes of that nature are not amenable to closure without proper consideration of their epistemologies and structural political, social and economic issues. Therefore, I attempt to disentangle scientific, ethical and

political claims that are intermingled in the controversy and evaluate the impact of social struggles and cultural contexts in validating knowledge claims regarding the ethics and science of stem cells. Chapter 2 outlines key scientific developments in hESC research and fundamental concepts in stem cell biology, including different types of stem cells and their clinical potential for regenerative medicine. I illustrate how the field of stem cell research has become the subject of heated public debates and how proponents and opponents of this biomedical innovation have offered competing interpretations of the biological properties and clinical utility of embryonic and adult stem cells in attempts to shape the public discourse and influence policy decisions. I also discuss recent developments in stem cell studies such as methods for the reprogramming of more differentiated cells (i.e., somatic stem cells) into induced pluripotent (iPS) cells, which are expected to resolve the ethical dilemma of using human embryos.

Chapter 3 looks at how the stem cell controversy has revived contentious debates over the moral standing of the human embryo, the role of religion in public life of pluralistic democratic societies, and the appropriate limits to biomedical research that infringes on human dignity. It provides an overview of religious arguments on the use of human embryos in stem cell research and related technologies developed by major monotheistic religions such as Catholicism, Judaism and Islam. This intercultural perspective on the ethical issues in hESC research aims to highlight discrepancies between the major monotheistic religions on thorny bioethical issues and address the intricate question about the validity of religious arguments in public debates over stem cell policies. The chapter also provides insight into the diverse ethics of hESC research

by analyzing three major bioethical issues that have become prominent in the US and EU public policy debates: (1) secular defenses of the embryo's moral status, (2) the ethics of human cloning, and (3) concerns about women's reproductive rights and health in embryo donation for stem cell research. These ethical considerations have influenced specific framings of the stem cell controversy in national policy debates.

Chapter 4 examines the role of mass media in setting the public agenda on stem cell research in a comparative US-EU context. My analysis emphasizes the active role of media in shaping and constructing public discourses on the ethics and politics of stem cells against the conventional understanding that media coverage of controversies in the field of science and technology is rather limited to reporting new scientific discoveries and technological developments. I look at how the news and print media represent an important site of struggle for different interest groups in their lobbying efforts to sway public opinion in favor of specific policy outcomes by gaining extensive press coverage. In this process, mass media have also followed their own agenda in framing and sensationalizing ELSI issues related to stem cell technologies and regenerative medicine. The chapter presents an overview of scholarly literature (Friedman, Dunwoody, & Rogers, 1999; Mazur, 1981; Weingart, 1998) on the role various media outlets play in engaging the public with scientific controversies by framing scientific uncertainty and providing legitimacy to knowledge claims, moral values, and political interests. I contrast and compare frames and narratives about risks and benefits of stem cell technologies presented and validated by mass media in the US and EU member states such as Britain, France and Poland from the perspective of two normative models for public discourse on

scientific controversies outlined by Gerhards and Schäfer (2009)—the science-dominated scientific public sphere and the contextualized scientific public sphere.

The concepts of risk society, biopolitics, and the public sphere can provide useful analytical lenses to examine political mobilizations around stem cell technologies in the US and the EU. Chapter 5 discusses how these contested theoretical notions allow us to reflect on the nature of public discourses surrounding hESC research. I refer to two major traditions of contemporary social and political thought that have suggested different theoretical reflections upon the unfolding of political modernity and its underlying institutions: Foucault's analysis of biopower and biopolitics, and Habermas's communicative theory. Foucault's thesis (1984) that the object of politics in modernity has become human life itself and we now live in a "biopolitical" age has provoked a continuous theoretical debate on the growing significance of the biosciences in the political and economic development of late capitalism (Lazzarato, 2002; Lemke, 2001; Rose, 2001; Rabinow & Rose, 2003). Recent shifts in the technologies and stratification of biopower have extended biopolitics beyond the anatomo-politics of human bodies and the bioeconomy of population into forms of molecularized biopolitics which include regulatory control on the micro level of human tissues and cells (Rose, 2001). I examine how stem cell technologies and regenerative medicine have given visibility to such structural changes in the stratification of biopower by redefining what is considered to be human or non-human, living or re-animated. In order to bring a normative perspective on divergent discourses on hESC research that simultaneously compete for policy initiative, the chapter evaluates the multidimensional model of discourse in the democratic public

sphere, proposed by Habermas (1991a, 1991b, 1996) as a normative ideal of democratic politics. This multifaceted notion of discourse presupposes that the pursuit of collective goals is best accomplished through rational processes of collective will formation in which power differentials attached to conflicting interest positions are neutralized. In the light of the stem cell controversy, I aim to gauge whether interest-oriented and value-based perspectives on stem cell innovation can be transcended in search for the common interest in a practical discourse of justification and, furthermore, to what extent the model outlined by Habermas represents a realistic normative ideal for public deliberations in the democratic public sphere. I argue that hESC research appears to be yet another ethical controversy which indicates that rational agreement on contested political and policy matters in pluralistic societies may not be an attainable goal when there are fundamental divergences in value orientation between participants in practical discourse.

A comparative perspective on the US and the EU stem cell policies is presented in Chapter 6. I examine different cultural, political and social forces which have led to sustained public discussions on the issue of stem cell research and have influenced policy outcomes in these two political entities. In the US, political debates on the morality of research involving human embryos and fetal tissue have their own complex history. The stem cell controversy constituted yet another chapter in a long-term policy debate instigated by the Supreme Court's ruling in Roe v. Wade in1973 which legalized abortion nationwide. I look at how a heated national debate on the politics of stem cells has unfolded in the context of vigorous anti-abortion advocacy, the existing congressional ban (i.e., the Dickey-Wicker Amendment) on federal funding for research that harms or

destroys human embryos, and America's relentless culture wars. I also outline the differences between the stem cell policy adopted by Bush administration and Obama's guidelines for federal funding for hESC research. The chapter discusses major socio-political factors and cultural differences between EU member states that have influenced policy decision regarding stem cell technologies in Europe. I analyze the complicated regulatory environment of the EU, with national governments which have adopted a variety of approaches to regulating stem cell research, while most research activities are currently being carried out with EU funding for transnational research networks and collaborations between different countries. I emphasize how the EU's strategic investment in the development of stem cell technologies and the regenerative medicine has largely been driven by the political goal of establishing the most dynamic and competitive knowledge based economy.

The concluding chapter compares the different ways in which the stem cell controversy has been brought to a conclusion in the US and the EU. My analysis draws on Beauchamp (1987) and McMullin's (1987) classifications of different modes of closure in scientific controversies to evaluate the type of ethical and political closures that have occurred in the US and the EU stem cell debates. I explore the role of epistemic (knowledge-based) and non-epistemic factors in resolving or terminating the public controversy over human embryonic stem cells. I suggest that non-epistemic factors, rather than scientific evidence alone, will continue to play a pivotal role in these debates.

Ultimately, my research aims to shed light on how the issue of hESC research has simultaneously evoked great hopes and strong fears about the biopolitics of the future, as

well as how these various utopian and dystopian representations have played out in the public arena. Like other contested applications of medical biotechnology, stem cell research has generated heated debates about whether or not its clinical promise is real and will be realized in a foreseeable future. The divergent futures of this biomedical innovation envisioned by scientists, politicians, religious groups, and lay persons remain contingent and contested. Research on the sociology of expectations has provided an analytical framework to consider the dynamic role that societal expectations play in the field of science and technology innovation (Brown, Rappert, & Webster, 2000; Brown & Michael, 2003; Novas, 2001). This recent sociological orientation within STS engages with the future as an analytical object by emphasizing "the situatedness of future-oriented discourse and the complexity of innovators' roles expressed in these overlapping accounts of established and emerging, networks and activities, certainties and uncertainties" (Brown & Michael, 2003, p. 17). It also conceptualizes how expectations differ between various social groups such as scientific communities, policymakers, the industry, and the public. The fast developing field of stem cell innovation invites such an analytical reflection on the "interpretative registers" used to construct multiple, contested or embraced biopolitical futures, including both the "retrospecting prospects" (recollecting past futures) and the "prospecting retrospects" (past futures integrated into the real-time construction of future) (Brown & Michael, 2003, p. 4).

CHAPTER 2

THE SCIENCE AND POLITICS OF STEM CELL RESEARCH

In his book *Risk Society: Towards a New Modernity*, Ulrich Beck (1992) conceptualized an epistemological shift in the unfolding of industrial modernity, an unintended, reflex-like movement from the industrial society towards a risk society, which confronts itself over the environmental, social and economic risks of technological modernization. This novel period of social change took the form of a reflexive learning about systematically produced dangers of unprecedented nature that could be neither gauged by the industrial society's own institutionalized standards, nor contained by the protective institutions of its provident state. Moreover, Beck (1992) claimed that we were witnessing a transition from a state of fatalistic passivity in late industrial modernity to a conflictual and self-critical risk society whose advent was manifested in a new form of reflexivity over the government of risks and an increasing public awareness about profound transformations in the industrial society's relationship to nature, its social practices and institutions, intimate relationships, politics, and democratic participation. The concept of "reflexive modernization" (Beck, 1996) is a complex term that cannot be limited to the idea of a passive reflection on conflicts of techno-scientific nature, but rather designates a societal process of self-confrontation of the consequences of modernization with its basis. Essentially, the self-reflexive modernity entailed a radical shift towards the democratization of societal self-critique, scientific expertise and the management of risk discourses. The notion of risk society allowed us to recognize the system-breaking consequences of potential and actual conflicts over the environment,

genetics, molecular biology and information technology. For Beck (1992), the paradigmatic case of incalculable hazards produced by technical-industrial development was the destruction of the environment, which transcended state boundaries and compelled modernity's self-reflection on the foundations of its social context. In the late twentieth century, environmental catastrophes and related ganders such as climate change, destruction of the ozone layer, water pollution, famines, and energy shortages exemplified the risk society's "conflicts of accountability" and led to the rise of environmental politics (the Green movement).

Nowadays, more than two decades after the apocalyptic event in Chernobyl, the tensions of risk society range from the imminent threats to human life, society and the environment presented by nuclear power and environmental pollution to societal conflicts over transgenic crops, genetic engineering, stem cell research, the limits of human genetic modification, security and bioterrorism, neuroscience, and the military uses of nanotechnology and converging technologies. As Sheila Jasanoff (2005) has pointed out in her book D*esigns on Nature: Science and Democracy in Europe and the United States*, these deep contradictions highlight the central role of science and technology in contemporary knowledge-dominated economies, in which state policies and interventions "are geared more and more toward nurturing and exploiting knowledge, with scientific knowledge and technical expertise commanding the highest premiums" (p. 4). They have also raised concerns regarding the partiality of scientific knowledge and have presented significant challenges for the governance of risks in democratic societies. Conflicts of accountability created by technological modernity are particularly visible within the

contested terrain of the life sciences, as new revolutions in biomedicine, genetic engineering and genomics in the twenty-first century are redrawing topographies of scientific knowledge, state power and economic investment (Jasanoff, 2005). Within the biotechnology sector, debates over the morality of embryonic stem cell research and other controversial human biotechnologies remain particularly salient.

It is commonly held that contested scientific and technological innovations should be debated, negotiated, resolved, or terminated through the use of an evidence-based approach which involves sound logical reasoning and rigorous analysis of empirical data (Engelhardt & Caplan, 1987). While reliance on the institutions of science and the validity of scientific authority may be an effective method for resolving some scientific controversies, this is not necessarily the case with debates that involve complex, overlapping scientific, ethical and political concerns. In their analysis of patterns of controversies and closure in science, Engelhardt and Caplan (1987) have argued for the need to map the interplay of scientific, ethical and political interests in scientific controversies that have heavy political and ethical overlays. In contrast to objectivist views, they have also claimed that the understanding of multidimensional conflicts in science and technology often entail reassessment of claims to rationality. Therefore, scholars should give proper consideration of "the extent to which the movement of science towards more ample and secure knowledge is shaped, directed, or impeded by forces external to science, such as the values and political forces of the scientist's cultural milieu" (Engelhardt & Caplan, 1987, p. 3). Scientific controversies with heavy ethical and political overlays often extend to philosophical questions about the impact of cultural

assumptions and political forces on scientific reasoning and the validity of objectivist perspectives on scientific knowledge as characterized by a clear distinction between facts and values, nature and culture (Engelhardt & Caplan, 1987). Resolution or closure of such disputes is of great importance to a variety of social groups, including policymakers, academics, activists, patients and the general public. The end result of greater public involvement with controversies in which scientific issues are amalgamated with ethics and political disputes is a higher degree of uncertainty about the validity of scientific reasoning and the internal logic of scientific investigation.

Controversies that stem from the central position of science and technology in modern society have also evoked sociological critiques of scientific knowledge such as Ulrich Beck's critical analysis (1996) of the unreflective "culture of scientism" which has shaped public discourses on risks in the industrial modernity. The perils of scientism in modernity are seen in the false claims and expectations it creates in society, but also the tendency to exclude reflexivity from deliberations on risks (Beck, 1992, 1996). The theory of risk society developed by Beck (1996) advances the notion of democratization of critique vis-à-vis the special authority delegated to technical and scientific experts to define the public agenda by setting up the major terms and *a priori* premises of risks discourses. Lash and Wynne (1992) have argued that such a democratized, reflexive critique can lay a moral claim to rationality which is equal to that of modern science. Furthermore, recent perspectives in science and technology studies have suggested the notion of dialogical democracy to challenge a deeply rooted belief that there is a profound difference between knowledge developed by professionals and that of

laypersons and have argued that we need to enrich political institutions and democratic participation in science policy (Callon, Lascoumes, & Barthe, 2009). The notion of "delegative democracy" is transforming traditional representative democracy by extending its political institutions to "hybrid forums" of scientific experts, politicians, and lay people (Callon, Lascoumes, & Barthe, 2009). Public forums for debating, negotiating, and resolving scientific controversies with strong ethical and political dimensions are also hybrid because questions are addressed at different levels and in a variety of seemingly disparate domains such as science, ethics, law, and politics.

Scholars have argued that in order to fully understand conflicts in science and technology that have been elevated to the top of the public agenda proper consideration should be given to both their epistemology and structural political issues (Engelhardt & Caplan, 1987; Martin, 1989; Kleinman et al., 2008). As Engelhardt and Caplan (1987) have pointed out, disputes over highly visible and contested domains of scientific knowledge and authority create challenges for researchers to bind the sociology and history of scientific controversies with their epistemologies and to disentangle scientific, ethical, legal and political claims that are intermingled in the scientific controversy. Understanding patterns of scientific disputes, therefore, is inextricably bound to the question of the individuation of different controversies that are blended in a single scientific controversy with a heavy political and ethical overlay (Engelhardt & Caplan, 1987). A possible resolution of such conflicts should involve a reconsideration of both epistemic factors, that is, claims to rationality raised by both proponents and opponents in the debate, and socio-political forces that influence the positions of the participants. A

similar critical perspective on the resolution of scientific controversies was suggested by Martin (1989) in his analysis of the fluoridation controversy through the lens of the relativist position in sociology of scientific knowledge. He claims that we need to develop a more critical attitude towards notions of objectivity in scientific debates and examine the ways in which scientific knowledge can be used as a resource in social struggles in controversies in the field of science and technology. We should also focus on how assessments of rationality in controversies over scientific developments are always socially negotiated and deeply influenced by cultural assumptions.

My analysis of the stem cell controversy draws on the afore-mentioned theoretical perspectives on contemporary controversies in science and technology to determine the number and nature of conflicts involved in the stem cell debate. By focusing on entanglements of science, politics and ethics, I aim to explore its competing epistemologies and illustrate how the issue has generated intense communicative interactions between the institutions of science, the government, the biotechnology sector and the public. I argue that stem cell research constitutes a paradigmatic case of scientific controversy with a heavy political and ethical overlay, and as such, it is not amenable to closure without proper consideration of its epistemology and structural political, social and economic issues. From a social constructivist perspective, it is also important to look at how scientific innovations in stem cell biology and regenerative medicine are embedded in specific cultural contexts and social relationships.

In this chapter I discuss the scientific dimensions of the stem cell controversy and major factors that have contributed to the extreme politicization of this field of

biomedical research. I present a brief overview of scientific literature from the fields of embryology, developmental biology and stem cell studies to clarify differences in biological properties and clinical potential of different types of stem cells: embryonic, adult and induced pluripotent stem cells. I then look at scientific advances in hESC research that have become the subject of heated public debate. While the field of stem cell biology has a long history, with major discoveries in stem cell studies on mice and mammals reported in the 1960s and 1970s, the chapter's primary focus is on scientific developments in from 1998 to the present. I have chosen this period for three major reasons: First, the stem cell studies did not receive significant public and media attention prior to the announcement of the isolation of the first human embryonic stem cell lines by Dr. James Thomson in the November issue of *Science* in 1998 (Thomson et al., 1998). Secondly, these new discoveries in stem cell research and their potential therapeutic applications in biomedicine have incited extensive public involvement in techno-science policy and decision making. As Jasanoff (2005) has argued, the recent spawning of collective action around biotechnology, biomedical research, and advancements in genetics and genomics has reaffirmed the significance of biopolitics as an indispensable axis of modern governance and has redefined preexisting political landscapes on both sides of the Atlantic. Thirdly, the potential clinical translation of discoveries in stem cell research has promised significant economic gains and has attracted key players within a globalizing biotechnology sector. It is safe to say that stem cell lines and tissues have become an indispensable component of an ongoing transition to a global bioeconomy. The major purpose of this chapter, therefore, is to provide the scientific context for a

critical examination of the role of economic, socio-political and cultural factors in validating knowledge claims regarding the ethics and science of stem cells. Such an analysis is further undertaken in Chapter 3 which examines and deconstructs risk discourses around the use of stem cell technologies in biomedicine.

Biological Properties and Types of Stem Cells

Since the concept of "stem cells" is relatively new for the general public, it is not surprising that many are still confused about the science behind stem-cell technology and its experimental and clinical applications. The US National Institutes of Health (NIH) has published two reports on stem cells and regenerative medicine that have introduced the public and policymakers to fundamental concepts in stem-cell biology, biological properties of stem cells from adult, fetal tissue, and embryonic sources, recent research on origin, isolation, and specialization of stem cells, and potential applications of stem-cell therapies in regenerative medicine (NIH, 2001, 2006). These reports present scientific research on both mammalian and human embryonic stem cells that points to the unique protean ability of these most versatile and primitive cells to undergo divisions for indefinite periods of time and differentiate into all types of specialized cells and tissues.

Stem cell researchers have used the term pluripotency to designate the capacity of certain types of cells to produce thousands of highly differentiated cell types in animal and human organisms (Chang & Cotsarelis, 2007). It is observed that a good indicator for pluripotency is the ability of a cell to differentiate into all types of adult cells, including germ line (Rossant, 2007). There are different types of stem cells that are usually classified based on their developmental potential which researchers assess through the

following functional criteria: 1) in-vitro differentiation, 2) teratoma formation, 3) chimera formation, 4) germline contribution, and 5) tetraploid complementation (Jaenisch & Yong, 2008). While there are more complex systems of categorization, stem cells are generally classified into two broad categories: embryonic stem cells (ESCs) and somatic stem cells (SSCs).

The category of SSCs includes endogenous progenitor cells, which are responsible for the regeneration and replacement of tissues in human bodies, and other cells and cell lines derived from fetal tissues, neonatal tissues and adult tissues, such as neural stem cells, mesenchymal stem cells, etc. (Rossant, 2007). Unlike normal somatic cells, ESCs have shown unlimited capacity for differentiation and self-renewal. When proper techniques are utilized in laboratory settings, these primordial cells preserve their protean ability and do not undergo the genomic, mitochondrial and epigenetic changes that characterize the developmental cycles and ageing of SSCs (Zeng & Rao, 2007). Scientists are presently able to propagate cell cultures indefinitely and in large quantities in vitro, well as to genetically manipulate and reinserted them into embryos to create animals with tissues and cells that genetically match the donor ESCs (Coutts & Keirstead, 2007). Tissue engineered products derived from ES cells have shown ability to integrate into many different organs, and could be used to repair damaged or diseased tissues in animal and human bodies (Coutts & Keirstead, 2007)

The differentiation of human tissue during early embryogenesis undergoes a number of stages as shown on Figure 5. Embryonic development begins with the fertilized ovum (zygote), a large diploid cell which is produced by the contact of a sperm

(spermatozoon) with a secondary oocyte (ovum) and the fusion of their pronuclei (the haploid nuclei of the sperm and ovum) carrying the two pairs of chromosomes (Moore & Persaud, 2003). The zygote constitutes a single totipotent cell that possesses the capacity to produce the specialized cells that form the extra-embryonic membranes and tissues, the embryo, and all postembryonic tissues and membranes (NIH, 2001). The process of cell division begins as the fertilized ovum travels down the fallopian tube and reaches the uterus after six days of post-fertilization development. Approximately 24 to 30 hours later, the zygote completes the first mitotic division into two daughter cells with identical sets of chromosomes into their nuclei. Through the process of mitosis these two genetically identical, totipotent cells continue to divide into a four-cell embryo, eight-cell embryo, etc. About 3 to 4 days after fertilization, the embryo assumes a spherical shape, known as morula, which contains between 10 and 30 dividing cells (blastomeres). The morula stage is followed by the formation of a fluid-filled cavity (blastocoel) which marks the transition to the blastocyst developmental stage. The blastocyst is composed by an outer layer of cells (trophoblast) around a hollow ball of cells which contains a cluster of cells called the inner cell mass (embryoblast). In the process of human embryogenesis, the trophoblast forms the placenta and other tissues needed for the fetal development in the uterus, whereas the embryoblast contains pluripotent stem cells that generate the multiple cell types in the human body (NIH, 2001). These pluripotent stem cells are also known as human embryonic stem cells and, over the last ten years, their derivation from human blastocysts as well as other sources has become a subject of continuing scientific, medical, ethical and political controversy. Through the process of cellular differentiation

ES cells develop into more specialized, multipotent stem cells which perform vital functions necessary for the human organism. For example, the hematopoietic stem cells located in the bone marrow and, in a small number, in the bloodstream as multipotent peripheral blood stem cells give rise to all the blood cell types and thus continuously replenish our blood supplies (NIH, 2001).

Clinical Potential of Embryonic Stem Cells

Stem cell activists have often defended hESC research with arguments that ES cells themselves are not human embryos since they have no capacity to become human beings by themselves. It was also argued that these cells cannot produce the placenta and other supporting tissues that make possible the actual implantation and intrauterine development of the embryo/fetus. Even if such cells are transferred to a woman's uterus, they will not develop into a fetus. Moreover, scientists and supporters of hESC research have emphasized the clinical significance of ES cells which is heightened by their unusual capacity to produce more differentiated cells from all three embryonic germ layers long after their derivation and development in a culture (NIH, 2006). In addition, their immortality is manifested through indefinite proliferation in laboratory culture which makes these primal cells an unlimited source of specific, clinically important adult cells such as bone, muscle, liver or blood cells as shown on Figures 6 and 7.

ES cells can be derived from a variety of sources: (1) pre-implantation embryos (i.e., unused embryos created during in-vitro fertilization procedures); (2) from fetal tissue obtained though terminated pregnancies; (3) by means of somatic cell nuclear transfer, or cloning; and (4) through parthenogenetic activation of eggs (Cibelli et al.,

2002). The first five hES cell lines were isolated from the inner cell mass (ICM) of human blastocysts in 1998 by Dr. James Thomson of the University of Wisconsin at Madison and his research team of developmental biologists (Thompson et al., 1998). Independently, that same year Dr. John Gearhart of John Hopkins University isolated similar hES cells from fetal tissue obtained from terminated pregnancies of fetuses older than eight weeks of development (Gearhart, 1998). His research team secured informed consent from the donors after they had already independently decided to terminate their pregnancy. Pluripotent stem cells were derived from that part of the fetus which was supposed to develop into the testes and ovaries (NIH, 2001).

While the term "stem cells" became prominent in the political discourse and everyday language after Thomson's groundbreaking discovery, life scientists have long been familiar with the concept (Maienschein, 2003b). The discovery of the stem cells' capacity to give rise to more specialized cell types was made as early as 1896 by E. B. Wilson (Maienschein, 2003b). In late 1950s, the use of bone marrow transplants for treatment of leukemia patients proved the significance of hematopoietic stem cells as a generalized source of other types of blood cells (Maienschein, 2003b). The discovery of the astonishing potential of ES cells can be traced to the early work of Kleinsmith and Pierce (1964) whose experiments demonstrated that a single embryonal carcinoma cell had the capacity for self-renewal and could generate multiple mature cell types. In the 1980s research on cell lines derived from cultured blastocyst-stage animal embryos provided additional evidence for the plasticity and potential of ES cells (Evans & Kaufman, 1981; Martin, 1981). A landmark experiment in stem cell studies (Nagy,

Rossant, Nagy, Abramow-Newerly, & Roger, 1993) was the use of mouse ES cell lines to generate completely ES cell-derived mice. As evidence confirmed the extraordinary plasticity of ES cells, the field raised a lot of interest among life scientists and medical researchers interested in clinical approaches to repair and replace damaged tissues.

Nevertheless, stem cell studies on mice and mammals conducted in the 1960s and 1970s did not receive serious public attention (Maienschein, 2003b). What really changed after the generation of the first hES cell lines in 1998 was our understanding about "the limits of stem cell capabilities and how differentiation occurs, epigenetically, during development" (Maienschein, 2003b, p. 251). Human embryonic stem research received significant attention within and outside the scientific community since it generated new and innovative ways to investigate fundamental questions of human biology (Maienschein, 2003b). Due to their capacity to generate all three germ layers in vitro, ES cells made possible the observation of embryogenesis at the cellular level, including germ-layer formation, which had been technically challenging to study in mammalian embryos (Nishikawa, Jakt, & Era, 2007).

Research on hES cells demonstrates great potential for at least three different areas of biomedical research, as shown on Figure 8. First, these cell types could help scientists gain a better understanding of human development and the factors that determine cell specialization and the cellular decision-making processes (NIH, 2006). Terminal medical conditions, such as cancer and various human congenital malformations, are caused by problems that occur somewhere in the process of cell specialization and cell division (NIH, 2006). Greater knowledge of the process of normal

cell development could allow biomedical researchers to develop procedures to correct abnormal cell specializations that cause terminal diseases. Secondly, hESC research could provide novel ways to develop medications and test their effectiveness and safety (NIH, 2006). The utilization of hES cell tissue in experimental drug testing could help minimize risks for human participants in clinical trials. Thirdly, the most promising application is the so-called cell therapies, the generation of cells and tissues to treat medical conditions caused by disturbances in cellular functions or destruction of vital body tissues (NIH, 2006). ES cells could become a renewable source of highly specialized cells and tissues in the human body, and could be used in transplantation therapies for the treatment of degenerative and other medical conditions (NIH, 2006). For example, the application of hES cell-based therapies to treat spinal cord injuries can be effective in a number of ways such as: 1) the replacement of damaged or diseased cells; 2) as a cell-based electrical 'relay' between neurons above and below the injury; 3) for amelioration of clinical deterioration and/or facilitation of regeneration by providing neuroprotective or growth factors; and 4) by playing other indirect roles in therapy, such as promoting neovascularization or providing a permissive substrate for regeneration of endogenous cells (Coutts & Keirstead, 2007).

Research on Adult Stem Cells

Opponents of hESC research have claimed that scientists should pursue research with adult stem cells since this alternative source of stem-cell tissue does not involve the destruction of human embryos. In the United States, the 2001 ban on federal funding for research on new hES cell lines was justified with ethical arguments against embryo

research and the belief that "great scientific progress can be made through aggressive federal funding of research on umbilical cord, placenta, adult, and animal stem cells which do not involve the same moral dilemma" (Bush, 2001, p. 13). Scott (2006) points out that between 1999 and 2002 a number of laboratories in the U. S. announced results which suggested that adult stem cells had the same enormous therapeutic potential as their embryonic counterparts. Religious groups and conservatives have used the data to claim that hESC research was not only immoral, but also unnecessary, and that more effort and federal funding should be invested in research on adult stem cells. These early experiments have clearly reflected the increased politicization of biomedical research on stem cells since their results could not be independently confirmed by other laboratories, and new discoveries refuted the original claims (Scott, 2006).

By contrast, a study conducted by Wagers, Sherwood, Christensen and Weissman (2002) showed little to no evidence for developmental plasticity of adult hematopoietic stem cells (HSCs). In order to examine the in vivo cell fate specificity of bone marrow HSCs, the team generated chimerical animals by transplantation of a single green fluorescent protein (GFP)-marked HSC into lethally irradiated non-transgenic recipients (Wagers et al., 2002). Whereas the HSCs reconstituted peripheral blood leukocytes in the experimental animals, these cells were not found to be efficient in generating non-hematopoietic tissues, such as brain, kidney, gut, liver, and muscle. The researchers also observed substantial chimerism of hematopoietic but not non-hematopoietic cells in GFP+:GFP- parabiotic mice (Wagers et al., 2002). The experiments led to the conclusion that transdifferentiation of circulating HSCs and/or their progeny is unlikely to occur

(Wagers et al., 2002). Other studies have similarly voiced strong skepticism regarding the prospect of in vivo transdifferentiation of cells derived from bone marrow, brain and skin into different cell lineages, as researchers have indicated significant flaws in either experimental design or interpretation of experiments with positive results (Wagers & Weissman, 2004).

Similar conclusions about the limited capacity of adult stem cells to differentiate and self-renew in culture were presented in the report entitled *Stem Cells and the Future of Regenerative Medicine* which was released by the US National Academies Committee on the Biological and Biomedical Application of Stem Cell Research in September 2001 (hereafter *Stem Cells and Regenerative Medicine*). The Committee was formed by the National Research Council and the Institute of Medicine to evaluate the potential of stem cell research and develop recommendations on relevant ethical and policy issues in consultations with renowned experts in stem cell studies, as well as philosophers, ethicists, and legal scholars (*Stem Cells and Regenerative Medicine*, 2002). Their assessment of research data on the therapeutic potential of adult and embryonic stem cells found that adult stem cells could not match the protean ability of ES cells to produce multiple types of human tissue (*Stem Cells and Regenerative Medicine*, 2002). By and large, leading scientists in the field of stem cell studies have agreed that research with adult stem cells does not hold the same potential for breakthroughs in biomedicine (Scott, 2006). Such research has shown that adult stem cells are more difficult to isolate and grow; their ability for transdifferentiation is very limited and does not measure up with

the capacity of ES cells; and they tend to contain more DNA abnormalities due to exposure to toxins and daily living conditions (NIH, 2006).

Attempts to misrepresent scientific results in the field of stem cell research are by no means limited to the US debate. In his book *Staminalia: Le cellule "etiche" e i nemici della ricerca* (Staminalia: Ethical cells and the enemies of research), the philosopher of science Armando Massarenti (2008) has indicated that opponents of hESC research in Italy have consistently spread false information about the therapeutic superiority of adult and induced pluripotent stem cells. He emphasizes the instrumental role of the Catholic political hierarchies and the media in creating confusion about the scientific and ethical aspects of stem cell research. Although the prevailing view within the Italian scientific community is that adult stem cells do not have the same therapeutic potential as stem cells derived from human embryos, Church leaders continue to claim that research on hES cells is unnecessary for the development of regenerative medicine. Moreover, the media and the Catholic political milieu have manipulated the public by emphasizing uncertainty and disagreements among stem cell researchers and by depicting the scientific community as equally divided on issue of what type of stem cells shows greater promise for clinical treatments.

The Use of Cloning Technology in Stem Cell Research

Scientists have predicted that the use of cloning technology in stem cell research could help generate embryonic stem cells that are immunologically compatible with the patient's own cells. Human cloning became a highly controversial issue after the world's first cloned mammal, Dolly the sheep was created by Dr. Ian Wilmut and his team at

Scotland's Roslin Institute in July 1996. Cloning, or somatic cell nuclear transfer (SCNT), involves the transfer of a cell nucleus from a normal somatic cell into an unfertilized egg cell from which its own nucleus had been removed. After such intervention, substances present in the oocyte activate the reprogramming of the donated nucleus and lead to the development of a blastocyst whose ES cells possess the donor genotype. Human cloning involves two separate technologies: reproductive cloning and the so-called "therapeutic" or research cloning. Reproductive cloning, as shown on Figure 9, is the creation of a cloned blastocyst, genetically identical to the donor cell used, which is then implanted into a woman's uterus, develops into a fetus and is brought to term (McLaren, 2002). By contrast, the cell nuclear replacement technique is used in stem cell research to create embryos that would be used for the cultivation of patient-specific hES cells and tissues (Figure 10). The cloned hES cell lines are likely to be immunologically compatible with their recipients and could be chemically induced to further differentiate into potentially therapeutically useful cells, such as dopamine-producing cells for the cure of Parkinson's disease (McLaren, 2002). The possibility of using human cloning for therapeutic purposes was put firmly on the agenda by leading research institutions and biotechnology companies such as the Roslin Institute in Edinburgh, UK, the University of California at Irvine, Advanced Cell Technology (ACT) in Massachusetts, Stemagen Corporation lab in La Jolla, California, and few others. The first announcement of cloning human embryos for research purposes came from the biotech company ACT in November 2001. The experiment had only limited success, as

scientists had produced eight cloned eggs, with only one of them capable of dividing into six cells before stopping.

Proponents of research cloning have attempted to draw a clear line between the two types of cloning with the argument that the cloned blastocysts used in stem cell research would be destroyed after the removal of their IMC and would never be implanted in a woman's uterus. Nonetheless, when stem cell researchers initially started experimenting with SCNT to develop patient-specific hESC lines, the general public was confused about the meaning of "cloning" and its applications in stem cell research. The Stanford Professor Christopher T. Scott (2006) has indicated this hype around human cloning in his book S*tem Cell Now: From the Experiment That Shook the World to the New Politics of Life*:

> Scientists and journalists used words such as embryo and cloning so cavalierly that the lay public wasn't sure what distinguished animal cloning from babies conceived through IVF and embryonic stem cell research. As the millennium drew to a close, many people felt that a knock on the door from their human clones seems a distinct possibility. (p. 8)

Public anxieties about the use of cloning technology in hESC research from the early years of stem cell debate reappeared in 2005 as a result of the Hwang cloning fraud. Significant international recognition was given in 2004 and 2005 to the experiments conducted by Dr. Woo-Suk Hwang in South Korea. Hwang had announced the successful derivation of hESC lines from cloned human embryos, until it was discovered that the results of these experiments were fabricated and the two articles he published in *Science*

were editorially retracted (i.e., Hwang et. al, 2004). The Hwang cloning fraud in late 2005 presented an unexpected setback for stem cell science not only because it once again raised questions about the therapeutic effectiveness of human cloning, but also due to the unethical collection of ova which was practiced by the Korean scientist. Research cloning usually requires a great number of high-quality human oocytes, and those are not easily available. There were numerous allegations that Hwang had forced female researchers in his lab to donate their eggs for his stem cell experiments.

Given that the applicability of cloning technology for yielding ES cells that possess the donor genotype was severely compromised, scientists have tested the efficiency of two alternative approaches that may lead to the generation of patient-specific stem cells for tissue engineering and cell-based therapies. The first method involves ESC fusion-induced reprogramming of adult cells, a process which triggers changes in adult nuclei function by in-vitro hybridization with ES cells and transforms differentiated adult cells into pluripotent cells (Chang & Cotsarelis, 2007). Successful nuclear reprogramming of somatic cells to a pluripotent state by creating such ES cell hybrids was first reported by Tada et al. (2001). The downfall of this procedure is genetic instability since each fused cell possesses two nuclei, as well as four copies of each chromosome instead of two, and it is still ethically controversial due to the use of hES cells. The second method to create donor-specific ES cells involves the application of genetic factors and/or chemical stimulation that induce somatic cells from a patient to revert to a pluripotent state (Chang & Cotsarelis, 2007). It is expected that this approach could eventually provide a resolution for the ethical dilemma by eliminating the need to

use human embryos for the creation of pluripotent stem cell lines. It was initially used in 2006 by Yamanaka and his colleagues, who discovered a set of four genes that triggered the reprogramming of mouse embryonic fibroblasts into cells with ESC characteristics.

Induced Pluripotent Stem Cells

While politicians have continuously debated the two alternatives in stem cells research (e.g. adult vs. embryonic stem cells), scientists responded by seeking ethical alternatives of ES cells that may replicate their therapeutic potential. Successful experiments to unlock the same regenerative capacity in adult differentiated mammalian cells were first conducted with mouse cells in 2006, and then with human somatic cells in 2007. Scientists used retroviral introduction of the four transcription factors Oct3/4, Sox2, c-Myc, and Klf4 in mouse skin cells (fibroblasts) to reprogram them to act like embryonic stem cells (Okita, Ichisaka, & Yamanaka, 2007; Wernig et al., 2007; Maherali et al., 2007). These genetically altered cells became known as induced pluripotent stem (iPS) cells.

The first announcements for the creation of iPS cells came in November 2007 when James Thompson and Junying Yuat the University of Wisconsin-Madison and Shinya Yamanaka and his research team at Kyoto University in Japan independently reported that they had used similar methods to reprogram adult human cells back to a pluripotent state. The process involved genetic modification of human skin cells by the integration of up to four DNA-transcription factors into the adult cell genome. The creation of iPS cells through reprogramming of somatic cells by defined transcription factors is believed to hold a great promise for regenerative medicine. Nevertheless, their

therapeutic potential is yet to be explored as genetically modified iPS cells contain a large number of viral vector integrations that limit possible clinical applications. As Harvard Medical School researcher George Daley stated in a recent interview, "These viruses can be mutagenic and have the potential to activate oncogenes, so at the moment iPS cells remain a research tool and not a potential therapeutic agent" (Anonymous, 2008, para. 2). Recently, researchers at the University of Edinburgh and Mount Sinai Hospital in Toronto reported the development of a safer non-viral plasmid vector for generating iPS cells that are applicable to regenerative medicine, drug screening and the establishment of disease models (Kaji et al., 2009; Woltjen et al., 2009). The new method creates reprogrammed hES cell lines from embryonic fibroblasts with dynamic expression of pluripotency markers and minimizes genome modification in iPS cells, as well as eliminates exogenous reprogramming factors (Kaji et al., 2009).

Jaenisch and Young (2008) have outlined three other techniques, besides the method of reprogramming by defined transcription factors, used by stem cells researchers for the conversion of somatic cells to a state of pluripotency (Figure 11). The three major strategies for reprogramming of differentiated cells into an embryonic state are: (1) nuclear transplantation, (2) fusion of somatic cells and embryonic stem cells, and (3) culture-induced reprogramming. These methods have shown to have different shortcomings and advantages for potential therapeutic applications.

Although the use of nuclear transfer for reproductive cloning is generally considered an highly inefficient process due to faulty reprogramming that either leads to deaths of clones shortly after implantation or results in births with significant

abnormalities, experiments have indicated the therapeutic utility of this method for the creation of patient-specific ES cells (Jaenisch & Young, 2008). This conclusion was confirmed by subsequent experiments that have clearly shown no biological or molecular differences between ES cells obtained from fertilized embryos and those produced through nuclear transfer (Jaenisch & Young, 2008). Nevertheless, the practical application of nuclear transplantation for medicine is still hindered due to the need to obtain significant amount of unfertilized oocytes which raises serious ethical concern about possible exploitation of women donors in research. Presently, the possibility that "cloned ES cells and mice can be generated from somatic donor nuclei transplanted into enucleated zygote recipients if drug-induced synchronization of donor cells and zygote is employed" is promising, especially if it is adapted to the human system (Jaenisch & Young, 2008, p. 568).

The second method for epigenetic reprogramming of somatic nuclei to an undifferentiated state discussed by Jaenisch and Young (2008) involves the creation of hybrids by fusion of somatic cells with ES cells or embryonic germ (EG) cells. The generation of murine hybrids has shown shared features with the parental pluripotent ES cells, as well as the presence of dominant pluripotent phenotype. Human ES cells have similar potential to reprogram the somatic nuclei of hybrid cells by triggering of silent pluripotency markers (e.g., Oct4) or reactivation of the inactive somatic X chromosome (Jaenisch & Young, 2008). This method, however, presents challenges for the possible clinical translation into customized, patient-specific stem cell therapies due to the inevitable formation of tetraploid reprogrammed cells. It is worth noting that the use of

such reprogrammed cells involves significant risks of creating large-scale genomic instability on the cellular level, especially when the technology is utilized to further generate diploid reprogrammed cells.

Jaenisch and Young (2008) also discuss methods of culture-induced programming in stem cell research by the means of prolonged explantation of somatic cells in culture. In recent years, scientists have suggested the possibility of reprogramming to a state of pluripotency donor cells derived from postnatal animals. These experiments have indicated that cells from the germ cell lineage, e.g. spermatogonial stem cells, which are unipotent in-vivo, have the potential to develop into pluripotent or multipotent ES-like cells after prolonged in-vitro culturing. Nevertheless, most of the pluripotent cell types generated by the method of expansion in culture do not comply with most functional criteria of pluripotency. Rather, it was only ES, EG, EC, and spermatogonial stem cell-derived maGCSs or ES-like cells that have demonstrated capacity for in vitro differentiation and teratoma formation. These cells have also shown an ability to form postnatal chimeras and potential to contribute to the germline. Presently, the method of isolating pluripotent cells from somatic tissues through expansion in culture doesn't seem to be an effective alternative, as it yet remains to be seen if somatic stem cells can indeed show greater plasticity in vivo and ability for transdifferentiation into other cell types and lineages.

Conclusions

Over the last ten years, the stem cell controversy has revived contentious debates over the moral standing of the human embryo, the role of religion in public life of

pluralistic democratic societies, and the appropriate limits to biomedical research that infringes on human dignity. The bioethical discourse around the embryonic stem cells has also extended to ethical, legal and social issues associated with human cloning, stem cell patents, translational stem cell research, access to stem cell transplants, and the emerging global bioeconomy. This chapter focused on the scientific aspects of the stem cell debate and examined factors external to scientific investigation that have influenced research efforts in stem cell studies. It also illustrated how proponents and opponents of this biomedical innovation have offered competing interpretations of the biological properties and clinical potential of embryonic and adult stem cells in their attempts to shape the public discourse and influence policy decisions. Most recently, the public discourse has shifted towards discussions about the potential of iPS cells to resolve the ethical dilemma in hESC research.

Historically, the field of stem cell research became the subject of political debate and media hype after Dr. Thomson reported the isolation of the first hESC lines and discussed their potential clinical applications in an article published in the 1998 November issue of *Science*. The subsequent decision of President Clinton's administration in early 1999 to allocate federal funds for research on stem cell lines derived from human embryos sparked criticism and controversy. While the early stem cell debate in the US reflected the existing political divisions around the abortion controversy causing significant mobilizations in both camps, the issue has also stirred public and academic debates over what type of political interventions will best serve the public interest in the development of regenerative medicine. Public discourses in Europe

have similarly framed stem cell technologies as a biomedical innovation that should be regulated and financially supported by both national governments and the supranational institutions of the EU. Collective mobilizations around the biopolitics of stem cell research on both sides of the Atlantic have indicated the rather complicated relationship between the institutions of science, regulatory bodies, the biotechnology sector, and the public which characterizes contemporary knowledge-dominated economies.

It is by no means surprising that recent developments in stem cell studies have reflected the significant politicization of this biomedical field. Leading researchers in the field have actively sought for ethical alternatives to the use of human embryos for derivation of pluripotent stem cells that could replicate their clinical potential by using a variety of methods for the reprogramming of SSCs into a state of pluripotency. The method that received most public attention was the conversion of more differentiated cells into iPS cells through genetic modification by means of defined transcription factors (i.e., viral integration). Although the media hyped the discovery by announcing that it would resolve the ethical dilemma in stem cell research, scientists are still skeptical regarding the use of iPS cells in regenerative medicine due the direct connection between the process of reprogramming and tumorigenesis which causes unwanted side effects such as cancer in some of the animals produced with iPS cells that ESCs would not normally show (Belmonte et al., 2009). Moreover, there are some recent reports that point to significant transcriptional differences between ES and iPS cells, including the ones derived without viral integration, that remain unexplained. The ESC lines derived from human embryos are shown to be more potent than the iPS lines, and presently, there

is no scientific evidence that all virus-free iPS cells are qualitatively equivalent to ES cells (Belmonte et al., 2009). Disputes over the clinical potential of iPS cells indicate that there are still lots of uncertainties in stem cell science and that the innovation process in the field is not immune to discursive conflicts and disagreements.

CHAPTER 3

RELIGION AND ETHICS IN THE STEM CELL CONTROVERSY

In the previous chapter I have argued that the issue of stem cell research has a multi-dimensional nature and that we should engage with the individuation of the different scientific, ethical and political conflicts that are intermingled in the controversy. This chapter continues the analytical work of determining the number and nature of conflicts comprising the stem cell debate. I investigate entanglements of ethics, religion, politics, and law that have shaped the public engagement with the biopolitics of stem cells in the US and the EU. I compare and contrast religious arguments on the use of human embryos in stem cell research and related technologies developed by major monotheistic religions such as Catholicism, Judaism and Islam. I also address questions about the validity of religious arguments in public debates over stem cell policies. Stem cell debates worldwide have often been framed in religious terms, especially in the United States, where significant political mobilization of religious constituencies around issues concerning the politics of life had taken place in the last few decades. Moreover, spokespersons of major religious traditions have given testimonies to US and EU advisory bodies, such as the National Bioethics Advisory Commission (NBAC), the President Council on Bioethics (PCBE) and the European Group on Ethics of the European Commission, and policy decisions have been informed by ethical arguments derived from religious principles and beliefs (Walters, 2004). Religion has greatly influenced regulatory regimes not only in America, but also in many of Europe's predominantly Catholic nations such as Ireland, Italy, Poland, Austria, Lithuania, Malta

and Slovakia. The issue of stem cell research has therefore become inextricably linked to the question of the role of religion in public life, and similar to other bioethical controversies, e.g. euthanasia, cloning, and human genetic modification, it has provided a paradigmatic case to test the legitimacy of religious values in the public policy debates and the cultural conflicts of the post-secular society.

The second part of the chapter provides an insight into the diverse ethics of hESC research by reviewing ethical and social challenges arising from its intersections with controversial technologies such as human cloning, assisted reproductive technologies (ARTs), and hybrid embryo (chimera) research. I focus on contentious bioethical issues such as philosophical defenses of the embryo's moral status, the ethics of human cloning, and concerns about women's reproductive rights and health in embryo donation for stem cell research. The discussion supports the central argument of the present inquiry into the biopolitics of stem cells that framings of the stem cell debate exclusively around the contentious issue of the embryo's moral status can impede the public understanding of its diverse ethical, legal and social implications. Similarly, reductionist framings of public discussions and deliberations around the false dichotomy of "ethics versus science" (i.e., the juxtaposition of the respect and protection owed to blastocysts to the moral obligation to conduct life-saving research) tend to simplify the overlapping controversies and complex realities of stem cell debates.

The endeavor to differentiate different disputes and levels of analysis within the stem cell controversy has a two-fold objective. First, a close examination of the interplay between science, religion, societal values, and political forces in the stem cell controversy

can highlight the many ways in which research data and scientific knowledge could be used as a resource in social and political struggles. I aim to illustrate how assessments of rationality by proponents and opponents have informed models of political decision concerning stem cell research and related conflicts of socio-technical nature. Therefore, my analysis highlights how both sides in the controversy have laid moral claims to rationality in attempts to validate their arguments as rational and to dismiss the opponents' position as purely irrational and, therefore, irrelevant for the policy debate. Secondly, the analytical work of disentangling the mesh of competing epistemologies, intersecting ethical concerns and structural political forces in the stem cell is consistent with notions of "technical democracy" advanced by Callon, Lascoumes and Barthe (2009). Therefore, I suggest that should we strive towards a potential resolution or closure of the stem cell controversy by promoting a participatory decision-making model that involves hybrid public forums for debating, negotiating, and resolving the complex ELSI questions raised by this biomedical innovation.

Religious perspectives on stem cells and embryo research

The stem cell controversy has highlighted discrepancies between the major monotheistic religions on thorny bioethical issues, including the fundamental question of the moral status of early embryos (blastocysts) and their use in biomedical research. While religious perspectives have become and remain prominent in public debates on stem cell research, many have questioned their validity for 21st –century decisions in the field of science and technology. At the risk of oversimplifying, the most significant critiques could be grouped in the following two questions: (1) To what extent

are moral judgments derived from ancient religious texts relevant to the rapid advancement of scientific knowledge in embryology, genetics, molecular biology, and biomedicine?, and (2) Do ethical concerns that are religious in nature provide a legitimate basis for public policy decisions in our secular, pluralist societies? The latter question is especially pertinent if we consider the reluctance of many lawmakers and state legislatures to impose narrow religious viewpoints on the rest of society. This policy-related concern is consistent with John Rawls's argument in *Political Liberalism* (1996) that the state should be neutral between various conceptions of the good and may not enact policies that ignore "the fact of reasonable pluralism," that is, the coexistence of incompatible yet reasonable comprehensive doctrines in modern societies. Nevertheless, a certain bifurcation of opinions could be observed on the issue of whether religious values should count in public debates on stem cell research. On the one hand, there is a tendency to easily dismiss religious concerns as irrelevant in policy making, particularly on highly technical questions such as stem cell research, genetic engineering and other biomedical research. Proponents of this view have argued that there would never be a happy medium between religion and science and, therefore, policy decisions on stem cell research should be primarily guided by scientific considerations. On the other hand, arguments have been raised that the exclusion of religious communities from public deliberations is unjust, as it would only empower non-religious groups that share similar values and concerns. In order to discuss further these two fundamental questions raised in the stem cell debate, I present a brief intercultural perspective on religious arguments regarding the moral status of the human embryo and the ethics of stem cell research. This

comparative perspective will also help us highlight fundamental differences between the major theological traditions on issues concerning the beginning and sanctity of life.

The Catholic Position on the Ethics of Stem Cell Research

In framing the public discourse on hESC research, the Religious Right and social conservatives in America have intuitively followed the Vatican's position that human life begins at conception and that the embryo at all stages of development should be considered morally equivalent to born persons. Although the Roman Catholic Church does not condemn all types of stem cell research, it does strongly oppose experimentation with pluripotent stem cells which are derived from human embryos. There is a widespread misconception that the Roman Catholic Church's strong opposition stems from the belief that embryos are persons. In his article, "The Catholic Church and Stem Cell Research," Father Tadeusz Pacholczyk (2008) presents a more nuanced and detailed account of the Church teachings on this moral dilemma. While the Catholic doctrine admits that there is no definitive answer on the question of whether human being is present at the time when fertilization occurs and that it is false to assume that zygotes or early-stage embryos are persons, it nevertheless teaches that the destruction of human embryos is always immoral. As he points out, this position was clearly formulated in the following statement from the *Declaration on Procured Abortion* which was issued by the Congregation for the Doctrine of Faith in 1974:

> This declaration expressly leaves aside the question of the moment when the spiritual soul is infused. There is not a unanimous tradition on this point and authors are as yet in disagreement. For some it dates from the first instant; for

> others it could not at least precede nidation [implantation in the uterus]. It is not within the competence of science to decide between these two views, because the existence of an immortal soul is not a question in its field. It is a philosophical problem from which our moral affirmation remains independent. (Qtd. in Pacholczyk, 2008, p. 77)

Subsequently, the moral affirmation of the Church regarding the status of the human embryo prescribes that "the human embryo must be treated as *if* it were already ensouled, even if might not yet be so [...] as *if* it were a person from the moment of conception, even if there exists the probability that it might not yet be so (Pacholczyk, 2008, p.77). Historically, the adoption of such more nuanced view on the status of the human embryo from the moment of fertilization has aimed to reconcile conflicting perspectives on the precise timing of ensoulment/personhood within the Catholic philosophical tradition. As Pacholczyk (2008) points out, the prevailing view in Christian history was the doctrine of delayed ensoulment (Figure 10), while the notion of immediate ensoulment having gained popularity from the 1600s onwards (Figure 11). Given that we do not have a certainty as to when exactly God ensouls the human embryo, and we may never resolve this dilemma, it would make sense that the ethical stance of the Church on destruction of early embryos in stem cell research should not be guided by attempts to determine the timing of personhood. Instead, the Catholic doctrine reasons that the human zygote should be considered a human being from the very beginning since it is the only kind of entity upon which God could bestow the gift of an immortal soul. In his account, Pacholczyk (2008) emphasizes the Catholic belief in "the absolute primacy of the value

of personhood over all other considerations," as well as the imperative that "the human person, even in his or her most incipient and precursorial installation in the embryonic human being, is to be safeguarded in an absolute and unconditional way" (p. 73).

The Vatican's present position on the use of embryos in biomedical research was initially outlined in a bioethical directive released on February 22, 1987 under the title of *Donum Vitae: Instruction on Respect for Human life in Its Origin and on the Dignity of Procreation*. Their latest instruction on bioethical issues by the Congregation for the Doctrine of the Faith, *Dignitas Personae*, issued on December 28, 2008 with the approval of Pope Benedict XVI, reaffirms the moral imperative of treating embryos as if they were persons from the moment of conception, even if there was a possibility that the act of ensoulment has not yet taken place. A fundamental principle defended by this declaration is the affirmation of human dignity from the earliest stages of embryonal development. It is, therefore, asserted that "the human embryo has, from the very beginning, the dignity proper to a person" (*Dignitas Personae*, 2008). In outlining the Church's position on the most significant beginning-of-life issues, the document condemns a whole range of embryo technologies such as the cryopreservation of human embryos in IVF, genetic manipulations that could lead to inheritable genetic modification, the use of somatic cell nuclear transfer for both reproductive and research purposes, hybrid embryo research (i.e., the creation of animal/human genetic hybrids), and a number of other biotech procedures dismissed as affronts to human dignity.

Commentators have observed that the new guidelines, which reiterate the Vatican's condemnation of hESC research, the destruction of embryos in in-vitro

fertilization, and the "morning after pill," are in some respects more restrictive than *Donum Vitae*, especially on some questions that have previously remained open to consideration. The new take on contentious points in the Catholic moral tradition is succinctly summarized by John L. Allen Jr. (2008) in his analysis of *Dignitas Personae.* According to him, the new guidelines differ from *Donum Vitae* on the following five issues. First, there is a rather critical perspective on prenatal adoption of frozen embryos, which would permit women and couples to bring other people's unused IVF embryos to term. Secondly, the church has advised caution regarding the use of the so-called "altered nuclear transfer" (ANT) method, which scientists have proposed as a morally acceptable alternative for the procurement of hESCs (Hurlbut, 2005). Thirdly, there is an ambiguity in the Church's position on the "morning after pill" which could affect the practice in Catholic hospitals of offering emergency contraception to rape victims. Fourth, there seems to be a stronger opposition against biomedical research that involves biological materials obtained from aborted fetuses or human embryos. Lastly, the new regulations express "a more negative view of genetic interventions passed on to subsequent generations than was offered in a 1983 speech by John Paul II, which hinted that such therapy could, at least in theory, be justified" (Allen Jr., 2008, p. 2). Regardless of some variations in the Catholic Church's position on the afore-mentioned bioethical issues, the new guidelines have preserved the spirit of *Donum Vitae* in their focus on beginning-of-life issues and the unconditional affirmation of the inviolable dignity of the human embryo from the very moment of fertilization.

The Catholic interpretation of the embryo's moral status is often contrasted to moral insight on the issue provided by other major religious traditions such as Judaism, Islam, and some Protestant denominations. While in Judaism and Islam the pre-implantation embryo does have a greater moral status than other body tissues and collections of cells, the respect owed to pre-personal life forms by no means contradicts the use of its cells for goals such as healing and saving life, to which the faithful should be committed (Weckerly, 2005). Generally, Jewish and Islamic religious traditions and practices seem to be supportive of research on human embryonic stem cells since they place an obligation on its followers to seek out knowledge, which is believed to be an indispensable component of human nature as created by God. Moreover, the acquisition of scientific knowledge is not only regarded as a form of worship, but it is argued that its practical applications should be guided by the imperative to ascertain equity and justice for all of humanity (Al-Hayani, 2008). Below I present major theological principles that have influenced perspectives on hESC research within these traditions.

Judaism and hESC Research

In the Jewish religious tradition, most interpreters of the Talmud have established that the human embryo prior to forty days of gestation is not recognized as an entity with the same moral status as a born person. Instead, the prevailing belief is that the fetus in the very early stages of development lacks "humanity" (Eisenberg, 2007). This position is well-articulated in the testimony given by Rabbi Elliot N. Dorff to the National Bioethics Commission (NBAC) in 1999 on the issue of the use of spare IVF embryos in stem cell research. He pointed out that "genetic materials outside the uterus have no legal status in

Jewish law, for they are not even a part of human being until implanted in a woman's womb, and even then, during the first forty days of gestation, their status is 'as if they were simply water' (Babylonian Talmud)" (Qtd. in Ruse & Pynes, 2003, p. 197).

In his article "Judaism and Stem Cells," Dorff (2008) discusses four major principles in Jewish theology that inform our understanding of the ethics of stem cell research. The first principle claims that our bodies ultimately belong to God and that we are obligated to preserve human life and health by taking proper care of them. This belief further entails the moral duty to actively seek and develop new medical treatments and cures. The second principle in the Jewish religious tradition that should guide our decisions regarding the ethics of stem cell research is the acceptance of both natural and artificial treatments of illness. In this sense, in Judaism physicians and healers are seen as the God's agents in fulfilling the act of healing. The third principle postulates that all humans are created in the image of God and should be valued and respected as such. The last principle that is used to derive an ethical perspective on stem cell research is the realization that humans are not omnipotent, but rather appear to be very limited creatures in comparison to God. What follows from this aspect of human nature is the requirement that our actions do not impose harm on ourselves or the world. The Jewish tradition, as Dorff (2008) points out, teaches a certain epistemological humility and a balanced approach to the pursuit of scientific knowledge and advancements in biomedicine such as embryonic stem cell research.

Due to this strong emphasis on healing in Judaism, it is believed that we have a moral duty to conduct stem cell research on the condition that human beings are not

harmed in this process. This imperative to heal, once again, raises the question of the status of human embryos in the early stages of development according to the Jewish law. As Dorff (2008) has indicated in his analysis of authoritative codes and statements of the Oral Tradition, the Talmud determines that the embryo during the first 40 days of gestation is "simply water" and has not acquired the form of a human being until the 41 day, when the gender of the child is already determined. Similarly to the Catholic position, Jewish religious perspectives on fetal development seek scientific evidence that would support Talmudic Rabbis' observations that early miscarriages looked as "merely water." Dorff (2008) points out that some interpretations extend the 40-day threshold to 56 days of gestation, counted by the Rabbis from the time a woman first misses her menstrual cycle. This interpretation is believed to be compatible with contemporary knowledge of fetal development since it is now well known that the fetus does not develop bone structure until eight weeks of gestation when it does start to resemble a human being of flesh and bones. Moreover, Dorff (2008) argues that the 40-day marker was prominent in Catholicism, with the concept initially developed by Aristotle, and then adopted by Augustine and Aquinas. The notion that the zygote should be viewed as a person was adopted in 1869 when the Fist Vatican Council attempted to affirm the virgin birth of Jesus Christ by presenting him as a person immediately upon conception by the Holy Spirit. In fact, the change in Canon Law did not happen until 1917.

Since Judaism defines the embryo until the fortieth day of gestation as "simply water," it assigns even lesser value to pre-implantation embryos (during the first 14 days of development) used in stem cell research. As Dorff (2008) points out, the standing of an

embryo situated outside the womb, which has no chance to develop into a human being given the current state of technology, "is *at most* "simply water" and, therefore, "our respect of such gametes and embryos outside the womb should certainly be superseded by our duty to seek to cure disease" (p. 82). Moreover, it is important to note that the argument about the embryo outside the womb being less than a person is not derived from the mere fact of its location in a petri dish. In order to procure viable embryonic stem cells, scientists are limited to the use of embryos prior to the development of neural streak around the fourteenth day of gestation, after which the capacity for differentiation of these stem cells appears to be greatly diminished. The embryo in a petri dish, Dorff concludes (2008), is different from a human being not only because of its location outside the womb and inability for further development *in vitro*, but also due to "its low level of cell organization, the short period of time that it will remain in this state, and its incapacity to live without further development" (p. 83). For this reason, Judaism asserts that embryonic stem cell research may bring enormous health benefits without posing any risks to human beings. Furthermore, couples are encouraged to donate their spare IVF embryos to stem cell research and this is seen as a *mitzvah*, a commanded act.

Muslim Perspectives on Stem Cell Research

The only textual source in Islam that provides guidance on how questions concerning embryonic sanctity and all other aspects of human life should be interpreted and answered is the Quran. Nonetheless, it does not provide clear definitions of terms like "embryo" or "fetus" and there is hardly any discussion of specific questions related to scientific experiments. This deficiency is by no means surprising given that the scripture

was compiled in the years 646-650 C.E. from sources that most likely had originated at least 200-300 years earlier. Currently, there are disagreements among Muslim jurists and interpreters of the Quran about the precise moment of the fetal development in which the ensoulment of the fetus occurs. The tradition does not help dispel uncertainty and confusion since there are no Quranic passages that refer to the embryo as a living thing from the moment of conception. Some Islamic scholars have claimed that this lack of clarity regarding the moral status of fetal viability and embryonic sanctity creates significant ethical and legal dilemmas, especially on the contentious issue of abortion, but also on questions concerning assisted reproductive technologies and the use of embryos in biomedical research (Sachedina, 2008). If the question of determining the ethical and legal status of the embryo and the fetus is so hard to resolve, than how can we come up with a clear answer as to whether abortion is legal or illegal? Similarly, if there are no ethical and legal reasons to prohibit abortion in general, after what point it should become illegal to abort an embryo or fetus? And, more importantly, does the embryo's ethico-legal status prohibit its use for stem cell research?

While it remains unclear exactly when the ensoulment of the embryo takes place, Muslim jurists have deducted claims about the dignity and legal status of the human embryo from precedents in criminology dealing with destruction of fetuses in abortions and miscarriages (Sachedina, 2008). The prevailing legal view is that the fetus has no independent claim to life outside of the mother's womb and, subsequently, no personhood and absolute inviolability until it becomes separated from the uterus and capable of surviving on its own. Therefore, abortion rulings in Islamic jurisprudence are

not framed in terms of conflicting rights, that is, the right of the pregnant woman versus the right of the fetus. This view has led to quite liberal attitudes towards clinical abortion in the Muslim world and, subsequently, to the wide acceptance of the assisted human reproduction technologies in most Muslim countries, including a rather permissive stance towards biomedical research on embryonic stem cells derived from frozen supernumerary IVF embryos. For some commentators, the failure of traditional Muslim sources to address the critical questions about the sanctity of life in the early stages of embryonic development and the morality of clinical abortion poses additional questions regarding the overall value of human beings in the context of Islam tradition. Sachedina (2008) has argued that the reason for this lack of ethical and philosophical reflection on issues concerning the beginning of life in Islam is that debates in Islamic jurisprudence have focused exclusively on the legal implications of feticide. Moreover, Muslim jurists have applied the sanctity of life principle only to the embryo in the womb, thus leaving the question of the moral standing of embryos that are outside the womb unresolved. Finally, Sachedina (2008) has claimed that their failure to extend this principle to embryos used for the purpose of assisted human reproduction or for biomedical research is indicative of a "total disregard for the embryonic inviolability" in the early stages of embryonic and fetal development (p. 92).

The Islamic perspective on the moral status of the human embryo is significantly complicated by the often conflicting rulings and opinions issued by leading Muslim scholars, both Sunni and Shiites. Moreover, it is rather impossible to identify a single, unifying position given that the Muslim world is divided into many sects and that

authoritative opinions on the issues of the embryo's moral status, abortion and stem cell research derived from the teachings of Quran and the Islamic Law (Shariah) sometimes vary. Nevertheless, as Weckerly (2005) has claimed, the fetus in the Islamic tradition has been perceived as human life only in the late stages of fetal development. More specifically, most commentators within the Sunni tradition have asserted that the ensoulment of the fetus does not occur until the end of fourth month of pregnancy (Weckerly, 2005). Similarly, Sachedina's (2008) comparative analysis of verses in both Shiite and Sunni compilations of the tradition clearly indicates that the event of ensoulment—described as the breathing of the spirit (*rūh*) into the embryo by an Angel sent by God—had been recorded as taking place either on the fortieth, forty-second, or forty-fifth night or after 120 days of gestation. While the developmental stage when the fetus becomes a human being has been identified, it should be noted that the moral-legal implications of the ensoulment have not been addressed by these traditions since "ancient Muslim jurists did not emphasize the distinction between two periods of pregnancy to deduce decisions about the culpability and accruing penalty in the matter of induced abortion" (Sachedina, 2008, p. 97). Some jurists have argued that the all three early stages of embryonal development described in the tradition, from a coagulated drop (*nutfa*) to a blood clot (*'alaqua*) to a lump of flesh (*mudgha*), are covered in the first forty days, rather than in the first 120 days of gestation as outlined in the Bukhārī's compilation (d. 870) which is considered to be the most authentic collection (Sachedina, 2008). They have also concluded that there is no spirit in the fetus until the end of the forty days when the Angel is sent to write the child's destiny regardless of the particular

stage of development. Their account of the embryo's ensoulment clearly contradicts the position that the fetus attains the identity of a person after the first trimester of pregnancy. Furthermore, it is worth pointing out that some Shiite traditions have suggested that the beginning of human life could be traced to the very moment of conception and have subsequently ruled out abortion as illicit, even at the earliest stages of gestation (Sachedina, 2008).

The challenges faced by legal Muslim scholars in outlining a coherent ethical and philosophical position on scientific innovations such as embryonic stem cell research are by no means limited to the discrepancies in the interpretative traditions outlined above. There are a variety of factors that contribute to the general uncertainty on contested issues in biomedical ethics, with the three most important ones identified by Al-Hayani (2008) as: 1) the lack of a religious hierarchy and a highest religious entity in Islam that would undertake the task of studying and evaluating the theological validity of new discoveries in biomedicine; 2) the significant variance in traditional and cultural practices, and 3) the profound distrust of non-Islamic science within the Muslim world. Defining the Islamic perspective on the moral status of embryonic stem cells is further complicated by the fact that there are many Islamic nations that have not yet caught up with the most recent scientific innovations in biomedicine and human biotechnologies. These countries have not yet declared their position on the moral status of pre-implantation IVF embryos, the ethics of human embryonic stem cell research and other controversial scientific innovations such as somatic cell nuclear transfer, human enhancement and inheritable genetic modification.

Religious Traditions and Scientific Knowledge

Regardless of the divergent ethical perspectives on the issue of respect owed to the human embryo that emanate from the major religious traditions, the stem cell controversy has often been framed in terms of the inevitable conflict between theology and modern science in our pluralistic societies. There are different considerations and levels of analysis employed to tackle the intricate, and undoubtedly very complicated, relationship between religious traditions and embryo science. While some regard value conflicts over stem cells and embryo science as imminent to the post-secular society, in which strong religious communities continue to exist in the context of ongoing secularization (Habermas, 2003), others have emphasized the extent to which different religions allow input from contemporary scientific viewpoints and are open to dialogue with rival traditions (Zivotovsky & Jotkowitz, 2009; Jones & Whitaker, 2009). The underlying assumption of these diverse approaches is that the relationship between these two positions should be reciprocal and that neither position should be dismissive of the contributions of the other. If religious traditions indeed strive to provide any meaningful contributions to bioethical debates surrounding reproductive technologies and stem cell research, they should take into consideration contemporary scientific notions and their ethical arguments should be informed by a scientific understanding of early embryonic development (Jones & Whitaker, 2009).

In their response to the Vatican's new bioethical directives in *Dignitas Personae* from the perspective of Orthodox halakha (Jewish Law), Zivotovsky and Jotkowitz (2009) have pointed out that new technology and scientific knowledge often requires

different application of fundamental theological principles that have remained unchanged during the long history of these religious traditions. While the teachings of both the Catholic Church and Judaism strive to incorporate contemporary scientific knowledge, recent bioethical issues in human reproduction have indicated an ongoing conflict between religious authorities and modern science, especially in religious rulings based on erroneous science (e.g., the Vatican's ruling over the morning after pill). Zivotovsky and Jotkowitz (2009) have also indicated the greater openness of Orthodox halakha to modern scientific views on key questions such as zygotic personhood, no-conjugal procreation, and producing benefits through illicit means vis-à-vis the new Vatican policy. The divergences often stem from the different authority paradigms adopted by the two traditions. In contrast to the pyramidal, hierarchical structure of the Church which delegates uncontested authority to the Pope and the Vatican in developing a single, uniform position on ethical issues, Judaism has developed as a more diffusive system of dispersed communities around the globe, with no central authority or judicial center and rulings largely based on precedent of specific laws, principles, and values. Besides the Hebrew Bible and the Talmud, three other genres have become indispensable for the development of halakha—the Commentaries on the Talmud, Codes of law, and Responsa literature, and have often allowed for more than one acceptable position on moral dilemmas. As Zivotovsky & Jotkowitz (2009) have claimed,

> While all three genres are ongoing, it is this final genre that is the primary means of development, refinement, and clarification of halakha today and exemplifies an important aspect of the nature of halakha—it is dynamic yet precedent oriented. A

> contemporary rabbi will typically examine earlier sources in search of analogous circumstances before deciding a point of law. No one will rule without citing the relevant passages from the Talmud, and usually from the early commentaries on the Talmud, and almost always the major codes. Many modern rabbis will often also heavily rely upon the responsa literature of the last few hundred years. (p. 27)

The requirement for openness to scientific input is consistent with arguments that religious traditions that are based on outdated scientist concepts need to be modified and reaffirmed in contemporary terms (Jones & Whitaker, 2009). In many ways, this is easier said than done. In the case of Judaism, the adaptation is greatly facilitated by their fundamental theological tenet that personhood does not begin until the 40 day after conception which does not contradict contemporary scientific assessments. It is unlikely, however, that most Christians will ever dispense with the notion of the inviolability of the human embryo and the need to protect embryonic life. Moreover, the assertion that all human life is sacred from conception is so central to their belief systems that any scientifically derived reassessment of embryonic status would be interpreted as an assault on the dignity of human life (Jones & Whitaker, 2009). The dialogue between science and religion, therefore, seems to be contingent on how compatible modern scientific views are with the major theological principles of the respective religious tradition.

Questions about the conditions under which religious persons may participate in science policy debates have become central to the stem cell controversy. If there is such an intractable and irresolvable conflict between moral discourse derived from religious traditions and scientific claims about embryonic development, how are people of faith to

engage in the bioethical debates of our secular, pluralistic societies which assume a certain distance from tradition and theology? Therefore, stem cell proponents have often questioned the legitimacy of religious arguments in the policy debate and have dismissed beliefs in the ontological status of the human embryo as narrow, highly contested religious worldviews that stand at odds with the society's public political culture. This position is well supported by analyses that have shown significant variations between different cultures and religions on the moral respect and legal protection that should be accorded to prenatal human life-forms and, respectively, the types of embryo research that should be deemed ethical (Ruse and Pynes, 2003; Waters & Cole-Turner, 2003). Most ethical and philosophical debates on the moral status of the blastocyst (the pre-implantation human embryo) have come to an impasse and the issue is presently considered irresolvable. As Finlay (2004) points out in his article on stem cells and cloning, "in a postmodern society there are no knock-down arguments by which Christians can compel others to adopt their ethical positions" given that their ethical perspective is not derived by "rationally defensible proposition, but from the stories by which we are formed" (p. 21). Similarly, Dworkin (2000) argues in his book *Sovereign Virtue: The Theory and Practice of Equality* that the issue of respect and protection owed embryonic life is a question of detached not derivative value, and that "opinions of such values are notoriously varied, even within a particular democratic culture, in large part because they are sensitive to the very different religious convictions that coexist in such cultures" (p. 431). While some believe that the embryo is a human person even in the very early stages of development and should be granted legal protection, others see it

simply as a collection of cells which is yet to develop human potential. Nevertheless, beliefs in the ontological value of human embryos are not only grounded in religious faith, but are also supported by Kantian deontological ethics. Sandel (2005) claims in his analysis of the ethical implications of human cloning that our reluctance to objectify the blastocysts used in hESC research has much to do with "the Kantian assumption that the moral universe is divided in binary terms: everything is either a person, worthy of respect, or a thing, open to use" (p. 245). Even opponents of stem cell and embryo research have admitted that the debate on the human status of the early embryo is complicated by fundamental differences in our theological traditions which cannot be resolved with rational arguments (Lawler, 2007). Intercultural perspectives on the ethics of hESC research have clearly illustrated that, while religious traditions are, in most cases, deeply concerned with questions of life, they significantly differ on the issue of respect and legal protection owed to pre-natal human life.

The prominence of religious arguments in stem cell debates in North America and Europe is by no means accidental; rather, it is indicative of the increasing influence of religious orthodoxies in contemporary pluralistic democracies. The continuous existence of strong religious communities in the secular West is becoming particularly visible in the post-secular society and its value conflicts on scientific and social issues such as abortion, voluntary euthanasia, genetic engineering, reproductive medicine, animal protection, and environmental activism (Habermas, 2008b). The acknowledgement that there are still highly ambivalent feelings towards secularization, not only worldwide, but also in the Western world, has incited critical assessments of the secularization paradigm

and self-reflection on the unfinished dialectic of our own occidental secularization (Habermas, 2003). In a secular society, religious communities are required to undertake the arduous task of accepting and adapting to religious pluralism, the authority of scientific knowledge, and the secular values of the liberal state. Habermas (2003) has suggested that the post-secular society demands a similar effort from secular citizens who are yet to conform to the ethical expectations of democratic citizenship. This need to accept the input of religious traditions in the informal public sphere, provided that their contributions are translated into generally accessible terms consistent with the principles of democratic political culture (i.e., the "institutional translation proviso"), is arising from the secular society's overreliance on the crude naturalism of science. Furthermore, he indicates that secular epistemologies and scientific doctrines often undermine our self-understanding as moral persons by abstracting nature from the social frame of reference of persons freely engaged in communicative interactions in the public sphere.

In response to contrasting evaluations of secularization, Habermas (2003) has developed as a critique of the replacement and expropriation models in secularization theory. Both perspectives have construed the process as a zero-sum game which entails the inevitable clash between religious and scientific worldviews. While the former asserts progressivist interpretations in the context of "disenchanted modernity" which have envisioned the replacement of religious ways of life and thinking by the rational, the latter proposes a theory of decline in the context of "unsheltered modernity" in which modern ways of life and thinking are discredited as illegitimately appropriated goods. Although Habermas (2003) advocates a distance from both strong religious traditions and

comprehensive doctrines, such as naturalism, he attempts to avoid narrow, secularist perspectives on the political role of religion developed within political liberalism. In an article published in the *European Journal of Philosophy*, Habermas (2006) considers two critical questions: (1) Is all religious discourse just a pre-modern residue?, and (2) Do secular citizens also have a duty to rise above their narrowly secularist consciousness in order to engage with religion in terms of "reasonably expected disagreement"?. In some sense, it may seem that his revised concept of citizenship in the post-secular society may have posed an asymmetrical cognitive burden on religious communities to develop specific epistemic attitudes and stances towards: (1) other religions and world views, (2) the independence of secular epistemologies from religious knowledge, and (3) the priority of secular reasons in the public arena. Nevertheless, he argues that such arduous work of hermeneutic self-reflection should also be undertaken by secular citizens who are presently expected to engage in reflexive self-understanding and a meaningful dialogue with religious persons. This act of cognitive adaptation is different from mere tolerance and respect for the existential value that religion may have for some persons; rather, it constitutes "a self-reflective transcending of a secularist self-understanding of Modernity" (Habermas, 2006, p. 15). Essentially, what he suggests is a change of epistemic attitudes in the secularized Western societies that would simultaneously accelerate the process of modernization and the adaptation of religious consciousness to the ethics of citizenship and help out secular citizens become epistemically adjusted to the continued existence of religious communities. This would require that in their conflicts with religious traditions secular citizens do not deny any cognitive substance to

religious arguments from the onset, but rather perceive these differences as reasonably expected disagreements. In this sense, religious perspectives on moral issues can greatly enrich the public discourse but only if citizens in the constitutional state are willing to change their epistemic attitudes and embark on "complimentary learning processes," as a result of which the religious consciousness will becomes reflexive and the secular consciousness will transcend its limitations.

This philosophical justification of the need for and right of religious discourse in public life is further extended by Habermas (2008a) in his book *Between Naturalism and Religion* which offers a revision of his invariable critique of the validity of religiously informed moral arguments in the public sphere. Religion, he argues, does not necessarily stand in the way of science and, therefore, religious reasoning should not be considered adversarial to the secular rationality of modern life. More importantly, religious traditions can help people articulate moral intuitions pertaining to vulnerable communal forms of life and encourage those who are not religious believers to engage in reflection on deep moral issues. The effort to understand their contributions seems worthwhile in the context of a prevailing naturalist worldview which establishes modern science as an autonomous practice with its own criteria of verification and as a measurement of all truths and falsehoods. The dangers of such naturalism are discernible in recent advances in genetic engineering, the reproductive technologies and the neurosciences which threaten to subsume moral persons under scientific descriptions and thus encroach on our normative self-understanding. In this case, the question of how science is related to religious doctrines seems to be implicated in the overarching philosophical concern about the

genealogy of Modernity's self-understanding and the recognition that modern science is a practice that is by no means separated from a history of reason that includes the world religious traditions (Habermas, 2008a).

Philosophical and political debates on the relationship between faith and knowledge have become implicated in the stem cell controversy, especially when the issue was debated beyond narrow bioethical concerns about the status of embryonic stem cell lines or technical questions concerning public funding. Rather than adopting a simplistic "science versus religion" framework of analysis, it is worth considering the relevance of Habermas's concept of ethical citizenship in post-secular societies to the public discourse on stem cells and set out specific limitations for religious arguments in deliberations over contested scientific issues in both the informal public sphere and the institutional arena of decision-making in contemporary pluralistic societies. I examine these questions in greater detail in chapter five which contrasts and compares specific modes and principles of deliberations adopted at the institutional level of bioethical advisory bodies and government commissions in the U.S. and the E.U.

The Diverse Ethics of Stem Cell Research

There are a number of different ethical, social and legal controversies that are blended in the stem cell controversy. In the United States, efforts by religious and right-wing interest groups to frame the public discourse on stem cell research in terms of the contentious issue of abortion rights have significantly influenced the major ethical considerations raised in the national debate. Within the field of bioethics, critics of the President Council of Bioethics (PCBE) have often laid the charge of embryo-centrism to

criticize the Bush administration's misguided attempts to develop an ethical framework for policy decisions regarding biomedical research and human biotechnologies (Annas & Elias, 2004; Turner, 2004). Moreover, some PCBE members have expressed concerns that the focus on contentious embryo politics came at the expense of ignoring the best possible scientific information which was either not incorporated or not communicated clearly in the Council's report on stem cell research (Blackburn, 2004). In the introductory chapter, I have suggested that public deliberations on the governance of stem cell technologies that are narrowly focused on the embryo's contested moral status inevitably tend to overlook the range of social and ethical issues related to the stem cell controversy that have been articulated elsewhere. In the following pages, I aim to provide insight into the diverse ethics of hESC research by looking closely at three major bioethical issues that have become prominent in public policy debates: (1) secular defenses of the embryo's moral status, (2) the ethics of human cloning, and (3) concerns about women's reproductive rights and health in embryo donation. I also examine specific framings of the stem cell controversy in the context of these ethical considerations. Ethical issues that arise from experimentation with hES cells are by no means limited to these three clusters of policy-related concerns. Rather, the bioethical discourse on stem cells currently extends to ELSI issues associated with stem cell patents, access to stem cell therapies, clinical challenges in translational stem cell research, and stem cell tourism. These are highly specialized bioethical debates that have not yet received significant public attention. I examine such supplementary ethical considerations in greater detail in the remaining chapters of the dissertation.

Bioethical Debates on the Moral Status of the Embryo

While the embryo's moral status remains highly contested, scholars have strived to develop a coherent philosophical defense of the full moral respect and protection owed to the embryo from the very moment of fertilization which is not grounded on theological assumptions and religious reasoning. These perspectives (George & Gomez-Lobo, 2005; George & Tollefsen, 2008; among others) advance the argument that the differing capabilities of early embryos to develop into human beings does not necessarily translate into a different moral status and, respectively, a different degree of protection owed to these entities. One of the most consistent attempts to assert the moral equivalence between pre-implantation embryos and persons is George and Tollefsen's book *Embryo: A Defense of Human Life* (2008) which provides a comprehensive overview of competing conceptualizations of the pre-implantation embryos' moral status that have been articulated in the stem cell controversy. The authors argue that the equal moral standing of the human embryo can be defended with secular arguments drawn from moral philosophy and the science of human embryology. They offer four major arguments in defense of this proposition. First, the underlying assumption of the book is consistent with what is known in moral philosophy as the "equal moral status view," that is, that "*human embryos are, from the very beginning, human beings, sharing an identity with, though younger than, the older human beings they will grow up to become*" (George & Tollefsen, 2008, p. 3). Secondly, the authors review some facts of embryology to extend the concept of moral personhood to human embryos at all stages of development. They argue that "the embryonic, fetal, child, and adolescent *are just stages*—stages in the

development of a determinate and enduring entity—a human being—who comes into existence as a single-celled organism (a zygote) and develops, if all goes well, into adulthood many years later" (George & Tollefsen, 2008, p. 51). Arguments about a human being present from the very moment of conception are grounded on their critique of the metaphysical notion of body-self dualism. This form of dualism is characterized as "inherently irrational," as a doctrine that is premised on problematic metaphysical claims about the organic and the personal substances in the human, and, finally, as "a lost philosophical cause, although it is perennially attractive" (George & Tollefsen, 2008, p. 69). Instead, the authors adopt a philosophical principle asserted by Thomas Aquinas that the soul constitutes not only the organizational life-principle of the human body, but it is also the vehicle that enables the human being to think and will. Body and consciousness, they claim, are parts of one unified entity, an animal organism bearing a rational nature, and that entity is present from the very moment of fertilization of the human zygote.

The third major argument in support of the "equal moral status view" is that full moral respect and protection is owed not only to persons, but also to human life forms in the pre-personal and post-personal stages of development. Embryos are, therefore, considered to be intrinsically valuable by the virtue of what they are, and not because of what they will become in the latter stages. Finally, George and Tollefsen (2008) address the moral dualism of philosophical perspectives that accord different status, rights and attributes to embryos and persons, and criticize developmental theories (Sandel 2007) and attribution views (Green 2001; Strong 1997) of moral personhood. Both theories, George and Tollefsen (2008) believe, are arbitrary in their assessment of when moral status

should be bestowed upon human beings, and fail to provide convincing arguments that "each human being throughout his or her life has inherent dignity and is the subject of moral rights and deserving of moral respect" (p. 132).

The philosophical arguments of *Embryo* will seem questionable to anyone who does not share the underlying assumptions of its authors about extending the concept of personhood to the embryo from the moment of conception and treating embryos in the pre-personal stages of development as full members of the moral community of persons. Not less problematic is the imperative that human embryo ethics should be no different from the ethical treatment of minorities or dependents. Despite the authors' well-rounded critiques of some shortcomings of moral theories and philosophies in addressing the ethics of scientific research, their argumentation in debating the moral status of the human embryo is dismissive of the role of deeply embedded cultural values and religious convictions that underlie our understanding of embryo science, embryo ethics and embryo technologies. While George and Tollefsen (2008) assert that their analysis is informed by the best scientific knowledge in embryology, it is worth asking the question whether their conclusion that full potential for personhood originates with the formation of a new diploid genome in the fertilized oocyte (zygote) is indeed supported by robust science, rather than based on certain theological assumptions and moral intuitions. It may be right to assume that the fusion of spermatozoon and ova is the point of origin of a new, *genomic* identity. It is problematic to assert, however, that the point of origin of a new *individual* identity with full potential for personhood can be traced to the moment of formation of a new genome in the zygote. It is well known that the zygote's haploid

genome may develop into more than one unique entity due to the possibility of monozygotic twinning, i.e. when a single embryo splits into two, in the early weeks of development. Given this possibility, it is widely believed that the conditions for personhood are clearly present around the 14th day, when there is a genetically complete individual entity and appearance of a primitive streak, a crumpled, rod-shaped thickening in the middle embryonic disc which indicates the beginning of neural tissues and the mesoderm. Based on this particular understanding of human embryonic development, policy makers in Britain have enforced the rule that all embryos used for stem cell derivation and other types of biomedical research are destroyed after the 14th day.

Nonetheless, not all supporters of stem cell research are satisfied with the twinning argument and the time of formation of a primitive streak as an indication for full human potential. In his book *The Morality of Embryo Use*, Guenin (2008) claims that monozygotic twinning by itself does not disqualify an embryo from being a person "nor does there obtain any reason to deny that an early embryo satisfies any condition of human individuality requisite for personhood" (p. 98). Rather, he believes that the threshold to personhood is intrauterine implantation. Therefore, the case for embryo research is argued strictly in relation to embryos (usually created and stored at IVF clinics) that will never be implanted in either a woman or in an artificial uterus because no more transfers are requested by the mother and they had already been donated by their progenitors for research purposes. This category of embryos is defined as an *epidosembryo* (from the Greek word *epidosis* meaning "for a beneficence to the common weal" or for the common good). In cases when the patients have already decided against

the transfer of these embryos, their developmental potential "fails of enablement." As Guenin (2008) points out,

> Thus one cannot accomplish anything, for anyone, by asserting that an embryo, as to which progenitors refuse intrauterine transfer, and that they wish to give to medicine, is a person for purposes of the duty not to harm or not to kill. Once progenitors have barred an embryo from the womb, its developmental potential is bounded such that the foregoing situation will not change. (p. 46)

This "developmentalist" perspective clearly indicates the event of intrauterine implantation as the crucial moment when the case for moral status can be made, and can be contrasted to attempts to establish the personhood of human zygote or conceptus through a rather metaphysical notion of potentiality based on the genetic evidence. Instead of asserting zygotic personhood and its deontic consequences, Guenin (2008) justifies the destruction of pre-implantation embryos for the humanitarian purpose of developing life-saving treatments with the argument that "permissibility of epidosembryo use follows from the embryo's presently bounded developmental potential and the end to be served by using the embryo (p. 53).

Furthermore, George and Tollefsen's claim that the zygote's full human status can be determined with references to scientific facts and a purely philosophical reasoning stands at odds with their emotionally-laden rhetoric and politically expedient arguments. Throughout the book, hESC research is consistently labeled as "embryo-killing for research," "embryo-destructive research," and as "wrongful killings" comparable to the murder of retarded children in order to obtain their organs, whereas blastocysts are

characterized as "embryonic human beings," "embryonic persons," "the youngest and most vulnerable members of the human family." In their critiques of hESC research, conservative members of the PCBE have often resorted to similar rhetorics and emotional appeals to provide ethical justification for the Bush administration's highly unpopular stem cell policy. As over the last ten years both sides in the contentious debate have become deeply entrenched, stem cell proponents have easily dismissed the "equal moral status view" as a religious doctrine that falls beyond the scope of a legitimate public debate on science policy (Silver, 2006). Therefore, conservative bioethicists and philosophers have undertaken the task of conjuring up sound epistemological and moral arguments that would count as acceptable ethical defenses of pre-personal life. In this sense, George and Tollefsen's (2008) philosophical defense of embryonic life and critique of hESC research resonates with conservative analyses of embryo ethics such as Sullivan (2001), Ponnuru (2004), and George and Lee (2005).

Some scholars have advocated a middle ground position between the notion of the pre-implantation embryo's full human status and arguments that such embryos have no particular moral status and could be used in stem cell research (Fukuyama, 2003, 2005; Sandel, 2005). In his article "Human Biomedicine and the Problem of Governance," Fukuyama (2005) has claimed that, contrary to the common belief that the PCBE has served a conservative, pro-life agenda, its deliberations have demonstrated a "healthy balance of views on the tortured "moral status of the embryo" question" (p. 195). Caught in-between the two extremes, several Council's members have defended the position that human embryos have an intermediary moral status. Fukuyama (2005) supports the view

that human beings develop full moral status gradually during the prenatal development and that this gradual acquisition continues during the postnatal development of the human. This proposition is illustrated by the fact that full political rights are granted only to adults, and not to children. While the intermediate status of the human embryo justifies its instrumental use for serious scientific research (e.g. the use of pre-implantation embryos as a source of stem cell tissue), it also entails a certain level of respect owed to these entities and social control to ensure their ethical treatment. Fukuyama (2005) also argues that we need to develop an appropriate regulatory system that would distinguish the legitimate use of embryos in stem cell research from their unethical use (e.g., the implantation of cloned embryos to produce children).

A similar perspective is provided by Sandel (2005) in his article on the ethical implications of human cloning. He claims that we cannot simply regard the human embryo as a mere thing that is open to all kind of use and interventions. At the same time, we do not necessarily need to assume that it is a full human being in order to assert the significance of nascent human life. The major problem with attributing full personhood to the human embryo is that the "equal moral status" view has certain far-reaching implications that render it implausible. For example, proponents of this view have maintained that the extraction of stem cells from six-day-old blastocysts is as morally wrong as the harvesting organs from babies. This proposition, Sandel claims (2005), seems very problematic in the context of the proposed U.S. anti-cloning legislation which imposes the penalty of a $1 million dollar fine and 10 years in prison, a hardly adequate punishment for such a gruesome act. If the destruction of pre-implantation embryos were

indeed equal to the murder of babies, then the legislation should have provided a more severe form of punishment for the scientists extracting stem cells from embryos, such as life imprisonment or the death penalty. Another problem for the equal moral status view is the high rate of embryo loss in natural pregnancies, with more than half of the embryos failing to implant. The way people respond to the natural loss of embryos (which often goes unnoticed) and early miscarriages indicates that they do not perceive embryos as morally equivalent to children. If the equal moral view holds validity, Sandel (2005) asks, wouldn't it make sense to carry out the same burial rituals for each lost pre-implantation embryo that we observe for the death of children? In other words, this perspective clearly stands at odds with people's moral intuitions about the significance of pre-personal human life and its implications defy the established legal and socio-cultural practices in pluralistic societies. Sandel (2005) suggests that we should be wary of an ethical doctrine which "risks turning every moral question into a battle over the bounds of personhood" and advocates a middle ground approach that will help us better "cultivate a more expansive appreciation of life as a gift that commands our reverence and restricts our use" (p. 246). Similarly to the position defended by Fukuyama, Sandel attempts to distinguish between legitimate and illegitimate uses of embryos in biomedical research. While he believes that the use of cloning technology for the creation of designer babies is "the ultimate expression of the hubris that marks the loss of reverence for life," he commends embryonic stem cell research, including the use of cloned blastocysts in it, as "a noble exercise of our human ingenuity to promote healing and to play our part in repairing the given world" (p. 246).

The Ethics of Human Cloning

The framing of hESC research as a moral issue closely related to the regulation of human cloning has become a major factor in sustaining the public controversy on both sides of the Atlantic. In the early years of hESC research, public fears were fueled by news stories about cloned human babies. The most publicized announcement came from the U.S. based company Clonaid established in 1997 by the Raelian cult. The Raelians, which believe that people are the result of a genetic engineering project run by highly intelligent extra-terrestrials, claimed that their scientists have produced the world's first cloned baby, who was allegedly born by Caesarean section on 26 December 2002 to a 31-year-old U.S. mother. Most scientists dismissed Clonaid's claims as groundless given that at the time even most technologically advanced labs had not succeeded in producing a viable cloned human embryo. Media investigations also supported suspicions that the cloning claim was hoax, as Clonaid's executives consistently refused to provide any evidence of cloning the baby, nicknamed Eve, or even of her existence. Despite Clonaid and other human cloning advocates' claims, the birth of Eve and cloned human babies has never been verified independently.

While some techno-utopians and cloning advocates believe that reproductive cloning has the potential to improve the vitality of the population by maximizing biologically determined behavior and intelligence, it is universally rejected on ethical grounds since "reproductive cloning would amount to a procedure in which *people* were the experiment, the outcome of which could not be known until they were shown to posses the capacity of producing normal children" (Finlay, 2004, p. 15). Regardless of

such general agreement that human reproductive cloning is morally reprehensible and should be banned, scientists, politicians, bioethicists, and the public still greatly disagree on the use of somatic cell nuclear transfer in hESC research. In America, Christian activists and anti-cloning advocacy groups have spread misconceptions that therapeutic cloning means making cloned human babies rather than innovative stem cell therapies. Religious leaders have also made appeals for an anti-cloning ban by representing all types of cloning as a giant step toward turning human procreation into manufacture. Around the time ACT announced they had cloned human embryos for stem cell research, a U.S. Orthodox Church leader compared cloning experiments with "crimes against humanity of a Nazi brand" and claimed that "the so-called therapeutic cloning is nothing other than the worst instrumentalization of a human being, sacrificed for the benefit of others" (News release by zenith.org, 27 November 2001). Public statements and media releases by opponents of hESC research have not only blurred the differences between cloning for reproductive purposes and therapeutic cloning, but also questioned the latter's viability for the production of stem cell therapies. The founding statement of *Americans to Ban Cloning*, posted on their website, exemplifies the efforts to make cloning for stem cell research redundant:

> A ban on cloning as a means of producing live born human beings will prove to be unenforceable unless it also bans cloning for any other purpose—including the use of cloning to produce human embryos as sources of stem cells or for other experimentation. Referring to this latter use of cloning as "therapeutic cloning" is prejudicial and misleading, since

> it has not been shown that cloning is necessary for or useful in the production of human therapies.(http://www.cloninginformation.org)

Similar concerns about the use of cloning technology in biomedical research were voiced by Christian bioethicists on the PCBE such as Mary Ann Glendon and Gilbert Meilaender, as well as by neoconservatives with little experience in academic bioethics like Francis Fukuyama and Charles Krauthammer. The conservative minority on the Council has strongly advocated a nationwide ban on both reproductive and therapeutic cloning. In his invariable critique of genetic engineering and biomedicine, Leon Kass, chairman of the Council from 2002 to 2005, has repeatedly referred to the dystopian themes of Aldous Huxley's *Brave New World* (1932) to characterize advances in human biotechnologies as an assault to human dignity. His essay "Preventing a Brave New World," published in *The New Republic* in June 2001, utilized a similar rhetoric to diminish the effectiveness of cloning technology in developing new hESC-based therapies:

> The technology of cloning is discrete and well defined, and it requires considerable technical know-how and dexterity; we can therefore know by name many of the likely practitioners. Nothing scientifically or medically important would be lost by banning clonal reproduction; alternative and non-objectionable means are available to obtain some of the most important medical benefits claimed for (non-reproductive) human cloning. The commercial interests in human cloning are, for now, quite limited; and the nations of the world are actively seeking to prevent it. Now may

> be as good a chance as we will ever have to get our hands on the wheel of the runaway train now headed for a post-human world and to steer it toward a more dignified human future (Kass, 2001).

By and large, opponents of hESC research in the United States have communicated their objections against research cloning in terms of the intersection of the two technologies, emphasizing that techniques developed in SCNT or CRNT (Cell Replacement through Nuclear Transfer) research can pave the way, scientifically and technically, for successful attempts at reproductive cloning.

While Christians and anti-abortion Republicans strongly oppose therapeutic cloning because it leads a deliberate destruction of human embryos, some pro-choice liberals also felt uneasy about prospect of this technology becoming a step toward human reproductive cloning. There were ethical concerns that the acceptance of cloning technology could legitimize questionable moral practices such as the instrumentalization of children and new forms of genetic discrimination. The U.S. debate over human cloning led to some unexpected political realignments, including a peculiar alliance between some pro-choice feminists and anti-abortion activists in support of the so-called Weldon-Stupak Human Cloning Prohibition Act (H.R. 2505) of July 31, 2001. [1] Many feminists supported the anti-cloning legislation, as they feared that the engineering of cloned embryos would be a yet another step toward the creation of "designer babies" and would turn women's eggs and wombs into commodities. The measure aimed to criminalize both reproductive and therapeutic cloning by establishing penalties of up to ten years in jail

[1] The full text of bill H.R. 2505 is available on http://usgovinfo.about.com/library/bills/blhr2505.htm.

and a fine of not less than one million dollars for attempts to clone humans. The House approved H.R. 2505 by a vote of 265 to 162, while rejecting by a vote of 249 to 178 an amendment that would have allowed limited creation of cloned embryos for biomedical research. The bill never became a law since the Senate did not act upon it.

While some stem cell advocates have emphasized the benefit of the advancement of knowledge and technologies associated with the cloning of human embryos by nuclear transfer, its potential for stem cell research remains questionable. In Great Britain, where therapeutic cloning was legalized in December 2000, despite strong opposition from the European Union, critics have questioned HFEA's decision to grant licenses for "performing research of a preliminary nature with cloned human embryos before conclusively demonstrating the superior therapeutic prowess of embryonic stem cells derived by nuclear transfer or validating the rationale for the proposed work in animal studies" (Cobbe, 2005, p. 298). As published research in the field has indicated, a very limited progress had been made in human cloning experiments. Similarly, a number of animal studies have resulted in a failure of engraftment of stem cell transplants derived from cloned embryos which were attacked by the natural killer cells in the recipient mice, although one experiment has indeed achieved successful engraftment in parkinsonian mice of dopaminergic neurons derived from ES cells following nuclear transfer (Cobbe, 2005). These animal studies, however, do not seem to provide convincing evidence that the ES cells derived by nuclear transfer are in any way therapeutically more effective than other types of ES cells. Since the cloning process often results in altered patterns of gene expression, it is wise to remain cautious about the clinical potential of therapeutic

cloning until research "demonstrated unequivocally that such epigenetic defects would not be responsible for problems associated with the transplantation of stem cells derived from cloned embryos (possibly due to misexpression of genes affecting an immune response)" (Cobbe, 2005, p. 299). Subsequently, there were concerns about the possible misrepresentation of the clinical potential of research cloning in the UK policy debate.

Stem Cell Research and Women's Bodies

Scholars have argued that the ethical issues in hESC research extend beyond the contested moral status of the human embryo and the potential for new medical treatments, with some key themes missing from public discussions such as concerns about women as the source of embryos, potential health risks and the existing therapeutic gap (Kitzinger &Williams, 2005; Dickinson, 2006, King, 2007). With the debate being presented as a strict binary opposition, little attention has been paid to regulatory issues that arise from the need to protect women who supply ova for stem cell technologies and the process of nuclear transfer. Dickinson (2006) has argued that the new biotechnologies have led to the feminization of all bodies; regardless of our gender we are reduced to the status of objects and both male and female tissue has equally become subject to commodification. Property rights in human tissue and in the human genome, she argues, have become the subject of a "new enclosures" movement by researchers, biotech corporations and governments. The ongoing commodification and objectification of human tissue has generated protests by patients' rights coalitions, academic commentators, media and the general public, but only because it affects men and women equally. The stem cell debate, however, has in some ways rendered the bodies of women

invisible. While there is almost no awareness in the mainstream media and bioethics literature about the commodification and objectification of female tissue, "in the stem cell technologies, by contrast, we see little outrage about the exploitation of female reproductive tissue" (Dickinson, 2006, p. 44). The fact that it is widely believed that stem cell research will become ethically acceptable if only scientists find ways to engineer hES cells without using human embryos further confirms the exclusion of women from the ethical equitation.

The position outlined above has led to reconsiderations of the narrow ethical scope of the stem cell debate in the United Stated and elsewhere. An example of such a shift from contested embryo politics towards more overarching concerns about the impact of recent advances in biomedicine on women's reproductive rights and health is the public debate on stem cell research in Canada, which was conducted in the context of a larger effort to regulate human reproductive technologies. Public bioethics in Canada presently stands in sharp contrast to the embryo-centrism that plagues bioethical debates in the United States. Rather than framing the stem cell debate around the moral status of the human embryo and the ontological significance of human germ line, feminist analyses of Bill C-6, known as the Assisted Human Reproduction Act of 2004, have deconstructed the dominant terms of the debate to draw the public's attention to issues concerning women's reproductive rights and reproductive health that are at stake with the development of stem cell technologies (Sullivan, 2005; King, 2007). Some Canadian bioethicists have also opposed the practice of donating healthy, viable embryos for stem cell research since it increases the possibility that women donors may afterwards have to

undergo additional IVF cycles in order to complete their reproductive projects (Baylis, McLeod, Nisker, & Sherwin, 2007). It is recognized that women's reproductive work in hESC research involves specific health risks. Repeated ovarian stimulations and eggs collection surgery, which are part of the IVF treatments, entail physical risks associated with the ovarian hyperstimulation syndrome, including side effects such as lower abdominal pain, nausea, vomiting, diarrhea, rapid weight gain, and respiratory difficulty. Some life-threatening complications are also possible, including renal failure, adult respiratory distress syndrome, hemorrhaging from ovarian rupture, and thromboembolism (Baylis et al., 2007).

Women are presently the primary tissue donors in the stem cell industries. There is a growing demand worldwide for continuous supply of oocytes, embryos, fetal tissue and umbilical cord blood. The expansion of new types of biomedical research is largely dependent on the feminized productivity in the bioeconomy, with women in the developing countries being the major supplier of biological material for the stem cell and regenerative medicine industries (Waldby & Cooper, 2010). Concerns about the ethical implications of the global trade in human egg cells intensified after the British Parliament's decision to allow the use of cloned embryos in hESC research. Since the cloning process requires high volume of donated oocytes, the subsequent HFEA's proposal to relax rules on importing human eggs came as no surprise. Nonetheless, this decision was met with significant opposition by most EU countries, which resulted in a resolution on the trade in human egg cells passed by the European Parliament in 2005. The document seriously questioned the Authority's attempt to facilitate a trade of human

eggs from impoverish female populations in Romania. Questions about potential exploitation of women in developing countries have thus became implicated in the E.U. stem cell/cloning debate.

Conclusions

In this chapter I illustrated how the positions of participants in public deliberations over stem cell policy have been shaped by their prior theological and moral commitments. A major concern in the stem cell debate was whether ethical arguments derived from religious traditions could be reconciled with scientific perspectives on human embryonic development. The value conflicts of the stem cell controversy have reflected increasing tensions between religious and secular worldviews in the public sphere of contemporary liberal states. In his analysis of such recent challenges to the process of secularization, Habermas (2006) has suggested that the clash between science and religion could be offset by adopting a new concept of ethical citizenship in the post-secular society. This position requires a certain degree of epistemic flexibility by both religious and secular citizens who willfully engage in complimentary learning processes to transcend the inherent limitations of both unreflexive religious beliefs and narrow secularist worldviews. My analysis of the role of religion in the stem cell controversy, however, indicated that the dialogue between science and religious traditions is greatly dependent on how compatible are scientifically derived assessments of embryonic status with the latter's fundamental theological tenets of the beginning of personhood. It is also contingent on the degree of openness of each religious tradition to scientific input.

The chapter concluded with an assessment of the diverse ethics of stem cell research by focusing on three major clusters of bioethical issues around which stem cell debates have been framed—the human embryo's contested moral status, the ethics of human cloning technology, and concerns about the exploitation of women who have become the major tissue donors in the global stem cell bioeconomy. Perspectives on the moral standing of pre-implantation embryos used in stem cell research have varied between ethical defenses of its full human status and claims that at this stage of development the embryo has no particular moral status. In an attempt to balance these two conflicting positions, some have suggested that embryos have an intermediary moral status which justifies their instrumental use for life-saving biomedical research but only under conditions that ensure their ethical treatment. This middle ground approach represents a way to assert the moral significance of early embryos as potential human life without accepting some far-reaching implications of the equal moral status view that render it implausible. The stem cell policy debate became deeply entangled with the cloning debate when scientists discovered that cloning techniques could be potentially utilized in the production of hESC therapies that would be compatible with a patient's immune system. Stem cell proponents have attempted to appease public anxieties by setting up a clear dividing line between cloning for reproductive purposes and the use of cloning technology in stem cell research. In the US the cloning controversy has created some unusual political alliances in support of anti-cloning legislation and also led to a proposal by the PCBE for a four-year moratorium on research cloning. The legalization of research cloning in EU countries with strong research agenda, i.e. Britain, raised

concerns among critics about the public misrepresentation of its clinical potential in hESC research. The strong focus on embryos in the public discourse on hESC research has incited feminist critiques which have deconstructed the dominant terms of the debate to draw attention to issues concerning women's reproductive rights and reproductive health that are at stake with the development of stem cell technologies. It was claimed that popular framings of the ethics of this biomedical innovation around questions of what kind of entity the embryo is and when exactly life begins had rendered the bodies of women invisible and excluded them from the ethical equation. Feminists have lamented the reluctance of the mainstream media and bioethics literature to address concerns about the commodification and objectification of female reproductive tissue in stem cell research and, more specifically, the potential exploitation of women donors in developing countries.

CHAPTER 4

STEM CELLS, MEDIA AND THE PUBLIC SPHERE

The mass media have played a significant role in shaping the public understanding of the ethics and politics of stem cell research. Both proponents and opponents of embryo research have used the media as a resource to mobilize public support for their position and to frame the public discourse according to their preferred policy outcomes. At the same time, the news and print media have followed their own economic and political agenda in framing the controversy. In contemporary democracies media themselves are political institutions that can influence the processes of public communication and involvement with policy making since they can "powerfully shape how policy issues related to science and technology controversies are defined, symbolized, and ultimately resolved" (Nisbet et al., 2003, p. 37). In a risk society, media have the resources to open up contested techno-scientific developments for public criticism and can provide a communicative forum for framing and negotiating uncertainty and public anxieties over the actual and perceived risks of the post-industrial society (Beck, 1994). The significance of mass media in contemporary mediated societies is heightened by their ability to shape the public discourse on ethico-political matters, influence political behaviors and set the agenda for public participation in the decision-making process. In the light of these considerations, this chapter aims to examine the role of mass media in setting the public agenda on stem cell research in a comparative US-EU context. My analysis emphasizes the active role of media in shaping and constructing public discourses on the ethics and biopolitics of stem cells against the conventional

understanding that media coverage of controversies in the field of science and technology is rather limited to reporting new scientific discoveries and technological developments. I look at how the news and print media represent an important site of struggle for different interest groups in their lobbying efforts to sway the public opinion in favor of specific policy outcomes. While both proponents and opponents of hESC research have competed for press and television coverage, mass media have also followed their own agenda in sensationalizing ELSI issues related to stem cell technologies and their applications in regenerative medicine. The chapter begins with an overview of perspectives in science communication that explore the role various media outlets play in the public communication of controversies in science and technology (Friedman, Dunwoody, & Rogers, 1999; Marks et al., 2007; Mazur, 1981; Weingart, 1998). These analyses emphasize the central position of mass media in framing scientific uncertainty and providing legitimacy to knowledge claims, moral values, and political interests and, therefore, provide a useful framework to consider specific media framings of the stem cell debate. I then contrast and compare frames and narratives about the societal implications of the stem cell technologies validated by news media in the US and EU member states such as Britain, France and Poland. The chapter concludes with an analysis of the role of mass media in advancing notions of stem cell research exceptionalism which considers two normative models for public discourse on scientific controversies outlined by Gerhards and Schäfer (2009)—the science-dominated scientific public sphere and the contextualized scientific public sphere.

In the earlier chapters I have discussed moral divisions in American society over the ontological significance of human embryos and their use as a source of stem cells. I have also illustrated how the framing of the stem cell controversy in terms of the contested politics of abortion has set the tone for a public debate along the conventional political and cultural divisions between left and right, liberals and conservatives, pro-choice supporters and pro-lifers. In their book, *The Promise and Politics of Stem Cell Research*, Solo and Pressburg (2007) point out that the stem cell debate has invigorated the public life in the U.S., although at the expense of an extreme polarization of the country before any informed public debate had taken place. The advent of stem cell technologies and the potential of regenerative medicine to improve public health, they claim, have marked "a new era of public life and participation in national policy making from the bottom up...[and] the promise of stem cell research has resulted in a radical and potentially transforming political experience for the country" (2007, p. 15). The Bush administration's decision to impose restrictions on federal funding for embryonic stem cell research in August 2001 incited strong public opposition and prompted science advocacy groups to wage aggressive public communication and media campaigns to promote the public engagement with stem cell policy and secure state and private funding for the development of hESC therapies. That same year, advocates for stem cell research formed the nation's leading pro-cure coalition—the Coalition for the Advancement of Medical Research (CAMR)—whose main objective was to increase opportunities for federal, state and private funding for biomedical research using hESCs. CAMR brought together nationally established patient rights' organizations, universities, scientific

societies, and foundations such as the American Society for Reproductive Medicine, the Association of American Universities, the Association of American Colleges, the American Association for Cancer Research, the Michael J. Fox Foundation for Parkinson's Research, the Christopher Reeve Foundation, the Juvenile Diabetes Research Foundation, the Stem Cell Research Foundation, the American Association for the Advancement of Science, WiCell Research Institute, and the American Society for Cell Biology, among many other organizations. Subsequently, the unprecedented level of public involvement and political activism on the issue of stem cell research led commentators to believe that research advocates had carried out the most successful advocacy and media campaign in the twentieth century American history (Callahan, 2007). The pro-stem cell research coalition accomplished that goal by enlisting the help of leading politicians from the Republican and the Democratic parties, the biotech industry, prominent public intellectuals, Nobel laureates, and Hollywood celebrities such as the Superman actor Christopher Reeve, left paralyzed from a spinal cord injury following a riding accident, and actor Michael J. Fox, who was diagnosed with Parkinson's disease in 1991. Stem cell research activists have also succeeded in organizing ballot initiatives in different states and mobilizing voters to pass referendums securing public funding for hESC research in California and Missouri. Just a few years after Thomson's discovery, stem cell research became one of the central issues in American political and public life and the general public was led to believe that public investment in research on human embryonic stem cells was crucial for the advancement of biomedicine and the economic competitiveness of the USA. The hype around the

development of stem cell therapies has given rise to claims about unwarranted stem cell research exceptionalism in assessing the ethical permissibility of controversial technologies used in stem cell studies (e.g., the generation of hESC lines by means of nuclear cell replacement, human-to-animal chimera experiments in stem cell research, the use of parthenogenetically activated oocytes for human embryonic stem cell derivation, as well as the creation of hES cell-derived, synthetic gametes).

It is worth looking at whether the ethical challenges presented by hESC research and regenerative medicine have provoked similar responses and increased public participation of EU citizens in science policy making at the supranational level. Media coverage and parliamentary debates in most EU member states have legitimized stem cell research as an important political issue. Therefore, it is important to consider to what extent political mobilizations around the biopolitics of embryonic stem cells have become visible not only within national public spheres of EU member states but also in a European-wide, transnational public sphere. Habermas's notion of public sphere and his proceduralist conception of deliberative democracy have become important in current discussions on European integration. A transnational public sphere in Europe would ideally provide a common communicative space for interaction between European citizens and the supranational institutions and empower transnational publics to influence EU decision-making. Scholars in political communication have argued that the formation of post-national democracy in this unique supranational polity, which is neither a state, nor nation, is largely contingent on the emergence of such an overarching communicative space that functions as a public sphere and ensures the realization of popular sovereignty

beyond the nation-state (Eriksen, 2005; Koopmans, Neidhardt, & Pfetsch, 2000). Many have envisioned the development of transnational public spaces in Europe as a direct result of the development of strong trans-European institutions but also as the outcome of a gradual Europeanization of the national public spheres. Presently, it is hard to substantiate claims about a unified European public sphere or a common European identity and culture. Nonetheless, some commentators have indicated that a still closer Europeanization has a visible impact on the national public spheres and the rich diversity of national and regional cultures in Europe (Bondebjerg & Madsen, 2008).

It is important to note that there is still widespread Euroskepticism about the true "transnationalization of public communicative spaces" supported by arguments about difficulties associated with Europeanization of "collective actors, media, and publics superimposed on the established national public spaces" (Koopmans et al., 2000, p. 3). This skepticism is largely informed by assumptions about *structural democratic deficit* inherent in the development of the EU as a supranational unity which does not possesses the proper characteristics and institutional structure of a federal state. More specifically, democratic deficiencies are associated with the weak European parliament, which many perceive as rather ineffective in comparison with national parliaments, the absence of European-wide parties, and problems concerning the lack of collective identity as a precondition for the development of a viable European public sphere (Scharpf, 1999). The lack of democratic legitimacy of the EU institutions is also discernible in the failure to set in motion appropriate political communication mechanisms and policies as an indispensable aspect of the process of European integration and the creation of "citizens'

Europe" (Kaitatzi-Whitlock, 2008). Subsequently, communication scholars have argued that there is a significant communication gap between governments and people which contributes to the alienation of citizens from supranational institutions and the elites that run them (Kaitatzi-Whitlock, 2008).

Nonetheless, political communication scholars have argued that the presence of some shared communicative spaces in Europe indicates a possible step towards the development of a transnational public sphere. For example, Koopmans et al. (2000) emphasize the analytical distinction between mass and elite public spheres and suggest that the transnationalization of national political discourses may not necessarily involve Europeanization of national mass public spheres. Rather, they envision the formation of a transnational, European public sphere "on the level of political, economic, and cultural elites, who can act as 'translators' carrying national discourses onto the European level and, vice versa, may introduce European perspectives into national public spheres" (Koopmans et al., 2000, p. 4). By contrast, others believe that the existence of transnational European audio-visual spaces constitutes an important step towards the Europeanization of national mass public spheres. Eriksen (2005) argues that such transnational communicative spaces are provided by electronic media such as the multilingual television channel EuroNews, BBC World, ARTE, *European Voice*, *Deutsche Welle* (broadcasting in English); influential print media such as *The Financial Times*, *International Herald Tribune*, *The Economist*, and *Le Monde Diplomatique* with editions in most major European languages; and, obviously, the Internet. This perspective also emphasizes the importance of social movements and political organizations across

borders as vehicles in the ongoing process of Europeanization. Therefore, Eriksen (2005) suggests that a pan-European press and media based on English as lingua franca could provide a potential space for the creation of a collective European identity and, furthermore, for a genuine Europeanization of public debates. However, he also notes that "common communicative systems of mass-media facilitating real public debates conducive to collective will formation are to a large degree lacking at the European level" (Eriksen, 2005, p. 351). Similarly, a general supranational public sphere in Europe, which would entail free and open access to opinion formation processes, is presently more of a potential than a reality.

The analytical framework I utilize to examine the role of media in European stem cell debates recognizes the contingency and fragmentation of the European public space, as well as the fact that transnational public debates in Europe currently originate within the EU policy networks. Although I recognize the validity of the "elite public sphere" perspective advanced by Koopmans et al. (2000), I also suggest that it may be worth exploring how issue-oriented polarization in Europe can contribute to a lively public debate across national borders and actualize possibilities for Europeanization of segmented mass publics within national public spheres on a case by case basis. This model presupposes the coexistence of both an integrated, transnational elite public sphere in Europe and thematically "Europeanized" national mass public spheres. I argue that the ethical controversy over hESC research presents an example of such issue-oriented, albeit temporal, transnationalization of public debate in Europe that can allow us to draw parallels with the unfolding of national stem cell debate in the American public sphere.

Since my focus in this chapter is on the impact of mass media on shaping science and society interactions on the issue, in the remaining sections, I explore, in a comparative perspective, how various media outlets enable the actualization of shared communicative spaces for public debate and negotiations over the ethical challenges presented by the stem cell technologies.

Mass Media and Scientific Controversies

In contemporary knowledge economies, the electronic and print new media have become the primary channel to convey scientific notions to the general public. The centrality of mass media in the public communication of science and technology is heightened by their ability to provide legitimacy to scientific issues and draw the public's attention by sensationalizing scientific research and discoveries. Research on mass media and risk communication has shown that different media outlets have the ability to frame controversies in science in ways that greatly influence societal attitudes and perceptions and could also provide a public forum for debate and negotiation between scientists, policy makers, interest groups and the general public (Mazur, 1981; Pellechia, 1997; Friedman et al., 1999). Moreover, lay people heavily rely on the media sources and media professionals for information and interpretation on critical scientific debates, especially when they attempt to understand controversial science in ways that relate to their own personal lives (Friedman et al, 1999). Similarly, media coverage and frames shape the ways in which the general public form opinions on how controversial developments in science and technology (e.g., fetal transplantation research, embryonic stem cell research

and human cloning, gene therapy, etc.) are symbolized, played out and resolved at the policy-making level (Nisbet et al., 2003).

Case studies of media coverage of scientific controversies have convincingly demonstrated the impact of news media on shaping the public understanding of scientific debates and citizens' participation in techno-science policy and decision-making. For example, Mazur's (1981) study of the impact of U.S. media on public attitudes in the nation-wide disputes over fluoridation and nuclear power has shown that "media coverage of scientific controversies may do more than define and amplify an event; it may have profound effects on public attitudes, the precise nature of which is difficult to specify" (p. 109). His analysis indicated a direct correlation between increased media coverage in a technical controversy and public opposition to the technology in question. The coverage-opposition effects were visible in the much-debated fluoridation controversy in the 1950s. While initially community acceptance of fluoridation was extremely high and there was little debate on its effectiveness, a raucous dispute was developed in Stevens Point, Wisconsin, where fluoridation was defeated by town referendum in 1950. Shortly after this conflict, public opposition to fluoride increased and more referendums were passed by 1952. Mazur's (1981) content analysis of popular U.S. magazines and journals showed a peak in media coverage on the subject in about 1952. At the same time, public opinion polls showed that public opposition to fluoridation had increased between 1952 and 1953, when the press article coverage of the issue was also at its peak. This was followed by a decline in opposition by 1956 which was parallel to the decline in periodical coverage. In the 1960s media and public opinion

trends were parallel and reached peaks in the 1965. However, there was an increase in media coverage on the issue at the end of the decade when a growing environmental movement raised public awareness about fluorides as a "water pollutant," and shortly afterward, the revived media interest was followed by a rise in public opposition as indicated by opinion polls in the early 1970s. These fluctuations in the media coverage of disputes over the fluoridation of water convincingly support the hypothesis for correlation between media framing of certain issues and public opposition to controversial technology. Mazur (1981) also traces similar correspondence between increased media coverage of citizens' activism against nuclear power facilities in 1969 and the subsequent peak of public opposition against nuclear power in the 1970.

The content analysis of media coverage of the cloning controversy in the UK conducted by Holliman (2004) also highlights the key role of mass media in raising awareness of scientific and biomedical issues and their ability to define the terms for public debate. His study focused on print and TV news coverage of cloning experiments over a two-year period, from 1 January 1996 to 31 December 1997, which followed the announcement by scientists from Roslin Institute in Scotland about the successful cloning of Dolly the sheep (a Finn Dorset sheep) by means of somatic cell nuclear replacement. Holliman's (2004) analysis of the media reporting on the issue focused on eight UK national daily newspapers and their Sunday equivalents. These included: four broadsheets (*Daily Telegraph*, *The Times*, *Guardian*, *Independent*), two mid-market tabloids (*Daily Mail*, *Daily Express*), and two tabloids (*Sun*, *Daily Mirror*). This representative media sample was extended to late evening news coverage of cloning experiments and ethical

debates on the issue from the four UK terrestrial television channels that were broadcasting throughout the two-year period covered by the study. The newspaper and television sample covered 300 items, 284 of which were newspaper articles, and 16 represented television news bulletins. The results showed that media coverage during the sample period was initially limited to reporting the scientific announcement of Dolly's birth. As public discussions gradually shifted towards political and ethical issues arising from the cloning technology, media reports on the scientific experiments were replaced by a focus on the societal implications of cloning and featured commentaries and opinions by prominent politicians, religious leaders, and scientists. Holliman (2004) points out that although the media were not consistent in their evaluations of the mammalian cloning experiments as ethically acceptable, dangerous or desirable, they routinely framed the issue in terms of dystopian, science fiction visions, such as Aldous Huxley's novel *Brave New World*, Mary Shelley's *Frankenstein*, and the film *The Boys from Brazil.* Media reports also made numerous references to historical links between eugenics, the political extremism of the 1930s, and the potential of cloning technologies to reproduce dictators. By drawing on these cultural references, media representations and frames greatly contributed to placing cloning in a negative light in the public eye during the time period analyzed in the study.

Besides the systematic analysis of media content, Holliman (2004) also conducted production analysis to examine the role of media professionals and the Roslin Institute in producing media coverage, as well as reception analysis (focus group interviews) to investigate audience beliefs, attitudes and behavior. This approach is informed by "the

circuit of mass communication" theoretical perspective, which challenges essentialist views of production and interpretation of media content and moves away from a linear towards circular model of mass communication. Within this methodological framework, the three elements in the process of mass communication (production, content, and reception) are perceived as interconnected, while mass communication is analyzed as a dynamic system that involves four sets of actors (the public, media, social and political institutions, and decision makers) whose interactions influence media coverage in a variety of ways. For example, the analysis of news production conducted by Holliman (2004) clearly illustrated that a range of actors aided media professionals in developing the media template for reporting the ethical controversy created by mammalian cloning. Although media professionals traditionally rely on the scientific community as a major source of science news, media coverage on the issue of cloning was also generated by other actors, such as politicians and officials, other professionals and experts, and activists, and the news value associated with "Dolly the sheep" was renegotiated in response to the developing societal debate.

Furthermore, the reception analysis aimed to test the impact of media coverage on the public attitudes and perceptions of cloning. The study involved twenty-one respondents, categorized as "scientists" and "non-scientists," who completed bulletins about their recollection of the media coverage of the cloning controversy and were asked to share their views regarding cloning. The results revealed that respondents in both categories tended to use references and phrases similar to those that had appeared in the media coverage of the ethical and political debate. Both scientists and non-scientists

associated the topic of cloning primarily with "Dolly the sheep" and discussed it within political and ethical contexts of human cloning, thus reproducing the media template for reporting this scientific development. In conclusion, Holliman (2004) states that although it is unclear whether the respondents' opinions on cloning were exclusively shaped by the media coverage, its significance cannot be ruled out given the similarities between the interviewees' frames of reference and the content of media reports.

Like the two case studies of media coverage discussed above, Pellechia's (1997) longitudinal content analysis of science articles in three major daily U.S. newspapers—*The New York Times*, *The Chicago Tribune*, and *The Washington Post*, highlights the impact of print news media in shaping the public knowledge on controversial scientific developments. Her study covered three different time periods—from 1966 to 1970, from 1976 to 1980, and from 1986 to 1990, and aimed to investigate trends in science news reporting that have occurred over three decades. During that time period, newspapers have become a major source of science news and journalistic accounts of science have helped laypeople develop practical scientific literacy. The longitudinal analysis of articles in three major daily newspapers revealed that "newspaper coverage of science over the last three decades did not differ substantially in terms of the range of topics covered, as well as information that has been both included and omitted from science news accounts" (Pellechia, 1997, p. 59). Although newspapers had provided an important forum for communicating factual scientific information to the public, there was also ample evidence indicating their failure to cover scientific controversies in an accurate and non-biased manner. Moreover, the content analysis showed that articles in all three newspapers over

all time periods results had reported primarily on the findings of scientific research and had frequently omitted both "contextual factors and methodological details" (Pellechia, 1997, p. 61). The study concluded that the lack of rigorous and comprehensive reporting on the process of scientific research had greatly contributed to the low levels of scientific literacy and had subsequently hindered informed and intelligent participation in science policy issues. Therefore, a more contextual approach to science communication would better foster meaningful dialogue between policymakers, scientists, and the general public.

Recent research on media coverage of new developments in biotechnology, biomedicine and the biosciences has clearly shown the ability of news media to frame controversial science and influence, albeit indirectly, public attitudes and perceptions (Kitzinger & Williams, 2005; Marks et al, 2007; Haran & Kitzinger, 2009). The research has also indicated that risk communication to the general public has become a major issue in these fast-changing scientific fields. Over the last decade, applications of biotechnology in agriculture and medicine have received significant public attention and extensive media coverage. The news media have played an important part in swaying public opinion in favor or against different types of research and technologies in the field. A cross-national study of mass media coverage in the United States and the United Kingdom by Marks et al (2007) analyzed and compared media framing of risks and benefits of two sets of biotechnology applications, medical and agricultural, over a twelve year period, between 1989 and 2001. The researchers specifically analyzed whether the media have tended to emphasize potential risks over the societal benefits of these

technologies or vice versa. They also looked at how the media framing affected public attitudes towards the two sets of technologies in both nations. The content analysis of media coverage included three major newspapers—*The London Times*, *The Sunday Times*, and *The Washington Post*. The search generated 750 articles related to biomedical technologies such as human cloning, gene therapy, and xenotransplantation, and 1,251 articles relating to agro-biotechnology coverage, with a focus on issues related to food and environmental safety. Although both types of applications relied on the same genetic engineering techniques, media narratives presented different assessments of potential societal, heath, and environmental benefits and risks. The longitudinal study of framing effects indicated that both the US and UK news media had consistently framed medical applications in a positive light, highlighting the benefits of these technologies to individuals and society as a whole. At the same time, newspaper articles about agricultural applications over the twelve-year period had continuously emphasized the perceived health and environmental risks associated with biotechnology (e.g., value, nutrition, safety and labeling of biotech foods, public safety, and regulatory input). The research data on the benefits-risks ratio was compared to results from national public opinion surveys conducted by the *Eurobarometer* from 1991 to 2002 and International Food Information Council in the United States. Correlations were thus established between the media reports and the general public's perception of the two sets of technology: positive for medical applications and more negative (or ambivalent) for agricultural biotechnology. Although these correlations do not necessarily imply causality, the findings have led the researchers to believe that media framing of

biotechnology had contributed to the formation of public opinion and perception during the period analyzed.

The final argument I consider in this chapter's literature review section concerns the key role of media organizations and media professionals, such as journalists, producers and editors, in the making of modern science. In an article exploring media responses to the high profile case of the South Korean stem cell scientist, Dr. Hwang Woo Suk, Haran and Kitzinger (2009) have suggested that the news media serve not just as a communicator of experts' opinions, but also have the ability to endorse or disallow scientific knowledge claims. The scientific breakthroughs in stem cell research and human cloning announced by Hwang and his team were initially embraced by both the scientific community and the media. These discoveries received significant media attention in South Korea and globally in 2004 and 2005, but were subsequently discredited as fraudulent in scientific publications and media reports in late 2005 and 2006. Haran and Kitzinger (2009) have also examined the rhetorical techniques employed by both the scientific establishment and news media to endorse, and later on repudiate, the work of Hwang. Their analysis utilizes the notion of scientific knowledge as produced through a regulated system of "witnessing," which has become central to the experimental contexts of early scientific discourse. This conceptual framework is greatly influenced by critiques of the realist epistemological paradigm in science, which has continuously constructed the modest scientific witness as a disembodied and disinterested observer (Shapin & Schaffer, 1985; Haraway, 1997). In particular, the work of the feminist critic of science, Donna Haraway, was influential in deconstructing traditional

notions of scientific practice as the pursuit of a disembodied, inviolable and neutral objectivity. Haraway (1997) questions the seminal figure of the modest witness in science by illustrating how women and others with dependent and embodied status had historically been excluded as modest witnesses or legitimate knowers. Rather, the forging of the modern witness through scientific discourse has facilitated efforts by men in the sixteenth and the seventeenth centuries to rewrite masculinity in order to protect science from feminization. Furthermore, Haraway (1997) argues that the presumed modesty in observing scientific phenomena have enabled scientists to uphold illusory visions of a disembodied science and conventional assumptions about scientific discourse as a single, objective and truthful representation of reality.

In order to illustrate the involvement of mass media in the process of scientific discovery and their role as privileged witnesses, Haran and Kitzinger (2009) employ "the modest witness figure as a heuristic lens through which to view the representation of Hwang as the principal actor in this drama, using it to trace implicit assumptions in contemporary representations of "good" scientists and their practices" (p. 635). The focus of their analysis, however, shifts from the centrality of scientific experts in the public communication of science towards the rhetorical work embedded in the communication processes and different communication contexts in which scientific knowledge is presented (e.g., mass media accounts, reports in scientific journals, grant proposals, policy documents, etc.). This conceptual framework of a rather broad spectrum of science communication deconstructs the strict boundary between genuine scientific knowledge and popular representations and can help develop a more nuanced understanding of how

literary and visual mediation shape the production of scientific knowledge in the public domain. It is also important to acknowledge the socio-political context of the stem cell research landscape which facilitated reception and interest in the work of the South Korean scientist by the research community and the general public. Hwang's discoveries took place at a time when the potential of the field was still questioned and results were much anticipated by both stem cell researchers and advocates of embryo research. The breakthroughs thus provided a golden opportunity for supporters of embryonic stem cell research to enlist continuous public support and financial investment. Subsequently, Hwang's announcement that his team had cloned the world's first human embryonic stem cell line was initially validated by the scientific establishment by being published in a prestigious peer-reviewed journal such as *Science*. His breakthroughs were also categorized as remarkable by the same publication and leading stem cell experts.

Haran and Kitzinger (2009) have traced shifts in rhetoric in media reports, coverage of events in the leading journals *Science* and *Nature* (2004–2006), and press releases from relevant UK and US government or science bodies to illustrate how representations of the Hwang case mutated from a story about genuine scientific breakthroughs to a scandal about fraud. Both the scientific establishment and news media clearly endorsed Hwang's work as a genuine scientific achievement in the period between early 2004 and late 2005. The authors have observed the deployment of the following rhetorical techniques to validate the breakthroughs: 1) "explicit assertions of Hwang's status as a *bona fide* scientist"; 2) "a range of declarations about the virtual witnessing of his work"; 3) "an emphasis on his international renown and

collaborations"; and 4) "a body language of representation designed to invoke confidence" (p. 640). After the scandal occurred in late 2005, the coverage quickly changed to stories emphasizing the Korean scientist and his research as inauthentic. While the initial representations showed Hwang as a genuine and humble scientist, who performed well the role of "modest witness," news reports after the exposure seemed to highlight his media profile, arrogance and delusions of grandeur. The most common rhetorical strategies, which enabled the news media to recast Hwang, included: 1) "reframing his claims as immodest and grandiose"; 2) "expelling Hwang from the community of modest witnesses"; 3) "orientalizing him and South Korea"; 4) "focusing in on his celebrity/"rock star" reputation"; and 5) "metaphorically repositioning his trajectory into the fictional genre" (Haran & Kitzinger, 2009, p. 643). The change in rhetoric was accompanied by a retrospective acknowledgement of the role of scientists and journalists in the mediation of events which was missing in the initial coverage. Nonetheless, the recasting of Hwang re-assigned the problem to the world of celebrity scientists and fictional genres and narratives, thus taking the responsibility away from news reporting and traditional science-media relations. As Haran and Kitzinger (2009) have indicated, during the scandal "attention was drawn to Hwang's courtship of the media [and] accounts of the original breakthrough press conferences were rewritten to highlight Hwang's celebrity-like behavior" (p. 645). Both scientists and journalists, however, were more interested in re-establishing their own position as truth tellers, rather than acknowledging the interdependency between science and media. Ultimately, the media coverage of the Hwang case has demonstrated the ways in which the media

becomes implicated in fabricating scientific truth and falsehood, as well as how "scientists and science journalists routinely disavow the media's intimate involvement in the making of "true science," but retrospectively scapegoat the media in the fabrication of "false science" (Haran & Kitzinger, 2009, p. 650).

The review of scholarly analyses presented above convincingly supports the argument about the key role of mass media in the public communication of scientific controversies. In the following pages, I will explore specific frames utilized by print and news media in the US and the EU to report the stem cell debate. I aim to highlight how news reporting has contributed to setting the agenda for public debate and has influenced public responses to the ethical and societal challenges presented by the stem cell technologies.

Media Framing of the Stem Cell Debate

Frames are routinely used in news reporting to call attention to some aspects of reality while obscuring other elements. The concept of "framing" emphasizes that the presentation of specific topics, facts, controversies, actors, and assertions is always selective. Entman (1993) points out that "to frame is to select some aspects of a perceived reality and make them more salient in a communicating text, in such a way as to promote a particular problem definition, causal interpretation, moral evaluation, and/or treatment recommendation" (p. 52). While rhetorical strategies and framing devices used by writers, editors, and journalists can provide a context to understand issues, they may also significantly influence the audiences' perceptions and limit the range of interpretations on the issues at stake. In their analysis of the U.S. press coverage of the early stem cell

debate, Nisbet et al. (2003) have indicated this ability of the news media to shape public opinions on a wide array of subjects by "framing" a discussion in a manner that garners the greatest amount of public support. They have also argued that, once an issue has been framed by the media in a particular light, public perception tends to remain stable over time. A common framing device for capturing the attention of the public is presenting news in dramatic storyline types of narratives. Media organizations often dramatize news to increase their audience share. This way of coverage usually receives the greatest amount of public interest, although the dramatization of events can potentially turn the audience's attention away from more complex and contextual information on the issue which enables people to make informed opinions (Nisbet at al., 2003). Similarly, Friedman et al. (1999) have shown that most scientific news reports are routinely framed through the use of images, concepts and vocabulary that would make the information "interesting, relevant and comprehensible for audiences" (p. 52).

Media coverage of the stem cell controversy is no exception to the tendency of using frames and dramatic storytelling to communicate science to the general public. Both sides in the controversy have used dramatic narratives to frame the issue according to their desirable policy outcomes and in ways that would help them garner the necessary public support. Nisbet et al. (2003) have indicated that opponents of hESC research in the U.S. have relied on media coverage to emphasize the ethically controversial nature of this biomedical innovation. Their descriptions of ethical implications heavily relied on arguments about "playing God," references to Dr. Frankenstein, Faustian bargains, and the Nazi human experimentations, as well as "adjectives such as *evil*, *murderous*, or

gruesome" (Nisbet et al., 2003, p. 44). By contrast, stem cell research activists have striven to portray their opponents as religious fanatics with backward, unjustified beliefs that were generally opposed to scientific progress. As Nisbet et al. (2003) have argued, "if on one side of the debate was the image of a mad scientist experimenting on human embryos, on the other side was the notion of a religious zealot impeding scientific and social progress" (p. 44). These dramatic representations have contributed to pushing stem cell research to the top of the U.S. media agenda.

Framing the stem cell controversy in terms of binary oppositions and through dramatic narratives was by no means limited to the press and TV news coverage. Public and policy debates on hESC research in America have similarly focused on dramatic representations, emphasizing the assumed conflict and polarization between science and morality. The terminology, utilized by bioethicists, scientists, politicians, and advocacy groups in deliberations over the ethical and policy issues arising from stem cell technology, reflects such divisions. On the one hand, opponents have often intended to provoke strong emotional reactions in the public by using emotionally-laden words such as "embryonic human life," "embryo-killing research," "stem cells obtained by killing human embryos," "brave new babies," and "the unprotected subjects of biomedical research." On the other hand, stem cell research advocates have frequently tended to avoid difficult ethical questions by adopting a rather neutral scientific and technical jargon and using phrases such as "blastocyst," "pluripotent stem cell research," "stem cells derived from the inner mass of blastocyst." Moreover, as Kitzinger and Williams (2005) have indicated in their analysis of the UK media coverage of the stem cell debate,

stem cell advocates consistently used the terms "pre-embryo" and "blastocyst," rather than human embryo, thus questioning the human status of pre-implantation embryos used in stem cell research. Maienschein (2003b) has suggested that a public consensus on how to regulate and fund regenerative medicine in the US was hindered by this representation of scientific knowledge and ethics as a strict binary opposition. She has also argued that policy decisions regarding stem cell research should be based on "the best available current science and the best moral thinking—and in the knowledge that science and morality are not intrinsically at odds" (2003b, p. 301).

This high level of dramatization in media coverage, which was accompanied by an extreme polarization of public opinion over the morality of hESC research, was not a singular characteristic of American public discourse. Similar trends in media representation and public opinion were observed in most EU member states which had held parliamentary and public debates over the regulation and funding of stem cell research and regenerative medicine. A number of scholars have suggested that news coverage in both US and EU contexts simply mirrored the nature of the debate as it had unfolded in legislative and public forums (Nisbet et al., 2003; Nisbet, 2004a; Nisbet, 2004b; Kitzinger & Williams, 2005; Shepherd et al., 2007). For instance, Nisbet (2004a) has shown that media coverage on the issue of stem cell research in the U.S. until 1998 had focused exclusively on new scientific discoveries and background information. It was only after the summer of 2001, when the federal ban on funding for newly created hESC was announced, that moral and strategic framing replaced the previous reporting in scientific and technical frames, and agenda-building activities significantly increased.

Moreover, the topic of stem cell research did not receive any substantial media attention prior to entering the overtly political arenas of the U.S. Congress and the White House, which are more open to a greater diversity of interest group involvement. Debates within these forums draw the attention of the general public and are often resolved by appeal to morality, rather than instrumental or rational values. Nisbet et al. (2003) have claimed that the close attention given to the stem cell controversy within the overtly political arenas of policy making over an extended period of time has contributed to maximizing its potential to be framed in dramatic terms. This explains why stem cell research ranked so high on the overall media agenda and received unprecedented coverage when compared to any other controversial development in biotechnology. Deliberations over biomedical research protocols in the U.S. have traditionally been contained within the administrative policy arena, i.e. NIH, DHHS, and FDA, where the policies are decided by scientific and technical experts, often without input from interest groups and the general public. The stem cell controversy constituted an exception from this tradition of insular decision making on techno-scientific issues.

Similarly, Kitzinger and Williams (2005) have argued that the UK media discourse addressing stem cell research had simply reflected the nature of the debate as it had been presented in the parliamentary arena and the lobbying process. Rather than being critical of the major terms in which the debate had been framed, journalists presented the controversy as a strict binary opposition with little room for cautious optimism. Their analysis covered the period between 2000 and 2001, when the so-called "Donaldson report" on the issue of hESC research received significant public attention

and became the subject of increased press and TV coverage in the United Kingdom. The report "Stem Cell Research: Medical Progress with Responsibility" was released in the summer of 2000 and included recommendations on stem cell research policy by an expert group, which was led by the chief medical officer, Liam Donaldson. These policy recommendations provided the basis for the HFEA (Research Purposes) Regulations of 2001 and were passed by the House of Commons on December 19 that same year. The UK Parliamentary vote in favor of hESC research, however, became the subject of intense debates not only in the country but also in the EU and received strong criticism by the German government and press (Kitzinger & Williams, 2005). On December 21, the *Daily Mail* published a press release by their foreign service in Berlin which included a statement by the German Chancellor that the German scientific community was opposed to ending the ban on experiments with embryonic stem cells prior to exploring the full potential of adult stem cells. Drawing on the sociology of expectations, Kitzinger and Williams (2005) highlight and contextualize the different rhetorical techniques used by proponents and opponents of hESC to speculate about potential societal risks and benefits in the future. They claim that, although two competing visions about the future of stem cell research have informed the public discourse in UK, the media has validated utopian hopes as more credible than dystopian fears about the societal impact of biotechnology. On the one hand, supporters emphasized the potential of regenerative medicine to free the world from sickness and disease and presented this biomedical innovation as "the start of a medical revolution," "the dawn of a new frontier," and the "key to unlocking a new chapter in medicine" (Kitzinger & Williams, 2005, p. 125). On the other hand, opponents

of the Donaldson's report claimed that support for embryo research would only set dangerous precedents for demeaning human life and for reproductive cloning. Embryonic stem cell research was subsequently characterized as "a huge leap in the wrong direction for mankind" and "a dangerous and slippery path" which will "open the floodgates" (Kitzinger & Williams, 2005, p. 125). While the opponents consistently referred to the technology of cell nuclear replacement (CNR) as "human cloning" in order to invoke visions of full reproductive cloning in relation to stem cell research, supporters were keen on using the term "therapeutic cloning," which emphasized the potential clinical benefits. Furthermore, supporters also avoided references to CNR as "experimental medical research" since it did not carry the same positive connotations (Kitzinger & Williams, 2005).

In both UK and US stem cell debates, traditional ways of claiming legitimacy were combined with more emotive discourses about social and family networks, as well as calls for compassion for the people suffering from degenerative diseases. It was by no means surprising that the bulk of media and public discussions revolved around key terms such as hope and potential, and that the human embryo was re-inscribed in the stem cell debate not as an entity of its own right, but rather as "a beacon of hope for the sick" (Kitzinger & Williams, 2005, p. 30). The concept of hope also became central to efforts by stem cell proponents to validate scientific claims and mandate action. As Franklin (2008) has indicated, the post-IVF reproductive "revolution" has not only constructed the interior of the stem cell as the new frontier of scientific exploration, but has also led to "an emergent, and more collectivized, form of 'reproductive hope' directed at finding

cures for disease by harnessing the special reproductive power of embryonic cells" (p. 13). Developing treatments for degenerative conditions has thus become a primary target of the "hope economy" (Franklin, 2003). This new hope economy has thrived on media representations of personalized accounts of patients. This tendency was explicit in the UK public discourse around the time of the Donaldson report, when supporters have heavily relied on such narratives to emphasize that the potential benefits of hESC for socially embedded "real" people vis-a-vis the ethical defenses of "abstract" embryos raised by their opponents (Kitzinger & Williams, 2005). The notion of stem cell research offering "real hope" has also become a key rhetorical strategy in American public discourse. *Life is for the Living* (2008), an award-winning documentary film about stem cell research, is a good example of media narratives shifting the focus away from the embryo's moral status by highlighting the patients' voices as central in the ethical debate. The storyline of the movie focuses on the personal stories of five American families, whose daily experiences are deeply affected by degenerative conditions such as juvenile diabetes, Parkinson's, and spinal cord injuries. The national debate on hESC research is deconstructed through the lens of three generations and their testimonies of personal suffering, frustration with President Bush's restrictive federal policy, and expectations that more funding for embryonic research will result in groundbreaking treatments for these fatal medical conditions. The film includes an introduction by the CBS newsman Mike Wallace, as well as interviews with leading stem cell researchers, political leaders, and advocates, emphasizing the "real" hope for curing disease brought by stem cell research.

In order to construct the "right" point of view, media accounts in the UK have tended to depict the stem cell controversy as a conflict between rationality and emotion, where factual evidence presented by scientists stands at odds with fictional representations utilized by opponents of embryo research (Kitzinger & Williams, 2005). Journalistic accounts in the U.S. have similarly framed the issue as a conflict arising from the inevitable clash between modern science and religious dogma. As Nancy Gibbs points out in her article in *Time Magazine*, "Stem cell research has joined global warming and evolution science as fields in which the very facts are put to a vote, a public spectacle in which data wrestles dogma" (2006, p. 28). In order to legitimize the pro-stem cell position, journalists have not hesitated to characterize stem cell research as "frontier science" (Gibbs, 2006). They have also implicitly supported efforts by proponents to monopolize rationality, realism and expertise by discrediting their opponents as backwards and even Luddites. As Kitzinger and Williams (2005) have argued, in the UK explicit references to science fiction were hardly used by critics of hESC research, however, Donaldson supporters have attributed such claims to their opponents in order to discredit their position. Furthermore, media coverage in both countries has emphasized the unity within the scientific community regarding the greater clinical potential of embryonic vis-à-vis adult stem cells and the need to aggressively pursue both alternatives in order to develop new therapeutic solutions for degenerative conditions.

In Italy, however, the media have succeeded in presenting the scientific community as equally divided on the question of whether adult stem cells hold the same potential for regenerative medicine as their embryonic counterparts (Cattaneo, 2008;

Gorbellini, 2006). The country held a referendum in 2005 to repeal a rather conservative law on assisted reproductive technologies and regenerative medicine (Law 40, February 19, 2004) which aimed to limit access of infertile couples to in-vitro fertilization procedures and outlawed procedures such as oocyte and sperm donation, cryopreservation of embryos, pre-implantation genetic diagnosis (PGD), as well as human embryo research. Although most Italians who went to vote supported the repealing of the law and the legalization of research on embryonic stem cells, the referendum was eventually invalidated since the voters' turnout was well below the 51% quorum required by the Italian constitution. The low turnout seems surprising when compared to the results of a 2006 Eurobarometer survey which showed that over 60% of Italians approve research on embryonic stem cells (Cattaneo, 2008). Advocates for embryonic stem cell research in Italy have largely blamed this failure on the media's complicity with efforts by the Catholic political milieu to misrepresent, similarly to the Bush administration in the U.S., the therapeutic superiority of stem cells derived from embryonic sources and convince the public that there was a widespread dissent within the scientific community on the issue (Massarenti, 2008). Political commentators have also explained the failure of the referendum with a current standstill or even a reversal of the process of secularization in Italy, which is presently one of the most religious EU member states (with only 6% atheists), and its political elites continue to maintain close ties with the Catholic Church hierarchies (Gorbellini, 2006). It is important to note that these analyses of the socio-political context for assisted reproductive technologies in Italy implicitly support the argument that media representations of the stem cell controversy in

most EU countries have often failed to deconstruct the dominant terms of stem cell debates held in legislative and public forums.

Moreover, the cross-cultural analysis of metaphoric schematization of embryonic stem cell research in France and Poland, conducted by Döring and Zinken (2009), indicated that fundamental differences in socio-cultural contexts and regulatory approaches do not necessarily translate into divergent metaphorical imageries and discursive repertoires used to conceptualize the controversy. Their analysis included articles published in the major newspapers of France and Poland, *Le Monde* and *Gazeta Wyborcza*, during the years 1998-2000, and aimed to assess whether the press coverage of the issue relied on cross-culturally shared or culture-specific networks of metaphors. In addition, the authors looked at how the initial schematization of stem cell research has contributed to shaping either convergent or divergent stem cell discourses. Although it was initially expected that the coverage on the issue would reflect the cultural differences between the two countries, particularly with regard to the role of religious values in public debates, the analysis showed surprising similarity in metaphorical frameworks for hESC research that had been utilized by the Polish and French media. Döring and Zinken (2009) have pointed out that both national discourses reflected a salient rational perspective on the potential of stem cell research to develop innovative treatments for degenerative diseases, which "underlines the potential of SCR of increasing human agency in addressing the 'limited durability' of the human body" (p. 27). When differences between the Polish and French discourses could be be detected, they seemed to be the result of contextual dissimilarities, such as the reliance of French news coverage

on a previously established bioethical tradition which had been largely shaped by the rationalism of the 18th century Enlightenment thought vis-à-vis the more emotive frames of reference (i.e., references to mad scientists and Frankensteinian monsters), which characterized the early coverage in the *Gazeta Wyborcza*. Therefore, Döring and Zinken (2009) have concluded that there were commonalities across languages in the discursive matrices and metaphorical networks shaping hESC research in the EU, and that differences could be explained "not in the sense of national cultures, but rather of 'ethical cultures' based in ideologically defined groups" (p. 27).

Science, Mass Media and the Public Sphere

In Western democracies, interests groups, advocacy organizations and social movements are agents of political communication and social change and social advocacy nowadays constitutes an essential component of democracy and civil society. As Rawnsley (2005) points out, developing good relationships with the media is very important for these groups, and therefore, many have professionalized their efforts to generate publicity by producing their own videos and distributing them to news organizations. Groups that are outsiders to the policy making and legislative process are dependent on the news media to appeal to public opinion and influence the policymaking communities. Nowadays most interest groups use the services of lobbying consultants in order to professionalize their PR and media campaigns. Rawnsley (2005) argues that professional lobbying is generally an American phenomenon, with over 16,000 lobbyists currently registered with Congress, compared to less than 200 in 1945. The major reasons for lobbyists being particularly effective in Washington are "the weak party structure of

the American political system, the divisions between legislative and executive, the strong committee system within Congress, the federal system of political organization, and the importance of financial contributions to Political Action Committees (PAC)" (Rawnsley, 2005, p. 107). The direct impact of lobbyists and interest groups on individual politicians, however, is significantly minimized in Britain, where there is stronger party structure and discipline, and the executive operates from within the UK Parliament (Rawnsley, 2005).

In his book *Endless Propaganda: The Advertising of Public Goods*, Rutherford (2000) has argued that civic advocacy, and most specifically, its television version, has presently become the most prominent example of propaganda practices in the affluent countries. The increasing marketing of 'public goods' as commodities in America and elsewhere undermines the rational-critical discourse of the public sphere and transforms contemporary mass democracies into "marketplaces of democracy." As Rutherford (2000) has characterized this novel type of propaganda,

> Since 1965, this type of adverting has become, increasingly and ordinarily, the chief mode of propaganda throughout the affluent world. The barrage of propaganda encompasses many different types: PSAs [public service announcements], government ads, charity appeals, corporate image campaigns, issue advertising, many religious messages, social ads, political spots, counter-ads, and cause-related publicity. Its chief sponsors are the state, the corporations, and voluntary associations, variously known as non-profits or non-governmental organizations, although in theory anyone with sufficient money—such as a Ross Perot—can publish or air advocacy, always assuming the compliance of the

> media. At the bottom, the prominence of civic advocacy reflects one of the attributes of postmodern culture: the ubiquity of publicity. (pp. 8-9)

The rise and further expansion of civic advocacy in the domain of political and public communication is considered to be essentially a postmodern phenomenon, associated with the "market revival" of America and the general growth in advertising expenditure in the aftermath of the World War II years (Rutherford, 2000). This type of political marketing has invaded the public sphere of the affluent countries and is currently instrumental in shaping our individual and collective identities. Propaganda is a term that does not lend itself to easy definition, as there is a whole range of cognate terms commonly used as substitutes, i.e. manipulative publicity, mass persuasion, public opinion management, etc. It is is a totalizing and essentially contested concept that has often been conflated with other forms of mass persuasion such as advertising and public relations, with which it shares common techniques. For instance, Pratkanis and Aronson (1991) have employed the term in a general sense to describe "the mass persuasion techniques that have come to characterize our postindustrial society" (p. 9), thus overlooking its complex political implications. By contrast, Rutherford (2000) argues that what makes communication different from other types of publicity is its overt political nature; advertising as propaganda is "both the language and the instrument of power" and "constitutes an intentional and sponsored message, a deliberate kind of 'symbolic practice' that seeks to persuade the body politic, or some significant constituency within the public sphere" (p. 9). Moreover, it seeks to change peoples' attitudes and behavior, but also to construct a model person. The effects of propaganda extend beyond setting the

agenda for public debate, and can also "prime discussion (determine what criteria are used to assess a person or issue), excite controversy (where news outlets take different stands), or generate support (where the media elaborate its message)," with the final outcome being "productive-of comment, argument, and discourse" (Rutherford, 2000, p. 268).

It is important to consider whether the marketing of public goods could contribute to promoting the public good, rather than just being a new brand of propaganda that effectively manipulates the public by "attaching" social and moral values to issues that serve private group interests. While some believe that civic advocacy advertising can bring numerous societal benefits, i.e., a drug-free society, social justice and equality, peace and prosperity, clean environment, better public health, safe neighborhoods, etc., there are also concerns that, similar to other types of promotional and public relations activities, it can deceptively manipulate individuals, control public opinion, and even stifle a rational critical public debate. In this sense, civic advocacy as propaganda falls into the category of "manipulative publicity" which Habermas (1991a) has critically discussed in his book *The Structural Transformation of the Public Sphere* (first published in 1962). He has argued that the misuse of publicity undermines the bourgeois public sphere in its "pristine form" of rational-critical discourse. Furthermore, it transforms politics into a theatrical performance where "even arguments are transmitted into symbols to which again one cannot respond by arguing but only by identifying with themselves" (Habermas, 1991a, p. 206). In a "mass-media dominated public sphere," political marketing sets the public agenda, determines views, favors a "staged display,"

and conveys "authorized opinions" in order to "display external unity" of political parties and organizations (Habermas, 1991a, p. 205, 216) . In his 1973 essay on the public sphere, Habermas (1991b) has claimed that the weakening of the public sphere is in principle opposed by "a welfare-state transformation of the functioning of basic rights: the requirement of publicness is extended from the organs of the state to all organizations acting in a state-related fashion" (p. 404). He has suggested that the extension of this mandate for publicity preserves the continuity with the liberal constitutional state and determines to a great extent whether the public sphere of civil society would be dominated by a public of organized private people or a public of private people dealing with each other individually. Under the existing conditions of a state committed to social rights, civic organizations can only participate effectively in a process of public communication on the basis of publicness enforced for the dealings of the organizations with the state and with one another. In *Structural Transformation*, Habermas (1991a) has indicated two competing tendencies in the transition from the liberal constitutional state to the social-welfare state—a "*critical* process of public communication through the very organizations which mediatize it" which counters "publicity merely staged for manipulative ends" (p. 232). While I will discuss the concept of the public sphere in greater detail in the next chapter, it is important to highlight this distinction when addressing the issue of how competing discourses on the societal implications of hESC research should be treated by the mass media.

The question of whether the marketing of public goods is further contributing to the transformation the public sphere into a mere "platform for advertising" or, rather,

institutes a rational-critical public debate over issues of common concern is particularly relevant to the stem cell controversy since social advocacy has largely shaped media debates and influenced discussions in other public forums. As I have illustrated in the previous section, media coverage in both US and EU contexts has emphasized the perceived benefits of stem cell research, with a new economy of hope emerging around expectations that human embryonic stem cells constitute a tool that will unravel the mechanisms of disease and enable the development of novel treatments for degenerative conditions. In this sense, hESC research has been embraced and imagined by social groups (e.g. scientific organizations, patient associations, stem cell research coalitions, etc.) as a pure public good. By contrast, opponents of embryo research have contested and deconstructed contingencies and futures envisioned for regenerative medicine. Anti-stem cell advocacy has largely focused on the marketing of social risks associated with the emancipation of hESC research from moral and ethical constraints. Rhetorical strategies have significantly varied: from "slippery slope" arguments to warnings about the fallacy of scientism (e.g. the notion that science is a law in itself and the search for scientific truth is a pure public good), from critiques of the "liberal culture of death" to claims about embryo research as way to legitimize abortion as a public good. A good example of "re-branding" hESC research as abortion is a statement by Scott Klusendorf, Bio-Ethics Director of *Stand to Reason*, an American organization which trains Christian ambassadors for public activism in the US, Canada and globally:

> There is evidence that ESCR (and fetal tissue harvesting in general) could enhance abortion's image as a moral good. At a minimum, it will convince some

> women that killing their unborn offspring redeems a desperate situation. While ESCR may not dramatically increase abortion rates among women not inclined to abort (pro-life advocates must be careful to not overstate their case here), it could influence those who are undecided. Research shows tremendous ambivalence among women facing crisis pregnancy, with many suffering intense anxiety in the 24 hours before the abortion. The prospect of "redeeming the abortion" to provide tissue for someone else throws a powerful motivation into a psychologically complex situation. (Klusendorf, 2008, ¶14)

Attempts on both sides to make and re-make the facts surrounding stem cell research have relied on the complicity of mass media in order to set the stage for public debate and participation and influence decision-making outcomes.

In the field of science communication, the mass media have been increasingly viewed as a key factor for the legitimation of science due to their ability to facilitate and institutionalize communicative interactions between members of the public, scientific community, policymakers, interests groups, and other social actors. In their comparative analysis of genome sequencing in German and US media between 1999 and 2001, Gerhards and Schäfer (2009) have identified two normative models in the scholarly literature that are used to conceptualize the role of science in public discourse: the "science-dominated scientific public sphere" and the "contextualized scientific public sphere" (p. 438). These two models set out different normative expectations for mass media as a communicator of scientific knowledge, but also as an interpreter of new and controversial science. The first ideal-type model, the science-dominated scientific public

sphere, is derived from the infamous "public understanding of science" (PUS) paradigm which was dominant in the 1980s. The key assumptions that underlie this "deficit model" of science communication are: 1) the notion of scientific knowledge as superior to other forms of knowledge, and 2) the perceived deficiencies in scientific literacy of the general public. Subsequently, there is added expectation that mass media should be improving scientific literacy and that their reporting of science should accurately reflect the scientific discourse. By contrast, the second model, which has been advanced in the scholarly literature, deconstructs assumptions about the special epistemological status of scientific knowledge and suggests a more contextual approach to the public communication of science. This notion of a contextualized scientific public sphere requires accepting that "science is only one source of knowledge among many, and the experiences of citizens and non-scientific actors are accepted as equally relevant" (Gerhards & Schäfer, 2009, p. 440). Furthermore, science depends on society's legitimation and therefore decisions regarding policies and regulation should involve extended public negotiations and participation of diverse actors. While the first model emphasizes the role of mass media as the primary channel of science communication, the contextualized approach encourages debates in a variety of public forums, i.e. consensus conferences, workshops, roundtable discussions, etc. The two normative models of the scientific public sphere set out different standards for media coverage of scientific issues. The science-dominated approach requires that media reporting provides an abundant amount of information on scientific research and events, often with the unstated goal of educating the public. Moreover, media debate should be dominated by scientific and

technical experts and should exclude non-scientific interpretations on the issues at hand. There are expectations that science should be represented in a positive light, rather than through a critical lens. The contextualized model associated with the public engagement with science and technology (PEST) paradigm, on the other hand, establishes different standards for media discourse on scientific issues. First, it requires that media reporting is not limited to scientific events and debates that originate within the scientific community. Second, rather than serving as an advocate for science, mass media is expected to provide a critical reflection on competing perspectives within society. Finally, there is an expectation for a more inclusive debate that would engage diverse social actors and citizens' groups and achieve "an evaluation and interpretation of science which is similarly pluralistic and potentially controversial" (Gerhards & Schäfer, 2009, p. 441).

Conclusions

In conclusion, it is worth using the two normative models outlined above to evaluate the type of media coverage that stem cell research has received in a comparative US-EU context. Regardless of the divergent regulatory approaches to this scientific innovation in these political entities, the literature review conducted in the chapter has clearly indicated striking similarities in framing devices and rhetorical strategies utilized by news organizations to report the controversy. Given that in recent years there has been a greater emphasis on more contextualized media coverage on controversial science, specifically within the context of science and technology studies (STS) and critical approaches to the public understanding of science, my assessment will focus on the standards for public communication of science set out by the contextualized normative

model. Therefore, I will look at whether the media coverage of hESC research has met the three major criteria for a contextualized, critical public discourse on scientific issues. Media discourses on stem cell research in both the US and the EU have clearly reflected the first condition for contextualization. As it was previously discussed, media reporting of the controversy was by no means limited to scientific developments and events; rather, the issue received significant media attention only when it reached the political, social, religious and moral arenas of society. Not only did media coverage of scientific facts related to hESC research become tightly enmeshed with popular discourses, but mass media also assumed an active role in the making of stem cell science in the public domain. In his article "The dominant view of popularization: Conceptual problems, political uses," Hilgartner (1990) has conceptualized this transition from the "expertise" of scientists towards the situatedness of scientific knowledge-making within diverse communication contexts and media of communication. He has argued that "when one looks carefully for the *precise location* of the boundary between genuine scientific knowledge and popularized representations, one runs into trouble, stemming from the fact that scientific knowledge is presented in many contexts" (Hilgartner, 1990, p. 524).

Media discourses on hESC research, however, have often failed to meet normative expectations about the democratization of public discussions on scientific issues. An underlying assumption of the contextualized approach to media reporting of science is that "scientific actors have no privileged status in the public sphere [and] actors from other areas of society and citizens' representatives should be equally well represented" (Gerhards & Schäfer, 2009, p. 442). As Haran and Kitzinger (2009) have

concluded in their analysis of media coverage of the Hwang controversy, the news media have failed to deconstruct traditional media-science relations and have thus become implicated, together with the scientific establishment, in fabricating scientific truth and falsehood. Moreover, scientists and science journalists have retained privileged status as communicators and negotiators of scientific claims in the public sphere by disallowing the involvement of media and other actors in the making of genuine science.

Finally, the literature review conducted in this chapter suggests that media discourses addressing the stem cell controversy in both the US and the EU did not pass the requirement for instigating a rational-critical public debate on the issue. Rather than deconstructing the major terms in which the debate was framed by stem cell advocates and their opponents, the news media simply followed discussions in political and legislative arenas which had presented the controversy as a strict binary opposition. In addition, science reporters and other media professionals did little to encourage critical reflection on scientific and rhetorical claims regarding the future of stem cell research and regenerative medicine.

CHAPTER 5

THE BIOPOLITICS OF STEM CELL RESEARCH

In his essay "Are There Metaphysical Answers to the Question: What is the "Good Life"?," Habermas (2003) argues that "the new technologies make a public discourse on the right understanding of cultural forms of life in general an urgent matter [and therefore] philosophers no longer have any good reasons for leaving such a dispute to biologists and engineers intoxicated by science fiction" (p. 15). Critical reflection is necessitated by the potential of biotechnology and genetic engineering to alter essential elements of the human situation, and thus undermine our normative self-understanding as moral persons. The vital questions which arise from the technologies of human genetic modification are not like any other moral dilemma. These are moral questions of a radically different nature, as they touch on the ethical self-understanding of humanity. A similar line of ethical reasoning is deployed by Cole-Turner (2003) in an article, titled "Religion Meets Research," which argues that the most recent technologies of the embryo, such as stem cell research and human cloning, have necessitated a reconsideration of religious perspectives on the meaning and ethics of the embryo. Advancements in reproductive technologies have allowed the creation of human embryos by means of somatic cell nuclear transfer, rather than through the process of fertilization, in which the fusion of an egg and sperm results in the creation of a novel genetic combination. This possibility raises ethical concerns about the capacity of these new types of embryos to become human life, as well as practical considerations, i.e. whether these entities are due the same respect we accord to the fertilized embryo. Both religious

and non-religious persons share the belief that human embryos are inherently valuable due to their potential to become actual human beings. The key question posed by Cole-Turner (2003) is to what extent the moral and ontological significance of nascent human life is defined by the particular technology used to create such life, especially when different methods of producing human embryos warrant different potential for further development. Moreover, assisted reproductive technologies have provided easy access to a large number of human embryos and their genetic material. The intersection of these embryo technologies with the techniques of inheritable genetic modification opens up the possibility of engineering the evolution of the human species. The question of the embryo's moral and legal status thus becomes inevitably intertwined with philosophical debates on the future of human self-modification. As Cole-Turner (2003) points out, the debate is not just about whether the embryo is a cluster of cells or a fully-fledged human being but it is "nothing less than the question of the species [since] embryo modification will become species modification, with the embryo as the point of access" (p. 12). Therefore, it is essential that we achieve a greater moral understanding of embryo technologies and a political capacity to regulate and guide their use.

Regardless of how problematic the notion of a stable biological identity as a defining quality of the humankind may seem to transhumanists and the like, the overarching concern is that science has provided us with the means to modify and manipulate the very biological foundations of human nature. This concern is well articulated by Hayes (2007) who claims that "the ability to manipulate human nature—in effect, to make the agent of change an object of change—destabilizes both the biological

and the social foundations of the human world" (¶ 5). Although the creation of genetically modified human embryos has been technically possible for the last several decades, no known attempts had been made prior to 2008 when researchers at Cornell University in New York announced that they have altered the genes of a human embryo (Center for Genetics and Society, 2008). It is by no means surprising that the engineering of the world's first genetically modified human embryo was considered a transgression of ethical boundaries and reinvigorated discussions about designer babies. It also prompted many scientists to call for an international moratorium on the creation of GM human embryos until holding public consultations and policy deliberations on biotechnology applications that are socially dangerous (Center for Genetics and Society, 2008).

In this chapter I explore key concepts in contemporary social and political thought, such as public sphere, discourse ethics, biopolitics, and risk society which can allow us to tackle vital political issues arising from stem cell technologies and their intersections with the technologies of the embryo and inheritable genetic modification (i.e. pre-implantation genetic diagnosis). I argue that both utopian and dystopian visions that have informed the public discourse on hESC research have linked this biomedical innovation to developments in genetic engineering and the biosciences that make possible the enhancement and self-modification of the human species. Moreover, policy debates on stem cell research worldwide have often become inextricably linked to ethical considerations regarding the deployment of related biotechnology applications for the common good. Similar to scientific controversies such as human cloning and assisted human reproduction, hESC research has been subjected to increased public scrutiny since

the issue was debated as being about defining and protecting life, and ultimately, about the potential of science to reshape human nature, whether for the better or worse. In order to achieve a better understanding of the biopolitics of hESC research, we need to deconstruct future-oriented discourse on the issue and examine the impact of both utopian bio-futurism and dystopian visions of biotechnological possibilities on the processes of public opinion formation in the public sphere. This chapter therefore suggests a critical analysis of notions of biopolitics, public sphere, and risk society, which can provide an analytical lens to examine policy debates and political mobilizations around the issue of embryonic stem cells in the United States and the European Union. I aim to examine how this biomedical innovation is embraced or contested as a public good through competing moral rhetorics, ethical vocabularies and political interventions. Collective mobilizations around the issue of hESC research undoubtedly reflect the rise of biopolitics as indispensable to modern practices of government and the profound effects of biopower as a modality of political control that regulates social life from its interior. At the same time, the unprecedented level of social activism on this biopolitical issue indicates a growing public awareness about the social ramifications of biopolitics.

Foucault's writings on sovereignty, governmentality and biopolitics, which have become widely influential in contemporary social and political thought, can shed light on the stem cell controversy since these theoretical reflections emphasize the link between paradigmatic shifts in the biosciences and biomedicine and the production of political rationalities and social practices. Post-Foucauldian scholars have suggested that "the theoretical urgency surrounding the question of biopolitics is both a response to, and

responsive to, the growing importance of the life sciences within the political and economic context of late capitalism" (Cooper, 2005, ¶ 5). In his examination of contemporary manifestations of biopower and biopolitics, Lazzarato (2004) has argued that the biosciences have constituted the major terrain of experimentation for the new revolutions of capitalism. While in his late work on biopolitics and governmentality, and more specifically, the seminars delivered at the Collège de France in the 1970's, Foucault (2003, 2007, 2008) examined in a systematic way the practices and theories of the life sciences and their cognate disciplines, more recent philosophers of biopolitics have tended to overlook this problematic. Articulating such links between political power and the biological was central to Foucault's project to write a history of the present, as well as to his critique of "the biopolitical state" of the twentieth century. Therefore, Cooper (2005) has concluded that revisiting the original conceptualization of biopolitics "necessitates paying more sustained attention to the transformations at work in the practices and paradigms of contemporary biology" (¶ 5).

Habermas's normative notion of the public sphere as part of social life, where public opinion on issues of common political concern can be formed, provides an analytical framework to consider whether regulatory responses to human embryonic stem cell research have reflected a consensus on the ethical dilemmas achieved through a rational-critical, public debate. *The Structural Transformation of the Public Sphere* (1989) has developed a model of deliberative democracy in which the public good is contested and negotiated through institutionalized practices of rational-critical discourse on political matters. I deploy the notions of the public sphere and discourse ethics to

develop a normative view on divergent public discourses on the public interest in the development of stem cell technologies which have simultaneously competed for policy initiative. I argue that the multidimensional ethical and political controversy around hESC research shows limitations in Habermas's model of universalistic justification of norms in practical discourse as a normative ideal of rational will formation and collective decision-making in the democratic public sphere.

I also aim to examine, in a critical light, the more recent concept of "the ethics of the species" which Habermas (2003) has developed in his book *The Future of Human Nature* as an ethical and philosophical response to advances in genetic engineering and reproductive and stem cell technologies. Although his critique focuses primarily on the issue of pre-implantation genetic diagnosis (PGD) and its non-therapeutics applications, such as optimization of desirable genetic make up to produce "designer babies," he also tackles the issue of stem cell research. For Habermas (2003), normalizing the creation and destruction of embryos for medical research would only pave the way for further self-instrumentalization and self-optimization of the biological foundations of human existence, and therefore, PGD and stem cell research are part of the same context. His major ethical objection to the so-called "liberal eugenics," which leaves the selection of genetic modifications to individuals participating in a market economy, is that even favorable genetic enhancements will infringe on the autonomy and "natural mode of person's physical embodiment" by foreclosing her right to an open future (Habermas, 2003, p. 21). Nonetheless, he admits that the dispute over the morality of hESC research and other controversial human biotechnologies cannot be resolved by giving the pre-

implantation embryo full human dignity and elevating its status to that of a subject of human rights. This position recognizes the existence of strong legal and philosophical arguments against extending human rights considerations to pre-personal forms of human life such as blastocysts, embryos and fetuses. Yet, Habermas (2003) claims that embryonic life has moral worth of its own which requires that we do not weigh its value against other high-ranking collective goods, i.e. the development of innovative medical treatments or freedom of research. While stem cell research and therapeutic applications of PGD are commonly defined as proactive medical care, and have been sanctioned with references to the "logic of healing," it is still unacceptable to instrumentalize human embryos to produce medical benefits for others, as this way of reasoning poses challenges to the ethical self-understanding of the species and will ultimately lead to the normalization of questionable eugenic practices. I will scrutinize the philosophical premises of "the ethics of the species" in greater detail in the remaining sections of the chapter. The concept itself is very problematic since its philosophical defense is based on a substantivist ethical position which represents a departure from Habermas's continuous philosophical defense of a deontological approach to moral questions. Although he claims that a retreat from a post-metaphysical, proceduralist standpoint to an ethical perspective committed to substantive values is both legitimate and necessary in order to prevent the self-instrumentalization of our species, theoretical perspectives such as "the ethics of the species" clearly stand at odds with the very notion of communicative freedom which had been central to Habermas's life-long philosophical project of rescuing the modern public sphere.

The concluding sections of this chapter examine approaches to ethical reasoning and methods of deliberation employed by the two U.S. national bioethics advisory bodies to develop policy recommendations on stem cell research and related technologies—the National Bioethics Advisory Commission (NBAC), appointed by the President Clinton in 1995, and its successor under the two administrations of President Bush, the President's Council on Bioethics (PCBE). Rather than elaborating on the validity of conflicting ethical positions on embryo research presented in the two reports on stem cell research, I intend to compare and contrast the types of public deliberations adopted by these bioethics panels. I also aim to evaluate whether their efforts to develop policy recommendations regarding hESC research have sought a wide public consensus according to the underlying principles of a democratic polity. In her analysis of the two U.S. national bioethics commissions, Cohen (2005) points out that the NBAC stem cell report and policy recommendations sought a consensus-oriented approach to public deliberation to incorporate Rawls's "the fact of reasonable pluralism" and thus acknowledge inevitable limitations in appeasing strong moral and policy disagreements. By contrast, PCBE did not initially endorse public deliberations oriented towards a wide public consensus, but rather emphasized the need to achieve a better understanding of ethical and social issues arising from controversial biomedical research. When this approach failed, the Council utilized an approach to deliberation that was more consistent with the shared fundamental values of a pluralistic democratic society (Cohen, 2005). As there is a growing public concern over the ethical and social implications of the new

biomedical revolutions, policymakers are faced with the urgent dilemma of what methods of reasoning and moral principles should inform the decision-making process.

Finally, I emphasize the adoption of deliberative democracy principles in developing public policies on stem cell research and other controversial biomedical technologies. Dryzek (2000) defines deliberation as a form of public communication, as well as a social process, which involves persuasion and consensus, rather than coercion and manipulation. The underlying assumption of this type of negotiations is that participants in public forums are open to changing their views on the issues at hand. Although contemporary democratic theory is dominated by a deliberative approach, there are different conceptions of what constitutes authentic deliberation and some theorists have attempted to impose limits to the legitimate plurality of views in the political domain (Dryzek, 2000). For instance, Rawls (1993) has proposed the distinction between reasonable and unreasonable conceptions of the good to determine types of argumentation that count in public policy deliberations. He also claimed that the outcomes of these debates should be consistent with widely shared values in pluralistic societies. Even proceduralist conceptions of deliberative democracy, such as Habermas's strong, consensus-oriented model of public reason, often come with implicit assumptions of procedure-independent standards for good outcomes. For instance, his strong epistemic model of democracy is predicated on the abstract ideal of communicative reason as a prior condition ensuring the fairness of proposed (ideal) procedures (Habermas, 1996). Scholars have indicated weaknesses in the normative concept of democracy, endorsed by Habermas, and have attempted to develop a weaker model of public reason that better

acknowledges profound disagreements existing at the level of basic moral principles and fundamental procedures (Bohman & Rehg, 1997).

By contrast, poststructuralists and scholars influenced by Foucault have been critical of deliberative democratic models of politics and have emphasized the conflictual nature of the political. Their disbelief in consensus-oriented approaches comes from inherent distrust for all dominant discourses, which are viewed as oppressive, rather than liberatory, power mechanisms of subjugating individuals by constituting them as subjects. This criticism is informed by Foucault's theory of governmentality which calls attention to how subjects are constituted in ways that make them amenable to government (Burchell, Gordon, & Miller, 1991). Ultimately, the suspicion towards deliberation as a process of social change is consistent with the assumption that social and political control are exercised through shared assumptions about politics that people dutifully accept, rather than through overt coercion and violence. In his work on risk society, Beck (1992) has developed a similar critique of the dominant discourses of risks in advanced technological societies, which appear to be instrumentalist and reductionist, rather than truly critical and pluralistic. The field of risk communication, shaped by the underlying premises of liberal pluralism, only creates the illusion of critical reflection on the techno-scientific dangers of modernity. Instead, such expert-dominated discourses are shaped by the culture of scientism and represent a strong defense against reflexivity. Since these discourses are constructed in relation with identities imposed on social actors by social institutions and their ideologies, Beck (1992) has advocated a democratization of societal critique on techno-scientific matters.

Biopower and Biopolitics

Foucault's thesis in the first volume of *The History of Sexuality* (1976) that the object of politics in modernity has become human life itself and we now live in a "biopolitical" age has provoked a continuous theoretical debate on how biopower and biopolitics have redrawn and redefined, in novel ways, the boundaries and the nature of the social and the political (Agamben, 1998; Lazzarato, 2002; Lemke, 2001; Rose, 2001; Rose and Rabinow 2003). In the chapter entitled "Right of death and power over life," he claimed that sovereign power initially had the right to decide life and death, although the sovereign exercised such seemingly unconditional power in a limited way and only when his own existence was threatened. Formulated in classical political philosophy as "power of life and death," this juridical form of sovereign power was exercised as a deduction and constituted "a right of seizure: of things, time, bodies, and ultimately life itself; it culminated in the privilege to seize hold of life in order to suppress it" (Foucault, 1984, p. 259). Since the seventeenth century, the Western countries have witnessed transformation of these mechanisms of power and the ancient right to take life was supplemented with the right of the social body to ensure and foster its life. Political power has become a life-administering power—biopower located and exercised at the level of life, the species, the race, and the entire population. Moreover, this new organization of power over life was exercised in two specific forms: as an anatomo-politics of the human body and as a bio-politics of the population. Originally, biopower worked to discipline and regulate the capacities of the individual body and, later on, was extended to the level of the species body as a series of regulatory controls pertaining to the management of population: its

propagation, rates of births and mortality, morbidity, level of health and vitality. Not incidentally, biopolitics was intricately related to the rise of clinical medicine, the life sciences and biotechnology, to the emergence of a whole series of institutions, techniques, procedures and analyses that facilitated the managing of a population through the optimization of life. Foucault's lecture on governmentality further elaborated such notion of "a government of population" in terms of the government-population-political economy relationship to reveal "the deep historical link between the movement that overturns the constants of sovereignty in consequence of the problem of choices of government, the movement that brings about the emergence of population as a datum, as a field of intervention and as an objective of governmental techniques, and the process which isolates the economy as a specific sector of reality, and political economy as the science and the technique of intervention of the government in that field of reality" (1991, p. 102). Furthermore, Foucault (1984) claimed that biopolitics as a form of government was indispensable for the expansion of capitalism since it constituted a configuration of social control which made possible the integration of individual bodies in the machinery of commodity production, as well as the management of the population's vitality in accordance with economic processes and cycles.

The concepts of biopower and biopolitics extended the critique of the political theory of sovereignty Foucault initiated with the notion of disciplines. In *Discipline and Punish* (first published in 1975), Foucault (1979) explored a historical shift in workings of power; a movement from the judicial power of sovereign right to a regime of disciplinary techniques constituting the individual and his body as a locus of power

practices. The notion of biopolitics brought a new element in the analytics of power—biopower was exercised at the level of population and led to the emergence of a social body as the object of government. Each of these approaches defined three types of targeted bodies in modernity: the body of the sovereign, the docile body of the individual subject, and the regulated body of the population. Although Foucault was not precise in the use of these two terms, others have indicated conceptual differences and have suggested more precise definitions. Rose and Rabinow (2003) have argued that the concept of biopower designated "more or less rationalized attempts to intervene upon the vital characteristics of human existence—human beings, individually and collectively, as living creatures who are born, mature, inhabit a body that can be trained and augmented, and then sicken and die and as collectivities or populations composed of such living beings," whereas biopolitics involved "the specific strategies and contestations over problematizations of collective human vitality, morbidity and mortality, over the forms of knowledge, regimes of authority, and practices of intervention that are desirable, legitimate and efficacious" (p. 2). Recent shifts in the technologies and stratification of biopower extend biopolitical interventions beyond the anatomo-politics of human bodies and the economy of population to include regulatory control on the micro level of human tissues and cells in the forms of molecular biopolitics (Rose, 2001, 2007a). The application of stem cell technologies in regenerative medicine exemplify such changes in stratification of biopower that redefine the boundaries of what is considered to be human or non-human, living or re-animated. Studies of politics through the analytics of governmentality and biopolitics demonstrate that the space of government "is always

intersected by other discourses, notably the veridical discourses of science and changing moral rhetorics and ethical vocabularies, which have their own histories, apparatuses and problem spaces, and whose relations to the problematics of government is not expression or causation but translation" (Rose, 1996, p. 22).

Changes in the forms of organization and technologies of the contemporary life sciences have not only led to the molecularization of biopolitics, but have also generated technologies of biopower in the form of risk politics. As Rose (2001) has pointed out, scientific disciplines such as molecular biology and genomics have opened up life at the molecular level for a variety of interventions, including the manipulation and engineering of the cellular processes in the human body. Contemporary biopolitics has therefore become the "politics of life itself." The purpose of these highly contested developments in the biosciences and biomedicine is not limited to the management of illness or the maximization of health, but rather extends to the management of human vitality itself. At present, technologies are emerging that will make possible the modification and transformation of all biological aspects of human life. These novel types of biopolitical interventions and practices of control are "fuelled not merely by the commercial interests of biotech companies, but also by parental desires for a perfect child in an age of manipulated consumerism and reproductive choice" (Rose, 2001, p. 2). Yet, many individuals and social groups are distrustful of the transformative power of the genetic life sciences as they fear that it could lead to the normalization of genetic discrimination and, subsequently, to the resurgence of scientific racism and the emergence of "new eugenics" as a system of mass control of the population. Rose (2007b), however,

dismisses sociological analyses predicting the rise of a new genetic and biological determinism, as well as bioethical discourse about the forthcoming "post-human" future, as rather fatalistic and reductionist assumptions about the potential of biosciences to control, engineer, and modify the capacities of human beings. He is reluctant to accept exaggerated expectations about therapeutic advances and revolutions in biomedicine. Instead, he claims that rather than being on the brink of an epochal change, we inhabit some sort of an "emergent form of life." At the same time, Rose (2007b) argues that regardless of the visible continuity in the mutations of contemporary biopolitics, i.e. molecularization, optimization, subjectivation, somatic expertise, and economies of vitality, each one of these new trajectories indicates a significant break with the past, the crossing of a new threshold. Rather than a dystopian future of geneticism, he envisions the emergence of a "novel somatic ethics," a future-oriented discourse which is placing specific demands upon the present. The new bioeconomy, which is thriving on the molecularization of biopolitics and the extraction of biovalue made possible by the biosciences, has also empowered individuals by providing them with new means to control biological forces on all levels and intervene upon themselves. At the same time, new trajectories of biopolitics are shaping a novel type of corporeal, neurochemical selves oriented towards a greater choice, prudence and responsibility in ethical actions, social practices, and political decisions. These personalities have developed a different sense of ethical choices and desires for self-optimization embodied in the practices of contemporary biomedicine. Bioethical discourse has occupied a central place in the biopolitics of the present, Rose (2007b) claims, due to "the problems of governing

biomedicine in an age of choice and self-maximization in which the body and its capacities have become central to technologies of selfhood (p. 8).

In his analysis, Rose (2007b) has repeatedly emphasized the novelty of contemporary biopolitics which stems from the dramatic increase in our capacities to understand, manipulate and engineer human life at the molecular level. Moreover, these possibilities to intervene into human vitality on all levels of developmental, biochemical, molecular and neurological processes have indicated an epistemic threshold and the emergence of new discourses of biomedical knowledge, political rationalities and technologies of government. Nonetheless, his analysis of the politics of life in our advanced liberal democracies is rather dismissive of the sense of urgency inherent in critical sociological and bioethical discourses on new developments in biomedicine and the biosciences. Instead, Rose (2007b) categorizes such deliberations and regulatory attempts to establish normative limits to biomedical interventions as simple effects of the apparatus of government and its biomedical technologies of the self which produce novel biological and neurochemical selves oriented towards somatic ethics and individual responsibility. When applied to the stem cell controversy, this analytical framework is counterproductive as it emphasizes the submission of discourse participants to scientism and rationality and generally overlooks the possibility for a reflexive societal critique.

Public Sphere and Discourse Ethics

Public debates on stem cell research around the globe have highlighted profound differences in value orientation, conflicting ethical positions on the moral status of the human embryo and disagreements on how to regulate and fund research. This raises

questions about the real effectiveness of a deliberative approach to techno-science policy and decision making, but also about the conditions under which fair outcomes could be achieved. For instance, a strong consensus-oriented model, such as Habermas's normative theory of the public reason, is premised on the assumption that the resolution of societal conflicts on ethico-political matters is largely dependent on how effectively power differentials between participants in deliberations are neutralized and their value disagreements are ultimately appeased. In the light of the stem cell controversy, I propose to examine the validity of this model for negotiating and resolving scientific controversies with heavy political and ethical overlays. Some of the key questions regarding the ethics and politics of hESC research I will explore in the following sections were previously addressed by Habermas (2003) in *The Future of Human Nature.* Nonetheless, I strive to provide a critical reflection on his ethical and political responses to the challenges presented by stem cell research, PGD and other contested innovations in the biosciences. I aim to elaborate in greater detail Habermas's concept of the democratic public sphere, as well as his theory of discourse ethics and communicative rationality which defends universal norms in the sphere of morality, by focusing on the following questions: "Is it possible to transcend interest-oriented and value-based perspectives on the ethics of embryo research in a search for the common interest in a practical discourse of justification? Can we find "universally accepted needs" and "a moral standpoint" that will enable a rationally-motivated consensus on the issue of hESC research and ultimately appease divergent ethical principles and competing policy initiatives? As stem-cell research and the cluster of technologies surrounding its applications in regenerative

medicine have reached the top of political agendas of national governments and have became enmeshed in powerful economic interests, is it legitimate to claim that these new developments have "acquired a dynamic which threatens to steamroll the inherently slow-paced processes of an ethico-political opinion and will formation in the public sphere" (Habermas, 2003, p. 18)?"

The notion of "public sphere" emphasizes that political participation is essential to any democratic society. It is central to Habermas's philosophical project to establish the foundations for a post-religious and post-metaphysical general theory of society and democratic politics. *The Structural Transformation of the Public Sphere*, which was first published in 1962, elaborated the normative ideals and historical evolution of the bourgeois public sphere from the seventeenth century until its decline in the mid-twentieth century mass welfare-states. The concept of public sphere was proposed by Habermas (1991a) to describe the realm of political communication and social interaction in the public life of European Modernity which made possible the rationalization of political authority in the medium of public discussions. The early bourgeois societies provided the ideal conditions for the institutionalization of rational-critical debates within public spaces which were open and accessible to everyone. The public sphere originated around 1700 as a pristine realm of public communication where no citizen was expected to enter the public discourse with an advantage over another. The "public" in this conceptualization of European social life and politics was perceived as a spontaneously formed collective of private persons who acted as citizens and engaged in rational-critical debate over issues of common interest. As Habermas (1991a) puts it,

> The bourgeois public sphere may be conceived above all as the sphere of private people come together as a public; they soon claimed the public sphere regulated from above against the public authorities themselves, to engage them in debates over the general rules governing relations in the basically privatized but publicly relevant sphere of commodity exchange and social labor. (p. 27)

The emergent public sphere, as Calhoun (1992) has noted in the Introduction to his edited collection *Habermas and the Public Sphere*, represented "an institutional location for practical reason in public affairs and for the accompanying valid, if often deceptive, claims of formal democracy" (p. 1). In bourgeois society, private persons acted as citizens when they engaged in rational discussions and negotiated fair agreements on societal issues without coercion and manipulation (Habermas, 1991a). The public sphere became an essential component of bourgeois society since it mediated between the state and society and legitimized political authority as a "rational" authority that served the public interest.

Habermas (1991a) envisioned possibilities for the realization of a public sphere in the liberal democracies from the early stages of capitalism in relation to actual physical spaces which allowed social interaction between citizens and deliberations on matters of general concern. In particular, he emphasized that public discussions about practices of the state were a common practice in the 17th and 18th century French salons and British coffee houses, as well as in Germany, where the learned table societies (*Tischgesellschaften*), the literary societies (*Sprachgesellschaften*), and the national societies (*Deutsche Gesellschaften*) became the first institutions of the rising public

sphere. These face-to-face societal debates on political issues received coverage and were continued in the eighteenth century journals of art and literary criticism. At that time, the media (mainly small-scale presses) increased the exchange of reasoned opinions and made positive contribution to the rational-critical debate over matters of general interest, although participation in the emerging public sphere was undoubtedly restricted to the literate. Nevertheless, the historical rise of a politically active and informed public in the eighteenth century Western European bourgeois states—the analysis suggested in *Structural Transformation* generalized from developments in Britain, France and Germany in the late 18th and 19th centuries—was followed by a gradual decline of the active, participatory bourgeois public sphere. Therefore, Habermas (1991a) extends the discussion of the historical genesis of the public sphere to a critical analysis of the evolving role of the public and its eventual transformation into a mass, especially in the twentieth century social welfare states, where public opinion was often manufactured by mass media under the political and economic pressure of competing private interests. The transformation of the bourgeois public sphere was parallel to a deeper transformation in the structure of society. Structural changes in the bureaucratic industrial society which led to the "refeudalization" of the public sphere were noticeable as early as the late 19th century. On the one hand, the public sphere was stifled by private economic interests that overshadowed the public political power and ensured the control of powerful corporations over the government apparatus and the media. On the other hand, the state's role and place in the civil society was changing and increased state interferences in the private sphere and everyday life gradually eroded the distinction between public and private realms. The

weakening of the public sphere entailed a decline in democratic participation; citizens became more interested in pursuing private interests than in negotiating societal concerns in public deliberations. The advance of capitalism and communication technologies thus weakened the liberal democracy of bourgeois society, whose success largely depended on a relatively small sphere of public authority. This waning of the public sphere as a political domain mediating the state with the needs of society resulted in a situation where public opinion was formed by the mass under the influence of the media and cultural industry and the citizens of contemporary democracies became passive consumers and media spectators.

It is worth pointing out that the distinction between a public and a mass society is essential to Habermas's concept of the public sphere. *Structural Transformation* emphasized the significant impact of nascent communication media (newspapers and journals) in sustaining critical public debate over matters of general interest. Habermas (1991a) claimed that rational-critical, face-to-face debates in bourgeois society were greatly facilitated by the forms of public communication, which at the time were limited to the small scale, independent presses. The nature of the public debate changed significantly when the potential of media production to bring profit was realized and it became largely commercialized. Revenue from advertisements limited the amount of criticism newspapers were willing to level at objectionable practices carried out by the advertisers. In time, economic and financial interests prevailed over the rational critical arguments which characterized the public debates of bourgeois revolutionary period and the commercial mass media gradually turned the critical and politically active public of

bourgeois society into a passive consumer public. With the advent of mass communication, the public sphere of modern constitutional democracies changed into a platform of political advertising which was serving the private interests of large-scale organizations and lobby groups. The influx of a staged, manufactured form of publicity contributed to the further erosion of the public sphere since it transformed rational-critical discourse into a form of public relations hiding secret policies of interest groups. For Habermas (1991b), the realization of a public sphere, which once was structurally embedded in society, is possible in the social welfare state only on a case-by-case basis and involves "a welfare-state transformation of the functioning of basic rights" in which "the requirement of publicness is extended by state organs to all organizations acting in relation to the state" (p. 404). Nonetheless, the promise of the public sphere is largely contingent on the ability of the state to restrain irrational relations of social power and political domination. Therefore, as Habermas (1991b) has concluded in his analysis, "the outcome of a struggle between a critical publicity and one that is merely staged for manipulative purposes remains open [and] the ascendancy of publicity regarding the exercise and balance of political power mandated by the social welfare state over publicity merely staged for the purpose of acclamation is by no means certain" (p. 235).

Scholars in the fields of cultural studies, literature, philosophy and politics have deconstructed the public-mass juxtaposition, which is central to the conceptual framework of *Structural Transformation*. For instance, both Ku (2000) and Polan (1993) have argued that Habermas's thesis of the decline of the public sphere after mid eighteenth century is a direct result of the integration of the dichotomy of public-mass

into his idealized notion of the bourgeois public sphere as a pristine realm of rational discourse on the common good, i.e. the juxtaposition between an educated bourgeoisie interested in critical discussions on cultural matters and a contemporary sphere dominated by mass media and mass culture. Polan (1993) has noted that Habermas's argument is reductionist since it conceptualizes "culture" as a type of media and thus overlooks the multifaceted nature of cultural production. Moreover, his analysis of the public sphere is informed by perspectives on media and political economy of communication that fail to consider the cultural meanings and counter-meanings communicated and transmitted by the public discourse. Furthermore, *Structural Transformation* does not suggest an analysis of the public as a shifting and contested category. For this reason, it is difficult to sustain the argument about the public sphere as a public space instituted in the private domain of civil society. It is important, as Ku (200) has rightly indicated, to define the notion of "public" in relation to its ties with both state and civil society, especially in the present when both entities are so intricately related that they "interact with each other in shaping the political and moral boundary of public life and that they are simultaneously subjects to a common cultural field that constitutes and regulates public life" (p. 221). Subsequently, it is necessary to redefine the notion of public towards the realities of contemporary politics and develop a more adequate category that would allow us to conceptualize questions of legitimacy, public culture and citizenship practice.

Critics have also claimed that Habermas's emphasis on rational discourse as the model for public communication and his rather idealized portrayal of the bourgeois

public sphere as a predefined realm of properly political activity does not provide an adequate conceptual map to understand the contemporary public discourse which is essentially permeated by power relations, large corporate interests, and privately owned media organizations. For instance, Fraser (1992) has suggested Habermas's model should be revised to offer a "category capable of theorizing the limits of actually existing democracy" (p. 111). Even Habermas himself had acknowledged that over the years the term has acquired more general meanings compared to his original conceptualization of the public sphere as a product of the immense economic and societal transformations in European societies between the Late Middle Ages and the eighteenth century. While critiquing Habermas's overdrawn emphasis on the rational aspects of public communication in the early liberal public sphere, Eley (2002) has defended the general notion of public sphere by emphasizing Habermas's revised conceptualization, which includes an expanded notion of the political as a structured space of contestation and negotiation over matters of common concern. He points out that the original meanings of the concept have shifted and presently designate "the general questing for democratic agency in an era of declining electoral participation, compromised sovereignties, and frustrated or disappointed citizenship" (Eley, 2002, p. 224). The new conceptualization envisions the formation of a public sphere as a space between state and society where "political action occurs with real effectiveness, whether in terms of the local effects, in building a sense of political agency or in behaving ethically in one's social relations and allowing some notion of collective goods to be posed, and thereby contributing to wider processes of political mobilization" (Eley, 2002, p. 231).

It is important to clarify that Habermas has continuously revised the original normative notion developed in *Structural Transformation*, and most recently, has emphasized the discursive constitution of the public sphere, but also internal relations between the informal and formal decision-making processes in contemporary states. In "Further Reflections on the Public Sphere" he notes that his conceptualization of democratic politics has evolved to include the distinction between "lifeworld" and "system" [the essay was included in the collection edited by Calhoun (1992)]. The concept of lifeworld is essential to a revised notion of the public sphere since it designates the immediate, everyday social and cultural realities of the individual actor vis-à-vis the system which is comprised by the market economy and the state apparatus. As an extension of the lifeworld, the public sphere constitutes an independent space for negotiating political power that offsets the colonizing encroachment of system on all aspects of the lifeworld. In *Between the Facts and Norms*, Habermas (1996) has further shifted the focus of his analysis from the public sphere as the fundamental locus of a sustainable democratic polity toward issues of constitution building and public law. Furthermore, in this book Habermas aims to link the informal processes of public opinion formation in the public sphere with formal decision making institutions in contemporary democratic societies that ensure the effective rule of law. Rather than being a purely cognitive exercise, political discourse mobilizes reasons and arguments that are derived from citizens' interests, values and identities. Habermas (1996) points out that such democratic processes of informal public opinion-formation in the public sphere generate communicative power that "has a real impact on the formal decision making and action

that represent the final institutional expression of political "will" (p. xxviii). He emphasizes that the constitutional state and its legal institutions provide mechanisms that allow the transformation of the communicative power generated through the public discourse into relevant administrative activity which generates social change. Therefore, law constitutes the major vehicle for the conversion of communicative power into administrative power and the attention is shifted to the functioning of particular legal systems in constitutional states, their major principles, goals and institutions that influence judicial decision-making. Regardless of the significant revisions Habermas has made to the concept over the last forty years, scholars have noted that the notion of public sphere still provides an important thematic perspective from which we could approach the problem of democracy in the contemporary world (Garnham, 2007).

When applying a public sphere perspective to the stem cell controversy, it is also necessary to examine the premises of Habermas's deontological, cognitivist and universalist discourse ethics and his emphasis on practical discourse of justification as a way of resolving ethical and political controversies in democratic societies. McCarthy (1992) has pointed out that Habermas's continuing effort to rethink the foundations of democratic theory has led him to develop a multidimensional model of discourse in the democratic public sphere. Such a multifaceted notion of discourse, outlined in Habermas' more recent works on law, politics and morality, presupposes the pursuit of collective goals through different types of "rational collective will formation" in which the power differentials attached to conflicting interest positions are neutralized. The multidimensional model is centered on practical discourses which sanction laws and

policies in term of the general interest, and involves an effectively institutionalized mesh of public communication, including "deliberations in which general norms are applied to particular situations, ethical-political discussions concerning basic value and collective identities, the negotiation of compromises under fair bargaining conditions, and pragmatic discourses concerning the means of implementing policies and attaining goals" (McCarthy, 1992, p. 62). Habermas has maintained that the institutionalization of practical discourses of justification is indispensable for the contemporary democratic public sphere. While practical discourses make it possible to negotiate conditions under which fair compromises could be achieved, their institutionalization guarantees not only the impartial application of general laws but also that the law themselves have passed discursive justification. Pragmatic discourses about methods and procedures allow for intersubjective understanding and the pursuit of shared goals beyond the value differences that result from particular ethical positions. Nonetheless, questions arise whether practical discourse indeed constitutes a realistic normative ideal for discourse in the public sphere. Unlike Habermas's previous emphasis on the democratization of governmentally relevant and publicly influential organizations, this new normative ideal of democratic politics situates "rational collective will-formation" outside of any formal organizations. The democratic public sphere is therefore actualized through a wide-ranging multiplicity of spontaneously formed publics engaged in informal discussions of issues of public interest. Central to this "web of informal communication" are voluntary associations and social movements that "concentrate on generating and disseminating practical convictions, that is, on discovering themes of relevance to society as a whole,

contributing to the possible solution of problems, interpreting values, providing good reasons and discrediting others" (McCarthy, 1992, p. 63). These citizens' associations are effective and influence formal decision-making, albeit in an indirect manner, i.e. by changing societal attitudes and values. The revised model of the public sphere, which incorporates the premises of discourse ethics, heavily relies on the articulation and adoption of a moral point of view shared by all participants in practical discourse who will be willing to transcend their interest-oriented and value-based perspectives. In the political discourse of pluralistic societies, however, rational agreement on practical-political matters is not always achievable, especially when there are fundamental divergences in value orientation between discourse participants. As the very normative standards of the debate are called into question, differences in identities, situations and experience become easily translated into value disagreements, and rational agreement on cultural values may not be an attainable goal. Moreover, the multiple value-perspectives of our pluralistic and individualistic culture are reflected in the voluntary associations, social movements and spontaneous publics, which Habermas views as agents of democraticization in the public sphere. As McCarthy (1992) has summarized the tensions in this model of discourse in the public sphere,

> If judgments of the relative cogency of reasons that cite needs, interests, feelings, sentiments and the like vary with interpretive and evaluative standpoints, and if there is no common measure by which to assess the relative weights of reasons articulated in different evaluative languages, then the distinction between

> argument and rhetoric, between convincing and persuading becomes less sharp than the discourse model allows. (p. 65)

A similar critique of Habermas's strongly consensus-oriented model of public reason is articulated by Bohman and Rehg (1997) who have indicated that his emphasis on "constitutional patriotism" in *Between the Facts and Norms* fails to acknowledge the impact of political values and cultural norms. As an alternative to this strong epistemic model of democracy, they propose a weaker model of public reason that reflects Rawls' notion of "reasonable pluralism" and acknowledges that conflicts and disagreements exist even at the level of moral principles and fundamental procedures.

In the light of above considerations, I argue that hESC research appears to be yet another ethical and political controversy that indicates limitations in Habermas's model of "universalistic justification of norms" in practical discourse. Such moral controversies also raise questions regarding the validity of Habermas's strong epistemic model as a normative ideal of rational will formation and collective decision-making in the democratic public sphere. Public communication campaigns and parliamentary debates on the issue worldwide have reflected a variety of divergent ethical views on the status of human embryo and its experimental use in research settings. Attempts to achieve an inter-subjectively shared "we"-perspective on the biopolitics of hESC research, which would enable all participants to bracket off interpretive and evaluative standpoints and agree on generally accepted moral norms and their applicability in this case, have commonly resulted in an impasse. Rather, policy deliberations on how stem cell technologies should be funded and regulated in both the United States and the European Union have

highlighted profound disagreements over conflicting ethical goals and have often failed to achieve outcomes that would be morally acceptable to the principals in the controversy. I will explore in greater detail the issue of justifying a closure policy regarding hESC research in the concluding section of the chapter. In the next section, I will provide a critical reflection on Habermas's philosophical response to the ethical and societal challenges arising from stem cell technology and other developments in human biotechnologies. I will address the question of whether the possibility for engineering human nature and novel forms of life indeed necessitates the abandonment of a proceduralist conception of reason as embedded in historical contexts of praxis and tradition in favor of a substantivist ethical position.

The Embryo and the Self-Modification of the Species

In *The Future of Human Nature*, Habermas (2003) has developed a philosophical critique of scientific innovations such as stem cell research, pre-implantation genetic diagnosis and other technologies for embryo manipulation and has outlined a normative theory based on the notion of the ethics of the species. His major ethical objection to the so-called positive or liberal eugenics is that even favorable genetic enhancements might negatively affect the autonomy of future persons by limiting their life choices to a life course set by others and thus foreclosing their right to an open future. This concern is particularly relevant in the light of emerging embryo technologies such as PGD, SCNT, human genome research, and bioinformatics which make possible the selection or modification of specific human traits through manipulation of the hereditary factors responsible for their expression. Arguments in favor of human enhancement technologies

are well summarized by Agar (2004) who has outlined two competing visions of human enhancement: authoritarian and liberal eugenics. The notion of authoritarian eugenics first originated in the nineteenth century in the writings of Francis Galton, who advocated a social system that would support natural selection and improve human beings. According to this doctrine, the state takes a leading role in determining what counts as good human life, and subsequently, state authorities implement programs in pursuit of a particular racial ideal that discriminate against racial and ethnic groups that are deemed inferior. By contrast, the idea of liberal eugenics shifts the emphasis from "races and classes of humans" to "individuals" and "individual choice." Philosophical justifications of this second type of eugenic practices are derived from liberal individualism which asserts that there are different, often incompatible conceptions of what constitutes the good life in liberal societies. Liberal eugenics is also consistent with beliefs in "procreative beneficence," that is, the notion that parents have a moral duty to maximize the life prospects of their children. Therefore, proponents have advocated freedom of individual eugenic choices, especially when advances in reproductive and genetic technologies are currently transforming human procreation from a "genetic lottery" into a "genetic supermarket" (Agar, 2004; Buchanan et al., 2000).

Habermas (2003) argues against the normalization of practices that would pave the way to liberal eugenics, and subsequently, to the instrumentalization of human life. Rather than seeing the technologies of human enhancement as a way to increase prospects for more fulfilled and meaningful individual lives, he claims that designing babies would only infringe on the individual's right to an open future and curtail the

processes of anticipatory socialization which ensure symmetrical relationships and mutual recognition between communicatively active persons in the public sphere. In order to justify normative restrictions on research involving the destruction of embryos and genetic modifications of humans, Habermas (2003) adopts an ethical standpoint that assigns an inherent value to human nature as the pre-condition for the development of ethical self-understanding and equal membership in the moral community of persons. Moreover, he suggests that this move toward substantivist ethics will prevent the forthcoming self-instrumentalization of human species which poses a threat to both our anthropological and normative self-understanding.

Habermas (2003) acknowledges that disputes over the ethics of hESC research are more complex and cannot be resolved with the simple argument that the embryo possesses human dignity and should be accorded the status of a subject of human rights at all stages of development. From both legal and philosophical standpoints, it is highly problematic to extend the argument of human rights to protect pre-personal forms of life. Nonetheless, he believes that the existing legal distinction recognizing the unconditional human dignity of persons vis-à-vis the rather provisional protection granted to embryos and fetuses does not necessarily reduce the controversy to an ethical calculus of weighing conflicting public goods, i.e., freedom of research and the healing imperative against the respect owed to embryos. In other words, the value of pre-personal forms of life cannot be principally weighed against other rights and ethical goals. Instead, the way we treat human embryos has profound implications for our self-understanding as members of the species, and according to Habermas (2003), such ethical reflection is intricately related to

our self-understanding as moral persons. Regardless of its promise, hESC research contributes to the instrumentalization of human life to produce medical benefits for others and thus indirectly undermines the ethical self-understanding of the species which determines whether we perceive ourselves as beings committed to moral judgments and actions. As in this case procedural justification of moral norms may not result in an alternative to the open-end weighing of competing goods, Habermas (2003) proposes that our political responses to the challenges of biotechnology are ultimately guided by the ethics of the species. For him, the only way to avoid measuring the value of pre-personal life in comparison to other high-ranking collective goods (i.e., the development of novel medical treatments for debilitating diseases) is to accord embryos some moral value of their own. This philosophical move is justified since the new biomedical and biotechnological revolutions destabilize the very conditions that render morality possible: our capacity of being ourselves and ability to perceive others as persons of equal birth. The technology of human genetic modification threatens to violate what is given to us by nature, namely, the integrity of our bodies. This threat to our bodily integrity further extends to our moral identity and personal autonomy. Habermas (2003) concludes that we now face the possibilities of a dystopian future in which humans treat other human beings as means, and not as ends, and thus foreclose their right to an open future. Therefore, it is our duty and personal responsibility to future generations to respond to these challenges by exercising proper moral self-restraint.

Habermas's philosophical reflection on the controversies over hESC research and PGD stands at odds with the invariable defense of a deontological approach to moral

questions in his previous work on politics, law and morality. Prior to *The Future of Human Nature*, the greatest strength of his conception of deliberative democracy was the abstract character of his proceduralism which presupposes that the political process is not shaped by any particular conception of the public good. While his model of deliberative politics reflects a commitment to a deontological conception of political fairness, it also emphasizes the constitutive role of actual democratic process in giving content to "unsaturated scheme of rights" (Habermas, 1996, p. 450). It is centered on the abstract ideal of communicative freedom as a prior condition to any set of procedures that may be identified and that secure fairness and equal opportunity. Furthermore, reasonable or fair democratic procedures are derived through reflection on the presuppositions of communicative reason and action. By contrast, his analysis in *The Future of Human Nature* suggests that a move away from the post-metaphysical, proceduralist standpoint towards an ethical perspective grounded on substantive values is both legitimate and necessary if we are to develop a proper ethical response to the moral collapse opened by biotechnology and genetic engineering. Moreover, Habermas (2003) claims that the normalization of liberal eugenic practices will subtly undermine the very project of European political modernity and will eventually lead to the self-instrumentalization of humanity. Nonetheless, his attempt to derive an ethical response to the societal challenges of the biotechnological revolution from "the ethics of the species" is problematic, especially in the context of the pluralistic public discourses of our democratic societies which have been largely shaped by a proceduralist and cognitivist post-conventional morality. Not less dubious is the assumption of a fixed biological identity as defining

aspect of what makes us human beings. Therefore, critics have perceived *The Future of Human Nature* as a betrayal of a proceduralist, post-ethnocentric conception of post-metaphysical reason which allows for a plurality of definitions about what makes us distinctively human and different from other species (Mendieta, 2003; Malmqvist, 2007). As Mendieta (2003) has summarized such criticisms of the substantivist ethical doctrine on human nature, defended by Habermas,

> The argument for the acceptance of an ethics of species masks the imposition of a Western understanding of what is essential to be human. There is no need to rehash here plurality of cultural perspectives on what makes human distinctive, or non-distinctive, from other species. It truly would be disastrous in an age of dialogical cosmopolitanism, or what Walter Mignolo has called "critical cosmopolitanism" to smuggle under the mantle of an ethical imperative an ethnocentric blackmail: either you are moral, by accepting our ethnic values, and rejecting genetic engineering, or you are not, because you reject our ethical value, and thus are doubly written off from the moral register. Such ultimatums and threats to be blacklisted are redolent of the worst forms of Eurocentrism. (p. 136)

Moreover, Habermas's ethical perspective on human nature overlooks some fundamental legal and political issues arising from innovations in biomedicine and the biosciences, such as the question about the negative rights of citizens to decide their own "correct life." While it is important to develop a critical ethical reflection on these challenges, we should not ignore emancipatory possibilities brought by medical advancements, including therapeutic uses of PGD and stem cell research, which can enhance a person's right to

life. In the pluralistic democracies, this right to life clearly has precedence over the right to make decisions regarding the correct forms of life. In this context, we cannot predetermine, prescribe or control how life should be lived and the forms that life takes; we can only make sure that the right to life is ensured and protected for all members of the human community. Mendieta (2003) has argued that contemporary pluralistic culture owes much to this "self-constrained, and abstemious power of political modernity" which has also allowed "the simultaneous acceptance of the culture of self-optimization with the culture of disability," as well as conflicting perspectives on whether the technologies of human genetic modification will ultimately lead to a dystopian future or help "nurture life not marked as diseased, but as challenged and requiring of our care and solicitude" (p.137). Therefore, Habermas's philosophical critique of PGD and hESC research from the perspective of "an ethics of the species" clearly stands at odds with the very aspects of communicative freedom that are central to the political project of modernity.

Bioethics and Public Deliberations

In their attempts to resolve the stem cell controversy in a manner acceptable to all constituencies, bioethics panels and advisory bodies have endorsed different methods of reasoning and approaches to public deliberations. In this section I analyze the methods of deliberation employed by the National Bioethics Advisory Commission (NBAC), appointed by the President Clinton in 1995, and its successor during the two presidencies of George W. Bush, the President' Council on Bioethics (PCBE). I aim to evaluate to what extent their efforts to develop policy recommendations regarding hESC research have sought a wide public consensus and outcomes in accordance with the underlying

principles of a democratic polity. I offer a comparative analysis of the stem cell reports published by these national bioethics commissions (NBAC, 1999; PBCE, 2004) in order to reconstruct the competing perspectives they have endorsed regarding what principles and procedures in public deliberations are adequate for resolving societal conflicts on ethically controversial developments in biomedicine.

In the early years of the U.S. stem cell debate, President Clinton's National Bioethics Advisory Commission ("the Clinton Commission") recognized that withholding federal funding for research that could lead to groundbreaking medical treatments would be unjust and unreasonable. After giving a proper consideration to diverse ethical perspectives and legal frameworks for stem cell research, the policy advisors concluded that federal funding should be provided for experimentation on hES cells from both cadaveric fetal material and supernumerary embryos from infertility treatments. The NBAC report *Ethical Issues in Human Stem Cell Research* (1999) indicated that the 1995 congressional ban on federally sponsored embryo research (an appropriation bill rider, known as "the Dickey-Wicker Amendment") had created serious ethical and policy concerns among constituencies with differing perspectives on the morality of embryo research. In Chapter 5 of the Report, "Conclusions and Recommendations," this prohibition was characterized as controversial because "the ban contradicts several of the ethical goals of medicine, especially healing, prevention, and research—goals that are rightly characterized by the principles of beneficence and non-maleficence, jointly encouraging the pursuit of each social benefit and avoiding or ameliorating potential harm" (NBAC, 1999, p. 69). The Clinton Commission argued that

public policy deliberations balancing difficult issues, such as stem cell research, should give proper consideration to diverse moral standpoints, the most current scientific and medical developments, as well as various legal, political, social and cultural factors. They insisted that their recommendations reflected such a diversity of perspectives on the ethical, scientific and legal aspects of the topic:

> We did not come to our conclusions simply by balancing potential medical benefits against the potential harms, because the possibility of social benefits, by itself, is not a sufficient reason for federal support of such controversial research, particularly given the interest in stem cell research in the private sector. Nor did we approach this issue based simply upon an interpretation of the existing legal environment. Instead, we combined, as thoughtfully as we could, a number of different perspectives on and approaches to this topic (p. 3).

The underlying principle of these deliberations was a thorough examination of shared medical, ethical and scientific considerations that are amenable to balancing, particularly on the much contested issue of the moral standing of human embryos. Moreover, the Clinton Commission pointed out that there were "the diverse and strongly held views" on the issue of stem cell research in American society, and therefore, their approach aimed to "develop policies that demonstrate respect for all reasonable alternative points of view and that focus, when possible, on the shared fundamental values that these divergent opinions, in their own ways, seek to affirm" (p. 67).

Cohen (2005) has indicated that, although the Clinton Commission did not explicitly define the deliberative strategies and methods of reasoning used to develop

their recommendations, their approach to public deliberations could be reconstructed from references to scholarship in different chapters of the report. Overall, the goal was to establish a common ground for a societal consensus on hESC research that would reflect shared societal values and beliefs. Their method of reasoning was largely derived from "rights-based" liberal theory, and more specifically, from John Rawls' analysis of the character and limits of "public reason" which he had outlined in *Political Liberalism* (1993). This account emphasizes that a democratic polity is characterized by the existence of a set of generally accepted common sense beliefs and ways of reasoning, as well as some shared perspectives regarding basic principles of justice. Although reasonable disagreements over moral issues and practices in such societies are unavoidable, citizens have a "duty of civility" to formulate the public policies they advocate in terms of the values of the public reason, rather than in accordance with any comprehensive religious, moral, or philosophical doctrine. When deliberating on the issue of what shared views can be built in public policy recommendations, the Clinton Commission utilized Rawls' distinction between reasonable and unreasonable conceptions of the good which provides a useful tool for policy makers to establish limits to the legitimate plurality of views in the political domain. In addition, they defended a consensus-based approach to the issue of stem cell research with references to the work of political theorists such as Nagel (1995) and Gutmann and Thompson (1996), who have emphasized the importance of the democratic process as a constitutive element in a conception of political rightness. As indicated in the report on stem cell research, the deliberations of the Clinton Commission were mainly shaped by: (1) Nagel's argument

that procedures of decision should strive to achieve outcomes that would be considered legitimate by the vast majority of people, and (2) Gutmann and Thompson's claim that the development of public policy on morally controversial issues should seek significant points of convergence between conflicting interpretations and beliefs on the topic under consideration. Therefore, rather than assuming that they were in a position to resolve the controversy, the NBAC members attempted to "to develop public policy recommendations regarding research involving the derivation and use of ES cells that are formulated in terms that people who hold differing views on the status of the embryo can accept" (p. 51).

The Clinton Commission's argumentation on the moral standing of the human embryo was strongly influenced by Dworkin's analysis of the abortion debate in *Life's Dominion* (1994) which was characterized as "an illustration of the complex middle ground" approach (NBAC, 1999, p.52). Dworkin has claimed there is a shared understanding in American society that the fetus is not equal to a human person. Despite the high rhetoric of the abortion debate, most conservatives do not actually believe that the fetus has a right to life and often implicitly agree with liberals that embryonic forms of life can be sacrificed to save people's lives. This widely shared understanding on the moral status of the fetus becomes clear when one considers the willingness of pro-lifers to allow exceptions to their proposed prohibitions on abortion, i.e. in cases when pregnancy results from rape or incest. As Dworkin (1994) has pointed out, these exceptions have indicated that it is "contradictory to insist that a fetus has a right to live that is strong enough to justify prohibiting abortion even when childbirth would ruin a

mother's or a family's life, but that ceases to exist when the pregnancy is the result of a sexual crime of which the fetus is, of course, wholly innocent" (Qtd. in NBAC, 1999, p. 52).

By contrast, the President's Council on Bioethics ("the Council"), which replaced the Clinton Commission in 2001, endorsed an approach to public deliberation in the two reports on human cloning and stem cell research (PCBE, 2002, 2004) that followed practical wisdom and tradition (Cohen, 2005). In accordance with the directives of President George W. Bush, the Council, under the leadership of its original chair, Leon Kass, did not express an overriding concern to seek a large societal consensus. Instead, their intentions were to achieve a deep understanding of moral and ethical issues arising from developments in biomedicine and the biosciences. Similarly, there was little concern about development of procedures that would guarantee a diversity of perspectives. Therefore, the Council did not include representatives from the larger community in their deliberations. Eighteen members were appointed to the Council, who were mainly academics selected from diverse fields, such as science, medicine, law, government, philosophy, theology, as well as other areas of the social sciences and the humanities. In the first report *Human Cloning and Human Dignity,* released by the Council in 2002, a majority of its members formally recommended a four-year moratorium on therapeutic cloning in both the public and private sectors, although a different majority had earlier supported the use of cloning for biomedical research (PCBE, 2002). Initially, ten of the Council's seventeen members (one had resigned) voted against recommending a ban on research cloning. A last-minute change in the

voting procedure, however, resulted in a majority of ten in favor of a four-year moratorium, which was an option that the Council had not previously discussed in meetings. The first majority of the PCBE members that supported human cloning for biomedical research had argued that human embryos are not morally equivalent to people and claimed that they have either developing and intermediate moral worth or no special moral status. They engaged in balancing the moral respect owed to early human embryos against the benefits of research cloning that may help develop innovative cures and alleviate suffering. The Council's majority then declared that objections to human cloning for biomedical research "are outweighed by the good that can be done for current and future individuals who suffer" and that "the moral balance lies on the side of endorsing and encouraging this activity" (PCBE, 2002, p. 128). The 2004 report on stem cell research, however, did not develop any specific policy recommendations. The justification for this decision stated that the field of stem cell research was too recent and underdeveloped to necessitate any comprehensive policy (PCBE, 2004). Rather than engaging in a utilitarian calculus of cost and benefits or a rights-based approach on the issue of hESC research, the Council, as stated by its Chairman Leon Kass in the report on human cloning, decided to ground their reflection on bioethical issues on "the broader plane of human procreation and human healing, with their deeper meanings" (PBCE, 2002, p. ix). In addition, Kass insisted that the goal of these deliberations was to present clear arguments on the issues, rather than seeking consensus within the Council, as he presumed that such approach may lead to suppression of the genuine opinions of the members on the issues at hand.

Cohen (2005) argues that this initial method of deliberation, influenced by the work of the political philosopher Leo Strauss, who advocated a return to a classical view of nature and natural law, was eventually abandoned. Instead, in the human cloning report, the PBCE members briefly resorted to the procedures and methods of reasoning utilized by their predecessor, the Clinton Commission, which were more consistent with the shared fundamental values of a well-ordered democratic society. The change in the method of deliberation was noticeable in the last section of the 2002 report, which contains the Council's recommendations for a four-year moratorium on research cloning developed by the second majority. The proposal for a moratorium was justified with the need for further democratic deliberations and the achievement of societal consensus on whether this type of research should be allowed to proceed. This time, the Council members claimed that more time was needed for reflection on the moral and practical issues arising from the use of cloning technology in biomedical research and suggested that a national consensus in the U.S. should be achieved on all research that involves human embryos. The moratorium was perceived as an acceptable compromise "warranted by the state of public opinion and justified by the supreme values in our democracy of informed and deliberate decision in matter of great moment" (PCBE, 2002, p. 214). In a similar fashion, the subsequent report on stem cell research referred to on the issue of public deliberations in accordance with an "appropriate democratic process," however, as Cohen (2005) has indicated, the Council "does not pursue this observation and does not refer back to a theory of public deliberation that it had begun to develop in its research cloning report" (p. 280). By and large, there was not rigorous effort to

develop an explicit method of public deliberation to guide the Council's decisions. Rather, the vision for this advisory body, which was significantly influenced by its chairman Leon Kass, was to provide an in-depth analysis of fundamental ethical and philosophical questions arising from revolutions in biomedicine, rather than developing weak arguments that are based on consensus and compromise. The conservative bioethical orientation pursued by Kass was significantly shaped by the thought of Hans Jonas, who promoted a "heuristics of fear" to hinder advances in biomedical research and claimed that bioethicists ought to employ horrific imagery and metaphors from sci-fi horror stories to depict the potential negative impacts of scientific advances. In his academic publications and contributions to the Council's reports, Kass has consistently referred to a particular strain in dystopian thinking, and more specifically, C.S. Lewis's *The Abolition of Man* and Aldous Huxley's *Brave New World*, to portray a frightening future of pharmacological hedonism, "hatcheries" and genetic under-classes as a result of advances in assisted reproductive technologies, human cloning and other areas of biomedical research (Kass, 2001, 2002, 2003; PBCE, 2002, 2003). Moreover, he has consistently criticized contemporary perspectives on justifiable methods of ethical deliberations and has defended methods that are substantive rather than procedural. As Cohen (2005) has indicated, the expectation set out by Kass was that the Council "would develop a method of public deliberation that provided deep and rich insights into the good for humankind. It would take account of tradition, the heir of generations of practical wisdom, hoping that what the neo-conservative thinker Leo Strauss has termed "the intrinsically high" would prevail." (p. 283). Although the Council included the best

available philosophical thinkers, it failed to accomplish this task. The PBCE members could not resolve the ethical dilemmas presented by hESC research and human cloning and did not achieve an agreement on policy recommendations. Neither could these thinkers agree on substantive insights and ideas regarding the challenges of advances in biomedical technology since "the Council members could not embrace a common understanding of human good in relation to embryo research" (Cohen, 2005, p. 284).

Discussions regarding the appropriate type of diversity that should be sought by national bioethics commissions intensified during the controversy surrounding the decision of President Bush not to re-appoint two of the eighteenth members of the original Kass Commission. The members dismissed after two years of service were two vocal dissenters from the cloning report William F. May, renowned religious ethicist from Southern Methodist University, and Elizabeth Blackburn, well-known scientist in cellular biology from the University of California, San Francisco. Another PCBE member, the Yale Law Professor Stephen Carter, had submitted his resignation at an earlier date. The mid-course change in personnel thus involved the addition of three new members to the Council. All three new members that were appointed, Peter Lawler, a conservative Catholic political philosopher, Diana Schaub, a former student of Kass, and Benjamin Carson, a director of pediatric neurosurgery at Johns Hopkins, favored the conservative views of the President and opposed the use of cloning technology in biomedical research. The change in membership raised significant concern about the conservative bias in the construction of this national bioethics advisory commission. Elizabeth Blackburn, in a commentary published in *The New England Journal of*

Medicine, claimed that political decisions had led to the infusion of conservative political values in the work of the Council and a general loss of balance, both professionally and philosophically (Blackburn 2004). She argued that since its establishment the Council's deliberations had been shaped by the conservative views of the President and the PCBE Chair. As a result, all three reports on human cloning, biotechnology and anti-aging therapies, and stem cell research, exhibited a conservative bias and tended to devalue hESC research, overstate the therapeutic utility of adult stem cells, and sensationalize concerns associated with anti-aging therapies and the possibility for significant prolongation of life.

In her comparative analysis of the NBAC and PCBE reports on human cloning, Kaveny (2006) has argued that the most appropriate approach national bioethics commissions should utilize in public deliberations is deliberative diversity which "is outlined in the Thomistic (and ultimately, of course, Aristotelian) practice of taking counsel as a key requirement of practical reason" (p. 314). Rather than pursuing political diversity which would generally guarantee a broad political legitimacy of their recommendations, a presidential ethics commission should strive to facilitate the President's process of taking counsel. Both the Clinton Commission and the Bioethics Council have failed to incorporate an adequate degree of deliberative diversity in their reports on the issue of human cloning. Instead, these two policy advisory bodies have sought different approaches to diversity. The Clinton Commission's deliberations were characterized by the so-called "forensic diversity," which is the type of diversity between contesting parties in legal cases, and the human cloning report of the Kass Council

exemplified an academic type of diversity found in a medieval *disputatio*. Kaveny (2006) has pointed out that, although the presidential directives given to these advisory commissions significantly differed, "the primary responsibility of both bodies was to identify and resolve the factual, moral, and jurisprudential complexities necessary to forge a coherent national policy with respect to human cloning" (p. 313). The most appropriate type of diversity for this task is epistemic diversity, that is, diversity in membership that provides the commission with the necessary knowledge and expertise to complete the assigned task. The general category of epistemic diversity includes all three types—forensic, academic and deliberative diversity. The Clinton Commission's report on the cloning controversy showed an orientation toward epistemic diversity based on the dominant model in the legal system. As Kaveny (2006) characterizes their approach to public deliberation,

> Most strikingly, the members of the Clinton Commission presented themselves very much like a neutral fact-finder does in a legal case. The individual personalities of the particular members are virtually invisible in the Report; virtually no trace appears of the ultimate normative commitments of any member, or even of the framework they advocate for approaching bioethical questions. (p. 316)

The adoption of this position towards decision making is by no means surprising given that most NBAC members came from the academic discipline of bioethics, which was established as a professional field dedicated to procedural resolution of moral controversies in biomedicine, rather than emphasizing ethical perspectives grounded on

substantive values. Subsequently, the recommendations developed by the Clinton Commission did not endorse any particular moral stance or legal perspective on the issue of cloning. Forensic diversity was demonstrated by the structure of the report, as well as the fact that the Commission functioned as a judge in a trial. They heard significant amount of testimony from diverse experts and community representatives and included verbatim excerpts from these opinions in the report without follow up commentaries and evaluations. The report, however, did not indicate if there were discussions between the NBAC members and the witnesses and if some intermediate assessment on the matters under consideration took place during the investigation. The Clinton Commission approached the task as an adjudicator between two conflicting views on cloning humans, and mainly aimed to resolve narrow, pressing questions. Therefore, instead of addressing the far-reaching implications of cloning technology for humanity, their deliberations focused on the immediate concern of whether it would be legitimate to produce children by somatic cell nuclear transfer at that time.

By contrast, the PCBE cloning report presented a significant departure from the forensic approach of its predecessor. Its emphasis on academic diversity resembled the medieval practice of *disputation*, a form of theological and philosophical speculation common for the European Universities in the thirteenth and fourteenth centuries. Solemn public disputations during this historical period were attended by the entire university community and were initiated by a master who formulated the question and was responsible for the organization of the event. Kaveny (2006) has indicated that this individual "distributed the various responsibilities, presided over the sessions, determined

the question, answered the objections, and finally, organized all the material in a written form" (p. 319). The PCBE report clearly endorsed this medieval practice of *disputatio* since it presented a moral vision of human cloning which was consistent with the moral and philosophical stance on the issue upheld by the Council Chair. Moreover, President Bush's preliminary directive was that Kass should provide moral and intellectual leadership to the Council, a mandate which stood at odds with the method of deliberation adopted by the Clinton commission, whose chair Harold Shapiro perceived his role as limited to providing procedural and organizational leadership. In the "Executive Summary" of cloning report, rather than adopting a method of operation suitable for procedural adjudication of moral controversies, the Kass Commission sought to establish a solid moral framework for analysis and develop appropriate vocabulary that would facilitate and situate their inquiry on the topic within a common philosophical and cultural tradition. This strategy shows close resemblance to the medieval practice of *disputatio* in which deliberations were situated within a well-established tradition in the academic discipline in which the question arose. Masters in disputations demonstrated full knowledge of the general field of inquiry in which the students serving as opponents or responders were trained over the years.

When the two approaches to diversity in deliberations are compared, it is noticeable that the forensic approach used by the Clinton Commission is not effective in developing creative solutions or a compromise on the issues. Instead, it becomes clear that there was "very little effort on the part of the Clinton Commission to minimize, mediate, or partially synthesize the conflicting testimony presented by the various

witnesses brought before it" (Kaveny, 2006, p. 317). On the other hand, the PCBE report demonstrates certain strengths such as the presence of a clear normative vision endorsed by Kass and the majority, as well as the critical consideration given to alternative perspectives on the ethical implications of human cloning. The Council also aimed to introduce readers to key texts by compiling a reader with a wide range of interdisciplinary scholarship that illuminates diverse aspects of the issue. Nonetheless, there are also some weaknesses to this model of diversity that diminish its effectiveness in resolving controversial moral issues. The report was primarily focused on the analysis of complex moral issues raised by human cloning and barely engaged with jurisprudential concerns relevant to the topic of human cloning. For instance, the Council did not address the question about the relationship between law and morality in a pluralistic society. In fact, the chapters on law and public policy do not provide a systematic analysis of the legal context and further implications of the proposed ban on different applications of SCNT. The major disadvantage, however, was that the fundamental moral stance endorsed by the Council did not show proper respect for diverse opinions, as their model of diversity based on *disputatio* did not incorporate a notion of diversity as equality. In this sense, the forensic model, which gives equal opportunity to opposing positions to present their respective cases in their own terms, appears to be more consistent with American political culture.

Based on the shortcomings of both epistemic models discussed above, Kaveny (2006) has proposed that advisory bodies such as NBAC and PCBE should adopt a model of deliberative diversity. This perspective is derived from "Aquinas's account of practical

reason and its attendant virtues" and, in particular, "his recognition of the need to take counsel before acting" which allows for diversity in perspective (Kaveny, 2006, p. 325). Aquinas has identified three virtues that guide all integral parts of the process of practical deliberation: (1) *euboulia* represents "the disposition to take good counsel;" (2) *synesis* is defined as "the disposition of good judgment about particular practical matters;" and (3) *gnome* is "the virtue of being able to recognize when one has a truly exceptional situation on one's hands" (Kaveny, 2006, p. 325). He has claimed that the best way to achieve a given end is to take counsel about the best means and has insisted that this fundamental principle remains constant when people engage in deliberations. Furthermore, the process of taking council frequently entails consulting other persons. Drawing on Aquinas's theory of prudence, Kaveny (2006) has suggested that the diversity sought by presidential commissions on bioethics should be gauged by the principles of deliberative diversity. The President plays a key role in this process since he is the major "deliberating agent" who requests counsel from the committee members of such advisory body:

> The diversity in membership required depends upon the particular question about which the President seeks advice. Seeking certain types of diversity would be highly inappropriate. As I noted above, it would be counterproductive to the deliberative process for the President to seek counsel from someone who doubted the worthwhileness of the end that serves as a basic principle of his deliberations. It would also not be productive for him to appoint someone who called into question his basic principles of morality, including political morality, or common sense truths about the nature of things. (p. 327)

Kaveny (2006) recognizes that such notion of deliberative diversity may seem incompatible with the values of representative democracy since there is an implicit assumption that participation in deliberations will be limited to those who share the basic views of the President. Nonetheless, she claims that the practical wisdom justifies the use of such method of deliberation since it is unrealistic to expect that the President will seek council from individuals who are fundamentally opposed to his worldviews. The method appears more efficient when the diversity of relevant expertise, practical solutions and theoretical approaches do not conflict with the mandate and moral parameters of the commission set out by the person seeking council, the President.

It is not clear, however, how exactly the underlying principles of the epistemic model of diversity proposed by Kaveny (2006) differ from the *disputatio* method utilized by the Kass Council, given that both methods presuppose that the decision-making process on controversial bioethical issues is shaped by one person's worldview on morality and law, either that of the master or of the deliberative agent, the President. The similarities are especially visible when one considers particular policy outcomes on bioethical issues that are produced by these methods of deliberation. In the cloning report, the Kass Council resorted to moral values derived from a conservative philosophical tradition of skepticism toward Post-Enlightenment philosophical perspectives on nature and law in order to recommend a ban on all human cloning that was not necessarily consistent with the existing legal framework and societal values. The deliberative diversity model, which has not been tested in actual policy deliberations yet, relies heavily on the practical wisdom of the person in charge of a particular institution in

the executive branch of government, the Presidency. It is unlikely, therefore, that policy recommendations of presidential commissions appointed by this principle will challenge the President's initial position on the issues at hand. The fundamental question which remains is how to ensure a broad political legitimacy of policy recommendations achieved by means of these two epistemic models of diversity, a goal which may not achievable by endorsing a comprehensive moral view incompatible with the shared values of democratic polity or by assuming that the President's actions as a deliberative agent will be essentially, and in all cases, guided by the principles of the public reason.

Finally, it is worth considering, in the context of the stem cell controversy, arguments that public policy outcomes on controversial moral issues should abide by an overarching moral principle. This position was endorsed by conservative PCBE members in the report on human cloning, and later on, during the Council's deliberations on the issue of stem cell research. Proponents of this mode of deliberation indicated that the controversy over the use of human embryos "should be resolved on the basis of a moral rule, not by shiftable tally on a balance sheet of benefits" (PCBE, 2002, p. 57). This mode of reasoning stood at stark contrast with the position of the Clinton Commission which deliberately refused to engage in moral analysis for its own sake on any of the bioethical issues under consideration. However, some PCBE members (i.e., the Chairman Leon Kass, Gilbert Meilaender, a professor of Christian ethics at Valparaiso University, Robert P. George, Professor of Jurisprudence at Princeton University, among others) aggressively advocated a deontological position in bioethical decision-making that postulates the absolute validity and non-contingency of moral rules in protection of early

embryonic life (Meilaender, 2001; George & Tollefsen, 2008). This moral absolutism rests on the assumption that the blastocyst is a locus of absolute dignity which necessitates the protection of its integrity at all cost. Subsequently, this position perceives the embryo at all developmental stages as morally equivalent to born people and advocates that pre-personal forms of life should be granted equal status in the moral community of persons. It is necessary to specify that this is only one strain of deontological thought since deontologists who support the developmental view of personhood insist that the blastocyst does not have the status of a human person. Unlike consequentialist moral theories that maintain that the rightness or wrongness of an action depends on its consequences, deontologists invariably believe that the rightness or wrongness of an action should be gauged in accordance with pre-existing, fundamental moral rules. The deontological approach to moral issues is commonly exemplified in reference to Kant's categorical imperative, and more specifically, the principle that persons must be treated as ends rather than as means. This principle translates into the notion of persons having inalienable rights and the moral imperative that under no circumstances can person's life be sacrificed to achieve some greater good. Under the categorical imperative, human life has an intrinsic value and cannot be treated instrumentally, that is, as means to achieve the common good. For those who advocate a deontological approach to the issue of stem cell research, the fundamental dilemma then becomes whether the categorical imperative applies to the blastocysts that are destroyed in the process of creation of hESC lines. Furthermore, is it legitimate to treat early embryos as persons that have inalienable rights? Should we take seriously arguments

against hESC research based on the assumption that the embryo, from the moment of conception, has full rights of personhood?

An intriguing deontological perspective on the issue of stem cell research was elaborated by the PCBE member Gilbert Meilaender in his article "The Point of a Ban or, How to Think about Stem Cell Research" (2001). In order to defend the federal ban on funding for hESC research, Meilaender (2001) has used the analogy of the ethics of warfare, and more specifically, Michael Walzer's theory of just war in which he distinguishes two kind of moral judgments: about when it is permissible to go to war (the theory of aggression) and about what it is permissible to do in war (the war convention) While endorsing a deontological approach to moral issues, Walzer has proposed the concept of supreme emergency as an ethical justification for the just war. The underlying assumption is that, even in the conditions of war, the moral limits set by deontology, i.e. the inviolable human rights of civilians, should always remain in place. These limits can be transgressed only in the most extreme cases of moral and strategic necessity. When such situations occur, the moral norms are temporary overridden; however, they can never be simply set aside. Although the limits set out by deontology are temporarily suspended for the reason of a just war, they must be promptly put back in place, or otherwise, the transgressors will bear a burden of criminality. In other words, while asserting the absolute validity of fundamental moral principles, Walzer has recognized that certain situations warrant a provisional adoption of a "utilitarianism of extremity," a position which is well-expressed by his maxim: "Do justice unless the heavens are (really) about to fall" (p. 231, Qtd. in Meilaender, 2001, p.10). Meilaender (2001) draws

on the Walzer's theory and the notion of supreme emergency to refute arguments by the bioethicists McGee and Caplan that a deontological position, which grants personhood and human rights to the embryo, does not rule out the possibility for an ethical justification for the destruction of blastocysts in hESC research. In their article, McGee and Caplan (1999) have emphasized the urgency of supporting biomedical research that has the potential to alleviate tremendous suffering and save numerous lives. They have also suggested that presently there is a supreme moral necessity of eradicating the worst degenerative diseases which can overrule fundamental moral principles protecting embryonic life. In contemporary societies where the lives of millions of people are threatened by fatal ailments, they claim, "the moral imperative of compassion [. . .] compels stem cell research" (McGee & Caplan, 1999, p. 153). Even if we accept the validity of deontological arguments about the embryo's equal moral status, the development of hESC research constitutes an ethical case of supreme emergency which justifies the killing of embryos in the interest of saving the community of human persons. The moral dilemma in stem cell research thus appears similar to "the dilemmas of war" faced by those whose cause is just and who cannot win unless they violate the war convention.

Nonetheless, Meilaender (2001) disagrees with this justification of sacrificing embryos in research and points out that it is hard to sustain claims about the development of medical treatments through stem cell research as an ethical case of supreme emergency, which can override the moral limits demarcated by deontology. In his view, relieving human suffering is a real concern; however, it does not constitute a supreme

imperative that necessitates resorting to a utilitarianism of extremity. He explains his position on stem cell research in reference to what Walzer has defined as a "sliding scale." In order to preserve the genuine dualism in just war theory (the two types of moral judgments), Walzer has warned that the moral urgency of winning a just war can make us impatient with moral prohibitions on means to achieve such victory. Subsequently, we may become tempted to violate moral rules that should never be violated and commit acts of war that are always wrong, even they are pursued for a good cause (i.e. actions that lead to destruction disproportionate to the good they would bring). The sliding scale is simply a way to erode the just war theory's distinction between the two kinds of moral judgments by resorting to utilitarian calculus on moral limits in war actions. Walzer emphasizes the need to resist a sliding scale by accepting that the rules of war are unconditional moral prohibitions that can never be violated even in order to defeat aggression. This approach is suggestive of a type of moral absolutism, "deontology with teeth" that preserves the important distinction between reasoning about how to fight and how to win a just war (Meilaender, 2001, p. 10). As Meilaender (2001) points out, although prohibitions on fighting in just war can make it more difficult to achieve the good ends, this does not warrant arguments against such prohibitions:

> The morality of warfare involves both judgments about values to be realized and rights to be upheld. When important values cannot be realized without violating rights, it would be peculiar simply to note this fact as an argument in favor of violating rights-as if a ban on such violation were out of the question. It might be

that we should do justice even if the heavens will fall, even if those values cannot then be realized or must be pursued in some slower, less certain, manner. (p. 10)

Nonetheless, Walzer is reluctant to commit to such moral absolutism and adopts an alternative approach which allows for the "utilitarianism of extremity." By contrast, Meilaender (2001) commits to a "deontology with teeth" approach and suggests that in the case of stem cell research we should be "doing justice even if the heavens are about to fall" (p. 15). Ultimately, he warns that lifting the federal ban on funding for hESC research would not only temporary override inviolable moral norms, but will eventually become a permanent condition that will normalize such morally questionable practices. There is a real danger that the goal to alleviate human suffering and eradicate would never be simply perceived as case of supreme emergency and would instead commit us to a utilitarian calculus in terms of a sliding scale.

Conclusions

In this chapter I reviewed contestations around the biopolitics of hESC research and related embryo technologies that can allow us to select the persons that will be brought into existence (Cole-Turner, 2003; Habermas, 2003; Rose, 2007b; PCBE, 2002). These perspectives alert us to societal challenges presented by molecular revolutions and predict a dystopian future in which human dignity and equality will be imperiled unless we develop political measures and moral guidance to prevent the self-instrumentalization of humanity. Although both reproductive and stem cell technologies are still considered controversial due to differing positions on the moral status of the human embryo, most urgent concern has arisen around intersections of these embryo technologies with the

techniques of inheritable genetic modification which have opened up the possibility for designing persons. One of these technologies, pre-implantation genetic diagnosis (PGD), has made possible the detection of a range of monogenetic disorders and chromosomal abnormalities in IVF embryos and its applications could enable prospective parents to select embryos for implantation that are free from specific diseases. Nonetheless, its non-therapeutic uses, such as sex selection and phenotype modifications in humans, remain highly contested, particularly as some regulatory environments have normalized the creation of designer babies. Over the last decade, stem cell research and related embryo technologies have increasingly attracted substantial investments by biotech companies and national governments. These new biomedical technologies are presently an integral part of the emerging global bioeconomy that thrives on permissive regulatory environments around the world. Therefore, it is by no means surprising that scholars across academic disciplines have strived to develop critical responses to new developments in biomedicine that could infringe on personal autonomy and alter essential aspects of the human situation. In *The Future of Human Nature*, which outlines a philosophical critique of liberal eugenics, Habermas (2003) has suggested that the vital questions arising from the technologies of human genetic modification are moral questions of radically different nature, as they touch on the ethical self-understanding of humanity. Furthermore, he has endorsed a departure from a proceduralist resolution of moral controversies towards a substantivist ethical doctrine of human nature based on the notion of "the ethics of the species." While his concern is understandable in context of societal challenges posed by PGD and stem cell research, it is problematic to assert that a

substantivist ethical perspective on human nature constitutes the pre-condition for the development of correct ethical self-understanding since such a philosophical position inevitably defies the proceduralist and cognitivist post-conventional morality at the heart of contemporary pluralistic discourse. Habermas's ethical perspective on new biomedical technologies has therefore renounced the abstract character of his proceduralism which presupposes that the political process is not shaped by any particular conception of the public good.

The chapter also provided a critical reflection on different theoretical frameworks that could be used to conceptualize the vital political issues arising from stem cell research and its intersection with other technologies of the embryo. I argued that sociological analyses influenced by Foucault's late work on biopolitics and governmentality tend to either overlook or simply dismiss the sense of urgency surrounding bioethical discourses on new developments in biomedicine and the biosciences. Scholars whose work is shaped by "the history of the present" paradigm view collective mobilizations in the field of biotechnology and regulatory attempts to establish normative limits to biomedical interventions as simple effects of the apparatus of government and the new trajectories of biopolitics which are producing a novel type of corporeal, neurochemical selves oriented towards a greater choice, prudence and responsibility in ethical actions, social practices, and political decisions. When applied to the stem cell controversy, the analytics of governmentality and biopolitics is counterproductive, as it emphasizes the submission of discourse participants to scientism and rationality and fails to recognize possibilities for a reflexive societal critique and

social change by means of consensus-oriented approaches. Therefore, I have suggested that the normative notion of public sphere as part of social life, where public opinion on issues of common political concern can be formed through rational-critical discourse, constitutes a more relevant analytical framework to examine scientific controversies with heavy political and ethical overlays, such as stem cell research and human cloning. Habermas's model of deliberative democracy and his notion of discourse ethics provide useful analytical lens to examine whether regulatory responses to hESC research have reflected a wide public consensus on the ethical dilemmas. Yet, I have argued that there are certain limitations in Habermas's model of universalistic justification of norms in practical discourse, as a normative ideal of rational will formation and collective decision-making in the democratic public sphere, which are reflected in public debates on the issue of stem cell research. Over the years, he has continually revised his original conceptualization of the bourgeois public sphere as a pristine realm of rational-critical discourse to incorporate the principles of discourse ethics and, later on, emphasize constitutional patriotism. Nonetheless, his strong consensus-oriented model of pubic reason requires that all participants in practical discourse of justification transcend interest-oriented and value-based positions in order to arrive at a shared understanding in accordance with universal moral norms. In our pluralistic societies, however, rational agreement on practical-political matters is not always an attainable goal, especially on highly contested moral issues, such as stem cell research, whose resolution requires that fundamental value differences between discourse participants are neutralized. Policy deliberations on such controversies, however, often lead to procedural disagreements

over the normative standards of debate, and subsequently, differences in identities, situations and experience between participants are amplified and become irreconcilable value disagreements. Therefore, critics have pointed out that Habermas's strong epistemic model needs to be revised to acknowledge that conflicts and disagreements exist even at the level of moral principles and fundamental procedures (Bohman and Rehg, 1997; McCarthy, 1992). Furthermore, we need to acknowledge the essentially conflicting nature of political discourse and the inevitable limitations in appeasing strong moral and policy disagreements in contemporary pluralistic societies.

Finally, the chapter examined methods of public deliberation, endorsed by the two U.S. national bioethics commissions in their reports on stem cell research and human cloning. The Clinton commission sought a consensus-oriented approach to public deliberation in accordance with the "reasonable pluralism" of philosophical, religious and other comprehensive doctrines or worldviews in contemporary democratic societies. The NBAC members recognized the diverse and strongly held moral views on the issue of stem cell research and emphasized the need to establish a common ground that would be acceptable to the vast majority of people regardless of their conflicting views on the moral standing of the human embryo. The Commission engaged in the balancing act of developing stem cell policies which would show respect for all reasonable positions on the issues at hand while, at the same time, emphasize fundamental values affirmed by these conflicting views. By contrast, its successor, the Bioethics Council appointed by President Bush did not initially endorse a method of reasoning oriented towards overlapping consensus, but rather sought to achieve a deeper understanding of the moral

dilemmas opened up by controversial biomedical research. The Council primarily aimed to develop substantive insights and arguments on the challenges presented by advances in biomedical technology, and therefore, its members showed little interest in outlining procedures that would guarantee diversity of perspectives. Neither did the Council members achieve a common understanding of what type of policies regarding embryo research would best serve the common good. Nonetheless, when this approach failed to produce adequate policy recommendations on the issue of research cloning, the Council resorted to the consensus approach endorsed by the Clinton Commission, which was more consistent with the shared political culture and underlying values of a pluralistic democratic society.

CHAPTER 6

TWO POLICY ALTERNATIVES

This chapter offers a comparative perspective on the US and the EU stem cell policies. It examines different cultural, political and social factors that have contributed to collective mobilizations around the issue of hESC research and have influenced policy outcomes in these two political entities. In the US societal controversies over the morality of research involving human embryos and fetuses have their own complex histories that have uniquely shaped the public responses to stem cell research. The stem cell controversy quickly became implicated in America's relentless "culture wars" as opinions on the issue were formed along the existing political divisions between liberals and conservatives. It constituted yet another chapter in a long-term science policy debate which originated with the Supreme Court's ruling in *Roe v. Wade* in 1973. This was a much-contested decision that legalized abortion nationwide, but also had some far-reaching social and political implications, as it placed women and their fetuses at the center of some of the most heated debates in contemporary American history. The landmark ruling that the fetus is not a person within the meaning of the 14th Amendment, and therefore does not have the constitutionally protected rights of a person, quickly raised concerns among social conservatives and anti-abortion activists about the use of aborted fetuses in biomedical research. As many women celebrated the affirmation of their right to choose, others imagined the possibility of horrific experimentations conducted on fetuses from terminated pregnancies. Subsequently, conflicts on the questions of fetal personhood and abortion became intertwined with discussions about

scientific research which uses embryos and fetuses. Some pro-life advocates in America had even perceived the use of neutral clinical terms such as "embryo" and "fetus" as nothing more than a dehumanizing tactic by their pro-choice opponents. Therefore, it is by no means surprising that in America opposition to abortion and opposition to biomedical research that involves embryo destruction go hand in hand.

The contentious public debate, which unfolded after the isolation of the first hESC lines in 1998, has revived some salient political themes of the earlier ethical controversies over abortion and fetal transplantation research. In the early 1990's clinical trials with human fetal tissue were conducted on patients with Parkinson's disease, aplastic anemia, thalassemia, insulin-dependent diabetes mellitus, the DiGeorge syndrome, Gaucher's disease, severe combined immunodeficiency, acute myelogenous leukemia, Fabry's disease, and the Hurler syndrome. Scientists and patients' rights organizations expected that a considerable number of patients with other conditions could also benefit from fetal tissue transplants. Based on the enormous therapeutic promise of fetal tissue transplantation, the Clinton administration did not hesitate to overturn the existing ban on federal funding. Under the directive of the previous Republican administration of George Bush, the Department of Health and Human Services (DHHS) had suspended financial support for fetal transplantation research. With the lifting of the funding restrictions, the controversy over fetal tissue transplantation quickly revived old concerns regarding the morality of abortion, but also raised some novel bioethical issues: "Will the demand for fetal tissue donation encourage elective abortions? Should pregnant women have the right to designate recipients of fetal transplants? Is fetal transplantation

indeed effective and necessary? Is informed consent required for the use of fetal tissue for transplantation?" Arguments for the morality of abortion entered the controversy since fetal tissue transplants could be obtained through induced abortions only. Moreover, the issue mobilized different interests groups which presented competing arguments regarding the therapeutic benefits of fetal transplants. Knowledge claims by proponents and opponents were often supported with references to privately funded studies, which raised additional concerns about the impact of public and private funding on scientific innovation. The multi-dimensional controversy over fetal transplantation research in the 1990's was not amenable to an easy closure or resolution, since it was not possible to constrain the arena of negotiation narrowly within any specific domain, such as science, ethics, law, or politics.

The initial cycles of development in the stem cell policy debate have closely followed patterns of conflict discernible in the controversy on fetal transplantation research. Convergences could be found in two interrelated questions that have become central to both controversies: (1) the contested moral status of human embryos and fetuses, and (2) concerns regarding the key role of federal funding in encouraging and fostering scientific innovation in the biomedical field. As Robertson (2010b) has indicated in his analysis of the legal and constitutional issues pertaining to stem cell research, the U.S. debate over that last decade has largely focused on ethics and funding issues, rather than on positive law. Although several states have passed bills prohibiting embryo research and human cloning, much of the controversy has been about federal funding and administrative policy. From the very beginning, hESC research invigorated

the pro-life movement and the politics of abortion became implicated in policy debates on the issue. While the Supreme Court's abortion cases bear relevance for the stem cell controversy, there has never been a ruling on the constitutional status of embryos and most states have no law on that matter (Robertson, 2010b). The ruling in *Roe v. Wade* that fetuses do not have constitutionally protected rights as persons could be potentially extended to embryos, however, the real question is whether the federal government or different states would decide to protect embryos by prohibiting their creation for research and further destruction in research. Although the state can have legitimate interest in showing respect for early human life, the Court's decisions in *Roe v. Wade* and *Planned Parenthood v. Casey* have established that the government's actions should not curtail women's access to abortion. It is possible to argue that since embryos are outside the body, rulings regarding abortion do not apply in the case of hESC and state restrictions would be justifiable. Whether such a law meets a "rational basis justification" is important, however, we should also consider the impact of state restriction (Robertson, 2010b). It is likely that laws that interfere with the creation of embryos for infertility treatments would be unconstitutional and would need more than just rational basis of justification since the interest in reproducing is constitutionally protected. Moreover, as Robertson (2010b) points out, whether decisions to restrict embryo research are constitutional valid "would depend on whether that research is part of a constitutionally protected right to research or is otherwise required as part of a negative right to obtain needed medical treatment" (pp. 193-194). If the restriction involves the content of ideas generated or knowledge produced in research, it is likely that the First Amendment will

be implicated, and therefore, the ban on research may turn out to be invalid. However, if it concerns only the methods or means used to generate knowledge, then such a method-based restriction may be constitutional. Constitutional protection for hESC research and treatments will really depend on how demanding courts are in applying the rational test basis, e.g. if the test is "more akin to the intermediate scrutiny standard sometimes used in evaluating non-content based restrictions on speech, then state restrictions on embryo research might be struck down" (Robertson, 2010b, p. 194). Furthermore, an additional basis for constitutional protection for stem cell research may be found in "a fundamental negative right to have and use effective medical treatments as part of a person's due process right to life or liberty" (Robertson, 2010b, p. 194). Although the courts have not yet recognized a negative right to receive necessary medical treatments, Robertson (2010b) hypothesizes that there might be a greater judicial scrutiny over hESC research in the future, especially when hESC therapies are established as safe and effective medical treatments and provided that any American state attempts to prevent their use.

Over the last ten years, the major issue in the U.S. stem cell debate remained the federal funding policy. This clearly demonstrates convergences between hESC research and the preceding controversy on fetal transplantation research, which has also largely focused on funding restrictions imposed by the administration. These two ethical controversies are indicative of how scientific innovation is traditionally regulated and funded in America. The major sponsor of basic biomedical research in the U.S. is the federal government, which usually relegates the responsibility for allocating funds to the NIH, a federal agency under the umbrella of the DHHS. Although private pharmaceutical

and biotechnological companies are generally interested in sponsoring biomedical research with potential commercial applications, basic research which generates fundamental knowledge in the biosciences and biomedicine comprises only a small percentage of all private sectors investments. As indicated a report on stem cell research commissioned by the U.S. National Research Council in 2001, private investments in biomedical innovation reached not more than 14 percent in the 1990s, with pharmaceuticals being the main area of interests for biotech and pharmaceutical companies (*Stem Cells and Regenerative Medicine*, 2002). It is rather paradoxical that, while the issue of federal funding became dominant in the stem cell debate, there has been little concern about restricting private investments in the developments of hESC therapies. This seems to be a peculiar characteristic of the U.S. science policy regarding innovations in biomedicine. Generally, regulation at the federal level is implemented through funding, rather than through federal or state laws, which often results in a regulatory vacuum (e.g., there is a regulatory discrepancy between publicly funded projects and research supported by privately sponsors). Therefore, my analysis of the U.S. federal policies on stem cell research during Clinton, Bush and Obama's presidencies (outlined in Table 1) will focus primarily on the debate on federal funding.

Furthermore, the US debate on the federal funding for hESC research was intertwined with overarching ethical and philosophical critiques of biotechnology and biomedical research. Over the last ten years, bioconservatives have become leading voices in America's bioethical debates and have succeeded in framing the issue of hESC research as intricately related to the negative impacts of modern science and technology

on the future of humanity and American democracy (Fukuyama, 2003; Cohen, 2008; Levin, 2008). Science debates on a wide range of topics, such as stem cell research, global warming, human cloning, and evolution have reflected America's culture wars. The most common reference for conservative critiques of the moral premises of modern science has become what the PCBE Chair Leon Kass has described as "the immortality project." Kass (2003) believes that the inability of people in contemporary society to come to terms with their own mortality, and subsequently, their desire to prolong youthfulness by sacrificing embryonic life in biomedical research, is deeply rooted in the individualistic philosophy of ethical liberalism. Others, like Fukuyama (2003) and Cohen (2008), have expressed communitarian concerns about the devastating social and geopolitical consequences of increased longevity. Fukuyama (2003) has claimed that advances in regenerative medicine made possible by stem cell research will lead to the prolongation of human life span far beyond what we can imagine today. While nowadays the average life span is roughly 75 years for men and 80 for women, the biotech companies aim to extend living to 125 or even 150 years. He argues that this possibility, albeit only hypothetical, raises significant ethical challenges concerning the biopolitics of aging. The normalization of extended life spans will lead to profound demographic and social changes in the advanced Western countries. These aging societies will face enormous burdens on their social security systems, but also strategic challenges in national and global politics.

Stem cell policy in the European Union is not less complicated, as it was shaped by diverse cultural contexts, national histories, political and religious divisions, as well as

by the ambitious project of European integration. While regulatory contexts for stem cell innovation in the member states significantly differ, science policymaking at the supranational level is influenced by the EU traditional consensus politics. Most research activities in the field of stem cell research are currently being carried out with EU funding for transnational research networks that involve collaborations between the member states. As indicated in the report the *Expert Group on Science and Governance* at the Directorate-General for Research of the European Commission, the EU's strategic investment in the development of stem cell technologies and regenerative medicine has largely been driven by the political goal of establishing the most dynamic and competitive knowledge based economy (Wynne et al., 2007). Currently, research across Europe is conducted on embryonic, iPS cells, fetal, adult and tissue-derived stem cells. Hovatta et al. (2010) have indicated that the field of stem cell research in Europe is so quickly expanding that there is a constant need to update policies both at the EU level and in member states that have passed laws to regulate research endeavors in regenerative medicine. Similarly, the ethical dilemmas are constantly shifting, as the controversy over hESC research is presently complicated by new ethical concerns arising from recent experiments with iPS cells. Hovatta et al. (2010) also point out that the European Science Foundation (ESF) has only recently updated the information on the stem cell policy in the 30 ESF membership countries (although there are 27 EU member states, the ESF funds scientific research in 30 European countries, with the non-EU members being Turkey, Croatia, and Norway). Based on their data, 25 countries have adopted legislation which explicitly prohibits human reproductive cloning (excluding Poland, Lithuania, Ireland,

Croatia, and Luxembourg). Seven countries have passed laws that sanction the derivation of new hESC lines from supernumerary IVF embryos (Belgium, Sweden, United Kingdom, Spain, Finland, the Czech Republic, and Portugal). These countries also permit SCNT, with the exception of Finland and the Czech Republic, where the law does not explicitly states whether the cloning technology is prohibited or allowed. Only three countries, Belgium, Sweden, and the United Kingdom, have adopted legislation permitting the creation of human embryos specifically for research, although under strict conditions. As of 2010, seventeen countries have explicitly permitted the derivation of hESC from supernumerary IVF embryos, while six countries do not have specific laws regulating stem cell research (Bulgaria, Croatia, Cyprus, Luxembourg, Romania, and Turkey).

In the following sections, I explore in greater detail how the heated U.S. national debate on hESC research has unfolded in the context of vigorous anti-abortion advocacy, the existing congressional ban (i.e., the Dickey-Wicker Amendment) on federal funding for research that creates or destroys human embryos, and America's relentless culture wars. I emphasize the differences between the stem cell policy adopted by Bush administration and Obama's guidelines for federal funding for hESC research. I also briefly outline some recent legal challenges to the current administration's permissive stem cell policy. The chapter further discusses major socio-political factors and cultural differences between EU member states that have influenced policy decisions regarding the funding and development for stem cell technologies. I analyze the complicated regulatory environment of the EU, as well as discrepancies between national

governments which have adopted a variety of approaches to regulating stem cell research. More specifically, I discuss four policy alternatives adopted by the EU member states: permissive, permissive compromise, restrictive compromise, and prohibited hESC policy.

The U.S. Debate on Federal Funding

Robertson (2010a) has indicated that the science policy of a country could be defined as the aggregate of laws and policies that determine the direction of scientific development and the overall use of science. This definition, however, is rather broad as it may be easily confused with general descriptions of innovation policy. He further points out that the term is better understood when used to describe a smaller subset of laws that have a direct impact on science practice, e.g. the laws and policies that can facilitate, subsidize, impede, enable, or regulate scientific activities. Robertson (2010a) has suggested that analyses of science policy should engage primarily with that particular body of laws and policies which can help us see the multifaceted and often complicated interactions between society and science that stimulate scientific advances and their practical applications. In most cases, the goal of science policy is to support and advance science in all reasonable ways, e.g. by providing subsidies for education, training and research, creating favorable patent and trade policies, and removing constraints on certain research activities. Sometimes, however, science policy aims to restrict certain ways in which science develops and limits how it is used.

The history of the stem cell controversy in the United States illustrates this dual nature of science policy (Table 2). Discoveries in the field of human stem cell research have raised concerns about the ethical regulation of scientific practices and general

disagreements about how biomedical science should develop. When on November 6, 1998 Wisconsin developmental biologist Dr. James Thomson and his team reported the first ever isolation of hESC lines in the prestigious journal *Science*, researchers, scientists and health administrators immediately predicted that stem cell research would lead to new therapies for some of the worst human diseases. The discovery took place in the political climate of strong pro-life activism and contentious debates over the morality of embryo research. It was not surprising that stem cell research was quickly implicated in a long-term science policy debate on the use of human embryos and fetuses in research. Moreover, the socio-political conditions for stem cell innovation were unfavorable since there was a strong opposition against any human embryo research in the Congress, which the Republican Party had taken back in the 1994 midterm elections. As I have previously indicated, basic biomedical research which generates fundamental knowledge in medicine and the biosciences is primarily funded by the federal government through the NIH, whose annual budget in 2007 was approximately $29.4 billion. Dr. Thomson's work on the isolation of the first hESC lines in the late 1990s was not eligible for NIH funding due to the 1995 congressional ban. The rider, known as the Dickey-Wicker Amendment, was attached to the 1995 appropriation bill and prohibited public funding for both research that creates human embryos and research that destroys embryos and fetuses. Therefore, the isolation of the first hESC lines was supported by private sponsors like the Wisconsin Alumni Research Foundation and the California-based biotech company Geron. It is worth mentioning that in America private funding for biomedical

research that involves the destruction of embryos has never been outlawed or regulated by the federal government.

The initial disapproval of hESC research by religious groups and pro-life constituencies was by no means surprising; the ethical controversy constituted yet another chapter in an enduring public debate on the morality of research involving human embryos and fetal tissue. The earlier constitutional debate on abortion provided a background for the development of the stem cell controversy. In 1973 the abortion was legalized nationally with the Supreme Court's ruling in *Roe v. Wade* that the fetus is not considered a person as defined by the Constitution, and therefore, it does not have constitutionally protected rights. In the aftermath of this legal precedent, interest groups and some members of Congress became concerned about the potential uses of aborted fetuses in scientific research. In 1973 the Department of Health, Education and Welfare (DHEW) established a moratorium on funding for research on live human fetuses. A year later, the U.S. Congress imposed a temporary moratorium on federal funding for clinical research which may use "a living human fetus, before or after the induced abortion of such fetus, unless such research is done for the purpose of assuring the survival of such fetus" (PCBE, 2004). The development of IVF technology by Dr. Robert Edwards and Patrick Steptoe and the birth of the world's first "test tube" baby, Louise Brown, on July 25, 1978 in Manchester, England significantly contributed to the ethical controversy over advancements in human embryo research. Between 1975 and 1993, the U.S. federal government did not fund any controversial embryo research, including promising new technologies in the field of assisted human reproduction. Restrictions on government

funding for embryo research had a negative impact on the overall development of biomedical science as the development of IVF technologies was relegated to the largely unregulated private sector, where there was little interest in supporting basic research and its non-commercial applications. Subsequently, scientists and proponents of embryo research have repeatedly voiced concerns that the lack of government sponsorship in the biomedical field during that period had significantly impeded medical research on human infertility, congenital disorders, cancer, as well as the development of innovative methods for diagnosis of genetic diseases in embryos (Dunn 2005; Scott 2006).

The federal science policy changed in 1993 with a historical decision of the Clinton administration and the U.S. Congress to allow federal funding for some types of human embryo and fetal research (i.e., fetal transplantation research). After his election in 1992, President Clinton asked the newly appointed Director of NIH, Harold Vamos, to develop guidelines for embryo research. Two years later, the NIH Human Embryo Research Panel (HERP) developed recommendations to fund research on both supernumerary IVF embryos and embryos created for research purposes. Regardless of the panel's recommendations, President Clinton was cautious and approved federal funding only on spare embryos created specifically for infertility treatments. However, the policy did not last long since the GOP took control of the Congress in 1994. The Republican majority quickly moved forward a bill prohibiting the use of federal funds for any research activities in which a human embryo is either destroyed or created. The 1995 congressional ban was attached to a bill appropriating funds for NIH, and has since been renewed by the Congress each year in consecutive appropriation bills. Thomson's

discovery showed such great promise for the advancement of biomedicine that the Clinton administration sought legal advice on the possibility of funding hESC research. In January 1999 the Department of Health and Human Services (DHHS) released the legal opinion of their top lawyer Harriet Raab that the Dickey-Wicker Amendment did not apply to hESC cells *per se*. She claimed that, although hESC lines were derived from human embryos, they were not living organisms and thus did not fall under the statutory definition of "embryo" in the Congressional ban (Dunn, 2005). Robertson (2010b) has indicated that Harriet Raab's legal advice was the key event in the federal funding debate on hESC research. Given that hES cells were not themselves embryos, there were no obstacles to funding research on these cells with federal money. Although opponents of embryo research insisted that funding for hESC research still violated the spirit of the Congressional ban, the legal opinion of the DHHS General Counsel was not challenged by either Congress or President Bush. Obviously, the Clinton administration was aware that taxpayers' money could not be used for the actual derivation of hES cells, a process which inevitable involves the destruction of human embryos. However, federal funding could be provided for research on existing hESC lines, on the condition that the derivation of these cells was carried out with private funds and took place in facilities not funded by the NIH. In 1999 the NIH, in consultation with the National Bioethics Advisory Commission (NBAC), immediately began drafting guidelines on the types of hESC research eligible for federal funding. It was ready to allocate grants when the new administration under President Bush halted such efforts in 2001.

In his presidential campaign, George W. Bush strongly opposed the decision to allocate federal funding for hESC research. Shortly after the 2000 presidential elections, stem cell research became one of the most significant political issues arising from the rapid development of regenerative medicine and new health technologies. Commentators have observed that during the first eight months of the Bush Presidency, hESC research was the leading domestic issue, and it was not incidental that there were federal legislators who sought to criminalize this promising biomedical innovation (Devitt, 2003). What stirred many people's emotions and made the issue especially contentious was the technology used to derive hES cells. The first hESC lines were extracted either from surplus IVF embryos, which were destroyed in the process, or from fetuses, which had been aborted and donated for research. In America, anything that seems to justify or support abortion is considered moral abomination by religious groups and social conservatives. The stem cell debate, therefore, became inextricably linked to the abortion controversy and moral questions of embryonic and fetal personhood and rights. The issue served well a conservative political agenda as it re-energized the pro-life movement and the religious right. At the same time, hESC research mobilized the pro-choice community, but also diverse groups that were not particularly concerned about abortion rights, such as patients' rights advocates, scientific societies, academic associations, and many citizens, who rallied in support of science and freedom of research. The controversy intensified when the Bush administration announced a new, more restrictive funding policy on stem cell research. In a televised address to the nation on August 9, 2001, President Bush expressed the moral reservations of the religious right about hESC

research. He used Christian and pro-life rhetorics to argue that each one of the embryos from which stem cells were extracted was "unique, with the unique genetic potential of an individual human being" (Bush, 2001, p. 12). He also emphasized the connection between stem cell research and human cloning by using the dystopian imagery of Huxley's *Brave New World*: "We have arrived at that brave new world that seemed so distant in 1932 when Aldous Huxley wrote about human beings created in test tubes in what he called a "hatchery." In recent weeks, we learned that scientists have created human embryos in test tubes solely to experiment on them. This is deeply troubling." (Bush, 2001, p. 12). The President further indicated that his decision to limit federal funding for research only on the already existing seventy-eight hESC lines was influenced by his deep ethical concern about embryonic life, as well as by the imminent threat posed by scientific developments to the moral foundations of society.

Stem cell research advocates have argued that the President's deep moral concern for the destruction of frozen embryonic life in research was nothing more than a rhetorical strategy to gain the support of conservative voters. The reality is that thousands left-over embryos are discarded from IVF clinics around the worlds annually and treated as medical waste. The chances that these embryos, whose viability decreases under prolonged cryopreservation, will ever be adopted are practically non-existent. Stem cell proponents have argued that if frozen IVF embryos are anyway routinely destroyed, then it is unlikely that a ban on federal funding for hESC research will save their lives. Over the years, public opinion polls on the issue of stem cell research have shown variations depending on the organization conducting the survey and the phrasing of the questions

asked. Nonetheless, polls conducted in the summer of 2001, around the time of the presidential announcement of the funding restrictions, have indicated that most Americans supported stem cell research which uses surplus IVF embryos. For instance, a Harris poll conducted in July 2001, which specifically asked about stem cell derivation from this type of embryos, showed public support for hESC research at 61% (Nisbett, 2004b). The restrictions on federal funding imposed by the Bush administration have prompted unprecedented level of grassroot activism on the issue. Many nationally established foundations, scientific societies, university associations and patients' rights groups have aggressively waged science education and media campaigns to promote stem cell research and secure private funding for the development of hESC therapies. In 2001, research advocates formed the nation leading pro-cure coalition, the Coalition for the Advancement of Medical Research (CAMR), whose main objective was to increase opportunities for federal funding of biomedical research on hES cells. The topic of stem cell research entered American pop culture when the Superman actor Christopher Reeve, left paralyzed from a spinal cord injury following a riding accident, and actor Michael J. Fox, diagnosed with Parkinson's disease in 1991, became keen advocates for stem cell research. Furthermore, hESC research has received bipartisan support in the U.S. Congress. Prominent Republican Senators such as Orrin Hatch, Arlen Specter, John McCain, among others, have opposed the Bush administration's policy and have claimed that federal funding for hESC research is a necessary precondition for the development of regenerative medicine in an ethically responsible way. Nancy Reagan, whose husband the former President Ronald Reagan died on June 5, 2004 at the age of 93 after a ten-year

struggle with Alzheimer's disease, has played a leading role in ensuring the Republican support for a bill in favor of federal funding for embryonic stem cell research. A bi-partisan bill, under the name of *The Stem Cell Research Enhancement Act*, was passed on May 24, 2005 in the Republican-controlled House by a 238-194 vote, with a group of 50 Republicans in favor of it. Nonetheless, President Bush has consistently opposed legislation that would restore the funding stem cell policy of the Clinton administration. On July 18, 2006 the Senate voted 63 to 37 to loosen restrictions on federal funding for hESC research, just four votes short of the two-thirds majority needed to override a presidential veto. A day after the decision, President Bush vetoed the bill with the argument that such legislation "would support the taking of innocent human life in the hope of finding medical benefits for others" (CNN.com, 07/19/2006). This was the first time Bush used his veto power in his presidency. In 2007 legislators on Capitol Hill made another attempt to ease restrictions on federal funding for hESC research. In June the House granted final congressional approval for the Stem Cell Enhancement Act, however, President Bush again vetoed the bill.

Other leading biotech countries' regulatory approaches to stem cell research, and related technologies, such as SCNT and hybrid embryo research, have influenced the U.S. science policy debate. Canada allowed hESC research using supernumerary IVF embryos, while prohibiting both reproductive and research cloning in 2004. That same year, the United Kingdom legalized the creation of hESC lines through SCNT. Its regulatory agency HFEA issued its first license for research cloning to a research team at Newcastle University's Institute of Human Genetics, which was working on the

development of hESC-based therapy for diabetes. The stem cell researchers were allowed to clone and grow human embryos for not more than 14 days for the purposes of extracting their stem cells (AP/CNN.com, 6/16/2004). This unprecedented decision made news around the world and provoked contentious debates on the global biopolitics of hESC research and human cloning. Some Asian countries, such as China, Japan and Singapore, have also regulated hESC research and legalized human cloning for research purposes. There is no federal legislation in the United States that regulates human cloning since the lawmakers could not achieve agreement on any of several drafts of cloning bills. Following the rejection of the Greenwood Substitute Amendment to allow the cloning of human embryos, the *Weldon-Stupak Human Cloning Prohibition Act* (H.R. 2505) of July 31, 2001 prohibiting all types of human cloning was passed by the House (241-155) on February 27, 2003. This bill was strongly supported by President Bush and the National Right to Life Committee, but also received bipartisan support by some pro-choice advocates, as many feared that the lack of regulation would lead to the normalization of ethically questionable practices such as the creation of "designer babies" and the commercialization of oocyte donation for stem cell research. The measure criminalized both reproductive and therapeutic cloning by establishing penalties of up to 10 years in prison and a fine of $ 1 million for attempts to clone human embryos. The bill, however, never became a law as the Senate did not act upon it and left the matter to the 108th Congress.

In the meantime, the Biotechnology Industry Organization has effectively lobbied legislatures in states with large biotech industries to legalize research cloning (i.e.,

California, New Jersey, Missouri, and Iowa). The Biotech Industry has also supported state initiatives and referendum measures that would secure state funding for hESC research (Table 3). California and New Jersey were the first U.S. states that passed bills allowing SCNT for research purposes. Currently, fifteen states have passed laws prohibiting or regulating human cloning (more detailed information of these statutes is presented in Table 4). There seems to be a great discrepancy between state laws regulating human cloning. The State of California banned human reproductive cloning in 1997. California legislature was followed by Arkansas, Connecticut, Indiana, Iowa, Maryland, Massachusetts, Michigan, Rhode Island, New Jersey, North Dakota, South Dakota, and Virginia, which all have prohibited the reproductive cloning of humans. Arizona and Missouri have measures regulating the use of public funds for cloning, while Maryland does not allow state funds allocated for stem cell research to be used to finance efforts for reproductive cloning, and possibly research cloning, depending on how one interprets the definition of human cloning in the statute. Louisiana also passed a bill that banned reproductive cloning but that law expired in July 2003. The laws of Arkansas, Indiana, Iowa, Michigan, North Dakota, and South Dakota have clearly prohibited cloning for research purposes. By contrast, the law of Rhode Island does not explicitly prohibit research cloning. Ambiguities exist in Virginia's law, which generally prohibits human cloning, although conflicting interpretations are possible since the term "human being" used in the definition of human cloning is not defined by the law. Human cloning is defined by this law as the creation of or attempt to create a human being by transferring

the nucleus from a human cell from whatever source into an oocyte from which the nucleus has been removed.

In Chapter 3, I discussed in greater detail how the framing of hESC research as a moral issue closely related to the regulation of human cloning has become a major factor in sustaining the public controversy on both sides of the Atlantic. Presently, there is no global agreement over the issue of human cloning for either reproductive or therapeutic purposes. The human cloning controversy was fueled by the U.S. media which gave extended publicity to Clonaid's announcement in 2002 that their scientists had produced the world's first cloned baby, a girl named Eve. Most EU countries dissented from the UK Parliament's decision to legalize cloning for research purposes in 2000 since there were concerns around Europe and internationally about exaggerated expectations and misrepresentations of the clinical potential of research cloning (Cobbe, 2005). The urgency around the issue of human cloning was exemplified by the United Nations' failed attempt to pass a legally binding bioethical treaty which would prohibit human cloning internationally. The legislative process was initiated in August 2001 with a French-German proposal to the U.N. General Assembly for an international convention against the reproductive cloning of human beings which was supported by all members. During a session of the U.N. Legal Committee in November 2001, the Vatican insisted on expanding this initiative to include a prohibition on cloning for research purposes. This position was also supported by the U.S. and Costa Rica, and the two countries jointly submitted an alternative proposal for a ban on all types of cloning. In 2003 the Ad Hoc Committee of the U.N. Legal Committee reviewed both proposals, however, they

could not reach consensus on a resolution. After a two year deferral, on November 6, 2005 the Assembly voted on the U.S.-Costa Rican proposal. The UN members could not decide if they should ban all human cloning, including the use of SCNT for stem cell derivation, or only reproductive cloning. The Unites States and 60 other countries supported a ban on both reproductive and therapeutic cloning, however, 24 nations wanted to prohibit only reproductive cloning. The treaty was not approved as the UN works on the basis of consensus. An international convention on human cloning was therefore not ratified, mainly due to the decision to conflate the issues of reproductive and therapeutic cloning.

State Initiatives and Referendums

Conflicts between national government and subnational governments over aspects of economic policy and social regulation often exemplify hidden tensions in federal systems of government. In the U.S. policy decisions of the Bush administration have triggered disagreements between the White House and state governments on key issues concerning education, welfare, homeland security, and environmental protection. The administration's approach to a variety of social issues, such as stem cell research, abortion, and gay marriage, has also prompted increasing state activism and policy initiatives. Stem cell policy initiatives in different states were developed in response to the federal government's failure to develop a comprehensive regulatory strategy for the advancement of regenerative medicine. Between 2001 and 2008, President Bush primarily aimed to appease conservative constituencies and adopted a policy of restrictive compromise, that is, federal funding was limited to research on the hESC lines created

prior to August 2001. There were no attempts to develop a national regulatory framework that would ensure the ethical governance of stem cell technologies and regenerative medicine. This approach to hESC research clearly illustrates the focus on deregulation and contentious embryo politics in the administration's policy decisions in the field of bioethics. Mintrom (2008) has argued that this lack of regulatory oversight at the national level had significantly undermined U.S. federalism by prompting states to assume a leadership role in the funding and regulation of stem cell research.

State initiatives to regulate and fund hESC research were also a direct result of the unprecedented grassroot activism and awareness raised around the issue. Over the years, the Bush administration's decision to restrict federal funding became highly unpopular with the American people (Reynolds, 2008). Although in the beginning the general public was not familiar with the highly specialized policy debate, the voters' support for hESC research and legislative initiatives to restore federal funding has steadily increased after 2004. Stem cell research became an important issue in the 2004 presidential race and then again in 2008. During both presidential races, the issue of federal funding was debated by the candidates in nationally televised presidential debates. Polls and public opinion research have shown that, for most Americans, the possibility of innovative medical treatments outweighed ethical concerns about the protection owed to embryonic life. According to a *CBS News* poll from May 24, 2005, a majority of Americans approved of the use of hES cells in medical research. Fifty-eight percent said they supported stem cell research, while 31 percent disapproved. Similarly, a July 2005 poll by *Princeton Survey Research Associates* for *the Pew Research Center for the People and the Press* and *the*

New Forum on Religion & Public Life indicated that 57 per cent of respondents believed it was more important to conduct stem cell research than to avoid destroying human embryos. Similarly, the poll conducted by *Knowledge Networks for the Genetics & Public Policy Center* in September 2005 showed 66.6 per cent of the respondents approving embryonic stem cell research. Based on the survey of the *Virginia Commonwealth University Life Sciences*, conducted in September 2005, 58 per cent of the people favored medical research that uses stem cells from human embryos. Most polls indicated that public support for hESC research has continued to increase since 2005. In May 2006, a poll by *the Coalition for the Advancement of Medical Research* showed 73 per cent of the Americans supporting ESC research, an increase of five points from the previous year.

There has also been a growing public support for the application of cloning technology in stem cell research, although the issue of human cloning remains extremely controversial. A public opinion study on the topic, which was conducted in the summer of 2005 by *Research!America*, showed 69 per cent of the respondents in favor of the use of SCNT to create embryos for stem cell derivation. Yet, when a similar question was asked using the term "therapeutic cloning" the level of support dropped by 10 percentage points to 59 per cent approval. The survey also emphasizes the general public's concern that the United States should be a global leader in all areas of health-related research, with 95 per cent of the respondents thinking that global leadership is important. At the time, stem cell research advocates argued that the presidential veto on the *Stem Cell Research Enhancement Act* of 2005 would further weaken the global leadership of

America in the field of regenerative medicine. They believed that private investments and state initiatives in California, Connecticut, Illinois, Massachusetts, Maryland and New Jersey would not be sufficient to move forward the development of hESC-based therapies. The midterm congressional elections in November 2006 clearly indicated that the politics of stem cell research had divided the Republicans, while giving the Democrats a "wedge issue" to win the Congress. Democratic candidates did not hesitate to make hESC research a campaign issue in the congressional races around the country in order to increase the voters' turnout. They also hoped to take advantage of the split between conservatives opposing scientific innovations and those Republicans who were in favor of stem cell research.

State initiatives (Table 3) in response to the restrictive federal policy started as early as 2004, with New Jersey becoming the first state to use taxpayers' money to finance hESC research. On June 25, 2004, the state legislators voted a state budget that allocated $9.5 million for the newly chartered Stem Cell Institute of New Jersey. On December 16, 2005, the State Commission on Science and Technology awarded $5 million to research teams throughout the New Jersey. The decision of New Jersey to support hESC research was quickly followed by a referendum measure in California. California voters passed *California Stem Cell Research and Cures Act (Proposition 71)* on November 2, 2004. This ballot initiative was voted during the presidential elections and amended the state constitution to include a "right to conduct stem cell research" that would ensure legal protection and funding for this biomedical innovation. Under *Proposition 71*, the state of California was authorized to allocate 3 billion dollars for

hESC research over a period of 10 years. Another response to federal funding restrictions put into place in 2001 came from Connecticut. On May 31, 2005 the state approved $100 million in funding for human adult and embryonic stem cell research over a ten year period. On June 15, 2005 Connecticut Governor M. Jodi Rell signed the public act which allowed hESC research, while prohibiting human cloning. Similar funding initiatives took place in Illinois and Maryland. In Illinois, the Democratic Governor Rod Blagojevich decided to bypass the State Legislature and issued an executive order for the creation of a state funded stem cell research institute on July 13, 2005. The order stated that $10 million from the budget of the Illinois Public Health Department should be allocated in funding for hESC research. A year later, Maryland implemented another stem cell funding initiative. On April 6, 2006 Governor Robert Ehrlich signed the *Maryland Stem Cell Research Act* which distributed $15 million in grants for hESC research.

By the time of the midterm elections of 2006, two states were also planning referendum measures in support of hESC research. In June 2006 the New Jersey State Senate approved a bill for a referendum to approve borrowing $230 million funding for stem cell research. The initiative aimed to provide research grants to universities, academic medical institutions, and other research facilities. Although the Senate voted 26-9 in favor of the bill proposed by Senate President Richard J. Codey and Sen. Barbara Buono, it was not considered by the Assembly before the August deadline and the referendum questions could not be included on the ballot. The ballot initiative in Missouri received significant media attention since the referendum was at the center of one of the most critical races for the U.S. Senate. In the months prior to the November elections,

The Missouri Coalition for Lifesaving Cures, which included patient rights' groups, medical organizations and ordinary citizens, had successfully mobilized voters and on August 8, 2006, the referendum measure was certified to be placed on the ballot as *Amendment 2: Missouri Stem Cell Research and Cures Initiative.* In the Senate race, the Democratic candidate Claire McCaskill supported a constitutional amendment to allow state funding for hESC research, while the Republican incumbent Jim Talent opposed it. A storm of media controversy developed around a campaign ad, in which Michael J. Fox suffering from Parkinson's disease emphasized the need for hESC research and endorsed McCaskill. The conservative media attacked the ad which showed the actor's body visibly wrecked by tremors. On the October 23 edition of his show, which reaches more than 13.5 million listeners each week, conservative radio host Rush Limbaugh accused the actor of "exaggerating the effects of the disease" and characterized his behavior as "shameless" and "purely an act." In an interview on CBS on October 24, Michael J. Fox responded that the uncontrollable shaking is caused by medications that keep Parkinson's patients from becoming stiff. Although Limbaugh apologized for his statements, he still claimed that the actor was "using his illness as a way to mislead voters into thinking that their vote for a single United States senator has a direct impact on stem cell research in Missouri." In November 2006, *Amendment 2* was passed and the state constitution of Missouri was amended to ensure protection and funding for hESC research.

Recent Legal Challenges

A shift in the federal funding policy happened when the newly elected President Obama took office in Washington, DC. On March 9, 2009, President Obama issued

Executive Order 13505 Removing Barriers to Responsible Scientific Research Involving Human Stem Cells (White House Press Office, 2009). This order revoked the governmental policy of August 9, 2001, limiting federal funding for research involving hES cells, as well as President Bush's *Executive Order 13435* of June 20, 2007, which had supplemented the August 9, 2001 presidential statement. The President ordered the NIH to issue new guidelines for hESC research within 120 days. The executive order opened funding for research on spare human embryos created by in-vitro fertilization for reproductive purposes, although it also made NIH funds available for research on certain uses of human IPS cells. The NIH prepared and released funding guidelines for hESC research on July 7, 2009.

The removal of the Bush administration's restrictions on federal funding for hESC research heightened expectations that an influx of federal funds would increase the rate of discoveries in stem cell science and finally move forward its much expected applications in clinical medicine (Robertson, 2010b). The decision of the Obama administration was timely since on January 23, 2009 the FDA had granted approval for the first clinical trial of a hESC-derived therapy in patients with acute spinal cord injury (http://clinicaltrials.gov/ct2/show/NCT01217008). Geron Corporation developed hESC-Derived Oligodendrocytes (GRNOPC1) as a regenerative treatment for spinal cord injuries, although the company expects that it may have therapeutic utility for other central nervous system indications, such as Alzheimer's disease, stroke and multiple sclerosis. Geron is currently developing two other cell therapy products from differentiated hES cells —hESC-Derived Cardiomyocytes (GRNCM1) for treatment of

heart disease and hESC-Derived Islet Cells (GRNIC1) which are insulin-producing cells (i.e. similar to pancreatic islet β cells) derived from hESCs (Geron.com). Another biotech company, Advanced Cell Technology (ACT), announced on April 28, 2011 that the Jules Stein Eye Institute at the University of California in LA has received institutional review board approval to conduct Phase 1/2 human clinical trials for Stargardt's Macular Dystrophy and Dry Age-Related Macular Degeneration using retinal pigment epithelial (RPE) cells derived from human ES cells (http://www.advancedcell.com/).

Despite these recent advancements in clinical applications, Obama's stem cell policy was unexpectedly challenged in court by two U.S. scientists, James Sherley and Theresa Deisher, who filed a lawsuit against the new NIH guidelines for research on hES cells. The scientists, whose work focuses on adult stem cells, claimed that the federal funding guidelines violated the Dickey-Wicker Amendment passed by the US Congress in 1995 and then renewed consecutively each year. This rider to a Senate appropriation bill prohibits the use of federal monies for research that creates or destroys human embryos. The plaintiffs also argued that allowing funding of hESC research would disadvantage scientists conducting research on adult stem cells, who would now face bias against their field of research, as well as harder competition for grant money. This was a surprising move since the NIH had already determined that allowing funding of research on hES cell lines, which had been previously created with private funds, would not constitute a violation of the 1995 congressional ban, especially since no embryos were to be created or destroyed in federally funded projects. Nonetheless, Judge Royce Lamberth, a district court judge in Washington DC, granted a preliminary injunction to stop all

federal funding for hESC research in August 2010, including research on previously established hESC lines with private funding. The federal government immediately appealed Lamberth's ruling. The injunction was temporarily lifted by the U.S. Court of Appeals for the District of Columbia in September 2010. On 29 April 2011, the three-judge panel issued its final ruling which vacated the preliminary injunction with a 2 to1 majority since the justices had determined that the NIH had correctly interpreted the Dickey-Wicker Amendment. Justice Douglas Ginsburg, the chief judge of the appeals court, wrote for the court: "Dickey-Wicker is ambiguous and the NIH seems reasonably to have concluded that, although Dickey-Wicker bars funding for the destructive act of deriving an ESC [embryonic stem cell] from an embryo, it does not prohibit funding a research project in which an ESC will be used." (http://www.courthousenews.com/2011/04/29/36224.htm). Another reason for overturning the preliminary injunction was that, in the opinion of the court, rather than protecting the funding efforts of the plaintiffs, the ban only unfairly threatens the government's significant investments in stem cell research projects. Judge Karen LeCraft Henderson, who dissented from the majority opinion, claimed that her colleagues on the panel had performed "linguistic jujitsu." She stated, "Breaking the simple noun "research" into "temporal" bits, narrowing the verb phrase "are destroyed" to an unintended scope, dismissing the definition section of implementing regulations promulgated by the Department of Health and Human Services (in case the plain meaning of "research" were not plain enough), my colleagues perform linguistic jujitsu." (http://www.courthousenews.com/2011/04/29/36224.htm).

The ruling in favor of Obama stem cell policy by the U.S. Court of Appeals for the D.C. Circuit, however, may not be the end of the legal battle. This decision referred the original case back to Chief Judge Royce C. Lamberth of Federal District Court in Washington, and it is possible that the case may eventually get to the Supreme Court.

The EU Consensus Approach

Policy decisions regarding hESC research at the supranational level in the European Union reflect differences in political culture and societal conditions for the development of stem cell innovation throughout Europe. In contrast to the restrictive policy adopted by the Bush administration, the EU made public funds for hESC research available in 2002. Research projects in stem cell science were funded under the Sixth Framework Programme for Research and Technological Development (2002-2006). Under this program, grants for stem cell research projects were allocated in accordance with strict ethical guidelines approved by the European Commission which had decided not to support the creation of human embryos for research purposes. Stem cell research on both embryonic and adult stem cells continues to be funded under the Seventh Framework programme for Research and Technological Development (2007-2013), regardless of the lobbying efforts of the Vatican to organize a "blocking minority" during the meeting of the Council of Research Ministers on July 24, 2006. At the time, some commentators viewed the failed attempt to block the Commission's proposal as an indication of the diminishing influence of the Catholic Church since the death of its charismatic leader, Pope John Paul II (Pichler, 2006). The political comprise on hESC

research achieved by the Council also exemplified the traditional EU consensus approach to political and social policy matters.

The health applications of the life sciences, genomics and biotechnology were a major area for investment and research spending under the Sixth EU Framework Programme (FP6). As shown in Table 5, the overall spending for this thematic priority area, under which hESC research was funded between 2002 and 2006, reached 2.2 billion Euros. This compares with increased opportunities for research funding under the Seventh Framework Programme (FP7), which has similarly established thematic priorities for research funding (Table 6). The EU Member States have earmarked more than 6 billion Euros in research grants for projects in the thematic area of "Health," spending second only to the 9 billion Euro investments in "Information and Communication Technologies (ICTs)." The primary aim of heavily funding biomedical and other health care related research, together with the "Food, Agriculture and Fisheries, and Biotechnology" research theme, is to build a *European Knowledge Based Bio-Economy (KBBE)*. In addition to defining thematic priority areas for funding, FP7 is structured in the following five programs: 1) *Cooperation*, which aims to foster collaboration between industry and academia in order to gain leadership in key technology areas; 2) *Ideas*, implemented by the European Research Council in support of basic research at the scientific frontiers; 3) People, which encourages mobility and career development for researchers both within and outside Europe; 4) *Capacities*, which aims to develop the capacities that Europe needs to be a thriving knowledge-based economy;

and, 5) *Nuclear Research* (the Euratom programme) which focuses on developing Europe's nuclear fission and fusion capabilities (FP7, 2007).

Institutional and social dimensions of EU science and government are discussed in the report *Taking European Knowledge Society Seriously* of the Expert Group on Science and Governance which was appointed by the Science, Economy and Society Directorate at the EU Directorate General for Research (Wynne at al., 2007). This report was ordered by the European Commission and was released in 2007. The working group initially convened in July 2005 and then met five times for about two days each at roughly four-monthly intervals. Participants recognized that their mandate focused on three major concerns: 1) how to respond to the traditional public unease towards science in Europe, and especially, the new science-based technologies; 2) the need to improve public participation in European science and governance; and 3) how to address urgent European policy challenges that are often considered strictly scientific in nature (Wynne et al., 2007). The group pointed out that there are two specific ways to manage and encourage innovation and technological change in contemporary societies—through a regime of economics of techno-scientific promises (ETP) or a regime of economics and socio-politics of collective experimentation. The first model has become particularly prominent in the governance of most new and emerging techno-sciences such as biotechnologies, genomics, nanotechnologies, neurosciences, and ambient intelligence. The regime of ETP "draws on an uncertain future" and promises easy upstream solutions for downstream problems; it is also derived from "a strong sense of urgency" around the overall impact of technological development worldwide, as well as the notion that "we

are in a world of competition and that Europe will not be able to afford its social model if it is not in the race" (Wynne et al., 2007, p. 25). Subsequently, the role of civil society is declining and society is simply viewed as a group of prospective consumers. The regime of ETP places new demands on scientists and technologists who are now required to ensure protection of their intellectual property rights at the earliest stages of research. This way of organizing innovation and technological change establishes new relationships between research, academia, and industry emphasizing patenting of basic knowledge. Although the EU Lisbon Agenda has heavily promoted this mode of governance, the Expert Group on Science and Governance has argued that, while technological promises could be incorporated in the emerging regime of collective experimentation, they should not be a leading consideration. Moreover, the report suggested that "a vibrant European knowledge society must in the long term be built on collective experimentation" (Wynne et al., 2007, p. 27).The alternative regime of innovation governance is exemplified by democratizing approaches such as: Open-Source Software, user-induced innovation and community-based innovation in the information and communication sector, the involvement of patient associations in health research, bottom-up innovations in low input agriculture, etc. All these examples evoke John Dewey's conception of policy as collective experimentation. As Wynne et al. (2007) have characterized this new regime,

> The experimentation is now at the technological level as well. Situations emerge or are created which allow to try out things and to learn from them, i.e. experimentation. Society becomes a laboratory... Here, however, the

> experimentation does not derive from promoting a particular technological promise, but from goals constructed around matters of concerns and that may be achieved at the collective level. Such goals will often be further articulated in the course of the experimentation. (Wynne at al., pp. 26-27)

This model of science governance, which encourages the participation of diverse actors, is considered productive since the participants are concerned about the specific issue and are thus more motivated to engage in innovation process. Furthermore, it would require innovative approaches to intellectual protection, as well as new forms of communication and interaction between scientists and other actors since laboratory-based science cannot claim authority over knowledge production.

The Report of the Expert Group on Science and Governance also addresses concerns about the unease of EU publics towards science which could potentially thwart Europe's innovation and economic ambitions, as well as policy efforts to resolve complex issues pertaining to health, climate or energy. Assumptions about any general mistrust of science, however, are not substantiated with evidence, and it is counterproductive to assume "public apathy over changing lifestyles to address such major problems as climate change, is a function of the same kind of public mistrust of science which has afflicted many – not by any means all - areas of innovation and technology" (Wynne at al., 2007, p. 17). This observation of the Expert Group is correct and could be supported with data from Eurobarometer surveys of public opinion conducted on behalf of the European Commission. For example, the most current report on biotechnology and the life sciences "Europeans and Biotechnology in 2010"

commissioned by the Directorate-General for Research has shown that Europeans have positive attitudes towards scientific innovation in these fields (Gaskell et al., 2010). The study of public opinion was carried out in February 2010 and included representative samples from 32 European countries. The European-wide survey showed 53% of respondents believing that biotechnology applications will have positive impacts on the future, and only 20% expected negative effects. The report, however, indicated inadequate knowledge of the general public about some important research areas and emerging technologies (Gaskell et al., 2010). For example, a majority of respondents had no awareness about the existence of nanotechnology (55%), biobanks (67%), and synthetic biology (83%). The Eurobarometer also showed an overwhelming public support for medical applications of biotechnology, provided that there is adequate ethical oversight and legal regulation. On the issue of stem cell research, 63% of respondents supported embryonic stem research (up from 59% approval in 2005) and 69% of the respondents supported non-embryonic stem cell research (up from 65%). In addition, 17% of respondents stated that they would accept hESC research under special circumstances, and 15% would conditionally approve non-embryonic stem cell research. The UK, Spain and Denmark were the EU member states where most respondents were generally supportive of hESC research and other biomedical applications.

The policy context for stem cell innovation across Europe is complicated and constantly evolving. Most countries have permissive policies for hESC research using supernumerary IVF embryos, but prohibit the cloning of human embryos for research purposes as shown in Table 7. However, not all EU Member States have hESC-specific

legislation in place as shown in Table 8, which presents data about the specific laws of EU and Europe-associated countries that are members of the European Human Embryonic Stem Cell Registry (hESCreg), and Table 9, which shows human cloning laws in EU member states. Most research activities in the field of stem cell science and regenerative medicine are carried out with EU funding and involve transnational cooperation in major research centres throughout Europe (i.e., European Molecular Biology Laboratory (EMBL), an intergovernmental research organization, which comprises five major research centers in Heidelberg, Hinxton (near Cambridge), Monterotondo (near Rome), Hamburg). The EU funds research on a wide range of biomedical applications of hES cells, as shown in Table 10, which includes a list of hESC research projects funded under the FP6. Between 2002 and 2006, the EU financial investment in hESC projects was not particularly large and reached only €21 million, which was about 0.85 % of the overall €2.45 billion budget for health research within FP6. Nonetheless, there is a strong moral commitment of the EU and EU institutions to hESC research. As the Director of the International Society for Stem Cell Research (ISSCR) Fiona Watt (2008) has pointed out, EU-funded research activities have allowed stem cell researchers to benefit from transnational research networks and collaborations in different countries. She has also indicated that the EU strategic investment in research and technological innovation is largely driven by political goals and aims at the establishment of the "most dynamic competitive knowledge based economy in the world." What makes the EU funding model unique is the added benefit of large-scale collaborations between

groups of scientists, as well as the opportunity for the expansion of the EU funded networks into long-term collaborations that continue after the initial funding period.

The development of stem cell research and regenerative medicine in the EU is considered to be a very complex issue due the significant variations in national regulations governing stem cell research. In term of their stem cell policy, the EU member states can be roughly grouped in four major categories: permissive, permissive compromise, restrictive compromise, and restrictive (The Hinxton Group, 2009). The first group includes countries with the most liberal or permissive stem cell policies, such as Belgium, Finland, Spain, Sweden and the United Kingdom. These countries have allowed derivation of hESCs from a variety of sources and the use of SCNT to clone human embryos under certain conditions. It is important to specify that under the Finish law regulating stem cell research, *the Act on Medical Research No. 488/1999*, the biological entities generated through SCNT are not considered embryos. The law, which has made supernumerary IVF embryos available for hESC research, does not explicitly prohibit the cloning technology; therefore, there is an implicit assumption that SCNT is permitted in this EU country. Most EU member states have adopted stem cell policies which constitute a "permissive compromise" (e.g., although there are legal prohibitions against the use of SCNT, hESC research using supernumerary IVF embryos is either specifically permitted or, at least, not explicitly prohibited). The countries that fall under this category are: Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, France, Greece, Hungary, Latvia, the Netherlands, Norway, Portugal, Romania, and Slovakia. By contrast, the policy option of "restrictive compromise" was adopted by countries like

Germany and Italy. Under this policy alternative, research is only permitted on hES cell lines created before a certain date or which originated outside of the country. Some EU member states have opted for prohibitive stem cell policies. In such countries, e.g. Austria, Lithuania, Poland, and Slovenia, research using human embryos or stem cell lines derived from embryos is completely prohibited. In addition, there are no favorable conditions for the development of hESC research in Ireland, where the Catholic tradition is dutifully maintained and the right of life to the unborn is presently written in the Irish Constitution. Not all EU member states, however, have developed policies and regulations for the development of stem cell research and regenerative medicine.

Conclusions

Although there has been more than a decade after hESC research became the subject of contentious ethical, political and legal debates, the scientific controversy remains unresolved and innovation in this biomedical field continues to create policy and legal challenges. This chapter elucidated convergences and divergences between the US and the EU regulatory and funding regimes for the development of stem cell science. In both federal states, techno-scientific promises have been a leading consideration in the governance of stem cell technologies and public investment in hESC research was largely driven by the political goal of establishing competitive knowledge-based bioeconomies. In accordance with the Lisbon Agenda, EU policymakers at the supranational level have heavily promoted the ETP model of science and technology innovation, rather than alternative democratizing approaches that aim to build a vibrant European knowledge society based on collective experimentation. Similarly, in the US, state initiatives and

efforts by stem cell advocates to secure public and private funds for research were driven by concerns that funding restrictions imposed by President Bush in 2001 would diminish America's leading role in the global bioeconomy. Another point of convergence is the positive public attitudes for medical applications of biotechnology on both sides of the Atlantic. Despite the widely shared assumption about the public unease with science in the US and the EU, survey research has shown an increasing public support for hESC research, especially when it is conducted under strict laws and ethical oversight. In addition, hESC research has prompted unprecedented grassroot activism in America and invigorated public participation in the legislative and policymaking processes. The issue has also mobilized EU citizens and increased public engagement in decision-making both at the national and at the supranational level.

Yet, divergences in the two approaches to stem cell innovation are clearly visible. A close examination of the unique trajectories of the US and EU stem cell debates reveals profound differences in formal politics and decision making, political culture, and social practices that shape the governance of science and technology. While Christian religious ideas became prominent in the US stem cell debate and shaped policy outcomes during the two-term administration of President George W. Bush, the EU institutions endorsed and maintained a stance on hESC research that was more consistent with fundamental democratic principles of secularism, religious pluralism, and freedom of scientific research. In America, the emerging field of hESC research was caught up in an enduring science policy debate on the use of human embryos and fetuses in biomedical experimentation and funding decisions were constrained by the congressional ban on

embryo research. From the very beginning, the stem cell controversy was implicated in the contested politics of abortion and a national public debate developed along the conventional political and cultural divisions between liberals and conservatives, pro-choice supporters and pro-life activists. The Bush administration's restrictive funding policy between 2001 and 2009 was highly unpopular and prompted state initiatives and referendum measures that undermined US federalism. Although President Obama lifted the funding ban in March 2009, there are still uncertainties regarding the future of his stem cell policy due to the litigatious culture that dominates American society. In addition, the present administration will continue to face broader policy dilemmas regarding human biotechnologies—the lack of a national strategy for the ethical governance of hESC research and regenerative medicine, a largely unregulated biotech industry driven by commercial interests, as well as strong opposition against embryo research as one of the defining aspects of America's culture wars.

By contrast, there is a strong moral commitment of the EU and its institutions to hESC research and the development of a unified platform for ethical regulation of regenerative medicine, although this appears to be a very complex issue due the significant variations in national regulations across Europe. While financial investment in this biomedical innovation under FP6 has not been particularly large, especially when compared to the overall spending for health research, the EU funding model has allowed stem cell scientists to benefit from large-scale transnational collaborations and to expand EU funded research networks into long-term collaborations that continue after the initial funding period.

CHAPTER 7

CONCLUSION

In this dissertation I have argued that proper consideration should be given to the interplay of scientific, ethical, cultural and political issues interwoven in the controversy over hESC research. My arguments were based on the premise that the stem cell debate had never been purely scientific; rather, as I have illustrated throughout the thesis, the controversy surrounding the derivation of the first hESC lines was largely shaped by non-epistemic factors (i.e., considerations other than scientific facts and empirical verification). This condition characterizes most scientific debates that have received significant attention from the general public (Engelhardt & Caplan, 1987). In the United States, the issue of hESC research was right from the outset framed in terms of the contentious politics of abortion and the policy debate revived salient political themes of the earlier controversy over fetal transplantation research. It was also drawn in a continuing political debate over the federal funding policies for human embryo research instigated by the Supreme Court's ruling in *Roe v. Wad*e in1973 which legalized abortion nationwide. In 2001 the Bush administration implemented a restrictive federal funding policy which triggered unprecedented grassroot activism, as well as state-level funding programs and referendum measures which eventually undermined American federalism. Although President Obama lifted the federal funding restrictions in March 2009, the new NIH funding guidelines were quickly challenged in court, and the issue of hESC continues to be caught up in America's culture wars over religion and morality. Concerns about the status of the human embryo were also paramount in Europe; however, the

policy debate at the EU level has followed its own unique trajectory. Efforts to develop a framework for the ethical governance of hESC research and its applications in regenerative medicine were intertwined with the issue of EU federalism, fundamental questions about European cultural values, and the traditional EU consensus-oriented politics. Subsequently, the governance of this scientific innovation was shaped by the economics of techno-scientific promises and was integrated into the EU strategic agenda for building the most competitive knowledge based bio-economy. Yet, the regulatory environment remains extremely complex since stem cell laws are considered a national competence and national governments within the EU have adopted a variety of policy options. Research on hES cells is funded under the EU 7th Framework Research Programme, however, research projects are carried out in member states with permissive policies and EU funds may not be used for the derivation of new hESC lines.

Furthermore, my dissertation emphasized the embeddedness of the stem cell policy debates in particular national contexts and political cultures and focused on contextual factors that had shaped legislative efforts to regulate stem cell research. For instance, in countries with strong religious consciousness, i.e. the United States and EU member states like Austria, Ireland, Italy, Lithuania, Slovakia, and Poland, religion has become a strong factor in sustaining the ethical controversy over hESC research. Stem cell debates in these countries have mirrored the value conflicts of the post-secular society in which the trend towards secularization is challenged by the power of religion to influence public affairs. Subsequently, attempts to resolve the stem cell controversy have become inextricably linked to the question of whether ethical arguments derived from

religious traditions could be reconciled with scientific perspectives on human embryonic development. I have argued that a consensus between contemporary science and religion on the issue of hESC research could be achieved provided that scientifically derived assessments of embryonic status do not contradict the respective tradition's fundamental theological beliefs regarding the beginning of personhood. The dialogue is also greatly contingent on the degree of openness of each religious tradition to scientific input. The role of contextual factors in regulating stem cell innovation was further exemplified by the contentious national debate in Germany which had revived old anxieties about eugenics, Nazi medicine, and the social acceptance of disabled people. By contrast, EU countries with leadership in biomedical research and innovation, such as the United Kingdom, Sweden, the Netherlands, and Belgium, have elevated the development of hESC therapies to the top of their national agendas by adopting liberal stem cell policies, including the use of SCNT under certain conditions.

Being one of the most contested applications of medical biotechnology, hESC research has generated both great hopes and strong fears about the biopolitics of the future. On both sides of the Atlantic, proponents and opponents of embryo research have evoked utopian and dystopian visions to construct multiple, contested or embraced biopolitical futures. The print and electronic news media have played a major role in the public engagement with stem cell policy by framing uncertainty as to whether or not the clinical promise of hESC research is real and will be realized in a foreseeable future. While mass media have tended to sensationalize the ethical controversy over hESC

research, they have also become a key site of struggle for various social groups in their attempts to influence the public opinion in favor of particular policy outcomes.

The underlying premise of my comparative analysis of the stem cell controversy in the US and the EU was Engelhardt and Caplan's (1987) argument that understanding patterns of scientific disputes is inextricably bound up with the individuation of different controversies that are blended in a single scientific controversy with a heavy political and ethical overlay. Therefore, I have aimed to differentiate between various controversies intermingled in the US and the EU stem cell debates and to determine the means by which the controversy has been settled in divergent cultural and political contexts. In these concluding remarks, I categorize the outcome of two policy debates by drawing on theoretical perspectives on patterns of controversy and closure in science (Engelhardt & Caplan, 1987; Beauchamp, 1987; McMullin, 1987). Although the term "closure" is generally used to describe conclusion, ending, or resolution of a scientific controversy, it is highly ambiguous and does not allow us to make important distinctions between the various ways in which such disputes are terminated, i.e. whether termination occurs by final resolution or without achieving final resolution or truth (Engelhardt & Caplan, 1987). It is important to establish some preliminary distinctions between the different means by which a dispute is brought to a conclusion: 1) by negotiation and consensus; 2) by administrative or political procedures; and 3) by appeal to epistemic considerations, which is the usual method of resolving scientific disputes. Beauchamp (1987) has differentiated five modes of closure in scientific controversies. The first type is characterized as the *sound argument closure*. This way of termination occurs when

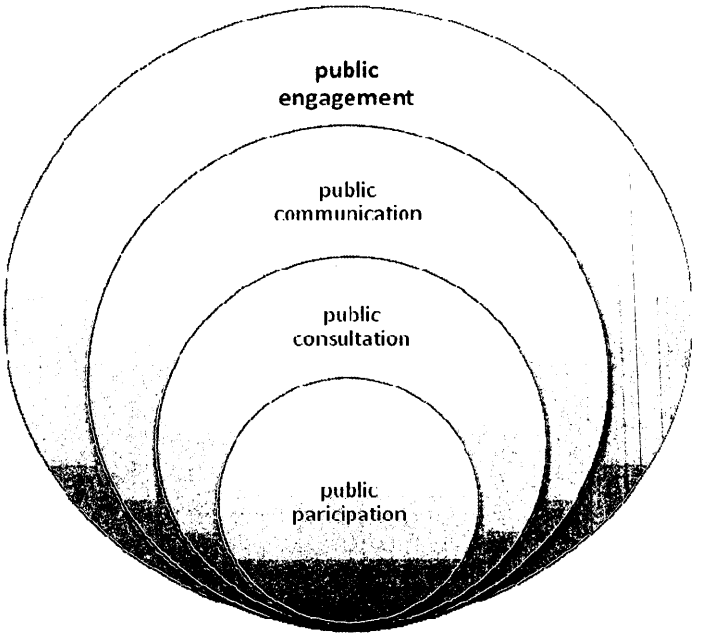
scientific controversies are perceived as purely rational debates, with only one rationally defensible position on the issues under consideration. The dispute is then ended when the opposing views are proved logically inconsistent or factually incorrect. It is unlikely, however, that controversial moral or public policy debates can ever be resolved by this form of closure. The second way of ending scientific controversies is through *consensus closure*. In this case, closure occurs when participants in a controversy achieve a consensus agreement that only one particular position is correct through means other than sound argument closure or some form of procedure or negotiation. The issues central to the controversy are subsequently considered resolved and are no longer matter of dispute. *Procedural closure* describes the termination of a dispute by formal, procedurally governed efforts to end the continuing debate between the opposing sides in the controversy. This way of closing a debate relies on the institutional power of legislatures, courts, and other social institutions and seems to be more or less a temporary solution. The fourth sense of closure is *natural death closure* which occurs when a controversy has come to an end through a gradual natural death, but also when the issue is no longer the focus of sustained controversy and interest. Finally, controversies can be settled through *negotiation closure*—an intentionally arranged and morally unobjectionable resolution, which is acceptable to all participants in the disputes, even when it is the result of a compromise. While the sound argument closure requires that there is only one correct and best answer to the central dilemma in a controversy, here compromise regarding moral principles is permissible. While scientific controversies are ended through different modes of closure, both Beauchamp (1987) and McMullin (1987) have pointed out that

some scientific disputes are never actually resolved. Closure and resolution thus constitute two different ways of ending a controversy. In cases when it is not possible to achieve resolution, non-epistemic factors may eventually lead to the termination of a controversy. McMullin's (1987) has argued that the term "closure" is only relevant when used to designate termination of a controversy in which non-epistemic factors are dominant and in which resolution is not eventually achieved. Therefore, in this broader use of the term, "*closure* suggests one particular sort of non-epistemic factor, namely, the employment of external authority to declare a controversy ended" (McMullin, 1987, p. 78). Based on McMullin's three-part classification, termination through *non-epistemic procedural closure* differs from *resolution* of a controversy through appeal to epistemic (knowledge-based) factors or its *abandonment* due to participants losing interest.

My analysis of the stem cell debates in the US and the EU has clearly illustrated that their policy outcomes most closely resemble non-epistemic procedural closure in the sense defined above. Although there has been a long-term policy and political debate in both cases, the ethical controversy has largely remained unresolved. Rather, efforts by policymakers in these two federal states to end the controversy have resulted in sealing off the debate through legislative efforts or administrative procedures. However, as Beauchamp (1987) has pointed out, procedural closure provides only a temporary solution to the dispute and, by contrast to the sound argument closure, "only rarely is moral controversy closed off from further discussion, even where procedures for closure are institutionalized" (p. 31). Therefore, it is by no means surprising that the issue of hESC research continues to generate new controversies and policy challenges.

APPENDIX A: FIGURES

Figure 1: Typology of Public Engagement Based on the Flow of Information Perspective (Rowe & Frewer, 2005)



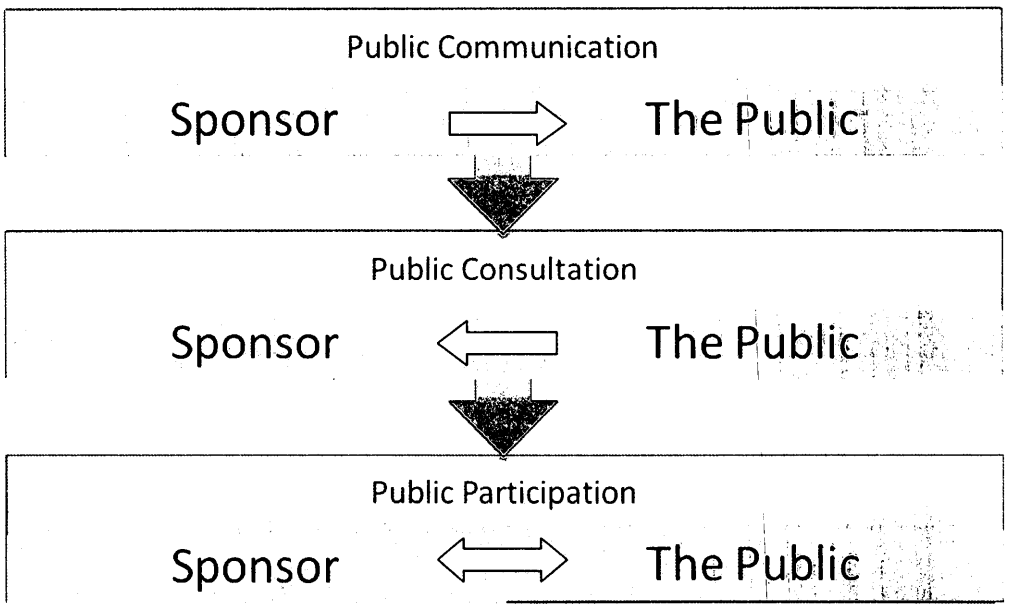


Figure 2: Stem Cell Advertisement by the Campaign to Defend the Constitution (DefCon), *New York Times,* May 2006

MEET AMERICA'S MOST INFLUENTIAL STEM CELL SCIENTISTS.

Rev. Pat Robertson

'Before long, we'll be harvesting body parts from fully formed people. Once you begin this sort of an abortion use of cells, then everything is up for grabs.'

Rev. Jerry Falwell

'The President was right to ban federal money going to this dangerous and unethical research.'

James Dobson

'Experiments on the blastocysts, which are fertilized eggs, has a Nazi-esque aura to it.'

It's been a year since the House of Representatives passed stem cell legislation. Since then, the bill has languished in the Senate, held hostage by religious extremists who hold enormous sway over Majority Leader Bill Frist.

Our backing by big labs and medical researchers believe that healthy cells created from stem cells (like the pain-relieving property many celebrity athletes once thought beyond the reach of medicine. Millions suffering from Parkinson's disease, Alzheimer's disease, spinal cord injuries, diabetes, multiple sclerosis, strokes, heart disease and many other conditions are waiting for the Senate to act. Polls show 81% of Americans support the research. But hope is being crushed because of the inappropriate influence of the religious right.

Not since the Dark Ages have religious zealots had such dangerous power over scientific research. Join us at www.DefendAmerica.org and call on Senator Frist to put our health-creating agenda of the national priority.

We're DefCon, protecting the Constitution from people like these. We believe our elected leaders put their hand on a Bible and swear to uphold the Constitution, not the other way around.

DEFCON

The Campaign to Defend the Constitution (DefCon) is an online grassroots movement to combat the threat posed by the religious right to American democracy. Join us at www.DefendAmerica.org

Figure 3: Stem Cell Advertisement by the Campaign to Defend the Constitution (DefCon), *New York Times*, June 2006

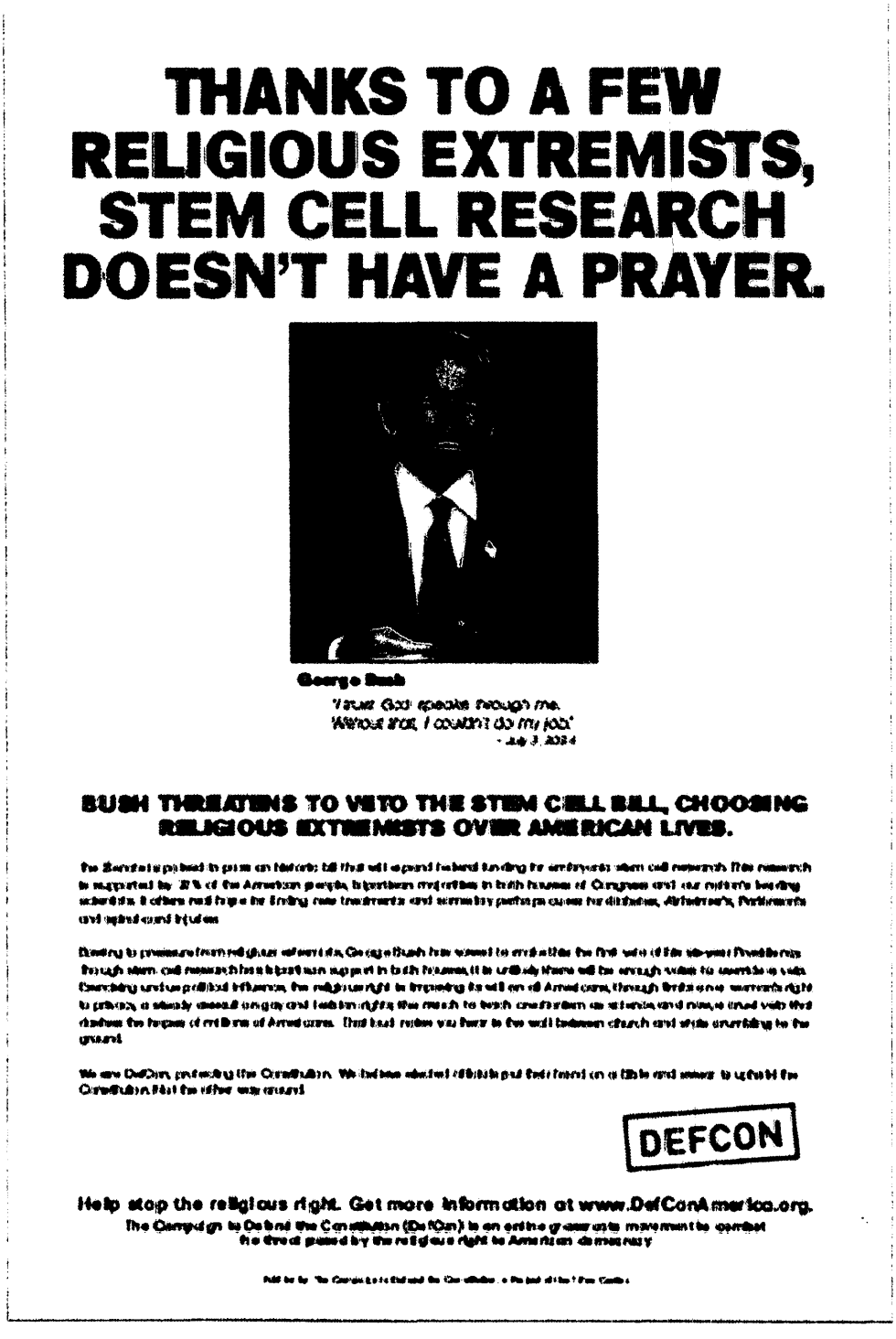


Figure 4: Spoof Ads of President George W. Bush's position on hESC research
Source: http://www.wrapped-in-the-flag.com/

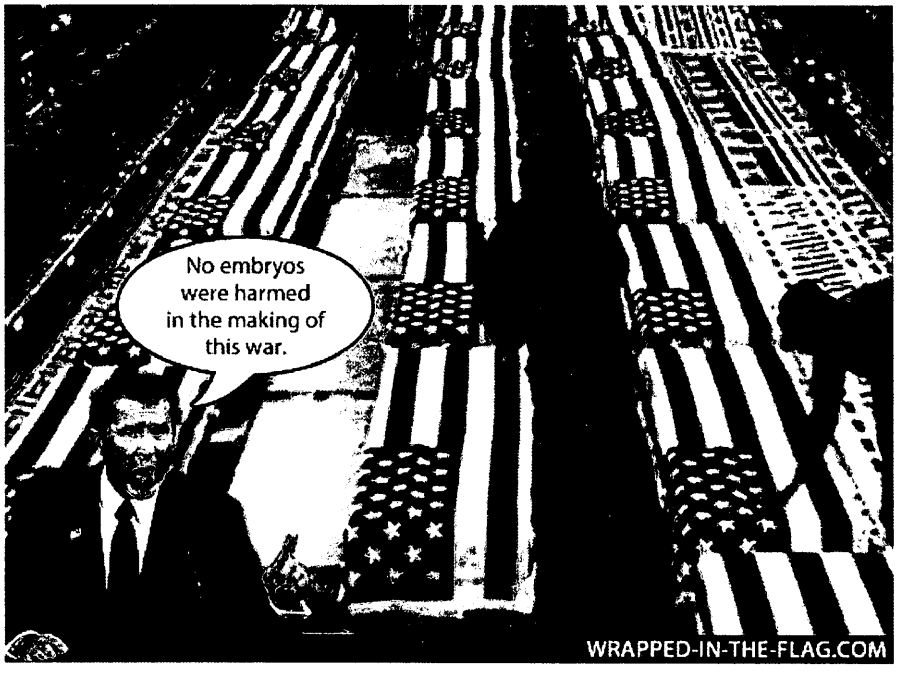


Figure 5: Differentiation of Human Tissues in the Early Embryo
Source: http://stemcells.nih.gov/info/scireport/chapter1.asp

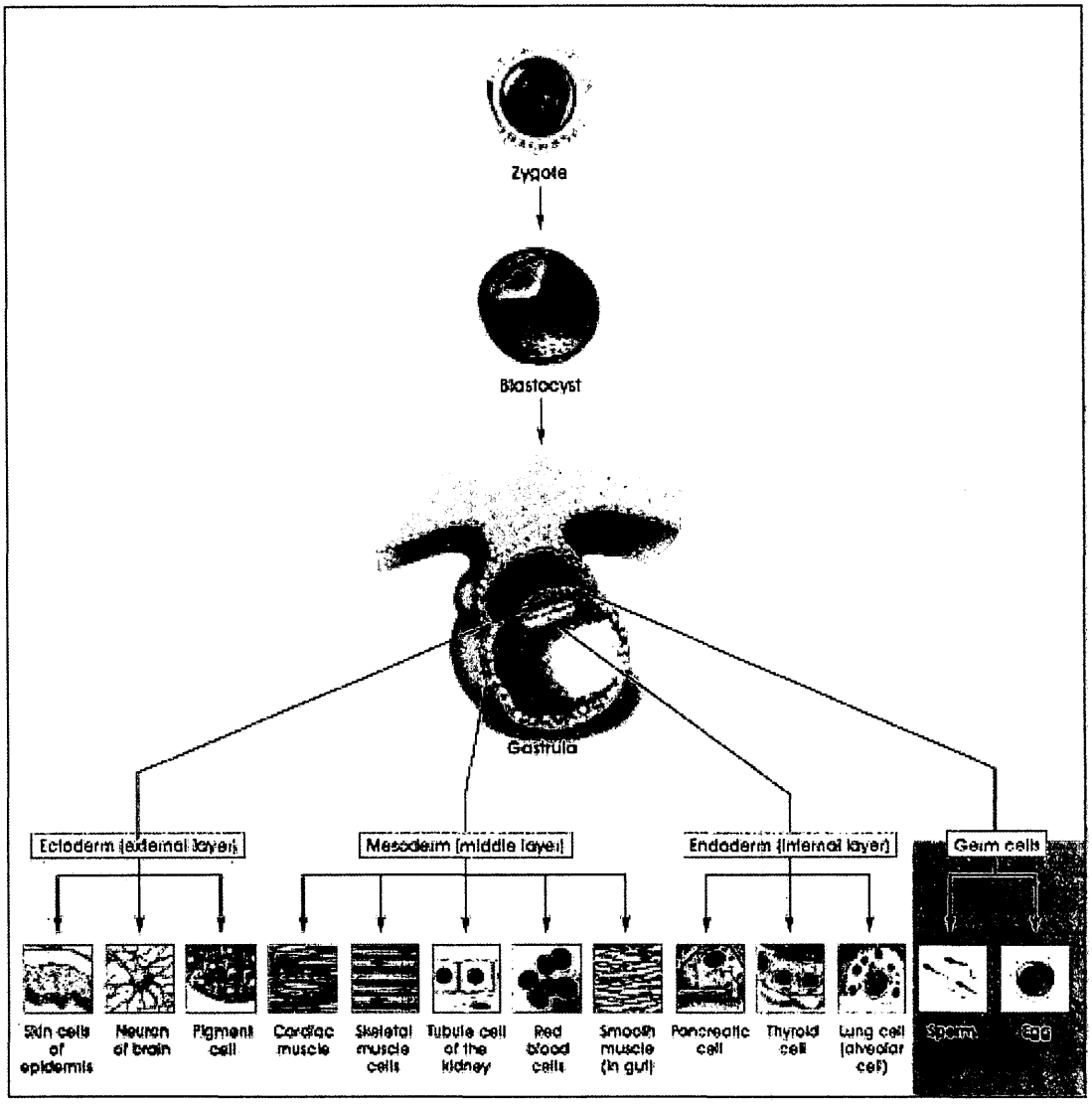


Figure 6: Derivation of Human Embryonic Stem Cells
Source: http://www.stemcellresearchfoundation.org/WhatsNew/Pluripotent.htm

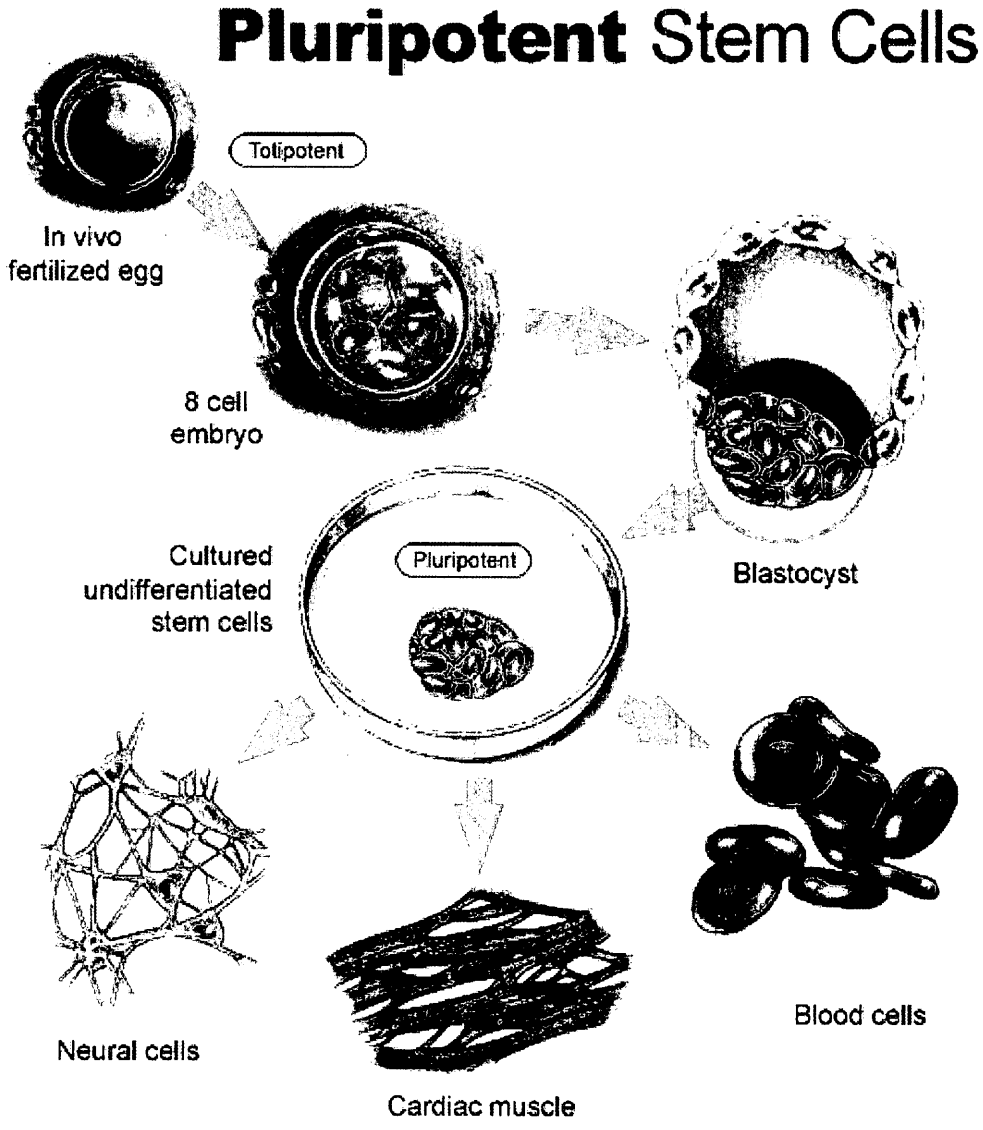


Figure 7: Origin, Isolation and Specialization of Stem Cells
Source: www.scq.ubc.ca/stem-cell-bioengineering/

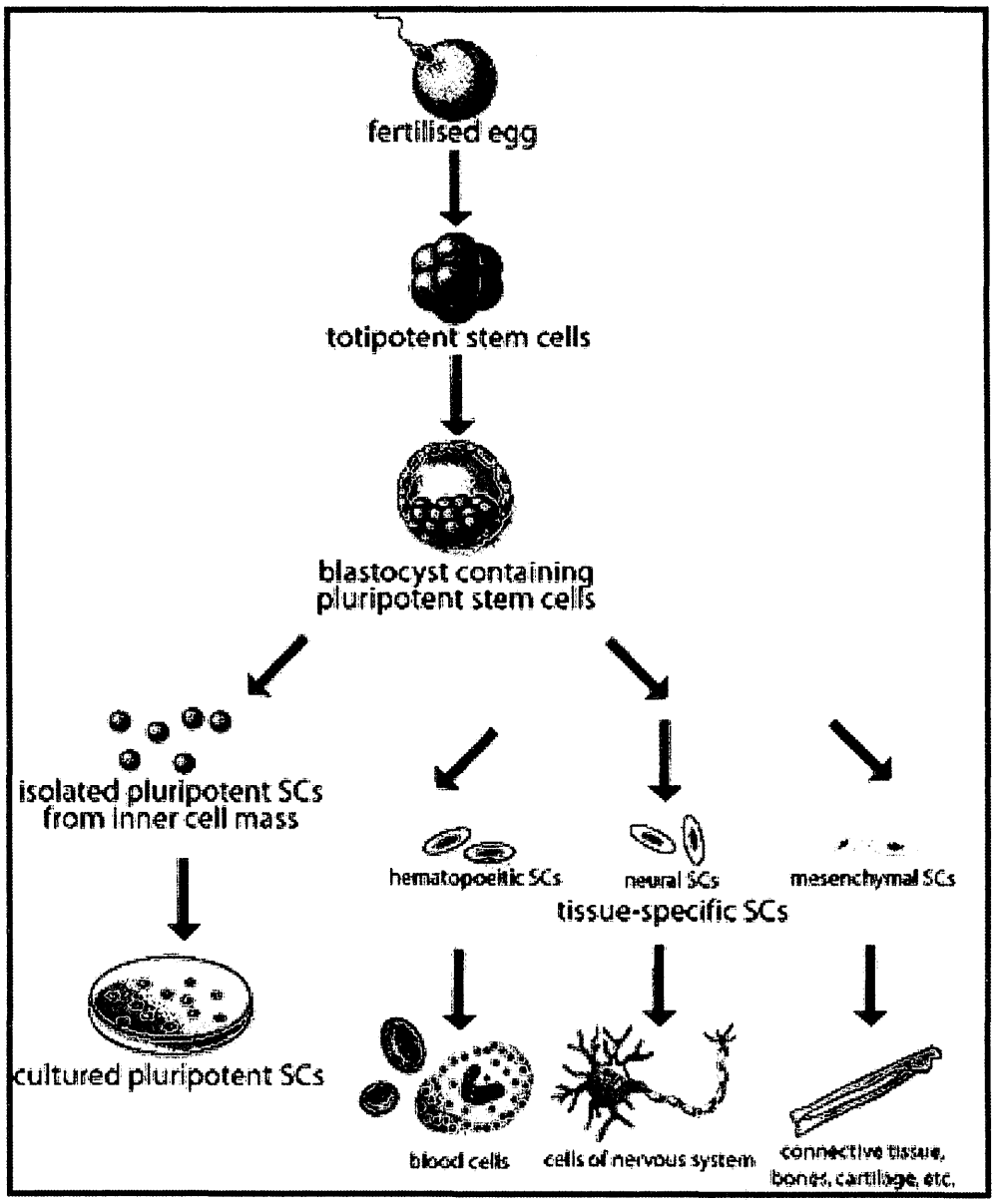


Figure 8: The Clinical Promise of Stem Cell Research
Source: http://stemcells.nih.gov/staticresources/info/media/DSC_1185.jpg

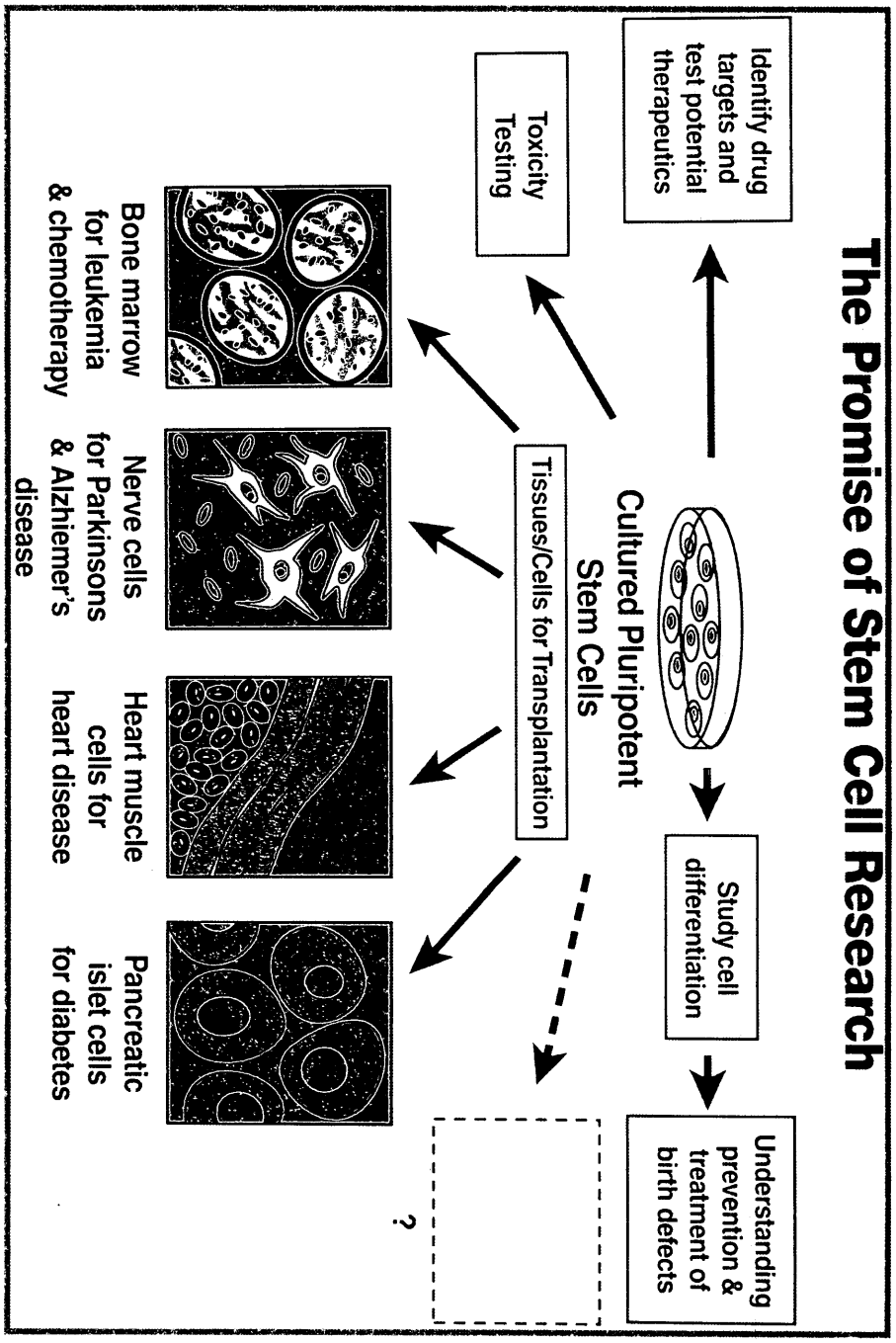


Figure 9: Reproductive Cloning
Source: http://www.biotechnologyonline.gov.au/popups/img_scnt.html

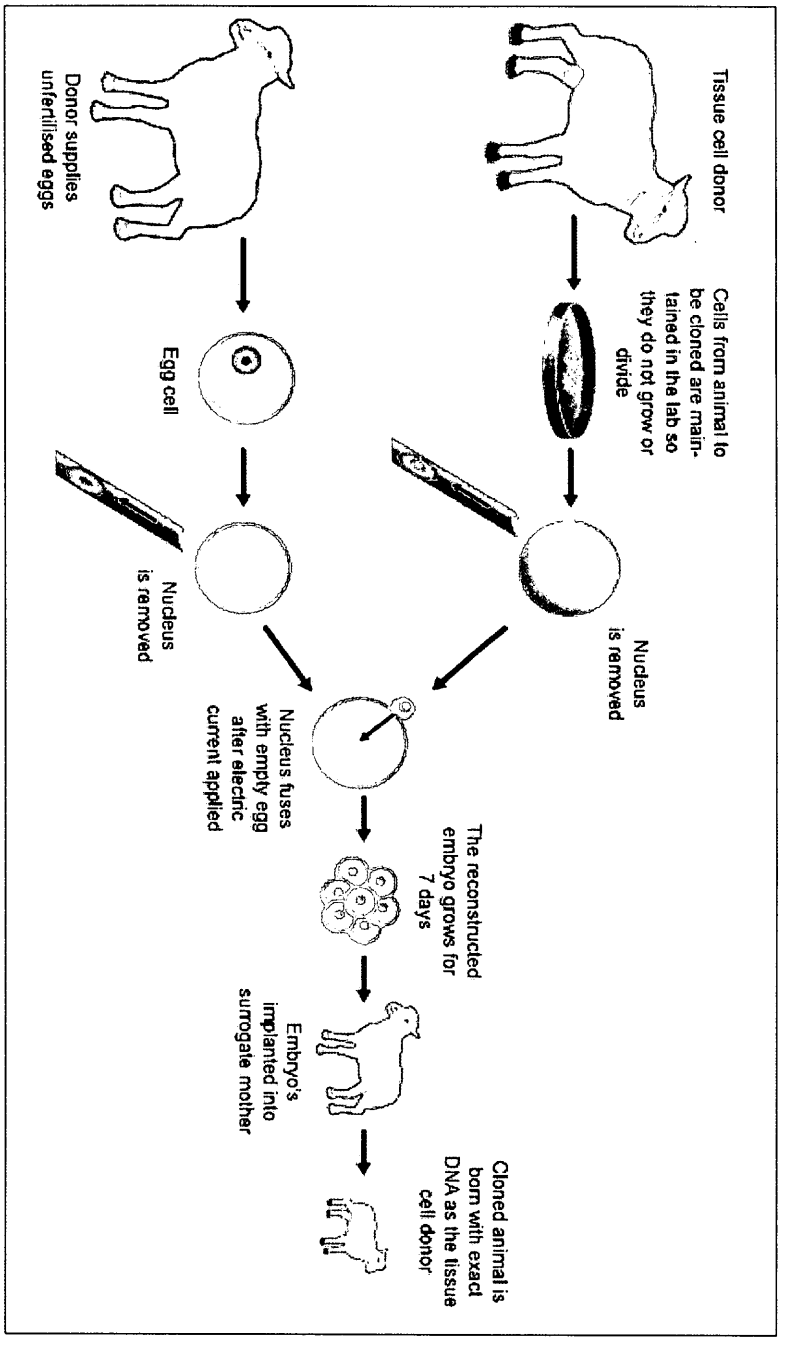


Figure 10: Research Cloning
Source: http://www.stemblog.net/?page_id=151

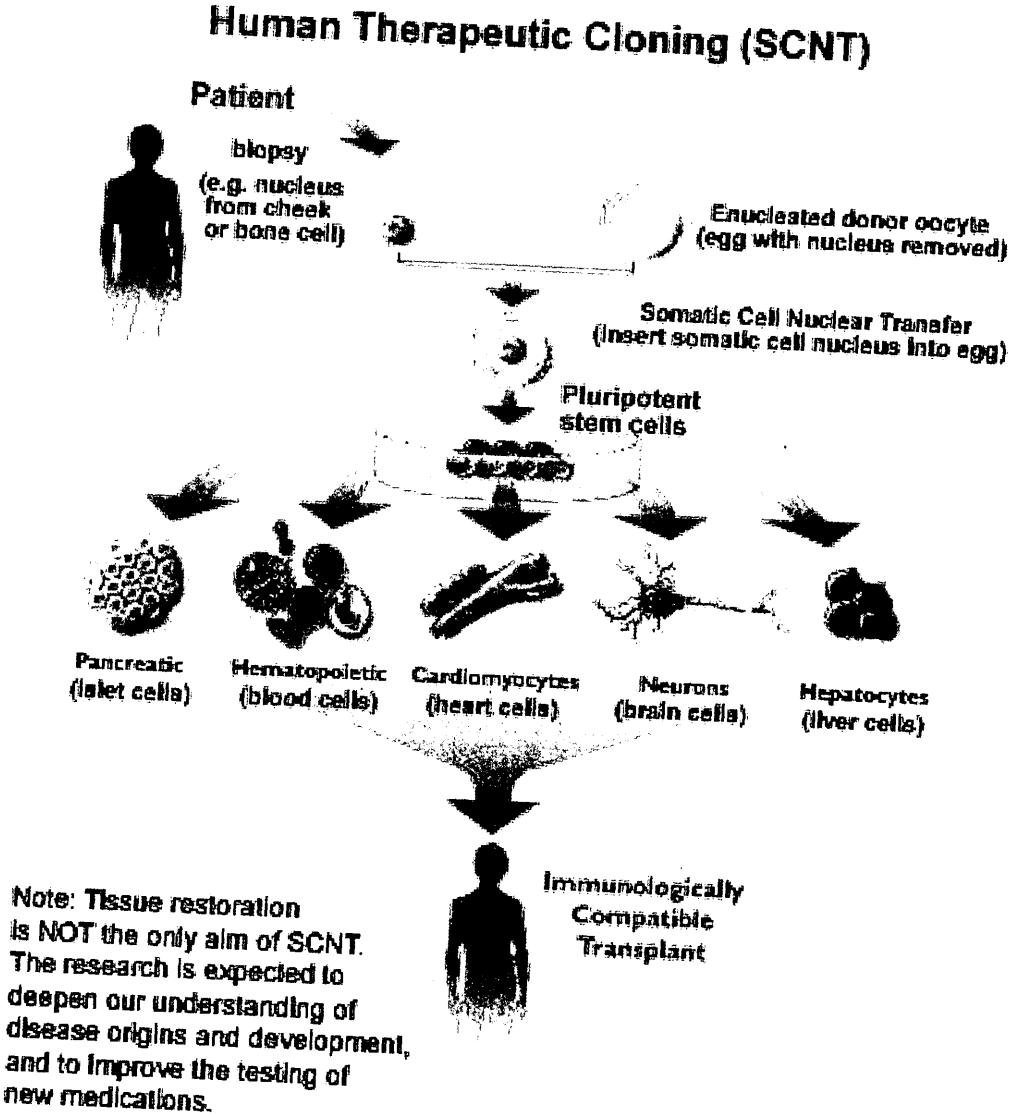


Figure 11: Four Strategies to Induce Reprogramming of Somatic Cells
Source: Jaenisch, R., & Young, R. (2008). Stem cells, the molecular circuitry of pluripotency and nuclear reprogramming. *Cell, 132*, 569.

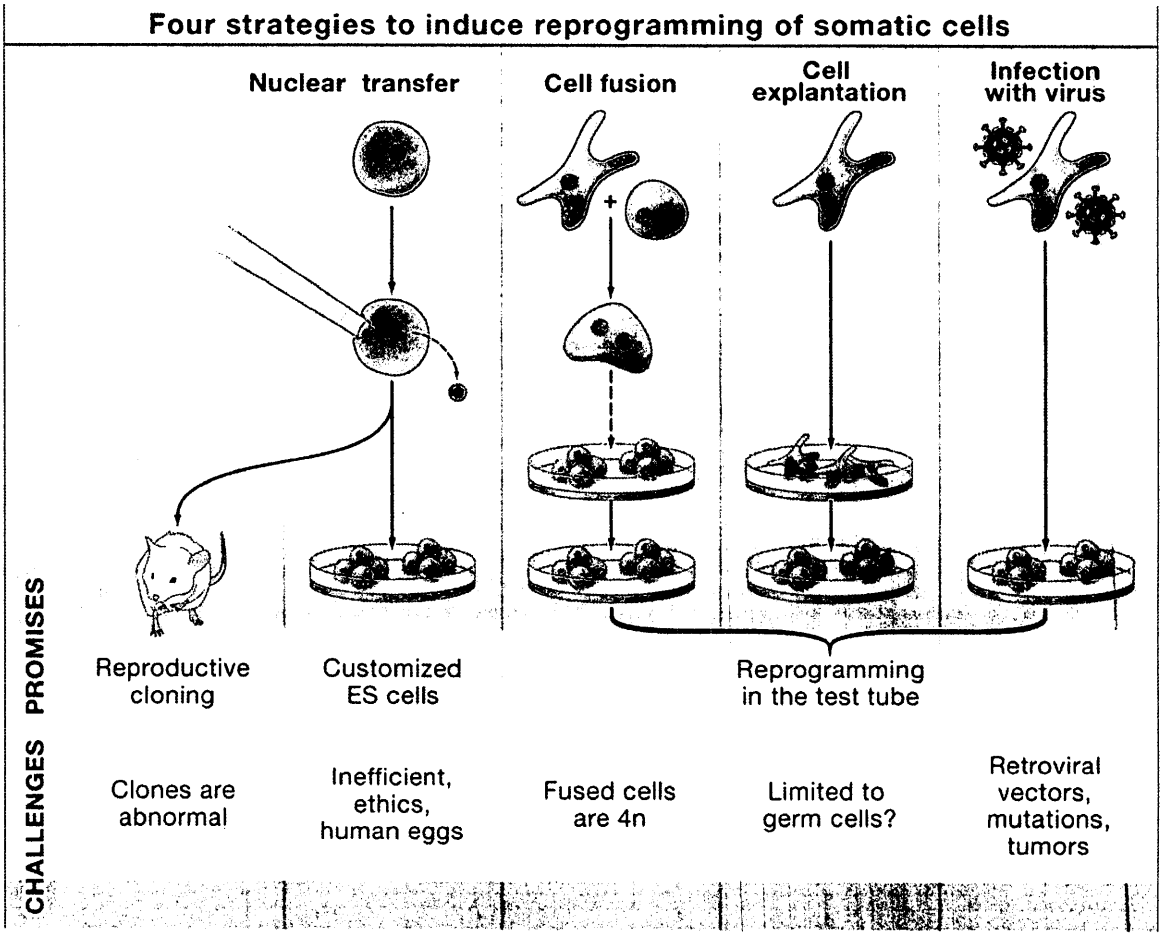
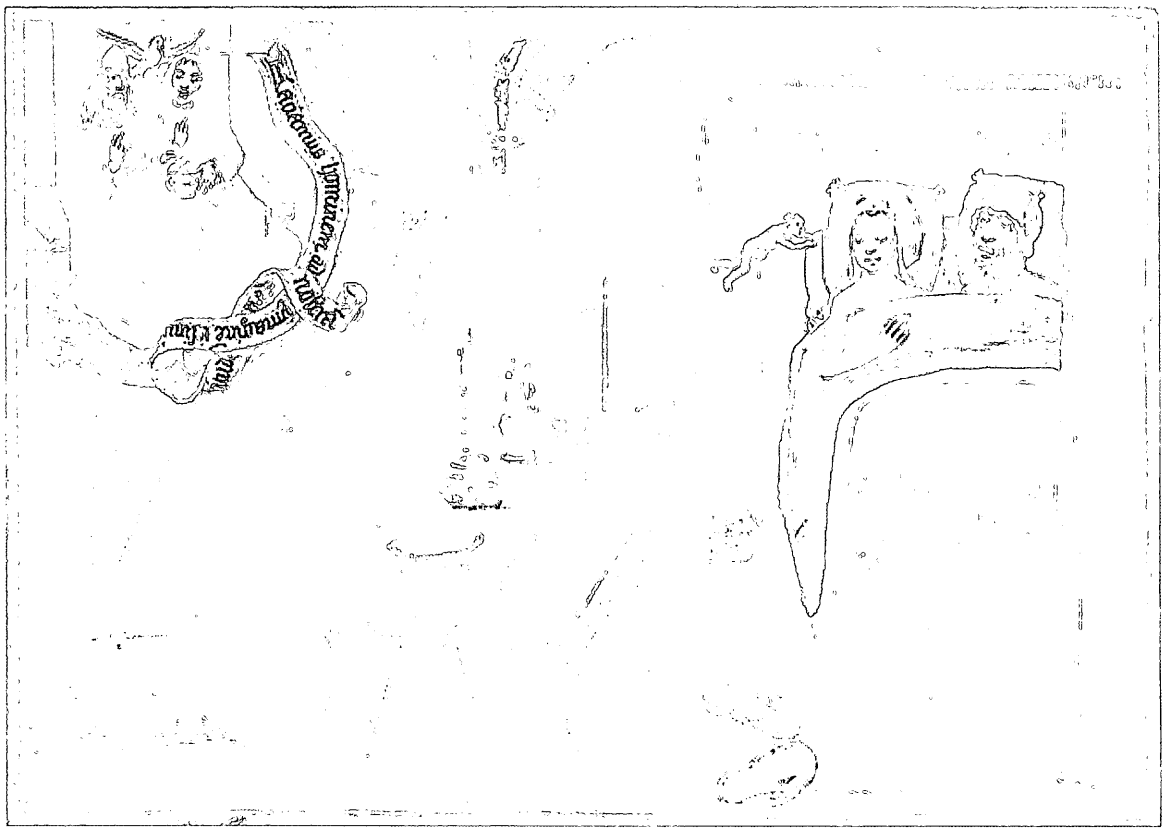


Figure 12: 13th Century Pictorial Representation of "Delayed Hominization" (Delayed Ensoulment of the Fetus)
Many Christians in the medieval period shared the Aristotelian-Aquinian notion of "delayed hominization" or "mediate animation" which postulated that God creates a new human soul, i.e. a rational soul, when the foetus is sufficiently formed.

Figure 13: 15th Century Pictorial Representation of "Immediate Hominization" (Ensoulment of the Fetus at Conception)
Jean Mansel, *Vie de Nostre Seigneur Jésus Christ*, *Bibliothèque Nationale*, Paris, France
Source: http://www.hps.cam.ac.uk/visibleembryos/s1_3.html



APPENDIX B: TABLES

Table 1. U.S. Federal Funding Policy on hESC Research

Timeline	Administration	Stem Cell Policy
January1999-January 2001	Clinton Presidency	**Federal funding allowed for hESC research but could not be used for the procurement of hES cells and lines.** In August 2000 the NIH issues guidelines for funding hESC research and starts reviewing proposals of research teams.
February 2001-August 2001	Bush Presidency	**Moratorium on federal funding for hESC research.** President George W. Bush suspends funding for research projects and orders a review of the NIH funding guidelines.
August 2001-March 2009	Bush Presidency	**Federal funding limited to hESC lines created prior to August 9, 2001.** President Bush announces his decision to restrict funding for hESC research in a televised address to the nation on August 9, 2001. In the period 2005-2008, the NIH spent $3.5 billion on stem cell research, of which only $260 million for hESC research. This policy became highly unpopular and prompted state activism and legislative initiatives to fund hESC research.
March 2009	Obama Presidency	**Funding restrictions for hESC research removed.** On March 9, 2009, President Obama issues *Executive Order 13505 Removing Barriers to Responsible Scientific Research Involving Human Stem Cells.* This order revoked both the governmental policy of August 9, 2001, limiting federal funding for research involving hES cells, as well as Executive Order 13435 of June 20, 2007, which had supplemented the August 9, 2001 presidential statement. The President authorizes the NIH to issue new guidelines for hESC research.
July 7, 2009	Obama Presidency	**Guidelines for Human Stem Cell Research** released by the NIH.
August 2010	Obama Presidency	Court grants an injunction to stop all federal funding for hESC research.
April 29, 2011	Obama Presidency	The Appeals Court's final ruling overturns the injunction. The injunction was temporarily lifted by the court in September 2010.

Table 2. Stem Cell Research in the United States – Timeline

1981	Embryonic stem cells first isolated in mice by two research groups led by Martin at the University of California, San Francisco and Evans at the University of Cambridge
November 1998	James Thomson at the University of Wisconsin and John Gearhardt at Johns Hopkins University report the isolation of the first hES cells. The first team derived stem cells from spare IVF embryos donated for research, and the other from aborted fetuses.
August 2000	The NIH issues guidelines for federal funding of hESC research based on Clinton administration's decision to fund this type of embryo research.
February 2001	President George W. Bush orders a review of the NIH funding guidelines and puts a hold on federal funds for hESC research.
August 2001	President Bush announces a new stem cell policy restricting federal funding to the already existing hESC lines. Most of the hESC lines eligible for funding later prove to be contaminated or have genetic mutations and were thus unsuitable for research.
November 2001	Scientists at Advanced Cell Technology claim to have cloned a human embryo with limited success - one of the eight cloned eggs divided into six cells before stopping.
December 2002	Clonaid announces the world's first cloned baby was born on 26 December 2002. The claims were never proven by an independent source but re-opened the cloning debate.
Ferbruary 2003	The House passes the Weldon-Stupak Human Cloning Prohibition Act. The bill prohibiting all types of cloning did not become a law since the Senate did not act on it.
June 2004	Legislators in New Jersey vote to grant $9.5 million to a new Stem Cell Institute.
November 2004	California passes Proposition 71, a constitution amendment which authorizes the state to spend $3 billion on hESC research over 10 years.
May 2005	The House passes the Castle/DeGrette bill to lift the federal restrictions on funding for hESC research. That same month Connecticut approves $100 million funding for research on both adult and embryonic stem cells over the next 10 years.
April 2006	Maryland Stem Cell Research Act signed. Provides $15 million for hESC research.
July 2006	The Senate passes a bill to expand federal funding for hESC research. President Bush vetoes the bill. This is the first time Bush uses his veto power.
November 2006	Missouri voters pass a referendum measure which protects and funds hESC research
April 2007	The Senate passes another bill to expand federal funding for hESC research
June 2007	The House grants the final congressional approval for the Stem Cell Enhancement Act which eases restrictions on federal funding for hESC research. President Bush again vetoes the bill.
March 2009	President Obama lifts the moratorium on federal funding for hESC research. FDA approves the first clinical trial with a hESC-derived therapy for spinal cord injuries.

Table 3. State Initiatives and Referendums on Stem Cell Research

Date	State	Measure	Outcome
June 25, 2004	New Jersey	State Legislature	$9.5 million budget for the new Stem Cell Institute
November 2, 2004	California	Constitutional Amendment (Proposition 71)	$3 billion hESC research over 10 years.
May 31, 2005	Connecticut	State Legislature	$100 million funding for research on both adult and embryonic stem cells over 10 years.
June 15, 2005	Connecticut	Public act signed by Governor M. Jodi Rell	$20 million for embryonic or adult stem cell research
July 13, 2005	Illinois	Executive order by Governor Rod Blagojevich	$10 million from the state budget to fund a new stem cell research institute
December 16, 2005	New Jersey	Commission on Science and Technology	$5 million awarded to research teams working on hESC research
April 6, 2006	Maryland	Stem Cell Research Act signed by Governor Robert Ehrlich	$15 million for hESC research grant
November 7, 2006	Missouri	Constitutional Amendment 2	State funding and protection of hESC research
February 28, 2007	Iowa	Legislation signed by Governor Chet Culver	Allows the creation of hES cells through cloning, while prohibiting human reproductive cloning
March 16, 2007	California	California's Stem Cell Agency	$75.7 million funding for established scientists at 12 non-profit and academic institutions in addition to $45 million approved in February, 2007

Table 4. State Laws on Human Cloning

State	Reproductive Cloning	Therapeutic Cloning	Statute Citation	Additional Information
Arizona	Prohibits public funding	Prohibits public funding	HB 2221 (2005)	This law prohibits the use of public funds for both types of cloning
Arkansas	Prohibited	Prohibited	§20-16-1001 to 1004	Punishable as a Class C felony and by a fine of not less than $250,000 or twice the amount of pecuniary gain received by person or entity, whichever is greater
California	Prohibited	Allowed	Business & Professions §16004-5 Health & Safety §24185, §24187, §24189, §12115-7	Licenses issued to businesses can be revoked if violations occur. Prohibits the purchase or sale of ovum, zygote, embryo, or fetus for the purpose of cloning human beings; subject to civil penalties
Connecticut	Prohibited	Allowed	2005 SB 934	Offenses punishable up to $100,000 dollars or imprisonment for not more than ten years, or both
Indiana	Prohibited	Prohibited	2005 Senate Enrolled Act No. 268	Allows for revocation of a hospital's license involved in cloning; public funds may not be used for cloning; prohibits the sale of a human ovum, zygote, embryo or fetus
Iowa	Prohibited	Prohibited [Amended Feb. 28, 2007 to allow cloning for hESC research]	707B.1 to 4	Punishable as Class C felony; shipping or receiving punishable as aggravated misdemeanor; if violation of the law results in pecuniary gain, then the individual is liable for twice the amount of gross gain; a violation is grounds for revoking licensure or denying
Maryland	Prohibited	Allowed	2006 SB 144	Prohibits the following: reproductive cloning; oocyte donation for state-funded hESC research; purchase, sale, transfer or obtaining unused IVF material that is donated to research; Punishable by up to 3 years in prison, a maximum fine of $50,000 or both
Massachusetts	Prohibited	Allowed	2005 SB 2039	Prohibits a person from purchasing, selling, transferring, or obtaining a human embryonic, gametic or cadaveric tissue for reproductive cloning; punishable by imprisonment in jail or correctional facility for not less than 5 or more than 10 yrs or by a fine of up to $1 mil.
Michigan	Prohibited	Prohibited	§§333.2687-2688, §§333.16274-16275, 333.20197, 333.26401-26403, 750.430a	Prohibits human cloning for any purpose and prohibits state funding for human cloning; civil and criminal penalties established
Missouri	Prohibits state funding	Allowed	§1.217	Bans use of state funds for human cloning research which seeks to develop embryos into newborn child
New Jersey	Prohibited	Allowed	§2C:11A-1, §26:2Z-2	Reproductive cloning is punishable as a crime in the first degree; prohibits sale or purchase, but not donation, of embryonic or fetal tissue, which is punishable as a crime in the third degree and a fine of up to $50,000
North Dakota	Prohibited	Prohibited	§12.1-39	Cloning or attempt to clone punishable as a class C felony; shipping or receiving violations punishable as class A misdemeanor
Rhode Island	Prohibited	Allowed	§23-16.4-1 to 4-4	Punishable by a civil penalty or fine of not more than $1,000,000, or in the event of pecuniary gain, twice the amount of gross gain, whichever is greater; for an employee without the authorization of the organization, punishable by a civil penalty or fine of not more than $250,000, or in the event of pecuniary gain, twice the amount of gross gain, whichever is greater
South Dakota	Prohibited	Prohibited	§34-14-27	cloning or attempt to clone is punishable as a felony and a civil penalty of two thousand dollars or twice the amount of gross gain, or any intermediate
Virginia	Prohibited	Unclear	§32.1-162.32-2	Unclear if therapeutic cloning is prohibited because human being is not defined in the definition of human cloning. The law establishes civil penalty not to exceed $50,000 for each incident.

Source: **The National Conference of State Legislatures** (http://www.ncsl.org/default.aspx?tabid=14284)

Table 5. Investment Priority and Spending under the 6th EU Framework Program for Research and Technological Development (2002-2006)

Thematic priority	**Budget in million Euros**
Information society technologies	3 625
Life sciences, genomics and biotechnology for health	**2 255**
Sustainable development, global change and ecosystems (including energy and transport research)	2 120
Nanotechnologies, multifunctional materials and new production processes	1 300
Aeronautics and space	1 075
Food quality and safety	685
Citizens and governance in a knowledge-based society	225
TOTAL	**11 285**

Source: http://ec.europa.eu/research/fp6/pdf/faq_en.pdf

Table 6. Investment Priority and Spending under the 7th EU Framework Program for Research and Technological Development (2007-2013)

Thematic priority	**Budget in million €**
Health	**6 100**
Food, Agriculture and Fisheries, and Biotechnology	1 935
Information and Communication Technologies (ICTs)	9 050
Nanotechnologies, Materials and Production Technologies	3 475
Energy	2 350
Environment (including Climate Change)	1 890
Transport (including Aeronautics)	4 160
Space	1 430
Security	1 400
Socio-economic Sciences and the Humanities	630
TOTAL	**32 420**

Table 7. EU Member States Regulations on Stem Cell Research

	Derivation of hES cells from supernumerary IVF embryos allowed by law	Laws for embryo research (incl. supernumerary embryos) without specific reference to hES cells	Derivation of hES cells from human embryos prohibited but the import of hES cell lines is allowed	Derivation of hES cells from human embryo is prohibited	No specific legislation regarding human embryo research	Creation of human embryos for derivation of hES cells allowed by law
Austria				X		
Belgium	X					X
Bulgaria					X	
Cyprus					X	
Czech Republic					X	
Denmark	X					
Estonia		X				
Finland	X					
France	X					
Germany			X			
Greece	X					
Hungary		X				
Ireland					X	
Italy			X			
Latvia		X				
Lithuania				X		
Luxemburg					X	
Malta					X	
Netherlands	X					
Poland				X		
Portugal					X	
Romania					X	
Sweden	X					X
Slovakia					X	
Slovenia			X			
Spain	X					
United Kingdom	X					X

Table 8. 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	**Law/year**
Belgium	Law on Research on Embryos *in vitro* (Loi relatif à la recherché sur les embryons *in vitro*)/2003
Czech Republic	Act on Research on Human Embryonic Stem Cells (Zákon 227/2006)/2006
Denmark	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	Bioethics Law (Loi no. 2004-800 relative à la bioéthique)/2004, Decree No. 2006-126
Finland	Medical Research Act (Laki lääketieteellisestä tutkimuksesta)/1999
Germany	Stem Cell Law (Stammzellgesetz StZG)/2008 - **hESC derivation prohibited**
Hungary	Health Care Act (CLIV/1997) - **hESC derivation not allowed**
Israel	Prohibition of Genetic Intervention Act (Human Cloning and Genetic Modification of Reproductive Cells)/1999, modified 2004
Italy	Law on Medically Assisted Reproduction (Norme in materia di procreazione medicalmente assistita)/2004 - **hESC derivation not allowed**
Netherlands	Embryo Act/2002; phase 2/2007
Norway	Biotechnological Act (Lov om humanmedisinsk bruk av bioteknologi)/2007
Portugal	Law on Medically Assisted Procreation (Procriação medicamente assistida)/2006; Opinion on Human Cloning (Parecer sobre clonagem humana)/2006
Spain	Law on Biomedical Research (Ley de Investigación Biomedical)/2007
Sweden	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	Stem Cell Research Act (Stammzellengesetz)/2005
United Kingdom	Human Fertilization and Embryology Act/1990; Human Fertilization and Embryology Bill/2001 and 2008 (still under parliamentary review)

Table 9. EU Member States Laws on Human Cloning

	Cloning of human embryos for stem cell research allowed by law	The creation of human embryo for research purposes and for the derivation of hES cells is prohibited by law or by ratification of the Convention of the Council of Europe on Human Rights and Biomedicine signed in Oviedo on 4 April 1997
Austria		X
Belgium	X	
Bulgaria		
Cyprus		X
Czech Republic		X
Denmark		X
Estonia		X
Finland		X
France		X
Germany		X
Greece		X
Hungary		X
Ireland		X
Italy		X
Latvia		
Lithuania		X
Luxemburg		
Malta		
Netherlands		X
Poland		
Portugal		X
Romania		
Sweden	X	
Slovakia		X
Slovenia		X
Spain		X
United Kingdom	X	

Table 10. hESC Research Projects Funded under the EU FP6

A given project can appear under several sub-domains, either in organ/tissues, or diseases. Projects not related to any of these domains were classified under "transversal issues." Projects are listed based on proposal acronyms. Full descriptions are available at http://ec.europa.eu/research/fp6/pl/stemcells/pdf/stemcell_eu_research_fp6_en.pdf#view=fit&pagemode=bookmarks

ORGANS & TISSUES	DISEASES	TRANSVERSAL ISSUES
Neurectoderm-derived tissues and organs: ARTEMIS, EuroHear, EUROSTEMCELL, EVI-GENORET, INTERDEVO, NanoEar, NEURONE, NEUROscreen, NSR, Plurigenes, RESCUE, STEM-HD, STEMS, STEMSTROKE, STROKEMAP, X-ALD. **Ectoderm-derived epithelia:** CORNEA ENGINEERING, EPISTEM, EuroCSC, EUROSTEMCELL, MCSCs, SKINTHERAPY, STEPS, THERAPEUSKIN, Ulcer Therapy **Endoderm-derived organs:** BARP+, BETACELLTHERAPY, CELLS INTO ORGANS, EPI-VECTOR, EUGENE2, EuReGene, EURO-Laminopathies, EuroSTEC, KIDSTEM, LIVEBIOMAT, REGULATORY GENOMICS **Mesoderm-derived tissues and organs:** AUTOBONE, CELLS INTO ORGANS, EPI-VECTOR, EURO-Laminopathies, EuroBoNet, EuroSTEC, EUROSTEMCELL, EXPERTISSUES, GENOSTEM, HIPPOCRATES, MYOAMP, MYOCARDIAL REPAIR, MYORES, NANOBIOCOM, NEWBONE, OsteoCord, SILKBONE, SmartCaP, STEPS, SyntheGeneDelivery **Organs and tissues of mesodermal and composite origin:** BIOSYS, CELLS INTO ORGANS, EURO-Laminopathies, EVGN, HeartRepair, INVITROHEART, LYMPHANGIOGENOMICS, MCSCs, MYOCARDIAL REPAIR, SC&CR, VASCUPLUG **Other organs and tissues of composite origin:** BARP+, BETACELLTHERAPY, CELLS INTO ORGANS, EPI-VECTOR, EUGENE2, EuReGene, EURO-Laminopathies, EuroSTEC, KIDSTEM, LIVEBIOMAT, REGULATORY GENOMICS	**Cancers** ALLOSTEM, Anti-tumor targeting, CONTROL CANCER STEM, E.E.T.-Pipeline, EuroBoNet, EuroCSC, EUROPEAN LEUKEMIANET, EUROPEAN MCL NETWORK, EUROXY, FIRST, GIANT, M3CS-TU TH, MCSCs, MOL CANCER MED, MSCNET, ONCASYM, REGULATORY GENOMICS, SENECA, TUMOR-HOST GENOMICS **Rare diseases** (and some less rare heritable diseases) CONSERT, EPISTEM, EURO-Laminopathies, SKINTHERAPY, STEM-HD, SyntheGeneDelivery, THERAPEUSKIN, X-ALD	3G-SCAFF, CARCINOGENOMICS, CellPROM, CLINT, CRYSTAL, Custom-IMD, DNA REPAIR, EMBRYOMICS, EMRS, ESTOOLS, EU hESC registry, EUCOMM, EUROCITS, EuTRACC, FunGenES, imgbchimerashybrids, INDUSTRYVECTORTRAIN, INTHER, INVIVOVECTORTRAIN, MODEST, NEURO, PREDICTOMICS, REPROGENETICS, ReProTect, SIROCCO, StemCellPatents, THE EPIGENOME, TherCord, TRANSCODE, VITROCELLOMICS

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