ABSTRACT  Policy entrepreneurs are political actors who seek policy changes that shift the status quo in given areas of public policy. This paper examines the actions of policy entrepreneurs who have sought government funding and favourable regulation to advance human embryonic stem cell research. Those policy entrepreneurs have faced significant opposition due to the morality issues at stake. By placing the actions of those policy entrepreneurs in a broader context, this paper makes two contributions. First, it explores how policy entrepreneurs pursue their goals in the face of intense morality politics. Second, it illustrates how the work of policy entrepreneurs can be both supported and inhibited by ideas, institutions, and interest-group politics.

KEY WORDS  Policy entrepreneurs, morality policies, human embryonic stem cells, regulation, governance.
Policy Entrepreneurs and Controversial Science: Governing Human Embryonic Stem Cell Research

The history of western civilization has been punctuated by controversies between scientific communities, governments, and religious entities. Those controversies have centred on issues of knowledge, power and control. To people of faith, knowledge claims disrupting the perceived natural order of things have been deeply threatening. For example, Nicolaus Copernicus’s sixteenth century works on the solar system, which ushered in the Copernicum Revolution, met with opposition from the Catholic Church. Among other things, that opposition manifested itself in one of Copernicus’s followers, Galileo Galilei, being convicted of heresy and placed under life-long house arrest. Likewise, Charles Darwin’s nineteenth century theory of natural selection, which revolutionised the life sciences, drew criticism from Christians adhering to Creationism or notions of intelligent design. A similar controversy has been fuelled by the announcement in 1998 that human stem cells had been derived from human embryos (Thomson et al. 1998). Human embryonic stem cell research – while promising future therapies that could both extend lives and improve their quality – “touches the very core of our attitudes towards life and thus has a deeply symbolic significance” (Schmidt, Jotterand, and Foppa 2004, p.500). Scrutiny of public debates and policy choices regarding governance of this controversial science can generate insights into contemporary politics, policymaking, and the design of effective governance systems (Mintrom 2009; Mintrom and Bollard 2009).

The work of policy entrepreneurs is given a central place in this paper. Policy entrepreneurs are political actors who seek policy changes that shift the status quo in given areas of public policy. Some governments have found effective ways to support this human embryonic stem cell research despite its controversial nature. While the morality politics surrounding the issue have been most salient in public debates, to focus solely upon them is to misunderstand the factors that serve to support or inhibit the production of leading research in the field. Through case studies of policy entrepreneurship and human embryonic stem cell research in the United Kingdom and Italy, the paper shows how policy entrepreneurs have sought to promote more funding and less restrictive regulation for stem cell science, with mixed results. In each case, these efforts have met with significant opposition due to the morality issues at stake.
By placing policy entrepreneurship in a broader context, this paper makes two contributions. First, it shows how policy entrepreneurs pursue their goals in the face of intense morality politics. Second, it shows how the work of policy entrepreneurs can be both supported and inhibited by ideas, institutions, and interest-group politics. The aim of this paper is to highlight instances of policy entrepreneurs operating in contexts where they face considerable opposition and the opposition is driven by moral disagreement. We want to know how they fashion their actions to the constraints of their operating context. We also want to know how their actions serve to shape policy outcomes. Work along these lines will enhance our knowledge, first, of the nature and limits of policy entrepreneurship and, second, of morality policies and the politics surrounding them.

THE WORK OF POLICY ENTREPRENEURS

Among contemporary theories of policymaking and policy change, three offer valuable insights into the dynamics of policy change, how the conditions arise that generate change, and the structures of interest groups and other alliances that provide the social capacity for change initiatives. Frank Baumgartner and Bryan Jones’ (1993) theory of agendas and instability in government combines knowledge of factors that propel major change with Charles Lindblom’s (1959) concept of boundedly-rational actors engaging in incremental change. Baumgartner and Jones argued that patterns of change in most policy domains exhibit “punctuated equilibrium” – that is periods of deep and rapid change that are both preceded and followed by much longer periods of quiet, business-as-usual. John Kingdon’s (1984) theory of independent streams suggests that policy change occurs in windows of opportunity where specific political events, the current state of the policy conversation among policy elites, and particular pressing problems align in ways that allow for disruptive agenda setting. Paul Sabatier’s (1988; 1993) theory of advocacy coalitions – the advocacy coalition framework – attends to interactions among diverse stakeholders. Here, the norm-shaping nature of discourse within coalitions over a sustained period of time serves both to generate ideas for policy change and focus the political forces needed to achieve that change. Within all three theories, the role of change agents – or policy entrepreneurs – has been recognized, but it has not been given careful attention.

Close focus on the work of policy entrepreneurs is a recent phenomenon. Michael Mintrom and collaborators have identified the actions taken by policy entrepreneurs (Mintrom and Vergari 1996, 1998), the ways that contextual factors serve to support or
inhibit their actions (Mintrom 1997, 2000), and the compatibility between these more detailed understandings of the work of policy entrepreneurs and broader theories of policymaking (Mintrom and Norman 2009). Those conceptual and empirical investigations suggest policy entrepreneurs are identifiable not so much by their success in securing policy change but by the actions they take in pursuit of that goal. Policy entrepreneurs tend to work hard at (1) defining and framing problems, (2) building powerful teams that tap relevant knowledge networks, (3) amassing evidence to show the workability of their proposals; and (4) creating strong coalitions of diverse supporters.

While the original theorizing about the role, actions and impacts of policy entrepreneurs drew on evidence from the United States, various scholars have adapted and applied the concept of policy entrepreneurship in the European context. Falk Daviter (2007) and Daniel Béland (2009) have indicated the importance of policy framing as a tool for promoting policy change, and they have highlighted examples of how policy entrepreneurs have employed policy framing to good effect. Marcel Braun (2009) and Dimitrios C. Christopoulos (2006) have each explored the actions of policy entrepreneurs within European policy networks, and how they have leveraged their network resources to promote policy change. The effective use of evidence by policy entrepreneurs in the European context has been explored by Giandomenico Majone (1989) and Arco Timmermans and Peter Scholten (2006). Finally, Geoffrey Dudley and Jeremy Richardson (1999) and David Natali (2004) have used case studies to illustrate how policy entrepreneurs have used broad-based advocacy coalitions to help achieve their policy goals.

Policy entrepreneurs reveal themselves through their efforts to transform policy ideas into actions. By definition, they seek to change status quo policy arrangements. This distinguishes them from many interest group leaders, for whom maintenance of current power relations and institutional settings are accorded highest priority. The focused attention policy entrepreneurs give to specific issues and their willingness to work effectively with others serve to increase the likelihood that they will secure the policy outcomes they desire. But two points should be kept in mind. First, competency matters and, inevitably, some policy entrepreneurs will be more adept than others at negotiating their operating context. Second, the operating context matters. Just as athletic performance is influenced both by the inherent capabilities of the athlete and the conditions on the day, so too policy outcomes are influenced both by the capabilities of policy entrepreneurs and the broader authorizing context in which they are operating.
In the case of policy entrepreneurs wishing to change regimes governing particular controversial science work, the broader authorizing environment will be shaped by a number of factors. In the case of human embryonic stem cell research, these factors can include the relative power and ascendancy of specific interest groups, such as the Catholic Church or the local science and innovation community. Their context can also be crucially shaped by the composition of elected officials in the legislature and relations between those officials and other powerful decision-makers (such as presidents or the judiciary). These contextual influences on the effectiveness of policy entrepreneurs have been discussed in detail by Michael Mintrom (2000). The impact of contextual factors on the advocacy of permissive governance of human embryonic stem cell research at the state level in the United States has been demonstrated by Andrew Karch (2012) and Michael Mintrom (2009). Differences in contextual factors can significantly influence the time needed for policy entrepreneurs to achieve desired policy outcomes. In turn, they can affect the nature of the work they do in the development and coordination of advocacy coalitions. Jocelyn Crowley (2003; 2008) has documented examples of policy entrepreneurship and advocacy efforts spanning several decades. Later in this paper, case studies highlight the relationship between the work of policy entrepreneurs and the broader authorizing environment, with reference to advocacy for more permissive governance of human embryonic stem cell research.

HUMAN EMBRYONIC STEM CELL RESEARCH

Stem cell research in itself need not necessarily be controversial. Although all cells within an organism contain the same genetic information, as they develop they become specialized, which allows them to carry out very different and specific functions throughout the body. In contrast to specialized cells, stem cells are uncommitted cells serving no specific purpose. They remain uncommitted until they receive signals to develop into specialized cells. Scientists have speculated about stem cells and their qualities for over a century (Ramalho-Santos and Willenbring 2007). The existence of stem cells was discovered mainly through investigations into animals, particularly mice. Stem cells are known to exist in both adults and embryos, and stem cell researchers have studied the behaviour of both adult stem cells and embryonic stem cells. However, questions remain concerning the plasticity of non-embryonic stem cells – that is, their ability to transform into a variety of specialized cells (National Institutes of Health 2006).
In 1981, researchers from Cambridge University in the United Kingdom reported methods for growing mouse embryonic stem cells (Evans and Kaufman 1981). In 1998, James Thomson and his team of researchers from the University of Wisconsin – Madison reported the isolation of human embryonic stem cells (Thomson et al. 1998). Embryonic stem cells are derived from cells called the inner cell mass, which is part of several-day-old embryos, or blastocysts. If left in the right environment, these cells would develop into an embryo. Once removed from the blastocyst, the cells of the inner cell mass can be cultured into embryonic stem cells. These embryonic stem cells are not themselves embryos and evidence has shown that these cells do not behave in the laboratory as they would in the developing embryo. After researchers have isolated stem cells from a human embryo, the cells can often replicate indefinitely if kept in the correct environment. This creates what is termed a “cell line.”

The ability of the Wisconsin team to isolate human embryonic stem cells and cultivate stem cell lines was a significant scientific breakthrough. Evidence subsequently emerged that these cells are capable of becoming almost all of the specialized cells of the body and may have the potential to generate replacement cells for a large number of tissues and organs, such as the heart, the pancreas, and the nervous system. Because of this, stem cells are seen as having several important scientific and medical applications. These include being used for repair or replacement of cells or tissues that are damaged or destroyed by a variety of diseases and disabilities, testing new drugs in a controlled and safe setting, and studying genetic function and development processes (National Institutes of Health 2001).

Morality Politics Associated with Human Embryonic Stem Cell Research

What is the moral status of the human embryo? The question of what constitutes independent human life is central to the debate regarding the use of human embryonic stem cells in research and research-based therapies. The question can be further broken down. First, does life begin at conception – at the moment when the human egg is fertilized – or at some later stage of development? Second, at what point in the development of the embryo or foetus should human rights and other legal protections be assigned to this life form? Human embryonic stem cell research is controversial science precisely because it forces explicit consideration of what counts as human life and who gets to decide that.

Some religious groups – including representatives of the Roman Catholic Church and other Christian traditions – contend that human life indeed begins at conception and from that
point forward the embryo or foetus should be accorded full respect and full rights as a human being. That position immediately renders destruction of the embryo as immoral and renders as inadequate any justification for pursuit of scientific inquiry that requires embryo destruction. Questions concerning trade-offs between the protection of the life of the human embryo, on the one hand, and the quality of life of people who could benefit from advances in human embryonic stem cell research, on the other, inherently involve relativist judgements. But relativism has no place in what is an inherently absolutist world view. Given this, in jurisdictions where politicians depend upon the support of organized religious groups to obtain and maintain decision-making roles – and those religious groups view human life in absolute terms – promoters of human embryonic stem cell research are likely to be stymied in their efforts. In contrast, in jurisdictions where relativism and more pragmatic arguments are able to hold sway, opportunities emerge for advocates to promote government funding and permissive regulation of human embryonic stem cell research. Simon Fink (2008) has shown that across 21 countries that have adopted laws around human embryonic stem cell research, the most restrictive laws have been adopted in countries where Roman Catholicism is a dominant religion and/or Christian democratic parties have been in ascendance.

Proponents of human embryonic stem cell research have pointed out that in the natural reproductive process, human eggs are often fertilized but fail to implant in the uterus. A fertilized egg, they argue, while it may have the potential for human life, cannot be considered equivalent to a human being until it has at least been successfully implanted in a woman's uterus (American Association for the Advancement of Science 2007).

While some have considered embryonic stem cell research to be justifiable for the advancement of scientific knowledge, they have worried greatly about the future (Fukuyama 2005). Looking ahead, the possibility arises of extensive growth in markets for the trading of human eggs. This would create incentives for women to produce and sell eggs that would then be fertilized to create embryos solely for the purpose of destroying them at the blastocyst stage to harvest the stem cells. As is, trading of human eggs has become common in response to the demands of infertile couples to gain access to donor eggs for making babies (Withrow 2007). Scientists seeking to work with human embryos for stem cell research obtain human eggs from in vitro fertilization clinics. In the process of treating infertility, more eggs are produced than are used for the purposes of creating viable embryos. Surplus eggs can be stored, discarded, or donated to research (Trivedi 2007). Proponents of embryonic stem cell research have held that it is morally permissible to use surplus embryos for potentially life-
saving biomedical research. Opponents have objected to this argument, however, saying that such research would still condone the destruction of embryos.

Some stem cell research is non-controversial. This includes stem cell research using animals and research using cells derived from human placentas discarded at birth or tissue from adult human skin cells. Indeed, work by James Thomson and his Wisconsin team announced in 2007 could eventually take much of the heat away from the controversy over embryonic stem cell research. That is because Thomson’s team discovered how to use genetic modification to reprogram non-embryonic human cells so that they exhibit the essential characteristics of embryonic stem cells (Yu et al. 2007). This work holds promise because it allows for the possibility of using a patient’s own skin cells to create genetically-matched stem cells that could be used to make replacement cells and tissues for that patient, without the risk of rejection by the immune system. However, questions remain about the distinction between embryonic stem cells and stem cells derived through genetic modification, making on-going work with human embryonic stem cells crucial to the advancement of this scientific work (Kolata 2007).

Issues surrounding human cloning also arise in the management of human embryos and the harvesting of embryonic stem cells. That is because the only technique known so far for growing stem cells genetically matched to a subject has involved injecting cells from that subject into a human egg to clone that person and then extract the embryonic stem cells from the blastocyst. Such a procedure and the moral issues associated with it could also be rendered redundant through the research into reprogramming of non-embryonic human cells into stem cells. However, the issue of cloning has created another point of deep controversy surrounding this research (Fukuyama 2005).

A number of previous studies have explored the politics associated with the governance of human embryonic stem cell research. These studies have focused on the role of religion in policy debates (Fink 2008), path-dependencies in such debates (Bankoff 2005), and inter-jurisdictional competition (Karch 2012, Mintrom 2009). However, the present paper is first to place an explicit focus on the activities of policy entrepreneurs in this issue area.

THE GEOGRAPHY OF HUMAN EMBRYONIC STEM CELL RESEARCH

Publication of original research articles exploring aspects of stem cell science have routinely appeared in two of the world’s leading scientific publications: Science and Nature.
Since 2007, another top scientific journal, Cell, has published articles on stem cell research in Cell Stem Cell. Following Mintrom and Bollard (2009), a place-of-origin analysis was performed on articles published in those journals in the period from January 1998 through to December 2011. This analysis counted original research publications where the term “stem cell” appeared in either the title or the abstract. Across the three journals during this period, lead authorship of articles was attributed to scientists located in 24 countries. Of those countries, 20 were members of the OECD and 16 were home of at least one university ranked as being among the world’s top 100 in the Academic Ranking of World Universities, 2011. Additionally, almost perfect correlations existed between the proportions of publications by place-of-origin across the three journals.

In all three journals, well over half of the publications were based on science conducted in the United States. The second-most common place of origin was Japan. Among European nations, scientists from the United Kingdom led the publication count followed by Germany. Publications from other European countries were sporadic. This pattern indicates that the primary predictor of a country hosting stem cell research is not the religious mix of the population but the wealth of the country and the commitments that successive governments have made to the funding of their research universities. Among countries hosting universities ranked in the world’s top 100 in 2011, the United States hosted 54, the United Kingdom hosted 11, and Germany and Japan hosted 5 each. France, Sweden, and Switzerland each hosted 3 top-ranked universities, while other European countries hosted two, one or none. This analysis suggests that in some countries the public debates over stem cell research represent little more than political and moral posturing because general, long-term government commitment to funding of premier scientific facilities (for any kind of science) has been lacking.

POLICY ENTREPRENEURS AND THE PROMOTION OF HUMAN EMBRYONIC STEM CELL RESEARCH

Studies of policy entrepreneurship have flourished in the past three decades (Mintrom and Norman 2009). Following John Kingdon’s (1984) path-breaking discussion of what policy entrepreneurs do, research on the activities of policy entrepreneurs has tended to employ case study techniques. There have been exceptions. For example, Mintrom (1997, 2000) used event history analysis to quantitatively test the impact of policy entrepreneurs and various contextual conditions on legislative agenda setting and policy change. However, to achieve
adequate control of other explanation of policy change, quantitative investigations of policy entrepreneurship require high levels of institutional isomorphism across the jurisdictions included in the study. Such isomorphism is present in many federalism systems but is rarely found across independent countries. A major challenge for policy researchers lies in establishing tractable ways to conduct cross-national studies of policy entrepreneurship.

For the present study, the research question was: How have policy entrepreneurs shaped the governance of human embryonic stem cell research in European countries? The geography of stem cell research served to limit the set of countries relevant to the study. To date, scientists based in just 11 European countries have published the results of stem cell research in *Science, Nature, or Cell Stem Cell*. Those countries are: Austria, Belgium, Denmark, France, Germany, Italy, the Netherlands, Spain, Sweden, Switzerland, and the United Kingdom. Since the research work was to be exploratory in nature, I chose to follow the “diverse case” selection approach (Gerring 2007). Two countries were selected as cases, each offering distinctive contexts with respect to the generation of human embryonic stem cell research and the broader political environment. The two countries were the United Kingdom and Italy. In each case, enough documented evidence was available to assist in the interpretation of the role policy entrepreneurs have played in each country. Analysis of aggregate statistics confirms the appropriateness of this choice of cases. Among European countries, the United Kingdom has one of the lowest populations of adults professing the Roman Catholic faith (at around 9%). In contrast, Italy has the highest population of adults professing Roman Catholicism (at around 90%). Further, comparing across European countries with respect to the mean levels of professionals working in the broad field of Research and Development, Italy tends to have a much less developed R&D sector than does the United Kingdom. In addition, proportionate to population size, among European countries Italian universities generate comparatively low levels of science graduates per year, while the United Kingdom generates comparatively high levels.\(^1\)

Substantively, the governance of human embryonic stem cell research is not dichotomous. Rather, it represents a continuum made up of several variables, including the permissiveness of regulations relating to what researchers can do, and the willingness of governments to fund research projects in this area. European countries differ considerably in their governance of human embryonic stem cell research. On a continuum, Italy lies at the highly restrictive end, while the United Kingdom lies at the permissive end. In their analysis

\(^1\) Author’s calculations using population data from the CIA’s World Factbook and the OECD’s databases on science and technology indicators.
of policy approaches to embryonic stem cell research in 50 countries, Rosario Isasi and Bartha Knoppers (2006) noted that the United Kingdom had a liberal policy regime and Italy a regime that essentially banned this form of research. In both instances, supporters of human embryonic stem cell research have faced significant political opposition based on moral principles. In reviewing each case, attention is paid to how advocates of stem cell research have sought to (1) define and frame problems, (2) build teams tapping relevant knowledge networks, (3) amass evidence to show the workability of their proposals; and (4) create strong coalitions of diverse supporters.

The United Kingdom

A permissive approach has been taken in the United Kingdom to the regulation of human embryonic stem cell research. While human reproductive cloning is banned, the current regime permits the creation of embryos for research purposes as well as for the derivation of stem cell lines and for cloning for research purposes. This permissiveness, and the existence of a long-established, well-supported scientific community has allowed the United Kingdom to stand as a leading jurisdiction for the advancement of human embryonic stem cell research. To the extent that policy entrepreneurship has occurred in this context, it has been undertaken quietly and within an institutional context that has facilitated huge expansion in human embryonic stem cell research. Moral issues have been widely canvassed, and heated debates have occurred, but they have not inhibited scientific research. Given this context, it is impossible to identify one specific individual as a policy entrepreneur. Rather, there have been “entrepreneurial moments,” where particular individuals have played decisive roles and have taken actions. Those individuals include Mary Warnock and Ruth Deech.

Relevant history relating to research on embryos in the United Kingdom dates back to the early 1980s, and what Michael Mulkay (1993) has termed the “Great Embryo Debate.” In Vitro Fertilisation was producing surplus embryos that were readily accessible material for research. This led to concern over the status of embryos. The medical community, which claimed more research would support better treatment, was opposed by critical voices in public and in Parliament. In 1982 the British Government established the Committee of Inquiry into Human Fertilisation and Embryology, chaired by Mary Warnock, a philosopher. In what now appears as a significant act of policy entrepreneurship, Warnock (1985) and her colleagues recommended that a government agency be established to regulate artificial fertility methods as well as embryonic research. At the outset, Warnock’s report upset both
scientists – who resisted strict regulation of their work – and religious groups – who wished to protect human embryos. However, following much debate, Warnock’s basic proposal was adopted into law. In 1990, the Human Fertilisation and Embryology Authority was established, responsible for all issues concerning human fertility and for research with human embryos. The new law resolved prior debate by acknowledging that the moral status of the human embryo is different from any other research object. However, a governing principle was established that the moral value accorded to human embryos may be outweighed by other serious moral considerations (Hauskeller 2004).

When stem cell research became a reality by the end of 1998, embryo research was already a regulated but normal practice in the United Kingdom. The established procedures of the Human Fertilisation and Embryology Authority created space for careful discussion of newly arising issues in the field. According to Christine Hauskeller “the procedures and practical questions of directing such research to be successful and effective as possible in favour of new therapies was prefigured both in the prevailing structure of ethical reasoning and the resulting institutions” (2004:515). From the beginning, the Human Fertilisation and Embryology Authority promoted human embryonic stem cell research. During the period from 1994 – 2002, the Authority was chaired by Ruth Deech, now Baroness Deech, who subsequently co-authored a book on the Authority’s work (See Deech and Smajdor 2007). Deech led the Authority in a manner that created more opportunities for human embryonic stem cell research to be conducted in the United Kingdom. HFEA Members are appointed by UK Health Ministers. The Members determine the HFEA's policies. In order that a perspective can be maintained which is independent of the medical-scientific view, the enabling legislation (HFE Act 1990) requires that the Chairman, Deputy Chairman and at least half of the HFEA's Membership are neither doctors nor scientists involved in human embryo research. Members are not appointed as representatives of different groups, but bring to the HFEA a broad range of expertise.

As chair of the Human Fertilisation and Embryology Authority, Ruth Deech performed many functions consistent with being a policy entrepreneur. In her role, she had the resources and the stature to work with others to (1) define and frame policy discussions. Through the Authority’s links to the scientific and policy communities, Deech was (2) able to assemble ad hoc teams to explore emerging policy issues. Deech and her colleagues at the Authority continually (3) amassed evidence to show the workability its proposals. Indeed, they took care to be transparent about the scientific work they authorised. As such, Deech
established for herself a powerful position for leading policy debate and (4) gained the support of strong, diverse coalitions.\textsuperscript{2}

The quiet, agenda-setting actions of Ruth Deech and the Human Fertilisation and Embryology Authority in the United Kingdom are illustrated by the process that led to adoption of the Human Fertilisation and Embryology (Research Purposes) Regulations 2001. In 1998, the Authority, in collaboration with the Human Genetics Advisory Commission, established a Working Group chaired by the Reverend Dr. John Polkinghorne, a former professor of mathematical physics at Cambridge University who had subsequently become an Anglican priest. That choice of chair illustrates how Deech and her colleagues sought to appear even-handed in its consideration of issues. In January 1998, the Working Group produced a paper, “Cloning Issues in Reproduction, Science and Medicine.” It argued that research using cell nuclear replacement (in which the nucleus of an adult cell is fused with an egg which has had its nucleus removed) could lead to new treatments for serious disorders by providing a source of new tissue. In response, in June 1999, the Government announced the establishment of an Expert Group chaired by the Chief Medical Officer, Professor Liam Donaldson, to advise on whether new areas of research using embryos should be permitted that could lead to broader understanding of, and eventually to new treatments for, a range of disorders where there is disease or damage to tissues or organs. Notably, Donaldson’s Expert Group was not asked to review from first principles the ethical issues of research involving embryos. Rather, it was asked to consider only new ethical issues that might arise from the creation and use of embryos for the extraction of stem cells.

The Donaldson Report was released in August 2000. It proposed the legalization of research with stem cells derived from embryos within fourteen days of fertilization. Such research, it contended, should be subject to rigorous scientific and ethical review and it should be conducted primarily with stem cells derived from embryos left over from in vitro fertilisation treatments. Following the advice initially promulgated by the Human Fertilisation and Embryology Authority’s Working Group, Donaldson and his colleagues proposed that the creation and cloning of embryos for biomedical research be allowed. New legislation consistent with this was adopted in December 2000.

The period from August to December of 2000 witnessed considerable debate. While it was initiated by actions of the Human Fertilisation and Embryology Authority, the agency itself remained silent through this period. Statements in support of cloning for research

\textsuperscript{2}I am grateful to Baroness Deech for verifying this interpretation of her activities at the HFEA.
purposes were provided from many quarters, including the Medical Research Council, the Wellcome Trust, the Nuffield Council on Bioethics, the British Medical Association, and the Royal Society. Patient’s groups, such as the UK Parkinson’s Disease Society, also backed the law change. Former American actor Christopher Reeve joined the campaign, and Colin Blakemore of the Medical Research Council described his role as “very significant” (Gottweis and Prainsack 2006). While scientists, Professor Donaldson, and Members of Parliament aligned with the governing Labour Party were most prominent in supporting the law change, Conservative Members of Parliament, religious figures, and pro-life groups were among its most vocal opponents (Williams, Kitzinger, and Henderson 2003). This successful action to promote stem cell research in the United Kingdom illustrates how effective policy entrepreneurship can set the terms for subsequent debate. It also illustrates how long-established institutions and the power of entrenched interest groups can assist those promoting policy changes fraught with moral issues.

Italy

In Italy, a virtual ban has existed on human embryonic stem cell research since 2004. This ban is a bi-product of an effort to protect and afford citizenship to the embryo from the moment of conception. The Italian Medical Assisted Procreation Law No.40 (2004) stipulates that clinical and experimental research on a human embryo can be conducted only for therapeutic or diagnostic purposes which are exclusively directed to the protection of the embryo’s health and development. In vitro fertilisation is allowed, but no surplus embryos are to be produced. Since this law is solely focused on the human status of the embryo, Italian scientists are free to work on stem cells lines derived from human embryos, so long as they are imported. (Human stem cell lines, once created, exist outside of the embryo.) However, this kind of research is difficult to sustain in Italy, because national funding for stem cell research is restricted to work using stem cells derived from adult tissues, from cord blood, and from aborted foetuses. The Roman Catholic Church has been active in efforts to restrict research on human embryonic stem cells (Metzler 2007) and in 2006 Cardinal Alfonso Lopez Trujillo expressed his view that excommunication from the Church was merited for researchers who destroyed human embryos (Rosenthal 2006).

The Italian case highlights two conditions that restrict efforts to advance human embryonic stem cell research. First, the Roman Catholic Church – an historically powerful institution in Italian society – has maintained a strong moral stance that accords the human
Embryo full status as a human being. So morality politics have played against policy entrepreneurs seeking support for human embryonic stem cell research. Second, the limited nature of the funding available to Italian scientists in this field has inhibited the development of institutional support for human embryonic stem cell research. Only when communities of scientists achieve a critical mass do we tend to see their work receive support from entities such as universities, scientific associations, and businesses that perceive commercialization potential in the research.

In the face of difficult circumstances, policy entrepreneurs have sought to advance the place of human embryonic stem cell research in Italy. Those policy entrepreneurs comprise a team of scientists lead by Professor Elena Cattaneo, Director of the Center for Stem Cell Research (UniStem) at Università di Milano. Cattaneo has published in *Science* and *Nature* on matters relating to neural stem cells and Huntington’s Disease.

To date, the actions of the Italian policy entrepreneurs have not provoked policy change. However, their actions are consistent with efforts of policy entrepreneurs elsewhere to (1) define and frame problems, (2) built teams tapping relevant knowledge networks, (3) amass evidence to show the workability of their proposals; and (4) create strong coalitions of diverse supporters.

With respect to (1) defining and framing problems, in 2007, Cattaneo’s group known as the Italian Researchers on Embryonic Stem Cells (IES Group) produced its “Manifesto for Scientific Research on Embryonic Stem Cells.” In response to their powerful opposition from those who wish to protect the life of human embryos, the signatories to the Manifesto stated: “we hold there is a moral duty to pursue … research on embryonic stem cells [because it] is an essential step towards understanding how human tissues are generated and become diseased. In our view, the gaining of this knowledge per se is already ethically sound and sufficient to justify protecting the freedom of scientific research, which is also consistent with [Italy’s] Constitution.” They also wrote: “We maintain that embryonic stem cell research is ethically sound and necessary, in particular when performed with cells that are already available, and otherwise destined to be destroyed or wasted.” The Italian researchers have also built teams tapping relevant knowledge networks. It is clear from documents associated with their advocacy work that they have gained insights from lobbying practices in other countries (see, e.g., Cattaneo and Corbellini, 2010).

With respect to (3) amassing evidence of the workability of their proposals, Cattaneo and her colleagues have run a series of annual conferences in Italy to bring stem cell researchers together and to showcase for the public the potential benefits of their work with
human embryonic stem cells. The creativity of the group has also been evident in their efforts to (4) create strong coalitions of diverse supporters. They have targeted young people to educate them in the nature of stem cell research and its potential social benefits. Along with holding public lectures, and days dedicated to high school students, they have been experimenting with social media and collaborating with theatre groups and film makers to get their message across in innovative ways. In March 2012 more than 9,000 students from 160 high schools in 20 cities throughout Italy got together with stem cell researchers to participate in UniStem Day 2012. This was the largest dissemination initiative about stem cells ever held in Italy. Activities on offer included lessons and meetings with researchers, visits to laboratories, games, videos, dance, and music. Here we see dedicated scientists battling against powerful opposing forces through creative political activities intended to bring new groups into the discussion and, hence, shift the locus of power in the public debate.

CONCLUSION: POLICY ENTREPRENEURS AND POLICY CHANGE

Policy entrepreneurs are political actors who seek policy changes that shift the status quo in given areas of public policy (Mintrom 1997, 2000). The functions and activities of policy entrepreneurs take place within broader contexts that have been effectively theorized through notions of punctuated equilibrium (Baumgartner and Jones 1993), windows of opportunity (Kingdon 1984), and advocacy coalitions (Sabatier 1988). By deepening our knowledge of these policy actors who have too often appeared “ghost like” in the policy literature, we also deepen our knowledge of the applicability of specific policy frameworks to the interpretation of diverse instances of agenda setting and policy change. This paper has examined instances of policy entrepreneurship in the pursuit of government funding and favourable regulation to advance human embryonic stem cell research in the contrasting cases of the United Kingdom and Italy. The concept of the policy entrepreneur offers illumination into the governance of human embryonic stem cell research, and cross-jurisdictional differences in governance arrangements. However, all forms of policy entrepreneurship take place in contexts that can have significant implications for the effectiveness of advocacy efforts.

The policy entrepreneurship highlighted here has been more effective in the United Kingdom, where there has been a general, long-term government commitment to funding of premier scientific facilities. It should not be a surprise that the most productive scientists working on human embryonic stem cells are located in jurisdictions like the United Kingdom with significant concentrations of universities ranked among the world’s top 100. The well-
established and well-supported scientific communities in such jurisdictions appear to have served as strong countervailing forces for religious groups who, on moral grounds, have opposed research on human embryonic stem cells. Nonetheless, the morality politics surrounding this science have been significant everywhere, and they have influenced governance arrangements.

With respect to governing this controversial science, it is clear that a period of intense policy change occurred in the United Kingdom in the 1990s and early 2000s. This period punctuated the longer period of policy equilibrium preceding it, and set the direction for future incremental policy changes. The work of policy entrepreneurs was crucial to achieving the major shift in the governance of human embryonic stem cell research in that country. In contrast, the Italian case illustrates the enormity of the agenda setting task confronting those who wish to challenge an entrenched status quo enjoying support from well-established and powerful interest groups. In such instances, efforts to create new advocacy coalitions appear the most effective course of action. However, such work takes concerted effort over an extended period of time. The focus of Italian policy entrepreneurs on educating young people about human stem cell research indicates their acute awareness of the need to engage in efforts targeted at long-term social and ideational change. In that instance, the focus of the policy entrepreneurship has been on coalition building, rather than tactical efforts to secure immediate change.

While the focus of this paper has been on policy entrepreneurship and a specific scientific agenda, the findings hold implications for those studying the dynamics of change across many substantive areas of public policy. Here, we have gained more clarity around the ways that policy entrepreneurs can pursue their goals in the face of intense moral debates. We have also gained greater awareness of how the work of policy entrepreneurs can be both supported and inhibited by ideas, institutions, and interest-group politics.
REFERENCES


