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Life Lines: Stem Cell Research in a Globalized World

A Dissertation Presented

by

Brooke Mackenzie Ellison

to

The Graduate School

in Partial Fulfillment of the

Requirements

for the Degree of

Doctor of Philosophy

in

Sociology

Stony Brook University

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Stony Brook University

The Graduate School

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Abstract of the Dissertation

Life Lines: Stem Cell Research In A Globalized World

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Matters of science traditionally have been looked at from two sociological perspectives. The Sociology of Scientific Knowledge (SSK) argues that science is similar to other socially constructed phenomena, and is a product of context. From this perspective, science and culture have an inextricable relationship. World Polity Theory (WPT), on the other hand, makes the argument that science is a rationalistic entity that exists outside of cultural forces, and brings societies from backward thinking to modern thinking. Taken together, WPT and SSK have explained many of the sociological features of scientific development, sometimes explaining different aspects of the same phenomenon. However, as science becomes increasingly complex and multidimensional, these two theories leave room for additional analysis. Bourdieu's Field Theory brings to light how interactions between social actors make certain social realities possible, and create the environments for the development of policy matters. This theoretical approach is a necessary addition to better understand science as it is codified in policy. The scientific field of embryonic stem cell research is an ideal site to apply these theoretical frameworks.

This analysis investigates stem cell research legislation in four contexts: the US, UK, Germany, and China. Each of these cases presents a set of considerations, which changes the landscape of the political field in which stem cell research has evolved. In these cases, the impact of four social actors has been addressed: the Catholic Church, scientific community, pharmaceutical industry, and patient advocacy community. How these actors operate in each context is dependent on a confluence of social forces. The US' stem cell policymaking has been defined by a battle for epistemic authority on issues of life. The UK case illustrates the role of expertise as authority in democratic policymaking. The German case illustrates the ways in which collective memory of iconic events operates through social actors. And, China represents a control case, indicating how policy can evolve in circumstances where the political field is limited. Taken together, these cases illustrate how Sociology of Scientific Knowledge, World Polity Theory, and Field Theory can work together to explain complex modern science.

Dedication Page

Life changing circumstances can befall any one of us at any given time. 21 years ago tragedy struck my entire family, when I was left paralyzed from my neck down as a result of a devastating accident. Despite these circumstances, I was intent upon returning to school to continue my education, and my parents made a commitment to me to make sure that would happen. However, my return to school and completion of my education was not as simple as my parents or I initially expected, and could only be made a reality with my mother's decision to attend school with me.

For 21 years, starting with my nine months in the hospital and then my return to eighth grade, my mother has been at my side, tending to my needs, and providing utterly selfless dedication to make my life as rich as it could possibly be. In these two decades, my mother has sat at my hospital bedside, at the junior high school desk beside me, in the college lecture hall, and beaming with pride as I graduate. The story of my educational journey, indeed the story of my life, is the story of my relationship with my mother. They are inseparable. Beautifully inseparable.

I have committed my life to the advancement of stem cell research, in the hopes that it might one day alleviate the suffering and physical struggles that so many people face. However, my dedication to this work has only been possible through my mother's dedication to me. She has fought as hard as I have, has seen me through moments of despair and moments of glory, and has made the goals I have set for myself priorities of her own. As I complete my education, as circuitous a path as it has been, and as I receive my PhD, I am and forever will be indebted to the sacrifices my mother has made to get me here. It is with the deepest gratitude and love that I dedicate this dissertation to my mother, Jean Ellison.

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List of Abbreviations

Chapter 1 Introduction

WPT- World Polity Theory

SSK- Sociology of Scientific Knowledge

hESC- Human Embryonic Stem Cell

ISSCR- International Society for Stem Cell Research

Chapter 2 Theoretical Framework

CAMR- Coalition for the Advancement of Medical Research

Chapter 3 United States

HERP- Human Embryo Research Panel

NIH- National Institutes of Health

SCNT- Somatic Cell Nuclear Transfer

USCCB- United States Conference of Catholic Bishops

ELCA- Evangelical Lutheran Church in America

GR- Government Relations

AAAS-American Association for the Advancement of Science

CBO-Congressional Budget Office

R&D-Research and Development

GSK-GlaxoSmithKline

NAS-National Academy of Science

ESCRO-Embryonic Stem Cell Research Oversight Committee

PhRMA-Pharmaceutical Research Manufacturers of America

NGO-Non-Governmental Organizations

ALS-Amyotrophic Lateral Sclerosis

JDRF-Juvenile Diabetes Research Foundation

LGBT- Lesbians, Gays, Bisexual & Transgender

CIRM- California Institute for Regenerative Medicine

NYSCF- New York Stem Cell Foundation

iPS- Induced Pluripotent Stem Cell

NSF-National Science Foundation

Chapter 4 United Kingdom

HFEA-Human Fertilization &Embryology Authority

IVF- *In vitro* Fertilization

UKSCI- United Kingdom Stem Cell Initiative

ALB-Arms-length Bodies

NHS-National Health Service

CCEW-Catholic Church in England & Wales

CBCEW-Catholic Bishop Conference of England & Wales

ANDPB-Advisory Non-Departmental Public Bodies

BBSRC-British Biotechnology &Biological Sciences Research Council

ABPI-Association of British Pharmaceutical Industry

NICE-National Institute for Health & Clinical Excellence
PPRS-Pharmaceutical Price Regulation Scheme
APPG-All Party Parliamentary Group
AMRC-Association of Medical Research Charities
BMRB-British Market Research Bureau
MRC-Medical Research Council

Chapter 5 Germany

EPA- Embryo Protection Act
DFG-Deutsche Forschungsgemeinschaft
CDU- Christian Democratic Union
NRW- North Rhine Westphalia
EU- European Union
CEO- Chief Executive Officer
IG Farben- Interessengemeinschaft Farben
VCT- Verband Chemische Industrie
BSH- Bag Self Help

Chapter 6 China

S&T- Science & Technology
UNESCO-United Nations Educational, Scientific and Cultural Organization
CPA-Catholic Patriotic Association
PRC-People's Republic of China
CCP-Chinese Communist Party
LAP-Labor Augmented Productivity
IST-Investment Specific Technology
MOST-Ministry of Science & Technology
GDP-Gross Domestic Product
SINOPHARM-China National Pharmaceutical Group Corporation
SPGC-Shanghai Pharmaceutical Group Corporation
CAPC-China Association of Pharmaceutical Commerce
APMHO-Alliance of Patient Mutual Help Organization
HRW-Human Rights Watch
BBC-British Broadcasting Corporation
NSFC-National Science Foundation of China
MOF-Ministry of Finance
SFDA-State Food and Drug Administration
MOH-Ministry of Health

Chapter 7 Discussion

UCS-Union of Concerned Scientists
MIT-Massachusetts Institute of Technology

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Christopher Reeve, who fought under unimaginable physical difficulty, to bring the stem cell issue to the world's attention. He is forever missed.

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Dr. Richard Daines, whose service as the New York State Commissioner of Health and Chair of the Empire State Stem Cell Board was as thoughtful as it was inspiring.

And, my students, who fill me with pride in their concern over the future of people's lives.

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BrookePAC: President and Co-Founder

A federal political action committee dedicated to promoting the passage of stem cell research legislation, and assisting in the election of pro-stem cell research candidates.

2006 Democratic Candidate for New York State Senate

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U.S. Congressional Briefing on Long-term Health Care
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2012 New York State Delegate for President Barack Obama

2008 New York State Delegate for Sen. Hillary Clinton

Served as a delegate from New York's First Congressional District for Sen. Clinton in her 2008 presidential bid.

2007 Federal Stem Cell Policy Implementation Playbook for Sen. Obama

Drafted an implementation plan for a federal stem cell research initiative for Sen. Obama's 2008 presidential bid, including what steps to be taken and factors to be considered for a federal policy to be initiated.

2007- Present Empire State Stem Cell Research Board: Ethics Committee

Gubernatorial appointee to the Ethics Committee of the Stem Cell Research Board in New York State, which commands a \$600 million initiative to provide stem cell research grants to New York scientists

2007- 2011 New York State Spinal Cord Injury Research Board

Appointee to the Board of Directors, which serves under the New York State Department of Health, to provide grants to spinal cord injury research.

2006-Present The Genetics Policy Institute: Strategic Advisory Board

Organization dedicated to establishing a positive legal framework to advance stem cell research.

2006 New York State Stem Cell Research Congressional Initiative

Initiative Contributor, acting in accordance with Congressman Israel and Congressman Crowley, as well as, members of the scientific and medical community.

2006-Present Suffolk County and Brookhaven Town Democratic Committee Person

2005 Partners for Youth with Disabilities National Mentoring Campaign Spokesperson

National Spokesperson, selected to fill the voluntary position in March, 2005

2000- 2006 Board of Directors of the National Organization on Disability

Served on the board with 19 additional members, including CEO of McGraw-Hill Bear Stearns, as well as, with actor/activists Christopher Reeve. N.O.D. initiatives have included Accessible America program, International Disability Award, and disability employment initiatives.

ARTICLES AND PUBLICATIONS

"Assessing the Risk of ovarian Hyperstimulation Syndrome in Oocyte Donation: Implications for Stem Cell Research".

September, 2011 issue of *American Journal of Bioethics*.

Book review of *The Stem Cell Hope* by Alice Park.

June, 2011 issue of *Cell Stem Cell*

"Stem Cell Research at a Crossroads"

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CHAPTER 1

INTRODUCTION

CHAPTER 1: INTRODUCTION

The role that science plays in society, and society's relationship with science, has long been a focus of great sociological interest, with differing perspectives arguing for a different relationship between the two. There are some social theorists who argue that science ought to enjoy a special status in society, distant from many divergent social pressures. The notions of "scientific truth" and the growth of the "knowledge economy" have given way to scientific globalization and standardization that allows for the discipline to proceed on a worldwide scale. When it comes to scientific autonomy and standardization, though, some fields of scientific exploration, like stem cell research, have been denied many of these privileges. What, then, explains the high degree of cultural construction that has surrounded stem cell research policy in countries around the world and the extent to which social forces, other than science have influenced the policy creation in different contexts?

Sociologically speaking, science has been viewed from two theoretical standpoints: World Polity Theory (WPT) and the Sociology of Scientific Knowledge (SSK). WPT looks at the status of science as an institution or *globalized* construct. While acknowledging the contextual nature of science, WPT emphasizes a "worldwide model" of science that has driven international economic expansion and has promoted policy isomorphism. Under this interpretation, science and scientific discovery travel through transnational networks of experts who can then advise policymakers on how to maximize the economic potential that science creates. The sociological school of thought, SSK, takes a different approach by arguing that the knowledge created by science is inherently social and cultural in nature, with scientists responding to features in their social, epistemic, historical, and work environments. From this standpoint, scientific knowledge is a *cultural* construct, with science becoming what societies believe it ought to be. In simplified forms, these two sociological perspectives are seemingly at odds with one another. However, upon closer investigation, they often explain different aspects of the same phenomenon, and can even be complementary.

As illuminating as WPT and SSK have been in establishing understandings about science in society, the nature of science has become even more complex in recent years. On an increasing basis, the evolution of science addresses a myriad of social concerns and integrates many epistemic questions, many more, in fact, than the scientific field can answer, alone. Similar to the interactive and multi-perspective approach that has elucidated other sociological questions in the past, the involvement of diverse actors in scientific questions makes the interactive nature of Bourdieu's Field Theory a necessary and important fulcrum to connect these theoretical approaches into a more comprehensive framework. From this integrated standpoint, it becomes easier to understand how science policy, and by extension science itself, become part of a more complex process that takes place in different fields.

In negotiating matters of science policy, policymakers are soliciting input from an increasing number of sources, not only the scientific community but also the industry sector, governmental regulators, and members of civil society. While WPT and SSK are informative in helping to explain the evolution of science as a *scientific* matter embedded in culture and state structures, Field Theory is especially useful in explaining how science is a product of the interactions among social authorities and conventions. This becomes particularly relevant as science is codified in public policy.

Bourdieu's Field Theory brings to light the social conditions and social actors that contribute to a given social outcome. Often Field Theory is applied to matters of public policy, where policy is the product of complex forces that make social interactions possible. As science increasingly becomes a matter of public policy, the relevance of this analytical framework becomes evident. According to Bourdieu, social "fields" are theoretical and multidimensional social spaces in which actors compete for some valuable resource, or "capital". Actors, who can come in many forms, operate in a relational manner, contingent on shifts in strategy, internal dynamics, cultural forces, and actions by other actors to pursue capital. The social field abides by its own logic, its own set of structures, boundaries, and sources of capital that define which actors are involved, and how they might influence one another. It is the field that defines a social reality and gives rise to a policy outcome. There is a common understanding of what is at stake, how capital is distributed, and whose voice is legitimately included in the discourse. Science as a matter of policy is well suited for this type of analysis, and stem cell research is a valuable instance of science as a policy matter.

Stem cell research represents an ideal site for examining competing theories of the sociology of science. In fact, in recent years, few, if any scientific issues have generated more public debate than stem cell research. In its short existence, human embryonic stem cell (hESC) research has become an aggressively pursued area of biomedical exploration, with the potential to provide understandings about the most devastating diseases and conditions that humanity faces. By many in the scientific community, embryonic stem cell research has been looked at as one of the most promising new fields in which to make revolutionary medical breakthroughs. What is sociologically interesting about this scientific question is that, in countries around the world, hESC research has been given its legitimacy or limitation through its codification in policy. Stem cell research is a matter of biology that incorporates complex epistemic questions like the status of life, respect for human dignity, and the value of science as a source of economic production. As a result, the policy surrounding human embryonic stem cell research takes on social contestation not directed to other areas of scientific investigation even within the biomedical sector. The *globalized* nature of stem cell research is seen in the establishment of organizations like the International Society for Stem Cell Research (ISSCR). The *culturally-determined* nature of stem cell research is seen in the diversity of local concerns that it highlights: concerns that incorporate ethical, epistemic, and economic questions. Both of these competing ideas come into play as

policymaking entities and powerful social actors negotiate ways to address the stem cell question. These circumstances have presented themselves repeatedly in various contexts around the world over the past decade.

In this analysis, a spotlight is placed on stem cell research policymaking in four important countries: the US, the UK, Germany, and China. While many other countries around the world have addressed the human embryonic stem cell research issue in some way, these four countries were chosen because each illustrates a particular confluence of circumstances and arrangement of actors that gave rise to a particular policy outcome. In the US, religion has a dominant role while, in the UK, the role of scientific expertise drives the policy. In Germany, historical events have a defining role, while in China, the autocratic State is paramount. In these cases, social phenomena like collective memory, path-dependence, epistemic authority and boundary work also impact the outcome. Even when taking into consideration common actors in different countries, their behaviors, interests, strategies, and positions are very different across social settings, in a way that highlights the diverse social concerns that are addressed when scientific issues are looked at from a position of public policy.

This analysis looks at the impact of four different social actors on the stem cell research policies in these four countries. The actors in this investigation are the Catholic Church, the scientific community, the pharmaceutical industry, and the patient advocacy community. While there are other actors who have been involved in this debate, these actors have a particularly close connection to the progression of this research. Some of these actors have a globalized, international composition, and as a result, they take on positions that may initially appear consistent across different social contexts. However, the value of Field Theory lies in how actors operate in conjunction with one another, and in relation to one another, in a specific social space. These context-specific interactions are what generate one policy outcome over another.

In this investigation, these contexts and interactions are laid out to present a clearer picture of the social conditions that have given rise to stem cell policy outcomes in the US, the UK, Germany, and China. Each of the four cases begins with a narrative about the nature of the country's stem cell policy, and how this policy relates to recommendations provided by stem cell research experts. The social actors who have influenced these policies bring individual positions and capital in order to shape the political field in which stem cell policy has been created, so attention is then placed on the role that each of the four actors plays in each country. For instance, where have these actors obtained their authority? How have they contributed or failed to contribute to the stem cell research policy question? Depending on particularities in each of the regulatory environments, the four actors in this analysis behave very differently and seek different sources of capital. Each chapter, then, concludes with a Field Theory, interactive analysis of how the four actors under investigation have operated together, in relation to one another, to arrive at some particular policy result. Within these

analyses, the arrangement of actors and the social structure in which they operate is often the result of factors only brought to light through the frameworks of WPT and SSK. Taken together, WPT and SSK address how local values and interests can, indeed, shape a globalized social institution in a way that challenges science's autonomy and authority. Field Theory allows for an analysis of how these competing forces work with social actors and create an internal structure that arrives at a social solution. This triadic approach is valuable for stem cell research as a policy matter.

This study will show how a "neutral" image of science is problematic. This comparative analysis of stem cell research in diverse contexts will demonstrate the need for a more synthetic approach among otherwise disparate analytical frameworks. The binary categorization of "permissive" or "restrictive" is useful only to a certain degree when it comes to classifying a stem cell research policy, as the question is more complex. In the US and Germany, there is a stem cell policy that has been characterized by some degree of restriction or ethical concern. Yet, even within these two, the restrictions were put into place for very different reasons: the US as a result of a battle between conservative religions and science, for the epistemic authority over the issue of "life"; and Germany as a result of concerns found in a collective social memory about the justifiable ends of scientific research. Alternatively, in the UK and China, there is a stem cell policy that has been characterized by a considerable degree of liberality or progressive nature. Similarly, within these "scientifically-friendly" environments, the liberal stem cell policy was put into place for different reasons: in the UK, this stem cell policy was the product of a focus on "expertise" as a measure of "authority" when it comes to matters in policymaking, and a historical acceptance of scientific work utilizing the human embryo; and in China, the unusually progressive stem cell policy is the product of a political structure that is both extremely aggressive in the use of science as a means of economic expansion and a political structure that restricts the input of dissenting social opinion. The result is four individual cases, two with a restrictive stem cell policy and two with a progressive stem cell policy, yet each with a set of internal dynamics that shapes the social field and influence how social actors operate within it.

For some, it may have been an easy assertion to make that the battle over the human embryonic stem cell research question is one of science versus religion. This assumption, however, explains only a fraction of this far more elaborate social debate. To arrive at a more complete picture of stem cell policymaking within context, World Polity Theory, Sociology of Scientific Knowledge, and Field Theory all play a part, both individually and collaboratively. As stem cell research has become defined by a variety of policy measures, each reflecting social concerns that incorporate diverse actors, the following chapters indicate precisely why this multi-theoretical and multi-actor approach is so useful. In order to fully understand the evolution of embryonic stem cell research policy in locations around the world, there needs to be an understanding of the epistemic environments, the authority of the science, and how actors view their stake in this question.

The implications of this investigation are multifaceted and have significant bearing on matters of science policy as science grows in complexity. Science can no longer be viewed as an isolated and institutionalized entity. As the stem cell research case illustrates, scientific advancements push the boundaries of epistemic authority, calling into question issues, like “life”, human rights, and economic advancement that historically have been under the epistemic jurisdiction of other entities. As a result, in the creation of policy surrounding these scientific questions, there is a competition among actors for ways to reconcile these contested questions. This does not deny the critical importance of scientific advancement like stem cell research, which not only contributes to the knowledge economy but, more importantly, plays a considerable role in the quest for medical treatment. This analysis brings to light the political-cultural features that influence a state of scientific autonomy and why some countries have failed in achieving this outcome. As societies move forward, with increasing demands for scientific solutions to address pressing social challenges, this study will have bearing on the scientific institution, stakeholders who influence science policy, policymakers who create this policy, and the adjudication of social conditions that influence science's authority.

CHAPTER 2

THEORETICAL FRAMEWORK

CHAPTER 2: THEORETICAL FRAMEWORK

BACKGROUND

Stem cell research is an avenue of scientific inquiry that uses a cellular medium to unlock the mysteries of disease. The human body is comprised of over 200 different types of cells: skin cells, muscle cells, neurons, blood cells, each specialized to perform some particular function. How these cells become “specialized” to perform their particular job within the body is the result of a complex series of information exchange between a cell and its chemical environment, forcing some genes and genetic information to be expressed, characteristics to emerge, and duties to be performed. When people are sick or injured, it is these cells that become damaged or affected in some way, preventing them from functioning correctly. For much of the history of medicine, treatments to disease have taken the form of managing disease progression, easing pain, or taking some remedial measures, rarely do these treat the underlying complications that have given rise to the problem. Understanding the root of disease and disability, conversely, often lies in understanding what causes cells to behave incorrectly, what features characterize a diseased cell over a properly functioning cell, or how to replace damaged tissue with healthy tissue. It is at this point that the promise of stem cell research lies.

First discovered in the 1950s, stem cells are unique cells that, contrary to the other, 200 types of cells found in the human body, are characterized two distinct features: 1) their ability to regenerate for prolonged amounts of time; and 2) their ability to differentiate, or specialize, into other types of cells. A veritable cellular blank slate, stem cells are the medium that keeps our bodies rejuvenated, replace dead tissue, and replenish cells that are lost throughout our lives. However, in a new wave of promise and understanding, research on stem cells has provided an avenue to allow these versatile cells to be the means to investigate how diseases arise, how to test potential medications and therapies, and possibly even create replacement cells and organs for those that have been damaged. This line of biomedical research stands to revolutionize medicine and treatment in nearly unprecedented ways, changing the focus of treatment to its most elemental form.

Stem cells are found throughout the body, throughout our lives. However, there are several different types of stem cells, adult stem cells, IPS cells, and embryonic stem cells, each with a particular therapeutic potential and distinct set of characteristics. Of these different types of stem cells, embryonic stem cells have demonstrated both the greatest potential, and the greatest controversy. Embryonic stem cells are found in what is known as the inner cell mass of an early-stage embryo, or blastocyst: a cluster of highly versatile cells that give rise to all of the tissues and organs found in a fully-developed human. First derived from a human blastocyst in 1998, the therapeutic potential for these cells was immediately clear. If scientists could direct these undifferentiated cells into becoming a specific cell type, or if they could embed genetic defects into a

dividing cell line, they could attempt to unlock the mystery of disease development, could create cellular replacements to correct cells that had been damaged, and could create a human cellular medium of disease-in-a-dish.

The progression of stem cell research, or more specifically human embryonic stem cell research (hESC research), has taken an unusual form in its history. In looking at stem cell research as a sociological phenomenon, two prominent sociological theories come to the fore: World Polity Theory (WPT) and the Sociology of Scientific Knowledge (SSK). Although these two theories offer, at times, contradictory or competitive perspectives on the relationship between science and society, within the case of hESC research, both of these theories offer something, yet neither explains everything.

A TALE OF TWO THEORIES

Science's relationship with and role in society has been a source of increasing sociological and cultural inquiry, particularly as the effects of scientific research have had a greater impact on people's lives, including effects from nuclear physics, environmental science, genetic research, and biomedicine. This increasing level of contact that science has had on people's lives has forced societies to look at science with some degree of skepticism, and to question how much autonomy ought to be afforded to science. The effects of this can readily be seen, with divergent cultural and social forces acting upon a highly legitimized institution. However, a notable, and in some ways detrimental, consequence of this has been a demonstrable reduction in the ability of stem cell science to standardize its practice across contexts, and for stem cell researchers to devise a common way to study disease through this work. This marks a break from many of the common understandings that early social thinkers, like Hobbes and Locke, and even some contemporary thinkers, like Meyer and Drori, have had about the nature of scientific inquiry. As a result of this shift in traditional thought about science, several primary questions have arisen: 1) how objective or universally accepted are the norms of science, as the world dynamics change and as science becomes more complex; 2) to what degree do countries rely upon the legitimacy afforded to the institution of science; and 3) what factors operate within a society to influence the autonomy afforded to or denied from science over other social forces?

To a large extent, efforts to answer these questions have emerged from two distinct sociological perspectives: globalization through World Polity Theory (WPT) and the Sociology of Scientific Knowledge (SSK). World Polity Theory has largely taken hold in the era of globalization and increasing global connectedness, and has come to view science as a legitimized, authoritative entity that abides by its own set of regulations and expertise, beyond the reach of social determinations. Sociology of Scientific Knowledge, on the other hand, is a discipline within sociological theory that investigates the methods of science, the content of scientific questions, and how these questions are influenced by

context. As these two interpretations of science that might seem incompatible, when looked at in a case-based manner, there is a complementary nature to be found between them. As these sociological frameworks have evolved, it has become of great interest to disentangle some of their contradictions and incompatibilities. This has become increasingly the case, as science has become more complex, global competition has become more strident, production-based economies have waned, and political partisanship has become more polarized.

The case of human embryonic stem cell research, and how it has evolved in the global scale, is a particularly valuable location at which to weigh some of the central arguments pertaining to these two sociological theories of science. Conversely, looking at human embryonic stem cell research as a sociological phenomenon allows for a better understanding as to how and why it has been approached so differently in different countries. Human embryonic stem cell research exists as one of the instances in scientific inquiry where the legitimacy of the science, itself, has been called into question as a result of complex social dynamics. What is more, however, is that human embryonic stem cell research, as it has manifested itself in differing cultural contexts, has been a cultural construct represented in public policy, with public policy existing as the conspicuous combination of national ideology, strategic aims of this state, and responsibility to the global culture. For these reasons, human embryonic stem cell research provides an ideal site to delve deeply into sociological theories of science, how they do or do not fully explain modern scientific thought, and what, if anything, needs to be addressed to reach a fuller understanding of science in society.

Globalization and World Polity

A theory of globalization, as pervasive as it is in sociological and political thought, has had important implications for a social construct like science. In recent years, the world has grown in its degree of interconnectedness and rate of information flows. An increasing international competitiveness that has resulted from globalization has driven a shift in economic priority from economies based on production to economies based on knowledge. Science has become the vehicle that creates a society built on knowledge. As a result, science has been brought under the lens of globalization as an entity that surpasses borders and is pursued internationally for strategic ends. For instance, according to theorists like Diaz-Balart and Rojas, the world is currently in an era of the “knowledge economy”, in which countries judge their wealth not on reserves of raw materials, but instead on their knowledge, research, technology, and innovation capacity (Diaz-Balart and Rojas, 2002). Central to the knowledge economy is the role played by science and scientists, who are increasingly becoming prominent figures in government decision-making, and in determining development strategies that foster the level of national industry and international competition that a globalized world demands. Minimal investment in science and technology, or failing to pursue important scientific questions, puts nations at a distinct

competitive disadvantage relative to their international neighbors. To illustrate, developed countries in the global North invest between 2-2.5% of their GDP in science and technology, while developing countries often in the global South invest significantly less, between 0.3-0.5% (Diaz). Competing within the global economy and globalized world is contingent upon the very type of economic development and work force building that investments in science, technology, and innovation provide, and this means remaining on the forefront of new scientific questions and the latest advances in specific scientific fields.

Why science has been looked at so closely from the perspective of globalization lies largely in three prevalent phenomena: 1) a growing movement toward rationalized governance built on modernity and the quest for international legitimacy; 2) an increasing sense that nation states will adopt similar strategies to maximize their economic and technological potential; and 3) the growing perception that the centrality of the nation state has changed or even diminished in response to a global statelessness. These phenomena were most predominantly brought to light in the work of sociological theorists, John Meyer, Gili Drori, and John Boli. These theorists posit that there is a worldwide movement altering nationstate governance that focuses on a world society (Drori, Jang, Meyer, 2006), and that this is fostered by a concurrent movement toward rationalized governance predicated on open exchange in international markets, clear strategic legislative goals, effective governmental management, elimination of misgovernance, and perpetuation of economic development.

It is with this common movement toward rationality and international isomorphism in mind that Meyer argues that the world is a stateless entity, and that nation states operate in a “world polity”. By “world polity”, Meyer describes a shared set of rules, models, and regulations that operate at the nation state level which reflect similar socioeconomic and strategic goals of nations, individuals, and specialized groups. Meyer argues in his theory of a world polity that, in a world that is increasingly dependent on transnational connectedness, it is logical and more practical to construct common cultural principles that produce desired outcomes of the world society. Meyer does not suggest that there is an overriding ruling body that has authority over the entire world but, instead, that nation states adopt similar behaviors and policies that are carried across cultures through the standardization and institutionalization of international organizations, international oversight, and a position in global economic competition.

Science of any kind, according to WPT scholars, is viewed as a highly rationalized and modernizing construct, and this claim can safely be made of human embryonic stem cell research. In purely scientific terms, the history of stem cell research rests on its pursuit to translate the depths of human understanding into ways to combat the diseases and conditions that have undermined human and social potential. The eradication or treatment of disease continually exists as one of the most coveted and broadly supported social goals that can be achieved through scientific understanding.

It is with the common strategic goal of eradicating disease and creating a healthy populace in mind that the globalization of human embryonic stem cell research has taken place in somewhat predictable patterns and pursuant to expected trajectories. With its origins in the US, with the first derivation of human embryonic stem cell lines taking place in James Thomson's laboratory in Madison, WI, the research has diffused to many countries around the world, first lauded in the pages of *Nature*, and then celebrated by many scientists, worldwide. At present, there are no fewer than 25 countries around the world that have permissive or flexible stem cell policies, including Australia, Belgium, Brazil, Canada, China, the Czech Republic, Finland, France, India, Iran, Israel,, the Netherlands, New Zealand, Portugal, Singapore, South Africa, South Korea, Spain, Sweden, Switzerland, Taiwan, Thailand, UK, and US (Walters, 2010), and it is arguable that research is practiced in other countries without implemented policies.

In acknowledgment of the rationalizing and economic development potential of science that World Polity Theory references, Levine has studied the performance of countries in relation to the composition of their stem cell policies. By "performance", Levine refers to a country's participation in the scientific field, for instance the form of hESC-related publications (Owen-Smith & McCormick, 2006), which the author argues is a major output of biomedical research (Levine, 2008). This was measured against the output of scientists within the same country in other scientific disciplines. Levine found that countries with generally progressive stem cell policies, including the UK, Israel, China, and Singapore, had the greatest degree of hESC overperformance. Unsurprisingly, countries with restrictive stem cell policies, most notably the US, had the greatest degree of hESC underperformance. This assessment of hESC underperformance in the US is despite the fact that US stem cell researchers publish the greatest number of stem cell-related articles and the world.

The process by which embryonic stem cell research has spread throughout the world holds tightly to the expectations of globalization and World Polity Theory. According to these theories, international diffusion of information and ideas takes place through international connections and information flows. As Meyer suggests, diffusion is shaped and accelerated by similarities among actors across contexts. World Polity Theory suggests that there are cultural linkages comprised of social entities belonging to a common social category that foster diffusion, with rational mimicking of reference groups for competitive emulation.

As WPT argues, diffusion increases in pervasiveness and speed as a discipline becomes more complex and "theorized" (Meyer, 1993), and this casts particular light on a social enterprise like science, which is characterized by theorization conducted by authority figures within the field. Stem cell research has been a prominent beneficiary of the very type of diffusion-through-theorization that WPT argues for. For instance, there is a great degree of information exchange across hESC researchers around the world, through such

cross-border and international organizations as The International Society for Stem Cell Research (ISSCR). Founded in 2002, the ISSCR is: *“an independent, nonprofit organization formed in 2002 to foster the exchange of information on stem cell research. With more than 3,600 members worldwide, the ISSCR has become the voice of the stem cell research community.”* (ISSCR, 2011).

An organization like the ISSCR promotes the statelessness, connectivity, and authority that WPT argues are so central to science through its two primary activities of: 1) annual meeting; and 2) journal publications. These are the very activities that, according to WPT, establish authority within a social discipline. As the ISSCR, itself, describes, its annual meeting is a near week-long event taking place in countries throughout the world, with the purpose of “provid[ing] an opportunity to learn of groundbreaking research from all areas of stem cell science. The meeting attracts over 3,500 stem cell research professionals each year and provides an excellent forum for scientists to present and discuss their latest research with participants from academic, industry and government settings from around the world.” (ISSCR, 2011). It is through conferences like that yearly coordinated by the ISSCR that tremendous exchanges of information across scientists and researchers can take place. In the annual meeting, stem cell scientists in attendance can learn techniques from one another, can talk informally about potential collaborative opportunities, and can discuss the future of the field. What is more, however, is that conferences like the ISSCR’s annual meeting serve to define the boundaries of the field, including who belongs to it and who does not, and to create authority within it. This notion of “boundary work” is central to a field defining itself and creating its authoritative location in society.

The field of stem cell research has also worked to define itself through the publication of peer-reviewed journals established entirely for scholarship in the stem cell field, and this is emblematic of the very institutionalization strategies that Drori argues is central to the authority of any social discipline. For instance, the ISSCR oversees two prominent stem cell-related journals which have served to define the state of the field: Cell Stem Cell and Current Protocols in Stem Cell Biology. As sociologists like Wagner have argued, it is through the establishment of and publication within specialized journals that expertise of a field is defined, opportunities for cross-border collaboration are created, and the information is shared among field practitioners. These characteristics of the current state of stem cell research have served to provide the authority that WPT emphasizes.

Through their creation of expertise and authority, international stem cell organizations, with the ISSCR being the most prominent and influential, are what Meyer refers to as, “rationalized others” (Meyer, 2000). Rationalized others, like scientists and professionals are central participants in world society, with authority from their ability to assimilate and develop the rationalized knowledge that makes action and actorhood possible. Meyer sees these extra-governmental entities as comprised of members of international organizations who have the aim of guiding policymakers into creating the most socially-

beneficial policy objectives. “Especially in the more rationalized and public arenas of social life, the sciences and professions are leading forces”.

When looking at stem cell research from a World Polity perspective, these are the very features one would expect to find: the diffusion of research practices from one part of the world to many others, the creation of boundaries and authority through field conferences, journals, and peer reviewed publication, and the establishment of international organizations of field experts that serve to define norms and protocols within the discipline. To this extent, a field of scientific inquiry like stem cell research has progressed and behaved in quite a predictable manner. As Meyer, Drori, and Wagner might acknowledge, stem cell research reflects many of the characteristics found in the "new invisible college" (Wagner, 2008), making way for broad-based international connectivity and information exchange. However, there are limitations to how far a World Polity explanation bears relevance to the stem cell research case.

A central feature of World Polity Theory lies in the observation that social reality has no cultural boundary, and that nationstates legitimize themselves according to adherence to worldwide norms. Especially in the instance of scientific practice, which has a uniquely rationalizing and modernizing quality, nationstates adopt isomorphic policies so as to maintain a global competitive edge and foster economic development. It is through the movement from culturally-defined ideals to those found in the world polity that actors not only gain legitimacy but also rationality and modernity as participants in a “common moral frame”.

Further, these policies are created based on the guidance and recommendations of scientific authorities who take the form of the "rationalized other" advising governmental officials. With this in mind, from a World Polity perspective, one would expect to see highly permissive stem cell policies that provide for the greatest economic benefit, and that these policies would be nearly identical from culture to culture, based on the guidance of stem cell experts. While these conditions are what one would expect, what one actually observes in the stem cell field is the diametric opposite.

True to WPT, the institution of international stem cell experts, namely in the form of the ISSCR, have worked to define the boundaries and potential of stem cell research. In so doing, this organization has crafted a set of recommended research guidelines within which to conduct human embryonic stem cell research. The science policies that nationstates create to regulate the operations of human embryonic stem cell research involve the very same considerations and principles that this body of recommended research guidelines focuses its attention on. However, rather than create a worldwide script, these research guidelines were created with particular attention given to "the international diversity of cultural, political, legal and religious perspectives" (ISSCR, 2011). First drafted in 2006, the ISSCR research guidelines were a product of scholarship from representatives of 14 different countries, including the US, Sweden, Israel, China, Korea, Singapore, England, the Netherlands,

Japan, Canada, Norway, Australia, Scotland, and Taiwan, with the goal of promoting responsible, transparent and universal research practices worldwide.

One of the primary objectives of the ISSCR recommended guidelines was to create a code of conduct, encouraging researchers to, "adhere to ethical and transparent practices for performing research and sharing research materials" (ISSCR, 2006). It was the intent of the scholars who worked on these guidelines that they could be easily implemented across cultural contexts, and could be adopted in the form of policy in many nationstates. The strategic goal of these research guidelines was to encourage the very type of scientific institutionalization for which WPT advocates, and the type of cross-national collaboration for which work on the "new invisible college" similarly advocates. As the ISSCR writes in the guideline introductions, "international scientific collaboration and mutual trust among researchers are vital to the success and advancement of science and should be encouraged." At the same time, however, the scholars acknowledge the degree of variability in local laws, stating "stem cell research shall be conducted in accordance with any applicable laws and regulations of the country or region where such research takes place."

In the guidelines, the ISSCR makes a blanket, broad condemnation of human reproductive cloning, which all countries have similarly adopted. The committee continues by establishing a set of criteria by which to evaluate what types of research ought to be permitted upon review, what ought to be permitted following extended review, and what ought to be prohibited because it lacks scientific justification or raises great ethical concerns.

The research that the ISSCR deems acceptable upon review, they include: experiments with pre-existing human embryonic stem cell lines that are confined to cell culture or involve routine and standard research practice. Of the research that the ISSCR recommends should require additional oversight, they include:

- research that requires informed consent
- research that involves the derivation of new pluripotent cell lines
- research in which the identity of the donors of the embryo is ascertainable
- research in which undifferentiated cells are transplanted into human subjects
- forms of chimeric research

Finally, of the research that the ISSCR deems prohibited, they include:

- research on human embryos that have developed past 14 days
- research in which undifferentiated cells are implanted into a human or nonhuman uterus
- research in which animal chimeras incorporating human cells are allowed to breed

Despite the fact that these guidelines were created after careful review by field experts with an emphasis on conducting research both collaboratively and ethically, the adoption of these recommended provisions has only taken place to a limited degree. In considerable opposition to what WPT would expect, though these research guidelines have been established by experts within the stem cell field, they have not become the worldwide model that WPT would predict. Countries around the world have adopted some form of these research guidelines, and have instituted them in policy, only to a variable degree, if at all. The experts that constitute the ISSCR policy and guideline task force are not, on a collective basis, the rationalized other who have helped to steer policy at the nationstate level.

In some countries, like the UK, Singapore, and China, the long-term benefit and potential of hESC has been embraced and understood, and as a result, they have adopted relatively broad stem cell policies that allow a great deal of autonomy to scientists. Alternatively, in countries like Canada, Brazil, and Taiwan, the potential of the research has been understood, however relatively less autonomy has been afforded to stem cell science, and the relevant policies are more restrictive in nature. Finally, in countries like Germany and Italy, fears about the ends of science have outpaced hopes for its potential, and have resulted in particularly restrictive stem cell policies that prevent scientists from engaging in many scientific endeavors. In considerable opposition to what WPT would allege, within the context of hESC research policy, there has been no universal script created, no worldwide model, and essentially no policy isomorphism. The result has been twofold: 1) stem cell research policy displays a great degree of variability across contexts that only partially reflects an attempt at a worldwide norm; 2) the experts who constitute the elite of the stem cell field have faltered in attempts to define an epistemic authority within this field.

Sociology of Scientific Knowledge

SSK has sought to explain the progression of scientific questions in unique societal contexts. SSK places scientific inquiries into their social context, focusing on the social structures and conventions that drive scientific activity, including social relations, social values, and the social aspects of research questions, themselves. As prominent sociologist of scientific knowledge, Steven Shapin, boldly stated, “SSK sought to show that knowledge was constitutively social, and in so doing, it raised fundamental questions about taken for granted divisions between ‘social vs. cognitive, or natural factors’” (Shapin, 1995, page 289). Less than 50 years old, interest has grown considerably in this burgeoning sociological discipline, with the social study of science becoming highly interdisciplinary across sociology, anthropology, and cultural studies. As its title suggests, Sociology of Scientific Knowledge seeks to demonstrate the ways in which scientific knowledge is understood as a collective good and process, with networks of individuals contributing to a prescribed end. These networks are built on common understanding of trust.

Throughout much of its existence, SSK focused on the important notion that when people, including scientists and the creators of knowledge, encounter an experience or question, they do so within a framework that has already been created and sustained by their community (Shapin, 1995). Similarly, SSK acknowledges and focuses on the idea that science is representative of other forms of knowledge, in that how it is formulated depends upon the context within which it is pursued (Shapin), and that science and knowledge are meaningless entities without taking into consideration the environment or dynamics that underlie them.

In many respects, stem cell research has progressed in a context-specific manner, and the policies that surround stem cell research differ considerably from one country to another. Falling into variable degrees of permissiveness, from permissive, to moderately permissive, to compromise, and finally to restrictive (Walters, 2007), each potential policy option is characterized by distinct features and levels of scientific acceptance.

Walters describes the features of the stem cell policy options in the following ways:

- permissive: accepting of the production of human embryos for research purposes through in vitro fertilization and/or nuclear transfer
- moderate: accepting of the derivation of new embryonic stem cell lines, however only from supernumerary IVF embryos
- compromise: permits research on existing stem cell lines but not the derivation of new stem cell lines through the destruction of embryos
- restrictive: does not permit hESC

How countries fall into the four main categories of stem cell policy: permissive, moderate, compromise, or restrictive, has not been determined solely on the potential of the science. The benefits derived from stem cell research impact societies in generally similar ways. For instance, the economic production resulting from this research is consistent across international borders, and the diseases and conditions that this research might benefit are found in rates that are similarly consistent across nations. With this in mind, there ought to be no strategic reason as to why one country might adopt one stem cell policy versus another. Additionally, the ISSCR guidelines were created with attention to collaboration and ethical oversight, so there ought to be no fundamentally unethical component to research that is given approval under these guidelines. This leaves a cultural component as important to understanding the stem cell research phenomenon, with the benefits, and perhaps even risks, of this research becoming culturally-defined.

It is not necessarily a country's relationship with science, in general, that influences its permissiveness on stem cell policy, but how it perceives this issue, in particular. Part of the unique nature of human embryonic stem cell research is its reliance on human embryos, which results in rendering these embryos

unviable. This factor has touched upon other issues that require competition for epistemic authority, including the meaning and origins of life, and the justifiable ends of science. In what ways different countries have balanced these social questions is the result of the very confluence of social, cultural, and political forces that SSK analyzes.

SSK theorist, Thomas Gieryn, takes a particularly close look at the notion of epistemic authority and how it is manifested in social acceptance of science. Gieryn argues that there is nothing particular about science that makes it unequivocally credible, and that the entire notion of "real science" is an entirely culturally constructed concept. He suggests that science is what takes place in journals and laboratories, and not anything more. The credibility of science, then, depends upon how successful the field is at defining itself as a source of authority, which it does by securing its boundaries, expanding its territory, and excluding those it believes to be outside of its work (Gieryn, 1999).

The contest between epistemic authorities that Gieryn discusses has a great deal to contribute to the evolution of stem cell research. How experts in this field have sought to define themselves and claimed rights to territory on questions addressed by other authorities, e.g. the origins of life as addressed by theologians or the ends of science as addressed by ethicists, stem cell research has not only seen its boundaries eroded but also has been at odds with cultures that value some epistemic authorities over others. To illustrate this idea, Walters presents some factors that have influenced the adoption of one policy framework over another. In the context of permissive policies, the benefits of stem cell science tends to be appreciated (Walters, 2007), while countries that adopt a compromise approach tend to value the moral status of the embryo above the benefits of science. In many ways, this differential can be looked at as a proxy struggle for territory between epistemic authorities.

Where SSK begins to fall short in the field of stem cell research lies in its focus on how knowledge is constructed and the actual content of scientific knowledge. For instance, much of SSK places its attention on the path by which scientific questions are generated, and the disputes among scientific camps on the legitimacy of the work they do. To a great extent, these are not the central questions or challenges that have brought about a discrepancy in stem cell research from one context to another. This is made particularly apparent in the subfield of SSK, Actor-Network Theory. Notable Actor-Network theorists, like Latour and Knorr-Cetina place their attention on the dynamics of the laboratory, and how the network of interactions between scientists, laboratory, and objects influence the knowledge that is produced. Similarly rejecting the absolute rationality of science, the SSK scholars, like Latour and Knorr Cetina, who focus on the actor-network relations of scientific production argue that context is absolutely essential to understanding the creation of knowledge.

Knorr Cetina argues that there is a lack of analysis in the truth-finding apparatus of the natural sciences (Knorr Cetina, 1991). What its features are, and how its features link together in the network of social relations. Within this

domain of SSK literature, there is the analysis of the "epistemic culture", which is comprised of the environment and actual goings-on of the experimental process. It is these factors that influence how science is produced, and according to this school of thought, scientific procedures can be sold off for time, money, competitiveness, manageability, or other nonscientific goods (Knorr Cetina). These trade-offs are strategies for producing scientific truth.

The Actor-Network approach to the Sociology of Scientific Knowledge, championed by Latour, Woolgar, and Knorr Cetina, is one that has taken significant hold in the field recently. Within this line of thought, scientists and objects in the laboratory are joined into behavioral circuits which influence how science reforms and reshapes itself. In the field of stem cell research, however, the type of context-dependence that is of most significant sociological interest is not necessarily the dynamics of the laboratory, itself, or the relationship between scientists and their materials but rather a broader, more legislatively-oriented environment within which science can operate.

As Leonard Zon, of the Harvard University Medical School, argues, it has been questionable policy framework surrounding stem cell science that has played the most significant role in the state of the field -- influencing not only the practice, itself, but also who enters it. With the funding, in the form of federal research dollars, and even legality of the research continually at risk, young scientists have notably been reluctant to enter the field, lest their work similarly become at risk (Zon, 2007). For this reason, it is how policy influences what can be done, who can do it, and how easily it can take place that has had the biggest impact on stem cell research progression around the world. In turn, how these policies are created is the result of cultural considerations framing social interactions.

Both World Polity Theory and the Sociology of Scientific Knowledge have important contributions to make to the evolution of stem cell research, helping to explain how it has been globalized and institutionalized, and helping to explain how it is a product of cultural determinations. However, these sociological frameworks offer insight into the progression of the science, itself, while stem cell research involves more social considerations and social actors than those found in science, alone. While WPT and SSK make important statements about stem cell research as a scientific and even cultural endeavor, they might not adequately capture the research as a product of dynamic social relationships and cultural realities that come into play during policymaking. With this in mind, it is necessary to look beyond purely the sociology of science to understand fully how human embryonic stem cell research has been institutionalized in its 15 year history.

The sociology of embryonic stem cell research lies at the intersection of science, ethics, and public policy. It is at this juncture that is illuminated not simply how embryonic stem cell research has become a construct of social production but, more importantly, when and why it has become the construct it has. When we "do" the sociology of stem cell research, we do it from a

sociological perspective that incorporates all of these factors. The very sociological framework that allows for this degree of analysis, an analysis that incorporates multiple players with vastly different social agendas, operating to produce a collectively striven-for social outcome lies in Bourdieu's Field Theory.

In countries engaging in human embryonic stem cell research, or countries that have actively tackled the question in some way, there has been a lack of consistency in the policies that have been produced. Even countries that fall into the same policy category, for instance countries that adopt a "permissive" policy, can have policies that look very different, and could have adopted them for different reasons. When it comes to policy making in different social and cultural contexts, there often are very different actors at play, different "rules of the game", and different capital that these actors are striving to maximize. This set of conditions is particularly amenable and fruitful ground for a Bourdieusian Field Theory analysis.

Field Theory

Science has increasingly become reliant on the government for necessary funds. As a result, governments create the regulatory environment within which funds are granted. Researchers seeking to obtain support from the government, in many cases, must adhere to governmentally-created guidelines, allowing federal governments to set the tone for how scientific research will take place in any given jurisdiction. Within the cluster of policies regulating stem cell research, some are more permissive than others, some offer greater autonomy to the authority of science, and some place the basis for restrictions on different social factors. In order to fully understand stem cell research, it is imperative to also understand it as a political, social, or legislative construct, and the factors that are in operation to create such a construct. With this in mind, when looking at an issue of public policy, stem cell research as a scientific endeavor has existed in the scientific field yet stem cell research as a social construct has largely existed in the political field.

Bourdieu's work provides an analytical method by which to investigate the interrelationships of actors in society. Bourdieu envisions society as a multidimensional space that is made up of semi-autonomous social fields, and each of these social fields embodies a set of relationships between participating actors (Meisenhelder, 2006). Society, then, operates according to factors of differentiation which guide the distribution of capital, which all actors seek and each field is defined by some autonomous internal logic. The logic pertaining to a given field amounts to specific principles that legitimate the distribution of social capital. Power within the field lies in the ability to declare the rules by which capital will be distributed (Meisenhelder, 2006), and the configuration of actors within the field is the result of struggles for capital. Broad social change, then, takes place when there is a transformation in how a field is structured and how capital is distributed. The capital which social actors strive for, in Bourdieusian theory, takes three forms: economic capital, cultural capital, and socio-political capital. For the purposes of this analysis, socio-political capital is of greatest

interest, and is comprised of the ability to influence social reality. This form of symbolic capital influences the ability to control the common ideology and belief structure (Meisenhelder, 2006).

What, then, is a *field*? The social spaces Bourdieu refers to occupy such social institutions as religion, the arts, the Academy, and the sciences. As society is arranged in such a way that some fields are more central to societal organization, this arrangement can change over time. In postindustrial society, the central field is the political field, which defines the "field of power" (Bourdieu and Wacquant, 1992), where capital takes the form of power to determine the organization of society. The struggle between actors in the political field is the control of the state and ways to structure other social fields. In essence, the political field is the "meta-field" or "field of fields"

As Martin describes, Field Theory is an analytical approach in the social sciences that seeks to explain the regularities in individual action by recourse to position in relation to others (Martin, 2003). Relative position in a field indicates the potential for a force exerted on the social agent, a force that comes from within the field. Field Theory allows for a reflexivity that is required in a sociological analysis of large-scale political and institutional questions, and forces the researcher to look at the entire social picture, or the "whole story" of how a particular outcome necessarily came to be.

Bourdieu's Field Theory is particularly well-suited for an issue like stem cell research for several reasons. First, much of the story of human embryonic stem cell research has been written in legislation in the form of public policy. Public policy, itself, presents itself as especially fertile ground for a Field Theory analysis, as various social actors can be seen as vying for sociopolitical capital in the form of influence over reality construction in their legislative jurisdictions.

Field Theory is a valuable, analytical framework for understanding stem cell research, as this social question touches upon jurisdiction over epistemic authority. To be specific, hESC research speaks to questions about the origins and meaning of life, the appropriate ends of science, what research territory can be defined as a "slippery slope", and the responsibility that society has to invest both in scientific advancement, as well as in the eradication or treatment of disease. Many of these questions were hitherto addressed by such epistemic authority entities as religion and bioethics. In negotiating the policy choices surrounding human embryonic stem cell research, representatives from all of these social disciplines compete for not simply the symbolic sociopolitical capital of defining the habitus of the social field or how this social capital will be distributed, but much more importantly the very identity of these social authority figures.

When looking at human embryonic stem cell research as a social issue and legislative matter from a multicultural perspective, it is possible to assess which social actors have played a role in the policymaking, what dynamics were at play, what fields of influence each actor may have pursued, and what the

source of capital may have been. A preliminary list of actors operating within the Field Theory network in multicultural contexts might include:

- **The Catholic Church:** according to this social actor, who has at least in recent decades attributed a full human moral status to the embryo, there can be no research conducted on human embryos or embryonic stem cells that does not violate fundamental bioethical principles. For this reason, the Catholic Church places no weight on the legitimacy of such research guidelines as have been drafted by the ISSCR. However, the controversy is not quite so simple as to be reduced to whether or not it is ethically justified to use human embryonic stem cells for research purposes. When looked at from a Field Theory perspective, the authority of science and the authority of religion are at odds with one another, similarly challenging one another for rights to epistemic territory held by the other. Strides made in science, for instance, in defining the origins and meaning of life, or in finding treatment to disease fundamentally diminishes the territory and authority of a religion like Catholicism. These two entities, stem cell science and Catholicism, challenge each other in a multidimensional way that only Field Theory unveils.
- **Patient advocacy groups:** most notably within the US where there is a considerable degree of public advocacy and debate on political issues, the salience of the patient advocacy movement has been central to the embryonic stem cell research question. Following the restrictions placed on hESC research early in the Bush administration, clusters of patient advocacy groups began to sprout across the country, and then began to join forces in order to influence policy making and reframe the tenor of the public discussion away from one of the morality of the embryo to the responsibility to find treatments. For instance, following the restrictions, the Coalition for the Advancement of Medical Research (CAMR) became a prominent force in lobbying and shaping public discussion. CAMR is a collective umbrella organization "comprised of more than 100 nationally recognized patient organizations, universities, scientific societies, and foundations advocating for the advancement of breakthrough research and technologies in the field of medical and health research" (CAMR, 2011). Representing the 100 million Americans suffering from diseases and conditions, this umbrella group focuses its attention on advocacy and education initiatives, as well as influencing the policy debate on Capitol Hill. Although CAMR, in specific, is a US-focused group, their influence on US policy and discussion affects similar initiatives in other countries.
- **Policy:** much of the progression of human embryonic stem cell research has been borne out through public policy. In opposition to the clear rationality, modernity, and economic gain that World Polity Theory argues are the pursued ends of policymaking, Field Theory and political philosophy argue for a much more Machiavellian and potentially self-interested approach to political decision-making. For instance, legislators

within democracies are beholden to the seduction of reelection, and with reelection comes the allegiance to groups and actors who can most significantly foster that reelection. Irrespective of whether a policy position brings a nation closer to rationality or meeting strategic goals, within a democracy, legislators will be bound by the policy position that will most likely result in their reelection. Those making policy decisions in more autocratic contexts, however, are not necessarily bound by these same considerations, and might very well pursue the strategic ends of economic development and international competitiveness in a much more aggressive way, looking not to sensitivities of specialized groups but, instead, to how this scientific research might bring about greater economic gain.

- **The scientific community:** Central to WPT is the claim that, by virtue of its high degree of rationality and theorization, science and scientists enjoy a respected, institutionalized, and authoritative position in society. Similarly according to WPT, it is through this position of authority that members of the scientific community become "rationalized others" and help to shape policy making. This prediction does not fully uphold in a discipline like human embryonic stem cell research, and it is not simply because of scientific rationality that they may or may not exercise epistemic authority. Much to the contrary, embryonic stem cell researchers have repeatedly been forced to make their case and articulate why this work is important. This has been case, so much so, that researchers, themselves, have had to testify before Congress, meet with Presidents and prime ministers, and have become their own lobbyists. However, the efforts of the scientists in shaping the cultural acceptance of human embryonic stem cell research is not limited to their interactions with policymakers, and stem cell scientists have moved to helping to influence public opinion, as well. As preeminent stem cell scientist, Dr. Doug Melton of the Harvard Stem Cell Institute, has argued: "Among the many lessons I've learned is that we, as scientists, should make greater efforts to explain what we are doing and why we are doing it . . . this needs to be done in newspapers and on TV, not just in scientific journals."
- **The pharmaceutical industry:** the pharmaceutical industry is a for-profit entity, and an exceedingly powerful one, at that. However, to varying degrees, the pharmaceutical industry has been very much on the sidelines of the human embryonic stem cell research movement, wary of how to wade in these waters. Until only recently, the pharmaceutical industry has not invested significant amounts of money or interest into this field, and it has only done so recently as the field has moved so rapidly to potential therapies. For instance, after not taking part in the research for quite some time, GlaxoSmithKline has created a partnership with the Harvard Stem Cell Institute. In an act of apparent threat of competition, Pfizer has recently moved its headquarters from New York to the Boston/Cambridge area. The pharmaceutical industry, thus, has demonstrated a very game-

and field-theoretic approach to the stem cell research question, balancing its support for the field with how it will gain from it.

This network of actors presents a cursory list of those competing for the sociopolitical capital pursuant to a human embryonic stem cell research policy. These actors operate both within their own defined fields, as well as in the political field, helping to shape the policymaking process.

What is of note is that how these actors seek influence is in part related to their respective positions in the field, as well as the source of capital under pursuit. Otherwise stated, how each of these actors operates within a cultural context is related not only to their level of influence within broader society but also what ideals this given society might value most highly. With that in mind, some of the most likely sources of sociopolitical capital pursued by the actors in each cultural frame might include:

- *a competitive edge in the global economy*
- *an ability to dominate the public discourse on epistemological questions*
- *the power found in reelection*

This does not dismiss the economic and cultural capital that might also be in pursuit, particularly by members of the scientific, medical, and pharmaceutical industries. How the story of human embryonic stem cell research unfolds has a significant impact on the economic future of each of these actors, and how they influence the policymaking process is, in some ways, associated with the economic capital that emerges out of the policy's success or failure.

With this in mind, a field theoretical analysis of the stem cell research policy making in cross-cultural contexts offers a valuable complement to the analysis that World Polity Theory and Sociology of Scientific Knowledge can provide. Both of these theories of the sociology of science allow for an in-depth look at how science, scientists, and scientific issues relate to either society or one another, and this is useful for understanding stem cell research as a scientific enterprise. However, mapping how human embryonic stem cell research has evolved in a broader context that goes beyond strictly the science requires an additional level of analysis for which Field Theory is particularly useful.

Particularly in the second half of the 20th century, the nature of science has changed considerably. Whereas in years past, starting in the age of the Enlightenment, science was viewed as a purely knowledge-seeking and knowledge-producing enterprise. Scientists, often self-funded or funded by philanthropic commissions, conducted their work often for no other reason than the fundamental understandings about the state of the universe that emerged from it (Wagner, 2008). When looking at science from this point of view, a sociology of science is well-equipped: looking at the content of the scientific method, investigating the dynamics of the laboratory, analyzing how and why

scientists arrive upon the scientific questions they ultimately pursue. Especially in the SSK literature, understanding and theorizing about this level of social behavior is of great value and has offered a significant amount to social understanding.

However, the state of science today has become one that is much more complex, much more socially integrated, and much more reliant on disparate forces operating within society. For this reason, theories that rest solely on the state of science come up a bit short in fully explaining an issue of considerable complexity, like embryonic stem cell research. To some extent, World Polity Theory and Sociology of Scientific Knowledge offer some potential to incorporate additional levels of analysis, for instance how policymakers seek insight from the "rationalized other" of science as addressed in WPT or how the content of scientific inquiry is affected by broader social dynamics like cultural or political environment. These, however, only take us part of the way. In order to delve more deeply into how society influences, and is influenced by, a scientific question like stem cell research, it is important to implement theory that does just that: looks at the social dynamics, struggles for power, fields of influence, and cultural capital involved in a complex system that goes beyond just science.

Though not the only sociological theory, Bourdieu's Field Theory is one that provides just this level of analysis. What is to be noted is that this is not useful solely for the case of human embryonic stem cell research. Much to the contrary, in fact, as science becomes increasingly complex, touches upon a greater number of social issues, becomes more distant from public understanding, and evolves at an exponentially increasing speed. To some degree, it is arguable that previous ways to investigate the sociological domain of science will prove unsatisfactory or even irrelevant to science moving forward. To this end, it is quite likely that incorporating an understanding that Field Theory provides will be nearly essential.

This analysis is an attempt to provide a sociological explanation for how and why the stem cell research question has been approached from such a disparity of policy regulations and guidelines. When, as World Polity Theory would argue, the use of science to conquer disease is so important to every culture, this investigation delves into the social interactions that have been at the center of policy differences. The impact of this is considerable, and extends beyond the critical quest for medical cures to other important scientific questions, as well. As science grows in complexity, where research ends, greater sociological questions begin. If society is to value stem cell research as a scientific endeavor, or any other scientific question, they must also be viewed as manifestations of social production.

CHAPTER 3: THE US
A STORY OF SCIENCE AND MORALITY

CHAPTER 3: THE US –A STORY OF SCIENCE AND MORALITY

This chapter explores the evolution of stem cell research policy in the US, which has developed against the backdrop of prominent social actors competing for epistemic authority. The case of the US is among the most surprising instances of stem cell policymaking, given the resources that the US has to invest in science and its historical commitment to the scientific field. The resulting policy is surprising to the extent that it has been characterized by restriction. World Polity Theory and Sociology of Scientific Knowledge offer some explanation into how advancements in stem cell science have taken place in the US. The stem cell research story in the US begins with the first derivation of human embryonic stem cells in 1998, and continues throughout the ideologically conservative perspective of the Bush administration. As WPT and SSK explain some, but not all, of the development in the US, Field Theory offers another analytical framework to look at this question. Central to Field Theory is the interaction among actors in a social space, and when it comes to stem cell policy, the actors who have been most centrally involved are the Catholic Church, the scientific community, the pharmaceutical industry, and patient advocacy groups. In addition, there are conditions specific to the US that have influenced how these actors have operated to bring about the policy that guides stem cell research in this context. Such unique factors include a political system that embraces both public participation and influence from special interests, and a president who has defined his own scientific stance on a “culture of life” rather than a commitment to scientific expansion. These factors have worked together to create one of the most complex cases of science in the political field: a story that intertwines ideology with the promise of scientific discovery.

This chapter begins by assessing the development of the stem cell policy in the US, followed by an analysis of how relevant social actors have contributed to the creation of this evolving policy in this context. The discussion concludes this chapter by analyzing how WPT, SSK, and Field Theory operate through these actors, and how they interact with one another to shape the political field.

US STEM CELL POLICY FROM CLINTON TO BUSH

Though the first derivation of a human embryonic stem cell line occurred in the United States in 1998, preceding this event the US already had policies surrounding human embryo experimentation, legislation that began to be put into place shortly after the creation of the first “test tube baby” in England in 1978.¹

¹ At this time, the US Supreme Court had not taken a position on what constitutional rights ought to be afforded to an embryo outside of the human body (Robertson, 2010). It was after the landmark Roe versus Wade decision that the idea of fetal rights entered into the legal vernacular. Prior to this case, under both British and US Common Law, the fetus was not recognized as having personhood or full rights (Wellman, 2002).

Although no grants were ultimately funded, the executive branch efforts to support human embryo research began in 1994. This took place under the Clinton administration, when NIH director, Harold Varmus, and the Human Embryo Research Panel (HERP) recommended that some forms of embryo research should, in fact, be funded by federal research dollars.²

The recommendations created by HERP (Appendix 1), which were the product of months worth of public hearings and meetings of field experts, were upended the following year when two pro-life Republican Congressmen, Jay Dickey and Roger Wicker, introduced a rider to be attached to the 1995 appropriations bill, claiming that no federal monies could be spent on research involving the creation or destruction of a human embryo. The amendment was drafted in such a way that, in order for a member of Congress to vote against it, he would also have to be voting against the entire NIH budget, thereby ensuring the amendment's passage. It was with this political maneuver that the so-called "Dickey- Wicker amendment" has been re-appropriated in every Congressional budget since 1995.³

In the 2000 presidential campaign, both Democrat and Republican candidates, Al Gore and George W. Bush, presented their tentative positions on embryonic stem cell research. Then-candidate George W. Bush expressed his position on hESC in a questionnaire issued to the presidential candidates by the US Catholic conference. In response to a question that asked, "what is your position on using federal funds for research that involves the destruction of live

² As a report issued by the 1994 Human Embryo Research Panel stated, "From the perspective of public policy, the Panel concludes that sufficient arguments exist to support the permissibility of certain areas of research involving the preimplantation human embryo within a framework of stringent guidelines. This conclusion is based on an assessment of the moral status of the preimplantation embryo from various viewpoints and not solely on its location *ex utero*. In addition, the panel waited for the important benefits that might be achieved if preimplantation embryo research were federally funded under stringent guidelines."

³ After the derivation of the first human embryonic stem cell line in 1998, the Dickey-Wicker amendment presented particular challenges for the future of this promising research—research that, despite their tacit disapproval prior, the Clinton administration wanted to take advantage of. After having sought legal counsel on this matter, the Clinton administration interpreted the Dickey Wicker Amendment to mean that embryonic stem cells were not embryos, themselves, and research on embryonic stem cells could be federally supported, so long as the actual stem cell derivation process -- which necessitates the embryo's destruction -- was funded through private dollars. By August of 2000, the National Institutes of Health were ready to issue its first complete set of research guidelines for human embryonic stem cell research (AAAS, 2011). These early guidelines stipulated that, in order to receive federal funding, researchers conducting human embryonic stem cell research must have derived these stem cells from embryos created for fertility purposes and no longer desired by the embryo's progenitors, as stipulated by detailed informed consent. Secondly, these guidelines mandated that clinics from which these embryos were obtained must not have received profit from obtaining the embryo.

human embryos to obtain their cells for experimentation (embryonic stem cell research)” (CNN, 2001) Gov. Bush stated, "I oppose using federal funds to perform fetal tissue research from induced abortions. Taxpayer funds should not underwrite research that involves the destruction of live human embryos."⁴ A mere two years following the first derivation of an hESC line in the US, institutions like the Catholic Church were already attempting to define the epistemic territory and claim some right to determine the nature of the debate. (Appendix 2)

In the early months of the Bush administration, there was anticipation felt on many fronts regarding how the new administration would grapple with the stem cell research question. Members of the White House were divided on how to proceed on this issue, and many of Bush's aides sought some type of policy compromise with congressional Democrats (Toner, 2001). The White House was also on the receiving end of an intense and steady lobbying campaign from a wide variety of social groups, including members of the science community, patient advocacy groups, the biotechnology industry, antiabortion lobbyists, and representatives of the Catholic Church. Each of these groups strove to influence the impending policy decision in some meaningful way.

THE BUSH POLICY

On August 9, 2001, President Bush delivered a primetime public address carried on most major networks to announce his political decision regarding federal funding for human embryonic stem cell research. Bush's twelve-minute speech incorporated political rhetoric and colorful language, and laid out his policy position (see Appendix 3 for full text of George W. Bush's speech).

Bush's speech adopted a tone that was more moralistic in nature than it was rational or scientific. The language the President used reflected ethical quandaries and the perilous ends of science, in a way that put the potential benefits of stem cell research as secondary to more primary moral concerns. For instance, in his speech, Bush stated, "As the discoveries of modern science create tremendous hope, they also lay vast ethical minefields." Bush was particular to juxtapose the potential of the research with the fears it would generate. Among the fears on which Bush placed attention was the possibility of human cloning, whether or not this was a viable concern. As Bush stated, "Embryonic stem cell research is at the leading edge of a series of moral hazards. The initial stem cell researcher was at first reluctant to begin his research, fearing it might be used for human cloning." Bush attempted to give

⁴ The reference to induced abortions was a misrepresentation of existing policy. While, under the Clinton administration guidelines, there were specifications about what types of embryos might be eligible for federal funding, the product of "induced abortions" was not among them. Thus, even in the very early days of this research, political positions taken on it were being shaped by non-scientific entities.

credibility to this fear by claiming, “Researchers are telling us the next step could be to clone human beings to create individual designer stem cells, essentially to grow another you, to be available in case you need another heart or lung or liver.”

What was paramount in Bush’s speech, however, was the need to protect “embryonic life”, and this was the defining feature of his subsequent policy. In bringing concern for the moral status of the human embryo to the fore, Bush argued, “I also believe human life is a sacred gift from our Creator. I worry about any culture that devalues life, and believe as your president, I have an important obligation to foster and encourage respect for life in America and throughout the world.” The result was an address that placed its attention on potential dangers of human embryonic stem cell research rather than on its promise. The reliance on moralistic principles as a basis for scientific policymaking is contradictory to the WPT framework, which expects policy on scientific matters to demonstrate rationalistic ideas.

Practically speaking, the policy put into place by the Bush administration was less of a set of guidelines than it was a general code of conduct and directives given to the NIH. It was built around three central features:

- 1.) The cell line on which the research was to take place must have already been in existence prior to 9 PM on August 9, 2001. The rationale for this provision was that, in utilizing these cell lines, the derivation and therefore embryo destruction, had to have already taken place before the announcement of the new policy, and the federal government could therefore not be considered complicit in the embryo destruction process.
- 2.) The embryo must have been created for reproductive purposes and no longer be desired by the donor. It must also have been obtained through informed consent without any financial inducements. This provision was identical to that recommended under the Clinton administration, although the correct procedures for obtaining informed content were not specified.
- 3.) The President’s Council on Bioethics would be chaired by a bioethicist, Dr. Leon Kass, from the University of Chicago, who would study the ethical complexity surrounding the stem cell research question.

At the time of this announcement, the Bush administration claimed there were sixty-four stem cell lines in existence prior to August 9, 2001, from which scientists could legally conduct their research.⁵ Scientists, however, questioned this number, suggesting there were in fact far fewer stem cell lines available. In addition, scientists raised five key concerns regarding the usability of existing stem cell lines, namely, 1.) Are the stem cells robust? 2.) Were they consistent with high ethical standards? 3.) Do they represent genetic diversity? 4.) Are they

⁵According to the Bush administration, these lines came from research institutions in Georgia (4), California (11), Wisconsin (5), Sweden (24), Australia (6), India (10), and Israel (4).

derived from cells that are safe for human implantation? and 5.) Are they available at a reasonable cost (American Association for the Advancement of Science, 2011).

The policy implemented by the Bush administration in 2001 came to define the US' approach to stem cell research throughout much of the first decade of the 21st century. (Appendix 4) However, there were attempts made at the legislative level to alter the regulatory environment in which embryonic stem cell research could take place, and this began with initiatives taken by individual states, which viewed the research either favorably or unfavorably, and desired to regulate it in their own borders. For instance, in 2004, the state of California passed a three billion-dollar bond initiative to fund stem cell research in the state, making it the home of the largest publicly-supported stem cell initiative. Shortly thereafter, other states, like New York, Maryland, Massachusetts, and Wisconsin, followed suit to establish their own funding sources for stem cell research.

The state-based initiatives were a tacit indictment of the failing federal stem cell policy, however this was also seen in the repeated attempts to pass federal legislation to rectify it. Twice during the Bush administration, in 2005 and 2007, both houses of Congress passed the bipartisan Stem Cell Research Enhancement Act, cosponsored by Congressman Mike Castle (R-DE) and Congresswoman Diana DeGette (D-CO), which was designed to relax the restrictions inherent in the Bush policy. Both passages were met with frustration, as they were vetoed by the President and Congress did not have enough votes to override the veto.

When looking at the US case from a World Polity perspective, attempts made to circumvent policy at the federal level might seem surprising. According to this sociological framework, the rationalizing nature of science and policy ought to take place in a more inclusive, rather than less inclusive, manner. However, what is of note is that these legislative attempts were made to embrace the modernizing aspects of stem cell research policy, demonstrating the tendency for governments, no matter how local, to look to science for economic advancement.

The researchers, legislators, and patient advocates who opposed the Bush stance on stem cell research found great hope in the 2008 presidential election, as both presidential candidates, Senator McCain and then-Senator Obama expressed support for science and stem cell research expansion. The shared hope was that the federal government – arguably the most important funder of science and the only entity able to provide necessary nationwide coordination – would assume what they considered its historical responsibilities to research.¹ Following the 2008 presidential election, support for expanding federal funding for human embryonic stem cell research was high, with 70% of Americans indicating that it was either “very important” or “somewhat important” for the new president to lift restrictions on embryonic stem cell research (Gallup/USA Today, 2009).

On March 9, 2009, President Obama gave an address and signed an executive order to relax some of the Bush administration's stem cell research restrictions. The President spoke from the White House to an audience of scientists, advocates, legislators, and ethicists who had been involved in the stem cell issue over the years. Using colorful language that, at times, was reminiscent of the language used by his predecessor, President Obama worked to erase the distinction between morality and scientific progress. For instance, the President stated, "in recent years, when it comes to stem cell research, rather than furthering discovery, our government has forced what I believe is a false choice between sound science and moral values. In this case, I believe the two are not inconsistent." He continued by arguing, "After much discussion, debate and reflection, the proper course has become clear. The majority of Americans – from across the political spectrum, and of all backgrounds and beliefs – have come to a consensus that we should pursue this research. That the potential it offers is great, and with proper guidelines and strict oversight, the perils can be avoided." (Appendix 5 for full text)

In the executive order signed at the address, President Obama gave the NIH the charge of drafting guidelines for federal funding for embryonic stem cell research, which were to be drafted within 120 days of the executive order. While, in principle, the objectives behind Obama's change in stem cell policy were widely applauded by many researchers and advocates, the draft guidelines established by the NIH workgroup fell below what many of these researchers and advocates had hoped. Specifically, the NIH guidelines called for five specific items or criteria: 1) that embryos from which stem cells were derived were created for reproductive purposes and no longer needed; 2) embryos were donated by individuals who gave voluntary written consent for the embryo's usage; 3) stem cell lines not meeting the drafted criteria could be submitted to the NIH for a case-by-case review for funding; 4) the NIH would not fund the actual derivation of stem cell lines, pursuant to the 1995 Dickey-Wicker Amendment; and 5) such scientific pursuits as somatic cell nuclear transfer and parthenogenesis will not be funded.⁶

⁶ While in many ways an improvement to the restrictions under the Bush administration, the guidelines drafted by the NIH task force and then implemented by the Obama administration have created their own set of difficulties. To start, the 2009 NIH guidelines initially stipulated that there would be no "grandfathering in" of existing or already-funded stem cell lines, meaning that even stem cell lines that were already being investigated—notably the 21 being funded by the Bush administration and others that had been derived using private funds—would not be eligible for federal funding if they did not meet the new regulatory criteria. This additional stipulation put into question what research would be eligible for funding—research that was already taking place—and what stem cell lines could be used. These questions arose because many of the stem cell lines that were already derived were not derived with the anticipation of such requirements now in place. The stipulation of "no grandfathering in of existing lines" was later moderately relaxed, when the NIH announced that it would investigate each stem cell line on a case-by-case basis, to see if the spirit of the guidelines was being upheld.

More recently, a challenge has arisen regarding the 2009 research guideline which stipulated that the federal government would not fund research that used embryos created for research purposes. In October of 2011, the New York Stem Cell Foundation announced that researchers in their lab had, for the first time, successfully created a human embryo using somatic cell nuclear transfer. Though not fit for therapeutic use, these cells offer an opportunity to study disease development and the potential of drug efficacy, and might yield insights into characteristics of embryonic stem cells. However, given the fact that these SCNT embryos were created for research rather than reproductive purposes, research done on these cell lines is not eligible for federal funding.

In addition, embryonic stem cell research met a legal challenge when, in August of 2009, a case was filed against the Obama administration by, among others, adult stem cell researchers, Sherley and Deisher. These scientists argued that expanding federal research dollars to embryonic stem cell research would cause irreparable damages to adult stem cell researchers looking for access to research dollars. To this argument, US District Court Judge Royce Lamberth issued a temporary injunction against the NIH funding of human embryonic stem cell work while he heard arguments and decided on the merits of the case. The injunction was lifted by the Court Of Appeals, allowing funding to proceed as Judge Lamberth weighed his decision. On July 27, 2011, Lamberth ruled in favor of the defendants, members of the Obama administration, however this decision was appealed by the plaintiff, Sherley, and awaits a final ruling. With this in mind, the social context in which the early Bush administration stem cell guidelines were crafted has had a continued impact on the dynamics of the field. The “culture of life” that defined the stem cell policy when the field began in the US remains even to this day.

The very fact that the plaintiffs were willing to take the federal government to court reflects doubts felt in many quarters regarding the credibility of science and its role in contributing to the formulation of public policies. To understand the nature of this continued opposition, as well as sources of support for stem cell research, we need now turn to examine in more detail some of the non-governmental actors involved.

US ACTORS

CATHOLIC CHURCH

The fact that President Bush, executive of the world's leading core nation, chose to approach the stem cell policy question from a perspective other than science is, in itself, of interest, and is not what one might expect to see when viewing the issue in World Polity terms. This is the case both by virtue of the authority denied from the institution of science, and the focus on more primitive moralistic principles in policymaking. In crafting his policy, President Bush sought the guidance of influential actors outside of the scientific research

community: guidance that most such actors were eager to provide. In describing the charge given to President Bush as he weighed his decision on how to proceed with federal funding for embryonic stem cell research, Bush adviser, Jay Lefkowitz, wrote that “[Bush] was not being asked to assess the legality or even the wisdom of stem cell research, per se. No law in the country banned it, nor was anyone in either party pressing for such a ban. Rather, the question being put to them was whether he would authorize the use of federal funds” (Lefkowitz, page 21). While this was, in fact, the case, it was also the case that, were federal funds for human embryonic stem cell research not available, the progress of the research, the entrance of new scientists into the field, and the public perception of this research would be affected.

According to Lefkowitz, the President “personally set in motion a highly unusual process of deliberation inside the White House”, which was comprised of a schedule of meetings with researchers, patient advocates, ethicists, and members of the pro-life community. As Lefkowitz writes, the President's schedule included “regular, 30 min. sessions... [to address] Bush's questions and challenges to the attendees”, with testimonies that were, at times, personal in nature, and were sociologically unusual given the diverse circles from which these individuals came.

During the months preceding President Bush's August 9, 2001 public address, representatives of the Catholic conference lobbied the White House and members of Congress in an effort to influence the policy decision that would be made into law. According to President Bush's memoirs, as recorded in his 2010 book, *Decision Points*, the hierarchy of the Catholic Church played a critical role in the decision that the President made, and included among the members of this Catholic hierarchy was Pope John Paul II, himself. As Bush's memoirs indicate, he visited the Pope in July of 2001, one month before his policy announcement, at a summit held at the Pope's summer residence. As Bush describes, the Pope provided an example for a “steadfast support of life” (116), which provided a strong moral framework for his pro-life policymaking. It was, in fact, Pope John Paul II who introduced to the US President the term, “culture of life” which came to define Bush's policy speech.

It was not, however, only the Pope who had such a strong influence over the 2001 policy decision, and in fact President Bush sought the guidance of such prominent Catholics as president of Notre Dame University, Father Edward Malloy (Lefkowitz, 2008), and members of the US Conference of Catholic Bishops. However, within the Catholic tradition, the Pope enjoys a status of “infallibility”, wherein the positions he takes on social questions remain the doctrine of the church and its official position. So, irrespective of the member from whom the President was soliciting advice, the official position of all Catholics is essentially the same, and is predicated on the position taken by the Pope.

The role that the Catholic Church has in the United States is noteworthy, but it brings with it a cause for concern among the church hierarchy, particularly in relation to its diminishing authority in the US. According to recent surveys and research conducted by the Pew Research Center, provided in their report "US Religious Landscape Survey", Catholics represent approximately 24% of the US population, with "Catholic" being defined as "all respondents who said they are Catholic, regardless of their specific beliefs and whether or not they attend Mass regularly" (Pew Research Center, 2008). Historically, and particularly over the last century, the Catholic presence in the United States has been a formidable one, commanding a notable ability to drive social influence. According to the same report, however, among US religions, Catholicism has seen the greatest reduction in its population over the decade. As the report indicates, "Catholicism has lost more people to other religions or to no religion at all than any other single religious group." (p. 22). Nonetheless, however, despite the fact that the percentage of Catholics in the United States has largely remained consistent, Catholicism remains a marked net loser when it comes to population numbers, as 31.4% of US adults claim to have been raised Catholic while only 23.9% of adults currently identify with the Catholic Church, signifying a net loss of 7.5 percentage points.⁷

This is the picture of the Catholic Church as it is presented in the US population, and though little of this picture might be surprising, much of it might be reason for alarm within the hierarchical ranks of the Church. First and foremost, the Catholic Church has seen its numbers dwindle throughout the population, itself a cause for concern, however the numbers decrease among younger adults, raising the problem of ongoing sustainability and relevance to younger people's lives. Further, the nature of marriage in the US has taken a significant turn in recent decades, showing a sharp decline in numbers of young adults who choose marriage over other relationship arrangements (Pew Social Trends, 2010). For instance, in 1960, over two thirds of twenty-somethings (68%)

⁷ In nearly every organized Christian tradition practiced in the United States, younger Americans tend to be considerably less religiously affiliated than their older counterparts, and Catholicism is no exception to this general rule. Of all age groups, the 18-29-year-old age bracket encompasses the smallest number of practicing Catholics, at 22%, while the overall average of practicing Catholics is 24% of (Pew, 2008). Of these numbers, Latinos occupy the greatest numbers, with 58% of Latinos identifying themselves as Catholic, and only 22% of whites identifying themselves similarly. Additionally, as the population becomes more educated, as noted by increasing years of formal education, numbers of self-identifying Catholics declines. To illustrate, of self-identified Catholics, 36% identify themselves as high school graduates, while only 10% identified themselves as having some level of postgraduate education.

Among other noteworthy demographic features of the Catholic population in the United States are that they are more likely to be women than men, by 25% of the population versus 22.7% of the population, and they are much more likely to be married versus any other relationship status, with 58% of Catholics defining themselves as "married". Interestingly, although Catholics are much more likely to be married than not, a full 61% reported having no children under the age of 18 living at home. And, finally, Catholics are more likely to live in the Northeast than any other geographic region, with 37% of Catholics living in this region.

were married while, in 2008, just 26% were. As Catholics see their greatest numbers coming from those who are married, this discrepancy presents an additional numbers problem, and certainly a relevance problem, as the teachings of the Church did not appear to have considerable resonance with many young Americans. Finally, as 61% of Catholics report having no children under the age of 18 who live at home, the possibility of empty pews in the upcoming decades appears relatively strong.

It is not simply a numbers game in which the Catholic Church finds itself, but the more sociologically interesting position of authority that is a result of these changing numbers. Despite its attempts at securing cultural capital, the legitimacy of the Church is significantly less than it was years before. The order that the Church has attempted to create, in terms of marriage, the composition of the family, and the necessity of regular church attendance, is likewise dwindling. If the Catholic Church is prone to lose its influence by a reduction in cultural capital, the institution will pursue some other avenue to maintain it. This is precisely what the Church has done through entering the political field.⁸ It is for this reason that an institution like the Catholic Church presents itself in the political field by the actions of a select group of actors: the USCCB.⁹

Following the Bush administration's policy announcement, and certainly following the policy changes by President Obama in 2009, the Catholic Church, with its infrastructure in place in the USCCB, had a great deal to say, indeed a great deal to oppose. Following both of these policy announcements, the USCCB issued statements that summarized their positions on the US policy (Appendices 6 & 7). Members of the Catholic Church, as well as other pro-life entities, have made numerous attempts to undermine the funding, and even legality, of human embryonic stem cell research.

There are many activities and avenues of social outreach in which the USCCB regularly engages, and likewise many issues which it believes are directly related to its interests, and these include commitments to a pro-life culture. On their website, the USCCB dedicates many webpages, articles, and links to the "pro-life activity" of rallying against human embryonic stem cell research. In an included pamphlet, the USCCB describes hESC research as,

⁸ The political field, as Bourdieu envisioned, is defined by its exclusionary practices, and social groups gain entry into the political field through the actions of highly legitimized representatives. As Bourdieu argues, "the political field is less the site of a competition for power which is carried out by means of a competition for the control of nonprofessionals or, more precisely, for the monopoly of the right to speak and act in the name of some or all of the nonprofessionals. The spokesperson appropriates not only the words of the group of nonprofessionals..., so the very power of that group, which he helps to produce by lending it a voice recognized as legitimate in the political field" (page 190).

⁹ Founded in 1917 by the bishops of the US to provide spiritual care and recreation services to servicemen of World War I, and reorganized in 1919 as an entity to work for social justice and peace, the USCCB is currently organized for operation in Washington DC and is supported by a staff of over 315 priests, deacons, and religious leaders.

“the deliberate killing of innocent human beings, a gravely immoral act” (USCCB, 2008). According to the eight-page downloadable document located on the Catholic Bishops' website, the Catholic Church acknowledges its appreciation for biomedical sciences which “open up unprecedented therapeutic prospects” (Pope Benedict the 16th, address on January 31, 2008). However, the Catholic Church pits this research against “the imperative to respect human life”.

The Catholic Bishops outline three central arguments upon which they base their perspective on the morality of human embryonic stem cell research: first, that utilitarian ethics do not apply when “used to justify lethal experiments on fellow human beings in the name of progress”. According to this argument, the potential benefits of human embryonic stem cell research, no matter how great, cannot justify the use of embryonic stem cells to bring about these benefits. Second, the Catholic Bishops claim that embryos, regardless of their point in development, are to be afforded full human, moral, and legal status, such that they are fully comparable to mature human life. According to this argument, human embryos from which human embryonic stem cells are derived are to be protected under the U.S. Constitution as American citizens. This belief lies in opposition to that presented by the Clinton administration’s Human Embryo Research Panel, which argued that the early-stage blastocyst does not constitute the characteristics of a “human being”, and is therefore not protected under the 14th amendment. Thirdly, despite the fact that the embryos from which human embryonic stem cells are derived are slated to be discarded, their usage in research cannot be justified. According to this argument, we are all, as human beings, destined to die, but that does not give anyone the right to perform experiments on us.

While the authority of the Catholic Church might be experiencing a decline in terms of population size, this loss has been offset by the authority it has concentrated in the political field, and this has particular relevance in the stem cell research question. Included on the United States Conference of Catholic Bishops website, under their list of “departments”, is located the USCCB Government Relations (GR) webpage. According to this page, the USCCB Government Relations “represents the USCCB before the U.S. Congress on policy issues of concern to the Bishops. GR coordinates and directs the legislative activities of the USCCB staff and other church personnel to influence the actions of Congress.” (United States Conference of Catholic Bishops, 2011). The GR operates in such a way that there is a specific policy issue assigned to a congressional liaison staff person who works in collaboration with USCCB policy departments. Of the issues that are deemed “of concern to the Bishops” are included “pro-life” issues, of which stem cell research is one.¹⁰ The US

¹⁰ As documented on the USCCB website, under their “pro-life activities” is the following:

The Secretariat of Pro-Life Activities, under the guidance and direction of the Committee on Pro-Life Activities, works to teach respect for all human life from conception to natural death, and organize for its protection.

Conference of Catholic Bishops (USCCB) represents a particularly formidable entity within US society, and certainly in the halls of the U.S. Congress. As Jodi Jacobson argues, “for some reason, when the Bishops pay a call, the entire House leadership shudders...” (Jacobson, 2009).

The interest and involvement of the Catholic Church in lobbying against embryonic stem cell research can be related to several factors. First, such research represents a serious challenge to the Catholic Doxa, or its dominant point of view and doctrinal positions. The Church has placed a considerable amount of its authority on defining the meaning and origins of life. In fact, of the over 400 dogmas of the Catholic Church, over 25 involve the origins of life and how it pertains to God or, by extension, the Church. For instance, dogma 72 states, “the first man was created by God”, dogma 73 states, “the whole human race stems from one single human pair”, and dogma 77 states, “every individual soul was immediately created out of nothing by God” (Ott, 1974). The very foundation of the Catholic Church is built upon the central notion that life is the creation of God, and that God is manifested through the Church. In this way, all human life is, by argumentation, under the direction of the Church.

As a result, in an effort to meet their pro-life legislative agenda, the USCCB's Pro-life Legislation and Government Relations webpage reads, “the USCCB advocates for policies that protect and respect human life and dignity, with special concern for those who are unborn, disabled, or terminally ill... and supports medical research that respects human life while opposing human cloning and harmful experiments on human embryos.” (USCCB, 2011). Of the legislative issues they include as paramount to pursue in the 111th Congress, the USCCB Government Relations itemizes stem cell research, stating that they “oppose research that uses stem cells obtained by destroying unborn human life; support funding for morally acceptable alternatives.”

Though legislative and lobbying efforts are the central means by which the

To serve this goal we:

- Develop educational material on pro-life issues
- Conduct educational campaigns in the Church – e.g.,
 - Respect Life Program that begins on the first Sunday of each October
- Conduct educational campaigns in the public square – radio, print, exhibit
- Circulate fact sheets and other information on critical issues
- Publish *Life Issues Forum*, a biweekly column for Catholic newspapers
- Publish *Life Insight* newsletter
- Encourage and enable programs to meet the needs of pregnant women, children, persons with disabilities, those who are sick or dying, and all who have been involved in abortion
- Provide dioceses with pro-life liturgical suggestions each month
- Coordinate/advise on public policy efforts concerning these issues
- Assist dioceses to implement major pro-life programs

The current Committee serves from November 2009 to November 2012 and is chaired by Cardinal Daniel DiNardo, Archbishop of Galveston-Houston.

Catholic Church can crystallize its position of authority, it has not abandoned efforts at influencing public opinion on this matter. The USCCB goes to considerable lengths to create a messaging and mobilization campaign to call its members to action (Appendix 8). On the Faithful Citizenship website, the Conference of Catholic Bishops provides statements for the issues of concern to them, and has implemented an “ad campaign” that contains three mail pieces touting the superiority of adult stem cell research over the immorality of embryonic stem cell research. Finally, the USCCB states that following its teachings and voting accordingly lies at the heart of responsible citizenship, and that behaving accordingly in political life is “a moral obligation”.

From a religious point of view, the opposition directed to human embryonic stem cell research has not solely, or even mostly, been due to the Catholic Church, and how religions have approached this issue is a source of ongoing consternation. In the US, among those who have expressed some of the most vehement opposition to human embryonic stem cell research are members of conservative Christian religions who echo the Catholic Church in their pro-life ideology. Among the most prominent and influential conservative Christians who have made a contribution to the stem cell debate was President Bush, whose religious ideology coincided with his tenure in the White House. This lent a powerful collaborative force between the institution of the Catholic Church and the US President.

The Pew Forum On Religion and Public Life conducted an analysis of various religions' perspectives on the acceptability of human embryonic stem cell research (Pew Research Center, 2008), which highlights the lack of consensus on the issue among Christian religions. For instance, as the Pew Forum investigation claims, the American Baptist Churches, one of the most conservative in the spectrum of Christian religions, has no explicit position on policy for this issue. Instead, the Baptist Church states, “one must be guided by one's own relationship with God and Scripture”. Similarly, the Evangelical Lutheran Church in America (ELCA) also has not adopted an official position on the issue. In 2005, the ELCA's Churchwide Assembly created a task force to investigate issues of genetics and biotechnology, to which it was supposed to respond in 2011. On the other hand, churches like the National Association of Evangelicals, in 2005, presented a statement voicing its opposition to stem cell research. A similar claim was made by the Southern Baptist Convention in 1999, which presented its “opposition to the destruction of human embryos... [and] support for the development of alternative treatments which do not require human embryos to be killed”. The National Council of Churches perhaps stated it best in 2006, when its Human Biotechnologies Policy Development Committee adopted a formal position stating, “as a result of a clear lack of consensus [among ethicists, academia, and scientists,] the National Council Of Churches neither endorses nor condemns experimentation on human embryos”. This lack of consensus across even the most conservative Christian churches has demanded a different approach to influencing the stem cell debate, and this has been done by challenging the science, itself, rather than adopting a unified

position.

Despite the fact that both Catholicism and conservative Christianity hold similar pro-life opinions on the stem cell issue, they have approached this question in very different ways. This speaks to the heart of some of the central arguments in both Sociology of Scientific Knowledge and Field theory, and how the organization of social actors and groups affects the way they operate. To illustrate, while both Catholicism and conservative Christianity are powerful religious institutions, Catholicism abides by a much more formal and well-established hierarchy that is integrated throughout the entire church structure. While Catholicism relies on the dictates of the Pope, bishops, cardinals, and priests, all of whom represent the very backbone of the religion, Christianity typically does not have such a hierarchy. While formal in organization, many forms of Christianity do not abide by the same hierarchical network of religious operatives who can disseminate a central message. As a result, the conservative Christian movement must rely on some other method to rally believers around a cause.

Catholicism has the Pope who, along with the bishops and cardinals, represents the living “infallible”. What is dictated by the Pope or the collectively-speaking bishops and cardinals is taken to be absolute truth, the word of God, that is jointly respected and observed by all Catholics worldwide. In such a way, the position of the Pope on an issue like embryonic stem cell research is one to be shared by all believers of the Catholic faith. In Christianity, there is no living “infallible” who can be the voice of a unified people in the same way as that seen in Catholicism, and as a result, the conservative Christian movement has relied on attempts to “disprove” the validity of stem cell science rather than simply adopt the position of a figurehead. The strategy implemented by conservative Christians, while still centering on a pro-life position, does not enjoy the leadership of any one particular individual who can serve as the “infallible”. As a result of this lack of central figurehead in the conservative Christian movement, it has relied on a direct targeting of the credibility of stem cell science, itself.

Attempts to undermine or challenge the validity of human embryonic stem cell research have been met at every turn in the embryonic stem cell research debate in the US. Beginning with the efforts of Christian congressmen, Jay Dickey and Roger Wicker, the conservative Christian church has taken direct aim at the necessity of using embryos for research purposes. The effects of these legislators were codified in the 1995 Dickey-Wicker Amendment, which has had perhaps the single greatest legislative influence on the evolution of stem cell research in the US. However, these strategies have been carried out in the public just as significantly as in legislation. To illustrate, Christianity Today, self-described as a “magazine of evangelical conviction”, has a series of articles devoted to human embryonic stem cell research, and nearly all of these make an indictment on the science of embryonic stem cell research. A 2009 article by Mike Pence, entitled “The Empty Promise of Embryonic Stem Cell Research” places its emphasis on “scientific breakthroughs [that] make the destruction of

human embryos obsolete” (Pence, 2009). In a similar vein, an article by Nigel Cameron, entitled “The Great Stem Cell And Other Mistakes” focuses its criticism on “what Americans really think about science”.

This serves to demonstrate how the Catholic Church has been collusive with the conservative Christian movement in representing a vehement opposition to human embryonic stem cell research. While the Catholic Church has both the social and political infrastructure to disseminate a common message based on the Pope's rejection of embryonic stem cell research, the conservative Christian movement could approach this question from the opposite direction by challenging the credibility of this research, altogether. These two religious entities have met in the middle in a profound way, with the Catholic Church offering a very tangible entity through which to address the policy matter. Operating together, these two religious institutions have gone to great lengths to call into question the authority of embryonic stem cell science. The Catholic Church has done this to secure its own status of authority on matters pertaining to life. In order to do this, the Church has expressed support for, and confidence in adult stem cell research. The Catholic Church has argued that this research represents the scientific equivalent of, and moral superior to, embryonic stem cell research. While any researcher would argue that both lines of stem cell research are important to be pursued in order to investigate the most challenging diseases, the Catholic Church has pitted the two types of research against one another.

The Catholic Church has positioned itself as not only champion of, but also benefactor for, adult stem cell research. As an institution, the Catholic Church has utilized its vast network of contacts and fundraising capabilities to raise tens of millions of dollars for scientists conducting research that the Church, itself, deems ethically acceptable. Among these initiatives were a \$10 million grant to adult stem cell researchers appropriated by the Catholic bishops of South Korea, \$50,000 (in Australian dollars) for similar research provided by the Catholic Archdiocese of Sydney, and the establishment of the Thomas Hartman Foundation for Parkinson's Research established by the Catholic Diocese of Rockville Centre in New York, which has raised tens of millions of dollars for adult stem cell-related Parkinson's research.

Most recently, however, on April 23rd, 2010, the Vatican announced a \$2.7 million collaboration with researchers at the University of Maryland who conduct adult stem cell research, to create an international consortium of adult stem cell research. What makes this most recent initiative particularly noteworthy is that it has been touted by the Church as an attempt to not simply support research they believe will bring about treatment but, instead, as a means “to do away with the need for embryonic stem cell research.” Rather than allowing the benefits of both lines of research to prove themselves within the confines of scientific and public debate, the Church is actively seeking to eliminate the work it deems objectionable or, as they often describe, “gravely

immoral”.¹¹

In globalization terms, there is no entity that more significantly reflects the principles of World Polity Theory than does the Catholic Church, with its international reach and adherence to ideas on a global scale. When it comes to the stem cell research question, the Catholic Church has taken a universal stance in opposition to this research, but this opposition manifests itself differently depending on the social context. This can be seen in the US in several important ways. It is not simply because human embryonic stem cell research uses embryos that the Catholic Church has expressed opposition to it. It is difficult to see exactly why and how the Catholic Church can be so strongly committed to the issue of life when its stance on life has been variable over the years. That is to say, if the Church has been known to be historically inconsistent on its beliefs about when life begins, it is curious why its current position is so strongly believed to be a matter of truth. There must be, then, some other variable or value that makes the issue of life so prominent, particularly in how it relates to human embryonic stem cell research.

In the confines of the stem cell debate, what is at stake for the Catholic Church is more than simply a difference of belief or opinion when it comes to the foreseeable ends of scientific research. This is not just an epistemic battle between religion and science. To be sure, there are areas of scientific inquiry that would appear much more threatening to the Church's authority, such as the quest for the “God Particle” or the investigation of the boundaries of the universe. However, it is embryonic stem cell research that has commanded so much opposition from the Church. It raises the question of what is at stake for the Church in this debate, what is truly being expressed in the Church's position, and why is it relevant to stem cell policymaking.

When it comes to understanding fundamental questions of existence, religion has played a critical role in assuaging public concerns. In this regard, when defining the creation and meaning of life, a religion like Catholicism has without question established the social Doxa. Irrespective of when the Catholic Church has come to believe life begins, what is important is the fact that their position is the dominant one, the one that society collectively believes to be valid.

¹¹ There are several key issues that are central to the concern of the United States Conference of Catholic Bishops, and these include international justice and peace, marriage/family protection, migration and refugee issues, and pro-life issues (USCCB, 2011). However, at every turn, pro-life issues ranks as the most pressing issue to the USCCB. According to the Catholic Mobilizers, among political issues, there are “five nonnegotiable issues” for Catholics, emphasizing that some issues are considerably more important than others, and these five issues are: abortion, euthanasia, embryonic stem cell experimentation, human cloning, and same-sex marriage. These five issues, it is claimed, involve “intrinsic evils that government can never legitimately authorize” (Doug Lawrence's Catholic Weblog, 2010). It is on these issues that the Catholic Church places a great deal of its authority, and it is through their positions on these five issues that the Catholic Church derives a great deal of its social legitimacy within the United States.

In other words, it is less significant that the Catholic Church, at least currently, believes that life begins at the moment of conception; what is more significant is that, when it comes to matters concerning the question of life, that the Church's opinion remains the primary one. Any threat to that, of which scientific explorations into embryology is certainly one, is likewise a threat to the entire legitimacy of the institution, itself. It is for this reason that the Catholic Church has resorted to such extensive lengths to influence both public opinion on stem cell research, as well as public-policy on this issue through the USCCB. The hierarchical system of the church has been especially amenable to this.

There is no shortage of scientific pursuits that may pose a threat to the epistemic authority of the Catholic Church. However, it is human embryonic stem cell research that has been the recipient of the greatest and most public scorn from the Church hierarchy. Why this has been the case speaks directly to how this specific issue has been borne out through the political field. Stem cell research has been framed in the context of public policy as a result of its need for funding and regulation. Though many other matters of scientific inquiry are likewise contingent upon funding from the government, specific scientific questions are often addressed outside of the legislative and political circles. The fact that embryonic stem cell research has been carried out through political channels creates two problems for the research: first, that its future is left in the hands of policymakers who enter congressional chambers with their own ideologies that might be unwelcoming to science; and second, that political circles in the US are especially favorable to some actors over others. To this second concern, the Catholic Church has benefited considerably and scientific establishment has lost. The Catholic Church has been so successful at focusing on this particular scientific portion over all others quite simply because stem cell research has evolved through policy and legislation, and the USCCB is masterful at affecting policy.

As a result, in the US, we are left with a social actor like the Church holding tightly to a Doxa that has far less to do with science than it does to other epistemic questions that are central to the Church's existence and authority. It can be argued, in fact, that there is no established social Doxa when it comes to stem cell research, but that an institution like the Catholic Church merely pretends to have created one and mimics a Doxic position, using its authority on other "life" related issues. The ersatz Doxa that has been established for stem cell research in the US, contrary to WPT, puts an institution like science at a distinct disadvantage from a Field Theory perspective. This is because the Catholic Church's ability to define the terms of a debate based on "life" was established centuries ago when religion played a much more central role in social life. Science's introduction into debates of life is, in relation, new and with growing persuasiveness. To whatever extent the Catholic Church can maximize his own position in this social debate, and diminish that of its epistemic adversary, it can improve its ability to dominate other important debates in the future. In short, commanding the Doxa on an issue related to life puts the Catholic Church in a better position to command other epistemic debates.

The Catholic Church's commitment to maximize its epistemic authority would be advantageous no matter what its levels of support might be the US. However, the limited degree of influence that the Church enjoys in the general public has forced it to pursue a message of intolerance that circumvents the public. While the numbers of Catholics in the US are dwindling, broad-based mobilization of Catholic churchgoers can only take the movement so far. The result is a need to mobilize legislators through extensive lobbying efforts, instantiating a social Doxa through legislation that bolsters public opinion. This is precisely the avenue that the Catholic Church has taken in the US, and it is how the tone of the stem cell debate has been struck.

The advantage that was created for the hierarchy of the Catholic Church was found in a president who held religiously-based beliefs as paramount, and a president who was particularly sympathetic to the Church's position on life. This was a critical alliance that needed to be forged: an alliance between the infallible Pope and the powerful president. An additional benefit afforded to the Catholic Church was that President Bush, in addition to being the Commander-in-Chief, was an icon of the conservative Christian movement, allowing for an alliance to be forged between these two religions. The result was a strong set of relationships between the Catholic Church and President Bush, President Bush and the conservative Christian movement, and as a logical result, the Catholic Church and the Christian movement. This has made for a formidable network of stem cell research opponents whose position is established on the basis of life, not the basis of science.

SCIENTIFIC COMMUNITY

Science in the United States enjoys a great deal of public support (Appendix 9), and this has been the case for quite some time. In 2009, the American Association for the Advancement of Science (AAAS) and the Pew Research Center conducted a study in the US about public levels of interest, support, and trust in science. 84% of those polled felt that science's effect on society was "mostly positive", and 70% felt that scientists "contribute a lot to society's well-being" (Pew Research Center, 2009). When asked about which avenues of science have had the most significant effects on society, a majority (52%) answered with advances in medicine, including health care, vaccinations, and medical cures. Similarly, when this question was asked of members of the scientific community, a majority, (55%) also cited biomedical achievements as the United States greatest scientific achievements in the past 20 years (Pew Research Center).

The importance of governmental support for research¹² is mirrored in the

¹² In the United States, there are many different funding sources for scientific research, and these include a mix of public funding, private industry, and philanthropy. Within the confines of the government funding of science, the National Institutes of Health, the National Science Foundation, the Department of Defense, and the Department of Energy play the biggest roles.

sentiments of the general public, as well. When questioned, 60% of the public said that government investment is essential to scientific progress, and a full 73% said that the government investments in basic research were beneficial in the long run (Pew Research Center, 2009). There is, however, quite a noticeable divide between the accomplishments of the scientific community in the US, as perceived by scientists, versus scientific accomplishments as perceived by the public. For instance, within the scientific community, 93% favor federal funding for embryonic stem cell research, while 58% of the general public feels the same. A central question that has persisted in the stem cell debate is that, if the scientific community enjoys such prestige and support from the public, why have stem cell researchers in the United States had such a difficult time commanding the debate, and why have their perspectives been so profoundly lost in the policymaking process.

To a considerable degree, the image of science in the US fits the description of science's role within World Polity Theory. Polls indicate that Americans view science as having an overall positive impact on society. As Meyer argues, "especially in the more rationalized and public arenas of social life, the sciences and professions are leading forces". However, one of the fundamental characteristics of rationalized actorhood is the actor's ability to influence policy decisions to help modernize society. While science has achieved a highly legitimized status within the US, its ability to influence the stem cell debate has not resulted in categorically positive results.

There is a distinction between how science, as an institution, is perceived versus how individual scientists and researchers are perceived, generating a critical break between how various sociological theories might approach the stem cell research question. For example, WPT might view science as a monolithic entity: a uniform institution that operates at a rationalized level of its own. It is by virtue of this institutionalized and rationalized nature that a discipline like science can play a role in policymaking. This argument can be coupled with SSK's argument for boundary work, in which a social discipline establishes its own system to determine who does and does not belong. In this way, science is distinct from religion, as the former gains its legitimacy through a practice of exclusivity, while the latter gains its legitimacy from inclusivity. This creates a difficult set of circumstances for the scientific community when it comes to influencing public opinion and public policy. Science is a rationalized entity—an entity that prides itself on the objectivity that a World Polity theorist like Meyer or Drori argue is essential to creating a status of rationalized actorhood. However, from a Field Theory perspective, it is not rationality that is critical in obtaining a

When asked which entities are the dominant funders in their work, 84% of scientists named "the government", 49% named the NIH, 47% named the NSF, 14% named the Department of Defense, and 13% named the Department of Energy. Outside of governmental entities, 30% of scientists mentioned foundations and nonprofits as most important to their funding sources, and 20% named industry and business.

role in policymaking, but effective utilization of the political field. It is this important factor that has most greatly challenged the scientific community: securing capital in the political field while maintaining its exclusive and rationalized status.

That is not to argue that the scientific community has not at all made its claim in the political field; much to the contrary, in fact.¹³ Leading up to the Bush administration's policy announcement, uncertainty across the scientific field was already starting to take hold. Then-director of public policy of the American Society for Cell Biology, Tim LeShan, stated, "we are hoping that Bush will really study this issue and not dismiss it out of hand... this is a science and health issue, a way to save thousands if not millions of lives" (Holland, 2001). Implicit in this statement was the acknowledgment that, even among scientific researchers, there was doubt that their position on human embryonic stem cell research would be heard by policymakers.

The fact that members of the scientific community have had difficulty in maintaining a dominant position in the stem cell debate puts the arguments of World Polity Theory at odds with the arguments of Field Theory. The nature of stem cell research has been such that it has evolved within the confines of public policy, however when science policy measures are negotiated through the political field, the scientific community is only one of several powerful actors in competition with one another over access to capital. WPT calls for a reliance on scientific institution by policymakers, while Field Theory places science in an interactive position with other actors. That the scientific community in the stem cell debate has had to challenge entities like the Catholic Church suggests that the dynamics of the political field have been given precedence over science as an institution.

How members of the scientific community attempted to affect public policy is multidimensional. During the months before President Bush's policy announcement, several prominent stem cell researchers, including Harvard

¹³ Long before the restrictive Bush administration stem cell policy guidelines, and long before the public debate surrounding human embryonic stem cell research, members of the scientific community had much to say about the issue and how the US ought to proceed with it. During the proceedings of the Human Embryonic Research Panel during the Clinton administration, a committee created to address the path forward for embryonic research in the US, the panel members relied heavily on the insight and testimony of researchers in the field in order to construct their policy recommendations. Despite the fact that the policy recommendations created by the Human Embryonic Research Panel were developed after consultation and guidance, recommendations that included provisions for research on human embryos and the permissibility of creating embryos for research purposes, the Clinton administration soon rejected these recommendations. As panel-member, Ronald Green, stated of the decision to overrule the policy recommendations, "abruptly overruling our recommendations without prior warning sent the message that a policy, was, at best, an ornament that could be used or discarded as political needs demanded" (Green, 2001).

University's Doug Melton visited President Bush to express the importance of funding their research (Park, 2011). Shortly following the Bush announcement, prominent researchers like Stanford's Irving Weissman took to the professional literature to express discontent for policymaking based on misinformation provided by the media. Even more, director of the National Institutes of Health, Dr. Elias Zerhouni marked a clear split from the Bush administration, stating "It is clear today that American science would be better served and the nation would be better served if we let our scientists have access to more cell lines. It is in the best interest of our scientists, our science, our country that we find ways—that the nation finds ways—to allow science to go full speed on both adult and embryonic stem cell research." (Wisconsin Stem Cell Now, 2011).

In many cases, the relationship between scientists and policymakers is a remarkably beneficial one, with policymakers seeking to base their positions on "scientific evidence" and scientists, themselves, benefiting from the support provided by the government. In most cases, scientific evidence serves as a predominant social force, shaping public opinion to reflect its own social Doxa. This is the case until, however, the scientific question is so broadly encompassing that it involves other social disciplines. This is increasingly becoming the case as science becomes more pervasive and resorts to greater opportunities for collaboration or integration. In the case of stem cell research and its inherent connection to embryology, this scientific question touches upon the ideologically-charged issue of life. While religious institutions have historically commanded the debate on this issue, the scientific community finds itself in a position to challenge the dominant position from a Heterodoxic standpoint, challenging the dynamics that an institution like the Catholic Church has attempted to put into play.

The commitment made by the scientific community to influence the stem cell debate has been consistent, even despite the appearance that little change would be made by the federal government. During the debates preceding the Stem Cell Research Enhancement Act Congressional votes in 2005 and 2007, many prominent researchers descended upon Washington to make their case to Congress, including Wisconsin's James Thomson, Michigan's Sean Morrison, Massachusetts' Kevin Eggan, and California's Hans Kierstead. Offering their insight to congressional committees, these researchers attempted to help science reclaim its position of moral authority when it comes to matters of science, and to help the United States government return to its responsibility as prominent investor in science. Differing from the powerful lobbying arm of the Catholic Church, many of these scientists arrived in Washington on their own, leaving their laboratories in order to do so.

The commitments that the scientific community made to the perpetuation of stem cell research did not abate following the relaxation of restrictions by the Obama administration. Following the 2009 unveiling of the NIH draft guidelines, these guidelines were open to public commentary and input. To this opportunity, the Harvard Stem Cell Institute stated, "We strongly support the development of

unambiguous, ethically sound regulation of the field of embryonic stem cell research, and will carefully consider these proposed guidelines and offer detailed response during the public comment period.” (HSCI quoted in Park, 2009). The researchers of this institution joined researchers in New York, represented by the Empire State Stem Cell Board, the New York Stem Cell Foundation, and the California Institute for Regenerative Medicine. While many in the scientific community lauded the relaxation of restrictions, many others voiced concerns that the new guidelines were still too restrictive.

In World Polity terms, US scientists have had an instrumental role in some aspects of policymaking. Scientists in the US have a considerable history of presenting their cases to federal and state legislators. Many scientific organizations and professional associations have close linkages with members of Congress and other policymakers, in a fashion similar to that of the United States Conference of Catholic Bishops. For instance, in 1989, Congress instituted a Congressional Biomedical Research Caucus, established to “broaden the support and knowledge of basic and critical biomedical research issues throughout Congress in a bipartisan manner” (Coalition For the Life Sciences, 2011). This caucus is comprised of 75 House members and eight members of the Senate. This Congressional Caucus, as their website indicates, “seeks to support the excellent efforts of the congressional committees and members of Congress with jurisdiction over the National Institutes of Health, the National Science Foundation, science research, and health issues”. Scientific organizations that contribute to the knowledge of this caucus include the American Society for Cell Biology, Genetics Society of America, Howard Hughes Medical Institute, The American Society for Biochemistry and Molecular Biology, The Journal of Clinical Investigation, and the Society for Neuroscience. Each of these organizations has a policy advocacy or a congressional liaison through whom it seeks to advise Congressional members on policy matters, including stem cell research legislation.

Representatives of these organizations, though, have been particularly vocal in regard to the stem cell issue. In 2009, prominent stem cell researcher from Children’s Hospital in Boston, George Daley, gave a presentation to members of the Congressional Biomedical Research Caucus about the state of and need for embryonic stem cell research funding. This presentation was coordinated by then-Congressman Michael Castle of Delaware, who historically championed stem cell research legislation in the form of the Stem Cell Research Enhancement Act. In his presentation, Dr. Daley said, “what we are facing is a constant need in the scientific community to continue to educate about the value of embryonic stem cells in research.” (Daley, 2009).¹⁴

¹⁴ In his presentation, Daley emphasized the ongoing need for embryonic stem cell research, despite new breakthroughs that have taken place in the field. However, in the same presentation, Daley addressed how science takes time and that some of the breakthroughs that were heralded in the advent of the field are still a ways off. What is more, Daley takes aim at some of the

The point raised by Dr. Daley addresses a critical and growing problem when it comes to the state of scientific research in the United States today. The challenge arises when the authority and credibility of the science is cast in doubt, and scientists must repeatedly emphasize the importance of the work they do—often being forced to place timelines on discovery or imply that the next major discovery is imminent. This puts scientific discovery in terms that people can generally understand, commodifying the nature of scientific investigation into terms that are measurable. Why this can be seen as problematic is that, when scientific breakthroughs do not adhere to these stated timelines, the credibility of science can be cast in doubt.

This calls to mind one of the biggest challenges facing science: how an institution that prides itself on its boundaries and discipline can effectively communicate a message that is reliant on the support of a more general audience, and the problems this generates in the field of policymaking. To be sure, complex science like human embryonic stem cell research is not well understood by many in the general public, yet the success of this research is dependent on the support of these very people. When members of the scientific community are unused to or ineffective at communicating the nature of their work to the public, at-large, an obvious conundrum is created. The institutionalization of a discipline and its success in the political field are at odds with one another. Contrary to the activities of a religion like Catholicism where it is, by design, predicated on outreach, science, on the other hand, is defined by its boundaries. From this point of view, the ability of the scientific community to disseminate its message broadly is somewhat limited. Without an ability to mobilize vast numbers of people, the ability to mobilize legislators is likewise reduced.

What is more, successfully operating in the political field is reliant on spokespersons and representatives. An institution like the Catholic Church is built upon its hierarchy, and it is often members of this hierarchy who interact most intimately with legislators. To a large extent, science is built upon its egalitarianism, such that scientists and researchers around the world can equally precipitate in the body of knowledge. The invisible college is built upon this very idea, that membership within the field of science implies a common ability to contribute to it. Through the rationalizing process of education, degree attainment, and lab study, scientists, including stem cell researchers, are trained in a highly similar way. With this in mind, there are no visible spokespersons, no representatives who rank any more highly than any other.

For certain, just as World Polity theorist, Meyer, argues, there are scientists and researchers who “earn prizes”, are inducted into prestigious

unreasonable expectations that have been put on scientists to provide access to the immediate cures that some feel this field has promised.

societies, or are recruited for exclusive research institutions based on their important work. There are scientists of such an elite caliber that they are regularly asked to participate in conferences or present their findings in public settings. However, within the US research community and contrary to an institution like the Catholic Church, there is little in the way of hierarchy in science, and almost none in the way of spokespersons. Without such spokespersons, the locus of contact between legislators and the scientific community is significantly reduced. This makes any one particular scientific position diffuse and seemingly without cohesiveness. In turn, without cohesiveness, it is much easier for opponents to divide the scientific community, or manipulate an otherwise consistent message. In other words, without any central voice, the strength of a common sentiment can be easily reduced. This, too, has been done to some degree of success in the US.

To illustrate, scientists have been heavily involved in the growing controversy between the pursuit of human embryonic stem cells and adult stem cells, a controversy that has been trumpeted by entities like the Catholic Church and Christian conservatives. In response, prominent stem cell researcher, Dr. Doug Melton of the Harvard Stem Cell Institute, stated, “there are camps for adult stem cells and embryonic stem cells, but these camps exist only in the political arena. There is no disagreement among scientists over the need to aggressively pursue both in order to solve important medical problems.” Additionally, pioneer in the field, James Thomson of University of Wisconsin at Madison, stated:

“The debate regarding whether adult stem cells or embryonic stem cells are ‘better’ is a creation of politics and the press, not of the scientific community. I know of no credible stem cell scientist that does not believe that both should be studied; human medicine will suffer if either is excluded. If politics were not involved, the field of embryonic stem cell research would be much more advanced than it is today. It is difficult to estimate just how damaging the current [Bush administration] restrictions have been to the field to date, but if the current restrictions are not eventually lifted, patients will suffer needlessly.”

Collectively, the scientific community is highly supportive of stem cell research and permissive stem cell research legislation. According to Mukherjee, a majority of scientists believe that “the benefits of stem cell research outweigh the costs in terms of embryonic life”, and scientists similarly believe, “embryos are not equivalent to human life since they are incapable of existing outside the body... and are fully devoid of any kind of consciousness” (Mukherjee, 2008, page 2). Similarly, a majority of Americans believe science is a social benefit, and that scientists ought to be Influential in providing policy guidance when it comes to policy decisions. Why, then, has there been a divide between what scientists believe, what the public believes, and how policy is created?

Part of the answer lies in the fact that achievements in science are communicated through scholarly publications that are not read by the general public. Whereas many researchers, like Daley, Melton, and Thomson are known

for having communicated the imperative nature of their work to members of Congress and other legislators, a comparable degree of communication to members of the broader public has been relatively lacking. This is the case for stem cell research, as well as many other domains of science. As the Pew Research Center reports, when administered a 12-question quiz about basic scientific matters, many questions were beyond the grasp of many Americans. For instance, when asked what the defining feature of stem cells is, only 52% were able to answer, “they are capable of developing into other types of cells” (Pew Research Center, 2009).

There is a decisive gap between what scientists are doing and what the public understands. Similarly, there is a gap between the authority that scientists have in advising on policy matters and how this is translated into policy decisions. When it comes to operating in the political field, science is not nearly as well equipped as other actors in this debate. For instance, in the very same Pew Research Center report, 77% of scientists say they have participated in public education or communications about their scientific findings. However, only 24% of the public have participated in or even heard about town hall sessions where science is discussed. Finally, the stem cell debate has largely been carried out in political circles. While the scientific community has previously involved itself in policymaking, this is not the area in which their influence carries the greatest weight. When scientists, themselves, cannot effectively communicate or educate about the science they conduct, there is an epistemic space created, wherein other actors seeking moral authority can define the terms of the debate.

As a result, the social discourse environment in which stem cell research has operated in the US is distinct from a scientific discourse, in a way that is significantly different from the predictions of World Polity Theory. Given the fact that the terms of the debate were largely established by an institution other than science in the US, the position of the scientific community could only act as a heterodoxy, irrespective of how influential this heterodoxy may have been to the social debate over the years. This is to argue that, despite levels of support for human embryonic stem cell research or a change in federal policy that is more amenable to the perpetuation of this research, this has only been achieved in light of overcoming a network of powerful social actors who preferred otherwise. It is perhaps for this reason that the stem cell debate in the US has taken the shape it has over the past 15 years.

PHARMACEUTICAL INDUSTRY

According to Reuters, the pharmaceutical industry in the United States is the largest in the world, with a total revenue of about \$315 billion in 2007 (Business Wire, 2009), and the growing revenues corresponds to an aging US population. Of the approximately 30 pharmaceutical companies operating within the US, the biggest actors include Pfizer, GlaxoSmithKline, Johnson & Johnson,

and Merck. Joining the other drugmakers in the US, the pharmaceutical industry is responsible for some 2900 drugs in the US (Business Wire), addressing a broad array of diseases and conditions. Through the marketing of these drugs, the pharmaceutical industry has posted breathtaking gains in its profits in the past several decades. For instance, in the 1970s and 1980s, of the Fortune 500 pharmaceutical companies, the average profit margin of pharmaceutical companies was twice the median for all other industries (Mullins, 2007).¹⁵

The high degree of profitability demonstrated by the US pharmaceutical industry has painted it to be an exceptionally attractive industry for venture capital firms and other investors. Indeed, there are few other industries that generate such an extensive amount of investment security. At the same time, the security of the pharmaceutical industry has begun to draw the attention of genetic and molecular biology scientists who could help to generate scientific advances and breakthroughs for these companies, particularly when public funding for research is questionable. Recent breakthroughs using such technologies as recombinant DNA, biotechnology firms like Genentech and Amgen have seen their stocks rise by astronomical numbers in the waning years of the 20th century.

As theory on the invisible college would predict, a critical component of the science-to-medicine translation lies in the publication and information sharing of research by researchers in the scientific Academy¹⁶. Within the stem cell field, there has recently been some criticism among scientists that the peer review process in medical journals is flawed. For instance, in a 2011 panel discussion presented by the New York Stem Cell Foundation, noted stem cell researcher, Irving Weissman of Stanford University, had a scathing interpretation of the peer

¹⁵ The pharmaceutical industry enjoys a fairly unique set of favorable circumstances that help to drive its soaring profits as well as its competitive position, and these include a fragmented market share with a high degree of specialization, the financial barriers that prevent new companies from entering the market, power held by pharmaceutical companies as purchasers of chemicals, and power held by pharmaceutical companies as provider of drugs resistant to price (Mullins). As a result of these circumstances, the pharmaceutical industry in the United States holds a particularly powerful position, not simply in the medical field but, even more importantly, in the industrial and political fields. Despite some recent regulatory changes to increase competition and reduce some of the power held by the pharmaceutical industry, circumstances—and, possibly better said, the advantages for powerful pharmaceutical companies have largely remained consistent. Some noteworthy changes involve the Waxman-Hatch act, which made it easier for generic drugs to enter the market. Additionally, due to the rise in managed care, it became more difficult for pharmaceutical companies to name their own price for their products. However, despite these changes, the pharmaceutical industry has remained highly profitable and highly powerful.

¹⁶ On its supplementary website, the ISSCR has written a primer for how science becomes fit for therapeutic purposes—a process known as clinical translation. The road from research to medicine begins in the laboratory, where basic research is conducted according to fundamental scientific principles, and preclinical research is initiated, where early tests are conducted on animals (ISSCR, 2011). It is only when the results of basic research and preclinical studies show promise that a potential treatment can move to a clinical trial phase conducted in human subjects.

review process, whether this peer review was for journals or the provisions of research grants. Weissman questioned the level of knowledge and expertise among reviewers, arguing that, for stem cell-based research, there is a particular level of mastery that reviewers must have, and that this can be undermined by conflicts with otherwise-interested entities who would rather not see the results of stem cell studies published (Weissman, 2011). This assertion came from his experiences with promising stem cell work not positively reviewed in important journals. As Weissman is one of the most skilled researchers in the stem cell field, serving on many boards and in many international organizations, the fact that some of his work is not being reviewed favorably in some journals is curious.

Why might this be the case? As SSK theorist, Charles Rosenberg, argues, “the more closely related to social problems [science is], the more likely is a scientific field to be influenced by society's ever present demands.” Rosenberg's assertion bears particular relevance for stem cell research's relationship with the pharmaceutical industry. All of stem cell research has as its aim the solution to the mysteries of disease and disability. However, when introducing the pharmaceutical industry into this question, it becomes that much more socially driven, that much more predicated on social problems and social demands. In this case, the science that is viewed as credible and worthy of pursuit is the science that meets the social demands of marketable products to treat disease within the pharmaceutical industry's business paradigm.

In the stages of scientific development, it is after the publication and peer review process that research moves to the clinical translation process¹⁷. However, especially recently with the exit of the biotech firm, Geron, from the stem cell field, a growing concern lies in who or what is responsible for the clinical trial process and ultimately bringing research to market. Scientists, themselves, are nearly solely responsible for the basic laboratory research, and regulatory agencies like the FDA have responsibility in monitoring the safety of the process. While some public and philanthropic agencies can contribute to the cost of some of these trials, given the great expense of translational research, it is the pharmaceutical industry, which ultimately reaps the benefits of biomedical research, who has historically stepped in to pay for the clinical translation process.¹⁸

¹⁷ During clinical translation, the government and medical community, put into place their checks and balances to protect the lives and rights of patients willing to test potential therapies (ISSCR). This process is highly regulated and, especially in countries in the West, subject to a great deal of oversight to monitor experimentation for safety. In the US, the clinical translation process is overseen by the FDA. Through a process of institutional review, risk and benefit calculations, trial design, and informed consent, research in the clinical trial phase is tested on humans an increasing number to ascertain the safety and efficacy of the protocol (ISSCR). Should these trials concluded with a positive result, the treatment can become a marketable therapy which, in the US, is approved by the FDA.

¹⁸ The favorable circumstances enjoyed by the pharmaceutical industry having been noted, the effort and steps taken to bring a drug to market are not to be underestimated. As Davidson and Greblov have documented, on average, it takes approximately 10-15 years and millions of dollars

For many years during the Bush administration and early days of human embryonic stem cell research, the pharmaceutical industry was uncertain about the fate of this research and what role, if any, the industry should play in the research's advancement. Traditionally, venture capital and private industry shies away from lines of research that will have a questionable political future or might not receive continued public support, both of which are case for stem cell research in the United States. Particularly after the first and second veto by President George W. Bush of the Stem Cell Research Enhancement Act, stem

in development in order to bring a new drug to market (Davidson and Greblov, 2005). What is more, only about one in 10,000 chemical compounds discovered by the pharmaceutical industry turns out to be effective and safe to be translated into a medicine, and then about half of all new medications fail in some point in the three-stage clinical trial of process. According to the National Science Foundation's "Research and Development in Industry: 2001", the pharmaceutical industry has one of the highest R&D expenditures as a percentage of net sales.

A report issued by the Congressional Budget Office (CBO) goes into extensive depth in terms of the R&D expenditures by the pharmaceutical industry in the United States. According to this report, there are complex economic forces that drive the drug-discovery process, some of which are not fully understood (CBO, 2006). The CBO's report discusses the R&D investments in the development of new drugs by the pharmaceutical industry, and distinguishes the investments made for a "new molecular entity" (NME), or a drug that has emerged out of an entirely new molecular or chemical compound, and "incrementally modified drugs", or drugs that are alterations or evolutions of already-existing medications (CBO). Unsurprisingly, NMEs command much more in the way of R&D capital, with upwards of 12 years from the early stages of research until the drug is marketable. Funds directed toward NME have increased significantly in recent years, as clinical trials have yielded higher failure rates, and as pharmaceutical companies have begun to set their sights on treatments for chronic, as opposed to acute, illnesses (CBO, 2006).

In terms of the timeline involved in the discovery and ultimate application of a pharmaceutical product, this is not meager, either. For NME drugs, the average length of time for the initial discovery and preclinical development is 4.3 years. For clinical trials and FDA approval, another 7.5 years is required. In total, the average length of time necessary for developing an NME and bringing it to market is 11.8 years. Within this process, there are three, and possibly four depending on definition, phases of clinical trial involved in bringing a drug to market. These phases include the phase 1 safety trial, which tests the drug's safety in a small sample of healthy human volunteers; phase 2 efficacy trial, which further tests the safety in a larger sample of people for whom the drug is intended to benefit; phase 3 large-scale clinical trial to establish and identify side effects; and phase 4, conducted after the drug has been brought to market, designed to disaggregate benefits of one drug that might be similar to another. The percentage of drugs that make it from the phase 1 trial to the market is only about 8%.

The funds necessary to conduct R&D work and subsequently bring drugs to market, however, are not entirely supplied by the pharmaceutical industry, itself. Instead, the federal government invests a great deal into health-related R&D. For instance, in 2005, the federal government spent more than \$25 billion on health related R&D. While the pharmaceutical industry often directs funds to the clinical and translational phases of biomedical research, the federal government often directs its monies toward basic research, which serves to stimulate the entire drug industry through aid to laboratory research assistants and postdocs. The government-funded basic research complements the more privately-provided translational research funds. Despite this, however, according to estimates by the NSF, total expenditures on R&D by the pharmaceutical industry have grown exponentially in recent years. In 1980, US pharmaceutical companies spent a total of \$5.5 billion, adjusted for inflation, on R&D, while by 2003, the number had jumped to \$17 billion, or an average increase of 5% per year in real terms (NSF).

cell research appeared to be on particularly shaky ground, causing fear for potential investors.¹⁹

In a panel discussion at University of Pennsylvania's Wharton School of Business in 2006, representatives from several big Pharma corporations, like Eli Lilly, Merck, and Pfizer discussed the industry's current R&D efforts and how recent scientific advances might affect the discovery process (Wharton School of Business, 2006). When addressing the potential of stem cell-based therapies and stem cell-based technologies as a benefit for the pharmaceutical community, reaction was decidedly mixed. The representatives indicated that the potential of stem cell treatments has been demonstrated in the lab and not in people, and that the political and social controversy surrounding the research has led to uncertainty in the field and a hesitation among the large pharmaceutical companies to invest in the research. However, given that science continued to move forward under the Bush administration and certainly under the Obama administration, pharmaceutical companies have found themselves in a position where they are essentially forced to enter the field. For this reason, in addition to the smaller, more nimble biotech companies, big Pharma has begun to move into the stem cell field, as well.

In a 2011 New York Stem Cell Foundation panel discussion, the relationship between stem cell research and the pharmaceutical industry was a topic of great discussion. Those deeply immersed in the stem cell field, like Weissman and the New York Stem Cell Foundation's Susan Solomon, noted that, for stem cell research, it seems no longer the case that basic research conducted in the laboratory can be easily passed off to the pharmaceutical industry for translational research. This change is the result of several things. First, given the "patient-specific" nature of stem cell therapies, potential therapies using these cells lie outside of the established pharmaceutical industry business model. Additionally, the pharmaceutical industry is noted for wanting to have its influence on every step of the research process, a source of control often resented by researchers, themselves. Given these circumstances, there has been a tense relationship between the stem cell research community and the pharmaceutical industry. Though on the surface the pharmaceutical industry is in the business of providing treatment, it is not so eager to seek these treatments from advances in stem cell research.

Despite the lackluster enthusiasm that the pharmaceutical industry has shown to stem cell research, the relationship would intuitively seem to be a

¹⁹ As Forbes reported in 2006, for quite some time, large pharmaceutical companies like Pfizer and Merck distanced themselves from the stem cell field. Fearful of the regulatory environment, big Pharma was willing to let smaller biotech companies invest and realize the potential of the research (Dolan, 2006). In these early years, small biotech companies were nimble enough to invest in "high risk, high reward" research, or research that is highly cutting-edge but can yield great return. Of these small biotech companies, Geron, Novartis, and Osiris led the way.

beneficial one, and there is ample reason to believe that the pharmaceutical industry might want to support the advancement of this work. One of the most immediate, yet often unmentioned applications of human embryonic stem cells lies in their ability to become cellular media upon which to test the safety and efficacy of new drugs. For instance, setbacks often occur in pharmacological research when compounds are moved from animal testing to human testing, as animals have a very different biochemistry (Munro, 2009). The cost of these setbacks can be extremely high, especially when drugs are close to being marketed or, even worse, already on the market. The classic example is the financial and human catastrophe caused by Merck's Vioxx, which was withdrawn from the market after claims of a risk of heart attack and stroke associated with the medication. Differentiating human embryonic stem cells into cellular media on which to test drugs without use in humans can greatly improve the safety of these drugs and can improve the quality of drugs tested. Pharmaceutical companies like Pfizer, GlaxoSmithKline, and Merck have seen the potential that lies in this application, and have begun to move on it by establishing alliances with research institutions and becoming more visible in research conferences. In World Polity terms, one would expect to see an industry as powerful and influential as the pharmaceutical industry enter the stem cell field. When science is looked at as a vehicle to build a "knowledge economy", industry's role in this development is critical.

Pfizer has a webpage devoted entirely to the benefits that stem cell research might have on the pharmaceutical industry and where it provides its "stem cell research policy", including a multi-statement declaration of its interest in and use of stem cells in pharmacological research²⁰. What is of interest in these policy statements from Pfizer is that they emphasize the ethical complexity of stem cell research above other forms of research. Indeed, Pfizer's policy on stem cell research joins just seven other issues on which the Corporation has

²⁰ Pfizer makes the following claims:

- Pfizer recognizes the enormous potential of stem cell research. Stem cells are important tools for modern biomedical research, including Pfizer's search for innovative new medicines.
- Pfizer has made in significant investments in animal stem cells and in human adult hematopoietic stem cells. The company will continue to invest in these stem cell technologies.
- Pfizer recognizes that human embryonic stem cells may provide even greater potential to their increased ability for self-renewal and capacity to form a wide variety of cells and tissues.
- Pfizer acknowledges the sensitive issues raised by this research, and we support proper ethical safeguards that take into account both the moral issues and public sensitivities.
- Pfizer will only engage in stem cell research projects that meet the highest ethical standards set by leading scientific authorities around the world, including the guidelines developed by the National Academy Of Sciences in the USA.
- Pfizer strongly opposes any efforts to clone human beings. (Pfizer, 2011)

developed policy statements²¹.

As Pfizer has written, “Pfizer scientists, like most medical researchers, have reason to believe technologies using stem cells have great potential to contribute to the development of new medicines and therapies. It is also likely that the need to source these stem cells from human embryos will be obviated by new technologies. Pfizer has sought to balance the respect for human life and the imperative to cure disease by establishing a reasonable policy on the ethical use of stem cells in clinical research” (Pfizer, 2009). As the Corporation indicates, since its R&D facilities lie in the US and the UK, Pfizer's policies “most closely track the regulatory requirements in the US and UK”. That Pfizer has an R&D facility in the UK speaks to the fact that it may have sought environments that were particularly welcoming to biomedical research. However, as Pfizer has acknowledged, as of 2001, though the UK policy was permissive of human embryonic stem cell research, and the US policy only placed restrictions on research that was federally funded and not privately funded, Pfizer chose not to conduct research on human embryonic stem cells. However, in 2007, Pfizer changed course, citing “compelling” evidence that human embryonic stem cell research was a very valuable avenue of scientific investigation, and wanted to collaborate with academic, biotechnological, and pharmaceutical entities around the world that were engaging in this research. To this end, Pfizer stated that it needed to ensure that the research was held to the highest ethical standards. In an interesting, though surely not widely discussed, step taken by Pfizer in 2007, the Corporation announced that it would “adhere to the research guidelines on ethically-derived stem cells established by the National Institutes of Health and the National Academy of Sciences. Pfizer scientists would not create or use new stem cell lines”²² (Pfizer, 2009).

²¹ The issues on which Pfizer has developed policy statements include: treatment use and compassionate use, compensation to human research subjects in clinical studies, compensation to investigators in clinical trials, global standards for interventional clinical studies, public disclosure and authorship, use of human tissue, and guidelines and policy in laboratory animal care.

²² In 2008, Pfizer announced the initiation of Pfizer Regenerative Medicine, a new research unit focusing on stem cells to develop future treatments, repair organs, and treat degenerative diseases. Located in both Cambridge, UK and Cambridge, Massachusetts, the new research unit marked a significant change from the policy held by Pfizer seven years earlier. Under this new regenerative medicine research unit, Pfizer declared that its operating regulations would comply with US standards rather than UK standards, as US standards were more restrictive. As Pfizer stated, “Pfizer does not conduct stem cell research anywhere in the world that would not be permitted in the US” (Pfizer, 2009). With this in mind, Pfizer has argued that its research regulations meet the highest ethical standards. Of the recommended standards Pfizer has stated:

All institutions conducting HES cell research should establish an Embryonic Stem Cell Research Oversight (ESCRO) committee to assess which regulations apply to the proposed research, and to review research proposals and ensure inappropriate research is not conducted and sensitive research is well reviewed the ESCRO committees should review research based on three categories:

GlaxoSmithKline (GSK) has issued a similar public policy document about “cloning technologies and stem cell research”. GSK has been more forthright in its position on the utilization of stem cell research as a therapeutic and research technology. While noting some of the same concerns that have surrounded human embryonic stem cell research in the social domain, GSK states that it is, “committed to working with governments to support appropriate legislation or regulation that addresses concerns while allowing research to continue so the full potential of cloning technologies and stem cell research can be realized. An all-embracing ban on “human cloning” must be avoided. Any ban should be specifically restricted to the ‘cloning of entire human beings’, otherwise there is a real danger of inhibiting research into currently untreatable or incurable diseases and medical conditions” (GSK, 2011).

Compared to Pfizer, GSK seems to have adopted a position that is much more in alignment with World Polity Theory, namely that experts have an important advisory role to play when it comes to matters of policy. GSK has offered recommendations regarding the future of cloning technologies, claiming that those who are most involved in and aware of the complexity of scientific research are the best suited to create policy around it. However, it is arguable that members of the pharmaceutical industry are not simply succumbing to policy that is beyond their control, policy that would otherwise undermine their work. As Field Theory might suggest, the pharmaceutical industry is particularly adept at navigating political and legislative circles, almost never succumbing to a policy it does not desire, and this is where the pharmaceutical industry has been most critically influential in the stem cell debate.

Given the benefit that stem cell research holds for the pharmaceutical industry, it stands to reason that the industry would have a significant influence on the stem cell research debate. This is especially the case, given the pharmaceutical industry's legendary influence on legislators in the United States. The pharmaceutical lobby goes by the acronym, PhRMA, or Pharmaceutical Research and Manufacturers Of America²³. As PhRMA describes, the

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- *Research is permissible after notifying ESCRO communities that it involves human embryonic stem cells that are pre-existing*
 - *Research is only permissible after additional review when research requires the creation of new stem cell lines or the introduction of human embryonic stem cells into nonhuman animals*
 - *Research is not permissible if it involves embryos that have developed longer than 14 days, if it introduces human embryonic stem cells into nonhuman primate blastocysts, then. Introduces HES cells into human blastocysts, or if it allows the breeding of animals introduced with human embryonic stem cells.*

These overall guidelines resemble the crux of the regulations governing human embryonic stem cell research in the US.

²³ PhRMA was founded in 1958, however in its most recent iteration, has been in existence since 1994 (PhRMA, 2011). The organization is headquartered in Washington DC, and acts as a representative of the leading pharmaceutical and biotechnological companies in the US. PhRMA represents several hundred biotechnology and pharmaceutical companies, including such big

organization is a conglomerate of entities, “devoted to inventing medicines that allow patients to live longer, healthier, and more productive lives”. According to PhRMA, the biopharmaceutical industry has demonstrated five general trends over the past 25 years, including an increased complexity in the research and development process, continued investment in R&D, increased use of medicines in healthcare, increased value for patients, and continued importance of patent incentives for integrative medicine. The stated purpose of the organization is to “conduct effective advocacy for public policies that encourage discovery of important new medicines for patients by pharmaceutical and biotechnology research companies” (PhRMA, 2011). PhRMA represents a formidable and structured entity through which the pharmaceutical industry can hone and disseminate its message at the legislative level, in a manner similar to the USCCB.

In an effort to meet its mission, PhRMA has focused on three central goals:

- Broad patient access to safe and effective medicines through a free market, without price controls;
- Strong intellectual property incentives;
- Transparent, efficient regulation and a free flow of information to patients.

PhRMA discusses a list of issues that it considers important to the pharmaceutical industry. It is under the issue, “FDA”, that PhRMA touches upon anything related to the stem cell research debate. In this issue description the organization argues that it is only in an open scientific and developmental environment that the greatest strides in medical and pharmaceutical research can be made, and that a commitment to such an environment ought to be a national priority. As PhRMA states, “the optimal regulatory environment needed to transform this promise [of new biopharmaceuticals and personalized medicine] into a reality has its foundation in a few key principles: science-based decision-making, innovation, collaboration, transparency, and accountability.” (PhRMA, 2011). Implicit within this statement is that the organization works to encourage the FDA and legislators to establish a research environment that is pro-science and a set of regulations that are based on scientific evidence.²⁴

names as Amgen, Bristol-Myers Squibb, Eli Lilly, GSK, Johnson & Johnson, Merck, and Pfizer. Collectively, these companies and corporations provide over 674,000 jobs, as of 2009, and have supported another near 3.5 million jobs throughout the economy.

²⁴ PhRMA has issued media releases on some 80+ topics in the biopharmaceutical world, including press releases on such things as cancer treatments, treatment disparities across nations, patent reform, and healthcare spending. Nowhere among the listed media releases is there any relating to stem cell research. Similarly, in a list of “fact sheets and policy papers”, offering policy positions on such areas as infectious disease, new drug approvals, and treatment for rare diseases, there is no policy statement on stem cell research. Finally, and perhaps most curiously, PhRMA issued a report on the evolution of research and development in the pharmaceutical industry, and why current development requires as much effort and time as it does. In this publication, PhRMA itemizes scientific advances that have facilitated progress in the industry. The organization states, “For the first time in history, scientists are beginning to

The pharmaceutical industry has been triangulated between the potential benefits that embryonic stem cell research holds for the pharmaceutical industry, the moralistic tone of the public discourse perpetuated by entities like the Catholic Church, and the uncertain regulatory environment for this research, and has, at times, tried to play all sides of this issue. Given the uncertain status of the pharmaceutical industry on the stem cell issue, instead of taking a strong position on any particular perspective, the industry has taken none, at least not publicly other than statements on their websites. In many respects, it is interesting that the pharmaceutical industry has been largely absent from the stem cell research debate, given that advances in the stem cell field might benefit this industry before any other. While several individual pharmaceutical companies have documented the benefits of embryonic stem cell research to their field, there has been little coordinated effort made by the industry as a whole to influence a protracted, contentious debate. While such actors as the scientific community, the Catholic Church, and patient advocacy groups have come to define the state of the debate, the pharmaceutical industry has not taken a leading role nor has it attempted to actively alter public opinion. This is despite the fact that, of the major social actors in this debate, industry plays a particularly influential role – perhaps the most influential role in the US. This does not imply that this industry has been altogether removed from the debate, but that it has not been highly present or visible.

It is quite possible that the pharmaceutical industry attempted to influence the stem cell research debate in a way that was removed from the public eye, and using more “political” channels to influence policymaking. In fact, the pharmaceutical industry has a long history of demonstrating great comfort in enacting change through legislative means. As the Center for Public Integrity and the Center for Responsive Politics report, the pharmaceutical manufacturing industry gave a total of \$6,383,285 in campaign contributions in the 2000 election cycle, when the stem cell issue was beginning to gain traction. Of this total, 73% went to Republicans and 26% went to Democrats. Of the legislators who received contributions in the House of Representatives, 190 were Republicans and 147 were Democrats²⁵. Of the Senators who received donations, 36 were

understand the inner workings of human disease at the molecular level. Recent advances in genomics, a Proteomics, and computational power present new ways to understand illness” (PhRMA, 2007). Interestingly, there is no mention of stem cells as a therapeutic or research development that can aid the industry.

²⁵ Center for Public Integrity reported that two of the historically biggest supporters of human embryonic stem cell research on Capitol Hill, Sen. Arlen Specter and Sen. Tom Harkin, received hundreds of thousands of dollars in campaign contributions from political action committees and individuals in the pharmaceutical and biotech industries (Center for Public Integrity, 2008). Additionally, notable stem cell research supporter, Sen. Orrin Hatch, as the Center for Public Integrity reports, was the top recipient of campaign contributions from the pharmaceutical and biotech industries, receiving a total of \$337,870 in the 2000 election cycle. These contributions came from a mix of Pfizer (\$33,000), PhRMA (\$18,775), and HealthSouth Corporation (\$38,255). In a similar vein, the Center for Public Integrity reports that former Sen. Bill Frist received \$161,873 in campaign contributions from pharmaceutical and biotech companies between 1995 and 2000, as Sen. Frist was a “practicing physician” who had performed more than 200 heart and

Democrats. As the stem cell issue has more traditionally been understood as a “Democratic” rather than “Republican” issue, it does not appear that the pharmaceutical industry has made overt attempts at aligning itself with Democratic legislators.

Evidence indicates that the pharmaceutical industry shows no hesitation in engaging in matters of policy and going to considerable lengths to make its influence known. With such data in hand, it is unclear how committed the pharmaceutical industry was, in reality, throughout the course of the stem cell research debate and subsequent policymaking. Some have been even a bit more cynical. For instance, “Islets of Hope”, an advocacy organization for diabetes research, issued an article entitled, “Stem Cell Policy Debate In the United States”, discussing the early years of the debate in the US. When discussing the role of private industry, the organization posed the following argument: pharmaceutical companies and biotech, in the early days of the stem cell debate, expressed little interest in moving the issue forward because they may have considered therapies based on genetically tailored cells to be less profitable than one-size-fits-all drugs (Islets of Hope). This echoes the same concerns offered by others who claim that potential therapies growing out of stem cell research do not fit the pharmaceutical industry's business model.

One could conceivably make the argument that, since the Bush administration stem cell restrictions applied only to research conducted with public funds and not research conducted by private industry, that pharmaceutical companies did not feel especially pressured to wade into the waters of this debate. To clarify, it is possible that, since pharmaceutical companies conduct their research with nongovernmental funds, they were not especially interested in those restrictions that did not affect privately-funded research. In such a set of circumstances, it might be unsurprising that the pharmaceutical industry might not have needed to play a particularly prominent role in this debate. However, in biomedical and pharmaceutical research, the lines of public versus private

lung transplants.

It is these “stem cell supporters” who the Center for Public Integrity suggests received a greater amount in campaign contributions than did research opponents, such as Sen. Brownback, Rep. Weldon, former Rep. DeLay, and former Rep. Armev. What is noteworthy about this claim made by the Center for Public Integrity is that, of the legislators who are mentioned, all except Sen. Harkin are or were members of the Republican Party. In fact, as the Center, itself, acknowledges, Sen. Frist, who received nearly \$162,000 in contributions from the pharmaceutical industry, only favored stem cell research in “a limited way”. Interestingly, one of the top recipients of campaign contributions from the pharmaceutical industry was Pres. George W. Bush, who received over \$1.5 million from the industry. Additionally, the numbers that the Center cites largely come from data derived prior to 2001, or in other words, prior to the point at which the Bush administration issued its restrictions and prior to the need for congressional action on the issue. This suggests that, while some noted stem cell research supporters in Congress may have received more in the way of campaign contributions from the pharmaceutical and biotech industries, it may have been for a reason wholly separate from the stem cell question.

research dollars are not so easily drawn, and thus the nature of the debate is not so easily defined.²⁶

The pharmaceutical industry lobby is, almost without dissent, the strongest and most influential on Capitol Hill. This fact has been the case for quite a number of years, and has been widely acknowledged in the media. As the Center for Public Integrity reported in 2005, the pharmaceutical and health products industry spent over \$800 million in federal lobbying and campaign donations at the federal and state levels between the years 1998 and 2005 (Ismail, 2005). In short, no other industry has spent more money in an effort to influence public policy and legislators than the pharmaceutical industry, as its combined political outlays on lobbying and campaign contributions are only exceeded by the insurance industry. What the pharmaceutical industry received in return for these sizable sums was quite astronomical, as well.

Were the pharmaceutical industry nearly as committed to the stem cell research cause as some members have suggested, it is likely that regulations would have been relaxed. Were the pharmaceutical industry lobbying on behalf of this research to any degree similar to its lobbying efforts on other issues, like the Medicare Modernization Act of 2003 or the Affordable Health Care Act of 2009, the story in the US would surely have been quite different. The reason for this ostensible lack of commitment can only be conjectured. It is possible that, as some have suggested, the pharmaceutical industry does not feel that regenerative and personalized medicine is within its economic interest, and therefore do not see the necessity in supporting it.

When looking at stem cell research from a Field Theory perspective, it is arguable that the pharmaceutical industry has had the single biggest impact on the research's policy and progression. What makes this so interesting is the way the industry went about securing this position. While many proponents of and opponents to human embryonic stem cell research have been outwardly vocal in

²⁶ According to a 2011 report issued by Battelle, the R&D pipeline for the biopharmaceutical sector is the product of a mix of private capital investment, venture capital investments, and public and private collaborations (Battelle, 2011). To be sure, the US government contributes more money to the development of new drugs than any other government in the world, and these contributions are in the form of tax breaks and subsidies to pharmaceutical companies (Ismail, 2005). What is more, the scientists who are in the pipeline to become researchers at pharmaceutical companies gain their training in the academic setting, which relies on a public support and governmental funding. To be sure, many PhD students and postdocs studying embryonic stem cell research receive support from government agencies, including the NIH, the NSF, the Department of Energy, and others. The federal government is, in fact, the biggest supporter and funder of postdoctoral researchers. As the National Science Foundation demonstrated in a recent study, of the 1939 doctoral recipients in the life sciences in 2008, 27.7% had commitments to enter into private industry or business for their professional career (NSF, 2008). These data indicate that government funding for embryonic stem cell research, and the public policy that surrounds any research restrictions, have a very real and immediate effect on the future of the pharmaceutical industry.

their opinion, this tactic may have had only a limited effect in the ultimate policy decisions. This is the case because, in the United States, these tactics have a similarly limited effect in the political field. The pharmaceutical industry did not need to engage in these efforts for several important reasons. First, it was within the industry's interest to appear supportive of scientific research, so as to maintain the pipeline of future scientists entering to their laboratories. For this reason, individual members of the pharmaceutical community have expressed mild support for stem cell research legislation. Second, though, the pharmaceutical industry could not offer strong or unequivocal support, lest it appear to be behaving in an "unethical" manner.

In relation to other social actors in the stem cell debate, why has the pharmaceutical industry remained so apparently passive? There are several ways to approach such a question. To start, there is some degree of opportunity cost in implementing efforts to influence a matter of public policy. No doubt, there are many public policy matters in which the US pharmaceutical industry involves itself, sometimes at great expense. However, given the regulatory uncertainty that has historically surrounded the stem cell research question, it is possible that this proved to be too big an undertaking for the industry to willingly take on. Instead, members of PhRMA could have chosen to focus their attention on more certain and less controversial issues.

The likelihood of this particular scenario, however, is reduced by looking at some of the other issues that the pharmaceutical industry has willingly taken on, issues that are no less controversial and certainly come with a great deal of cost. It stands to reason that, were the pharmaceutical industry to find some more immediate benefit in this research, it would have more actively engaged in its advancement. This is where arguments like those posed by many in the stem cell community come to the fore.

To be sure, particularly of late, the pharmaceutical industry has begun to engage in stem cell research, developing collaborations with research institutions in the US. For instance, over the past few years, Pfizer has moved its headquarters to Cambridge, Massachusetts, home of research being conducted at MIT and the Whitehead Institute, among others. Similarly, GlaxoSmithKline has established an alliance with the Harvard Stem Cell Institute, where some of the most advanced stem cell work is taking place. However, engaging in these types of activities places little demand on pharmaceutical companies to alter their operations. Rather, it keeps the onus on members of the scientific community to advance this work. As yet, the industry in the US has made little effort to reorganize itself so that it is more amenable to the advances of this work, a business model that supports personalized medicine. It is possibly because of this set of circumstances, particularly a field of research that the pharmaceutical industry in the US does not envision itself taking part in, that it has remained on the periphery of this issue.

When it comes to the stem cell question, the pharmaceutical industry has found itself in a difficult position. From the point of view of its public image,

though this image is only given limited credibility, the pharmaceutical industry is in the business of treating disease and illness. To whatever extent US citizens give authority to the pharmaceutical industry as the source of immediate medical remedies, the stronger its position is. However, this is complicated by the desire to, in a capitalist and, some may persuasively argue corporatist, society, maximize profits. How these corporations are able to navigate questionable political and social environments has a direct impact on their financial bottom line, as well as their public representation. In the present investigation, there is a pronounced disconnect between the pharmaceutical industry's ability to present itself as a source of medical treatment, maximizing its financial bottom line, and advancing stem cell research. These three concepts cannot fit together for the pharmaceutical industry, as advancing stem cell research cuts into the established pharmaceutical industry business model. For this reason, the pharmaceutical industry has had to be very skillful in how it has operated throughout the stem cell debate. To its own advantage, the pharmaceutical industry is particularly adept at navigating these very types of issues, namely presenting itself in the most favorable light in complex social circumstances, and this is precisely how it has operated in this debate.

Were it not the case that embryonic stem cell research were so vehemently and vocally opposed by the Catholic Church and others, the circumstances might have been very different for the pharmaceutical industry. However, in an environment wherein the Doxa was being established by the Catholic Church on the issue of life, the pharmaceutical industry, a much more powerful social actor than the Catholic Church, could easily present itself as nothing more than a player in a set of conditions on which it had no control. Essentially, the pharmaceutical industry has presented itself as quite similar to the scientific community, adhering to a public discourse, which it could not influence. This was done despite the fact that, of all players in this debate, the pharmaceutical industry likely has the most significant ability to influence policy on a very practical level. The established social debate and attempts to create a social Doxa, quite conveniently, gave the pharmaceutical industry something behind which it could hide, misrepresenting a true position of opposition to the research as hamstrung but “ethical” support for the research. In this case, the social Doxa has been used as a tool for the gain of a social actor that is highly skilled in deception and political influence.

PATIENT ADVOCACY GROUPS

The patient advocacy community might be new to the political field, yet in the relatively short time that it has operated within it, members of this social group have sharpened their skills considerably. One of the most visible and memorable patient advocates who worked to advance the stem cell issue, particularly shortly following the Bush administration decision, was actor and director, Christopher Reeve. Nearly immediately following his paralyzing horse riding accident in 1995, even while he was still in rehabilitation, Reeve began to

use his celebrity and situation to increase public awareness around spinal cord injury research, and then stem cell research (Christopher Reeve Homepage, 2011). Reeve, shortly after his accident, took to the public speaking and media circuit, for instance a widely acclaimed and viewed 2002 interview with Barbara Walters, to emphasize the need for research funding. More significantly, Reeve began to lobby the government and members of the NIH to increase the research budget. Finally, partnering with philanthropist, Joan Irvine Smith, Reeve founded the Reeve-Irvine Research Center in California to conduct cutting-edge biomedical research. Pursuant to his lobbying and advocacy efforts, Reeve stated, “it is one thing to present legislators with statistics, but quite another to make them face real people who testify at Congressional hearings or speak out in the media” (Christopher Reeve Homepage).

Reeve’s work fundamentally changed the way people who might benefit from the advances in biomedical research could help perpetuate the future of this research. Following Bush’s decision, Reeve stated, “my message to the president would be to rethink his position in light of the fact that there is overwhelming popular support [for stem cell research]. I think he really needs to look again at this position and to reevaluate it.” With Reeve’s death in 2004, though, the patient advocacy movement in the US has not diminished, and in some ways, it has grown by virtue of the path he forged.

From a sociological standpoint, the responsibility and role that have been taken on by members of the patient advocacy community is quite noteworthy. What members of the patient advocacy community are seeking is a means to develop a measurable voice for themselves and establish a stake in a debate that, though directly affecting their lives, is often taking place in circles beyond their capacity to influence. However, the methods by which patient advocates have attempted to achieve this goal are diverse, forcing them to create collaborations that they may not have had in the past, and engage in activities typically relegated to the political field.

At present, there are no fewer than several hundred patient advocacy groups that have worked to influence the stem cell debate or stem cell legislation. Many of these groups have collaborated to form the Coalition for The Advancement of Medical Research (CAMR), which describes itself as, “the nation’s leading bipartisan pro-cures coalition... comprised of more than 100 nationally recognized patient organizations, universities, scientific societies, and foundations advocating for the advancement of breakthrough research and technologies in the field of medical and health research” (Coalition for the Advancement of Medical Research, 2011). Primarily, this organization focuses its attention on advocating for stem cell research and somatic cell nuclear transfer, which they believe will have a direct impact on the lives of those in the representative groups²⁷.

²⁷ An organization like CAMR has aided the patient advocacy movement in the US, and in so doing, the stem cell research question, by acting as a voice on Capitol Hill, speaking to influential

The collaborative efforts of these nonprofit groups reflect some of the fundamental arguments found in Meyer's World Polity Theory. According to this line of thought, when governments fail to enact or adhere to policies that bring about a social good, nonprofit organizations and NGOs step in to either provide services or call attention to policy failures. From this perspective, networks of patient advocacy groups have banded together, in an effort to rectify or compensate for the gap created by the US' challenges in stem cell policy.

In a manner that is similar to the Catholic Church's lobbying and policy-influencing strategies, CAMR has its own "advocacy" strategies that involve: a list of reports and documents about stem cell research basics and the nature of research funding, public polls gauging levels of support for stem cell research, a portal from which interested advocates can contact their federal and state legislators, text of and information about stem cell-related bills in Congress, relevant action being taken at the state level, and links to outside organizations that are involved in stem cell research. To the extent that an organization like CAMR attempts to influence public opinion, it has issued press releases on legislative and legal action taken on the stem cell question.

CAMR has as its slogan, "dedicated to advancing stem cell research", a mission that is nearly unprecedented for a collection of civilians, as throughout much of recent US history, the importance of biomedical research and the quest for cures were reliably supported by the federal government. In the instance of stem cell research, however, an important avenue of biomedical research has been rejected by the funding arms of the US government, initiating a mobilization and advocacy response not heretofore seen.²⁸

There are hundreds of patient advocacy groups in the US that have attempted to influence or have contributed to the stem cell debate, and these include patient groups for Parkinson's, cancer, spinal cord injury, diabetes, neurological disorders, spinal muscular atrophy, and many other chronic

legislators, and involving themselves in a media campaign. as many patient advocacy groups fall under the category of "501(c)(3) nonprofit organizations", and are thereby restricted in the amount of lobbying they are able to do, CAMR, essentially, is a collaborative entity that can do the lobbying for them. While most of the comprising organizations have some variability in the degree of public educational services they provide, lobbying must be kept to a minimum.

²⁸ Many of the component groups of CAMR conduct their own advocacy efforts, as well. For instance, the ALS Association has an advocacy center comprised of tips on how to become an advocate, a list of legislative priorities that members of the ALS community ought to care about—like protection of Medicare and Social Security, and the need for greater funds to promote research, and a calendar of upcoming "advocacy days". In a very similar fashion, the Missouri Coalition For Lifesaving Cures, another member group of CAMR, has an advocacy center which involves grassroots mobilization efforts, sign up portals for "action alerts" regarding legislative efforts and strategies to influence these efforts, and initiatives for writing letters to the editor in local Missouri newspapers to express support for stem cell research (Missouri Coalition for Lifesaving Cures, 2011).

conditions. Some of these groups work within communities dedicated to their own disease and related circles, while others have formed inter-state or inter-disease collaborations. Many of these organizations sought the advice of stem cell experts to draft information with which to arm advocates, whether these advocates were working to affect public policy or public opinion. For instance, the patient advocacy group, Unite 2 Fight Paralysis, has an “advocacy toolkit” comprised of information provided by healthcare lobbyists, lawyers, and researchers, to provide nearly anyone with the basic skills necessary to become an effective advocate. As the Unite 2 Fight Paralysis Advocacy Toolkit states, “a pro-lobbyist’s insider knowledge and political relationships are invaluable, but they aren’t as compelling as the sincerity of someone who is personally affected” (Unite 2 Fight Paralysis, 2011). Within this same document, the organization has provided several “elevator speeches” to use to lobby legislators or inform reporters. Of the importance of stem cell research, Unite 2 Fight Paralysis offers, “we need to pursue all forms of stem cell research because we don’t yet know how any of these therapies will work in human beings. If we stop any avenue of research, we will lose critical time in the effort to cure serious injuries and disease.” (Unite 2 Fight Paralysis).

It is here that the impact of the patient advocacy movement in the US has been so influential, particularly from a Field Theory perspective. Since the first days of the stem cell debate in the US, when President Bush took to the airwaves and announced his policy decision, the debate was set in terms of “slippery slope”, unfettered scientific investigation, and most significantly, life. Public opinion soon mirrored the idea that this research pressed unethical boundaries, put human beings at risk, and was fundamentally demeaning to a “culture of life”. In Field Theory terms, when a social actor has limited resources at its disposal, limited ways to act as a rationalized other, one of its best possibilities for creating an influence is to work to change the boundaries of the argument. This is precisely what the patient advocacy movement has done, by working to reframe the stem cell argument into one of cures rather than one of fear.²⁹

The research advocacy group, Research!America has been particularly aggressive in coordinating a comprehensive and effective message among the researchers, the public, members of Congress, and the media. In what is an extensive advocacy initiative, which includes information specific to general audiences: the public, members of the research community, scientists, and members of the media, Research!America has provided information to nearly any interested party. For members of the public, Research!America has provided a series of fact sheets about the benefits of research to the economy and global health, information about funding agencies at the federal level, public opinion and polling data about levels of support for research, and how the investments made

²⁹ This is not to argue that every patient advocacy supports this research in similar ways or at all. In fact, there is no shortage of patient advocacy groups who reject the notion of having to be “cured” of anything at all, and would much rather see resources directed to quality of life matters.

in research translate into better health. These tools can be used by the advocacy community to sway legislators.

For all intents and purposes, the patient advocacy community is a grassroots movement, different from the instantiated hierarchy of the Catholic Church, different from the institutionalization of the scientific community, and different from the skilled political player of the pharmaceutical industry. As the patient advocacy community is unlike many other social actors and works with a different skill set, the methods by which it has sought to influence the social debate are, likewise, very different. For instance, while some patient advocacy groups have attempted to assert their influence through meeting directly with legislators, others have taken a different tactic, like issuing collections of policy recommendations and positions for legislators to review independently.

For instance, the large and influential Juvenile Diabetes Research Foundation (JDRF) has created a position paper for members of its community to use for advocacy purposes, and in this document, they include a position stating, “JDRF’s scientific position is aligned with that of leading stem cell scientists, prominent research organizations, and Nobel Laureates: research should be vigorously pursued on all promising stem cell sources.” (JDRF, 2011).³⁰ What makes these circumstances noteworthy is that, there have been many instances of patient advocates working to bring attention to the conditions they face or the need for increased research dollars. In the fight to influence stem cell research, however, activists have had to fight for the very legality of the research they hope will have an effect on their condition.³¹

The extent of the efforts of patient advocates has been vast and multidimensional. While many advocates have taken to legislators’ offices with personal stories of struggle with illness or disability, others have had the opportunity to testify before either a congressional committee or even the entire Congress. For instance, in 1999, speaking before a U.S. House of Representatives subcommittee about NIH funding, activist Christopher Reeve

³⁰ Patient advocates from JDRF have similarly testified before Congress on the importance of research, have provided its supporters with advocacy portals like social media and mass texting opportunities, the creation of “Type I Talk” events, and the creation of a Government Relations Newsletter to inform supporters of the actions being taken by legislators in Washington DC. All of these strategies have been put into place as a means to mobilize the many individuals suffering from diseases and conditions in an effective and coherent way, so as to have an impact on the policy that is created.

³¹ In essence, the patient advocacy community in the stem cell research debate has had to act as its own lobbyists, interacting with legislators and public policy in ways that they may not have before. . In some ways, the patient advocacy movement for stem cell research in the United States has mirrored the advocacy work conducted by the LGBT community in the early years of the HIV/AIDS epidemic, with those possibly formerly unfamiliar with the legislative or lobbying process, essentially, thrown into the halls of Congress, fighting for needed research and even a rights

stated, “we live in a time when the words ‘impossible’ and ‘unsolvable’ are no longer part of the scientific community's vocabulary. Each day we move closer to trials that will not just minimize the symptoms of disease and injury, but eliminate them” (Christopher Reeve Homepage, 2011). Reeve continued by stating, “Without your support, spinal cord victims will continue to sit in wheelchairs draining the resources of insurance companies as well as Medicaid, Medicare, V.A. Hospitals and nursing homes; but with your continued support, it is very possible that within the next three to five years people who are now afflicted with a wide variety of disabilities will be able to overcome them. They will regain their rightful place in society to rejoin the work force and at last be relieved of the suffering they and their families have had to endure. So the plea for adequate funding cannot be ignored.”

The efforts taken by the patient advocacy community, however, have not been restricted to advocacy, itself, but also have involved grassroots mobilization and even scientific feats. Some of the most notable among these were the efforts taken by the California real estate mogul, Robert Klein. Klein, father of a son battling juvenile diabetes, was one of the driving forces behind the development and passage of California's Proposition 71, a \$3 billion stem cell research initiative in California.³² Passed in November, 2004, California's Proposition 71, “California Stem Cell Research And Cures Act” was designed to be a response to Bush's 2001 federal restrictions on stem cell research. While credit for this initiative ought to be shared among several patient advocates in addition to Klein, like Hollywood producer Jeff Zucker and spinal cord injury research activist, Don Reed, Klein has largely been given the credit for the passage of this legislative initiative accomplished in a time of questionable economic certainty and attention given to matters of national security.³³

³² California's Proposition 71 was proposed and put on the electoral ballot in California, November 2, 2004, as a means to secure public funding for cutting-edge stem cell research (California Polytechnic State University, 2011). While the Bush administration's restrictions on research applied only to federal funds issued by the NIH, the restrictions were silent on the legality of the research, in general, and on what individual states could fund using their own public dollars. California, through Proposition 71, was the first and biggest state to move on this issue. Of the nearly 12,000,000 voters in California in 2004, 59.1% voted in favor of the ballot measure, and 40.9% voted against. The proposition created a public funding stream, of about \$256 million per year for 10 years, to be spent on embryonic and adult stem cell research in California, and to support the infrastructure of advanced medical research facilities throughout the state. Specifically, the bill called for several key provisions, including: the establishment of the “California Institute For Regenerative Medicine” (CIRM) to regulate stem cell research and provide funding through grants and loans for research and research facilities; the establishment of a constitutional right for California to conduct stem cell research while prohibiting human reproductive cloning; the establishment of an oversight committee to govern the Institute; the provision of up to \$3 million placed in a general fund for administrative and implementation costs; the authorization of general obligation bonds to finance the initiative and costs up to \$3 billion; the appropriation of monies from the general fund to pay for bonds.

³³ While not all of CIRM has been completely successful, with challenges in California courts over the Institute and the research more generally, the passage of Proposition 71 sparked a shift in attitudes about how important scientific research could be funded. While the US federal

Following the success of Proposition 71, several other states have taken it upon themselves to fund stem cell research, states including New York's Empire State Stem Cell Board, efforts in Connecticut, Massachusetts, Maryland, and Illinois to fund the research without a specific governmental agency or entity, and efforts to determine the legality of the research in Missouri and Michigan. While some US states, like Oklahoma, Alabama, and Louisiana, have prohibited the research altogether, success in other states is in no small part the result of advocacy movements. For instance, the 2006 and 2010 legislative efforts, in Missouri and Michigan, respectively, to criminalize human embryonic stem cell research were thwarted by the work of organizations like Missouri Coalition for Lifesaving Cures and Michigan Citizens for Stem Cell Research and Cures.

An additional impact that the advocacy community has had on embryonic stem cell research, though not necessarily from a policy standpoint, has been the direct support these organizations have given to the research, itself. Many major patient advocacy organizations, like JDRF, the Michael J Fox Foundation, and the Christopher and Dana Reeve Paralysis Foundation have an endowment that is extensive enough to fund stem cell research projects using their private philanthropic funds. For example, as the JDRF accounts, in fiscal year 2008 alone, it funded nearly \$5 million in human embryonic stem cell research grants to researchers conducting diabetes research. Similarly, several smaller organizations have supported the efforts by making direct donations to the labs of stem cell researchers. Each of these has been founded by patient advocates, themselves, looking to make a difference in the stem cell debate and context.

Finally, in an increasingly significant feat, a select few patient advocates have taken it upon themselves to create a veritable research safe haven wherein to conduct their own stem cell research in the quest for cures to diseases. Notably, in 2005, patient advocate, Susan Solomon, whose son faces juvenile diabetes, cofounded the New York Stem Cell Foundation (NYSCF), whose mission is "to accelerate cures for the major diseases of our time through stem cell research" (NYSCF, 2011). Through its extensive connections and financing, NYSCF has created its own stem cell research laboratory, collaborating with a broad network of researchers at premier academic institutions, providing for these researchers a privately funded laboratory in which to conduct their work outside of governmental restrictions. NYSCF also has an extensive postdoctoral Fellowship program, internship program, and series of conferences to foster a new generation of stem cells scientists.

Critical collaborations have been forged not simply between diverse patient advocacy nonprofits, but also between these nonprofits and the

government remains the biggest funder of scientific research and has the capacity to coordinate projects across state borders, Proposition 71 made a clear statement that the States could also make a valuable contribution to this research. Many of these state initiatives have been the result of grassroots work done by local patient advocates.

researchers who conduct the stem cell work. In fact, in some ways, this collaboration has been a necessary one, as the scientific community, alone, has struggled in defining the terms of this debate. At the heart of stem cell science is the drive to pursue medical treatments and cures. Were this message to ring hollow for those suffering from disease, there would be essentially no traction gained by scientists advocating for funds to pursue this work. Similarly, as the institution of science relays its message through channels not appreciated by many in the general public, patient advocates provide an additional medium through which to reach a broader audience. These two actors have melded to establish a multidimensional voice in this multidimensional debate.

From the start of the stem cell debate in the US, attempts to define the social Doxa and details of the argument were set in terms of respecting “embryonic life” and the need to protect the supernumerary embryos on which the research was to be conducted. Otherwise stated the terms of the stem cell debate in the US are the product of the pronounced influence of such social conservatives as the Catholic Church. Were the debate not characterized by such ideas, it is quite possible that members of the patient advocacy community would not have felt such a pressing need to take part in its evolution. In other words, if the stem cell debate in the US were not focused on the question of life or protecting embryos, and instead were more legitimately focused on advancing science, the patient advocacy community in the US may never have felt the need to enter or contribute to this debate. In this way, the social Doxa and nature of the discourse has had an immediate effect on which social actors have felt the need to influence it.

The role that the patient advocacy community has played in the stem cell question in the US is to reorient the issue and reframe it in terms of a pursuit of medical cures. Rather than center the question on respect for life for the human embryo, the patient advocacy community has sought to center it on respect for life for the *patient*. In essence, it has been the need of patient and disease advocates to reclaim the issue, to take ownership over an idea that has been claimed by a wholly separate social entity. To a significant degree, members of the patient advocacy community have felt as though this issue has been “robbed” or undermined, and it is only through advocacy efforts that it can be reclaimed.

This position, in turn, is not an outlandish one. For many within the patient advocacy community, the prevailing sentiment has been that the lives of the patients have been pitted against the life of the embryo. While “the embryo” had its advocate or fiduciary in the hierarchy of the Catholic Church, the patients needed to serve as their own. The advocacy done by this social group, then, was a direct attempt to shift the balance in favor of medical advancement.

What have also been interesting are the alliances that members of the patient advocacy community have forged with otherwise unlikely groups. First, many prominent patient advocates have established close relationships with scientists and researchers conducting stem cell research, in an effort to educate themselves and to help fund or promote the work they do. In other

circumstances, it might be quite unlikely that patients and scientists would ever find themselves in similar circles. Next, patient advocates have sought out the assistance of lobbyists and political insiders, in an effort to better communicate their message locally or on Capitol Hill. In this way, this social group has directly infused itself into the inner workings of the political process. And, in addition, some members of the advocacy community have developed deep and close relationships with legislators, themselves, who might be particularly sympathetic to this cause. This alliance serves as an important countervailing force to the relationships struck between the Catholic Church and legislators, and the pharmaceutical industry and legislators. Finally, through their common concern for the advancement of medical research, many patient advocacy groups have forged alliances with one another, creating a network of similarly-minded advocates whose collective impact on the issue is that much greater.

The effect of the patient advocacy movement on the stem cell issue is not a modest one. However, it may never have taken place at all, were the social landscape not so heavily dominated by the ideas and influence of the Catholic Church. As a result, the composition of the US field has been the direct result of the controversy in the field.

DISCUSSION

Taken on face value, the case of human embryonic stem cell research in the United States is among the most baffling and unpredictable. The United States is a case, however, of how science policy evolves in a domain of science that might not be viewed as contributing to the knowledge economy. Stem cell research in the US, particularly under the Bush administration, has been prioritized as a moralistic question rather than a scientific question, and as a result, does not fall neatly into some of the expectations found in theories of the sociology of science. The US is home to a stem cell research policy that has been characterized by restriction and is the product of a broad array of social actors. Prominent sociological theories of science, however, provide a clearer framework to understand how the US has arrived at this policy outcome. Both World Polity Theory and Sociology of Scientific Knowledge join the explanatory power of Field Theory in providing a comprehensive approach to analyzing cases like stem cell research in the United States.

World Polity Theory argues for a status of science that is instrumental in policymaking, with national governments desiring “knowledge” as the basis of a growing economy. As WPT is built on the interconnectivity generated by globalization, it is the common actors in diverse contexts that establish these connections and influence policy in similar ways. The networks of scientists and scholars that WPT predicts have lied at the heart of stem cell research's expansion in the US, from a scientific point of view. Collaborations across scientists in diverse locations have been made possible through the channels that only a highly institutionalized field like science can offer, channels that run

through journals, conferences, and the institutionalized system of credentials that move researchers through field ranks. It has been through this level of connectivity that a field so young by scientific standards has advanced so quickly and gained such notoriety that breakthroughs take place on a regular basis, in any one of hundreds of stem cell research institutions across the country. This network and infrastructure has been the backbone upon which the field has been built.

To the extent that the institution of stem cell research has had policy influence, WPT has also had much to offer. During the limitations imposed by the Bush administration, the economic and intellectual loss that was taking place as a result of the federal policy failure was being felt on governments at the state level. The establishment of state-based policies like those seen in California, New York, Wisconsin, Massachusetts, and Illinois reflect the very type of progressive policies built on knowledge economies that are predicted by World Polity Theory. To emphasize this idea, the stem cell policies put into place by state governments in the US, with few exceptions, resemble one another, with none desiring to put into place a backwards policy in relation to its counterparts, lest it be left behind. In an effort to establish comparable policy environments, and in a way that brings WPT into focus, many of these state programs build their policies both on the input from stem cell scientists, themselves, as well as legitimized scientific organizations like the NAS and ISSCR, which give credibility to the policies.

Finally, World Polity Theory accurately represents some of the impact that unexpected groups, like patient advocacy organizations, have had on the stem cell issue. Specifically, the ways in which nonprofit organizations have delved into the stem cell policy matter and have sought to rectify policy failures represent some of the fundamental argumentation in WPT. Working around the shortcomings of the US policy, patient advocacy nonprofits have built a formidable network, calling attention to the divide between the role of the government and the services it has been failing to provide. In this way, how the institution of stem cell research has grown in the US draws upon the most defining features of Meyer's World Polity Theory.

To the extent that science, including stem cell research in the US, is also a product of context, Sociology of Scientific Knowledge plays an essential explanatory role. SSK theorists, like Shapin and others, argue that the knowledge brought about by science is necessarily social, often bound by the context in which it is created. As the stem cell field has developed in the United States, this argument has been keenly brought to light. The social dynamics that were put into place in the final years of the 20th century, driven by a desire to adhere to conservative values, gave strength to a socially conservative movement that pitted science against religion in many prominent debates, and created an environment not wholly welcoming of scientific advancement. There was no clearer example of this growing sentiment than the election of George W. Bush to presidential office in 2000 and 2004, putting into place a commander-in-chief who

had a nearly tangible effect on the types of research permitted, and the funds allocated to this research. The conservative ideology of President Bush served to augment the voices of stem cell research opponents who found an ally in the White House.

The social context in which stem cell research in the United States has experienced its development has, in very real ways, impacted the knowledge that has been created in the field, true to SSK theory. The most visible example of this idea lies in advances made in induced pluripotent stem cell (IPS) research. In an effort to develop ways around the restrictions imposed by the Bush administration, leading stem cell scientists discovered methods by which to “reprogram” fully-developed somatic cells, and return them to an embryonic-like state on which to research. Advances in IPS and cellular reprogramming, though still not fully understood, have fundamentally changed the stem cell field, and were a product of the social environment in which this research was taking place. Finally, given the landscape in which stem cell research has been operating in the US, with continual questions about the research's acceptance, the production of scientific knowledge has been altered by precisely who chooses to enter the field. The questionable funds directed to this research, and the potential risk of engaging in illicit activity should legislation change, has prompted largely the highly committed and strong-of-heart to enter the field. What is interesting is that this demographic of researchers has created a field built on tenacity and dedication, with researchers continually looking for ways around complex problems.

As illuminating as World Polity Theory and Sociology of Scientific Knowledge have been to the progression of stem cell research in the United States, they do not capture all of its complexity. The emphasis that WPT places on science as a “rationalized other” serving to guide policy decisions creates a disconnect with how stem cell research has evolved. The scientific community exists as one of several social institutions that have played a role in the creation of stem cell research policy in the US, and how the scientific community has operated is as much a reflection of its own institutionalized status as it is a response to its relationship to others. In addition, according to WPT thought, the rationalizing and economically-beneficial aspects of science ought to encourage modern societies and policymakers to embrace rationalistic principles over primitive ones. This, according to WPT, ought to especially be the case for countries, like the US, that have resources to direct toward scientific inquiry. The US, especially under the Bush administration, has failed to live up to this prediction, and chose a policy based on moralistic principles rather than scientific principles.

However, when it comes to science more generally, the United States does not necessarily represent a context that chooses traditional beliefs over modern beliefs. Science, in general, is broadly supported in the US, and the culture of restriction appears not to apply categorically as a means to define the epistemic culture that SSK might expect, but has been confined to the stem cell

matter most particularly. Further, the boundary work that is so central to establishing epistemic authority, and is likewise central to SSK, has been so porous in the stem cell question that it has been looked at as much as an issue of religion and ethics as it has been looked at as an issue of science. These circumstances pose challenges to the prominent theories on the sociology of science, but call to mind some of the arguments found in Field Theory.

These two sociological frameworks, WPT and SSK, offer valuable insights into how stem cell research has evolved in the United States, and were it not for these analytical approaches, broader explanations for events seemingly peculiar to the US might be missed. However, as the analysis of actors involved in the US stem cell debate highlight, when it comes to the creation of policy that has regulated this research, Field Theory serves as a critical additional perspective from which to view the issue. While additional actors could have been included in this overall analysis, the Catholic Church, scientific community, pharmaceutical industry, and patient advocacy community interact to create an elaborate picture of how this social question has developed, not only as it relates to policy but also in a more complex multidimensional space.

Bourdieu offers a model of how actors operating in a field can be visualized, and according to this model, actors in the United States' stem cell debate can be demonstrated in the following way:

United States



Doxa based on the culture of life

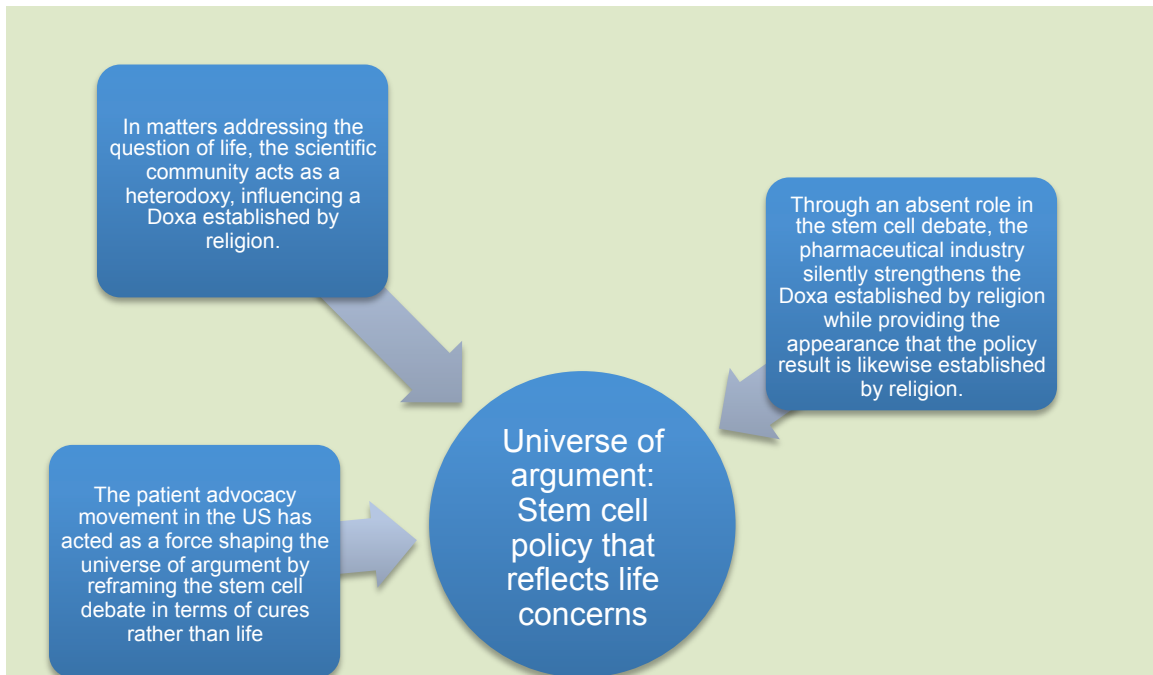


Figure 1: Field Theory Diagram of US Stem Cell Policy

In the US stem cell debate, there is a constellation of actors vying for the ability to access and influence capital in the form of epistemic authority. The quest for epistemic authority, particularly between religion and science, has been at the heart of the US case, as the Catholic Church has experienced a steady decline across the population but maintains a profound political structure to affect policy. A restrictive stem cell policy like that found in the US violates predictions of WPT that emphasize the support for scientific expansion. However, this policy outcome can also be looked at from a Field Theory perspective, which looks at policy outcomes as a product of social interactions that work in conjunction with the institution of science. As a result, the actors of the Catholic Church, the scientific community, the pharmaceutical industry, and patient advocacy groups respond to and compete with one another to arrive at a policy outcome.

In the US, the antagonistic, or the *Doxic* and *Heterodoxic*, relationship between the Catholic Church and the scientific community speaks to their mutual effort to claim rights to the epistemic questions that embryonic stem cell research touches upon. The source of capital that results from this question lies in the resolution of positions of epistemic authority, which both actors seek. From the Catholic Church's point of view, as has been represented in the words of Pope John Paul II and the language of the Bush policy, there is the protection of a "culture of life" which is under threat from a field of scientific research that equally claims rights to this complex question. An institution like religion might feel as though its own position of authority is at risk, given the advances that science has made in the field of embryonic research, which joins its diminishing relevance in US society. It is rare that a religious institution could have such a prominent impact on any scientific question, especially when the religion's position is at odds with that of the scientific community, and when the religion's social influence is on a decline. What has been to the Church's advantage is that the stem cell question has been, to a large extent, negotiated in the political field: a field in which it has a great deal of experience and savvy.

It is because of the close and collusive relationship that the Catholic Church had with the Bush administration and its network of lobbyists that it has been able to instantiate its message and promote its opinion as the dominant one. As a result, all other voices in this issue must be viewed in light of the dominant position that the Church has held. In defining its ownership over a question that is scientific in nature, the scientific community has had to oppose the authority that the Church has claimed over the issue of life. When challenging an institution like the Catholic Church on the stem cell research question, however, it is more than simply a battle over epistemic territory, as SSK theorist, Gieryn, might suggest. Instead, as this issue has been decided in largely political circles, it has been the scientific community's ability to navigate these channels that has been put up against a skilled and long-standing USCCB. It is here that even a respected and credible institution like the scientific community has fallen short, at least at the federal level.

As an established and institutionalized entity, the scientific community may well have been unused to presenting and discussing scientific issues in terms separate from science. This may have created a surprise for members of the scientific community, and may have left stem cell researchers in a position of unexpected uncertainty in the early days of the question. What is more, embryonic stem cell research has represented an instance of new ground for scientific exploration, the very kind of shift in scientific thinking that is wrought with stops and starts, wrong turns and dead ends—the very types of challenges that are characteristic of an expanding scientific landscape. It was just as this scientific landscape was beginning to be explored that a strong light was cast on it. The attention that was placed on stem cell research forced some researchers to make uncertain claims and put unrealistic timelines on their work. Failures to meet these arguably unreasonable projections and timelines have allowed research opponents like the Catholic Church and conservative Christians to call into question the credibility of this research, forcing an unusual interplay between the declarations of the science community and the ways these declarations have been used to others' advantage. Both of these conditions carry through to this day, such that members of the scientific community continue to have to contextualize the science in terms favorable to the Catholic Church, forcing a counterfactual rather than dominant position.

The fact that the stem cell issue has been negotiated in the political field has been particularly advantageous for an actor like the pharmaceutical industry, which, not unlike the Catholic Church, is very skilled at navigating these channels. In fact, among the variety of industries in the US, there is essentially no other that is as adept at navigating the political field as has been the pharmaceutical industry, with its extensive lobbying network and financial capital. Despite the skill set with which the pharmaceutical industry enters the political field, it has influenced the stem cell debate in a way that reflects its relationship to other actors involved and the capital it pursues

One might expect the pharmaceutical industry to have a collusive relationship with the scientific community, serving as allies to promote research that would aid in creating medical treatments. However, as has been demonstrated, the pharmaceutical industry, despite its political influence, has remained largely removed from the dynamics of the US stem cell debate, adhering to the ethical considerations established by entities like the Catholic Church rather than attempting to influence the restrictions that have resulted because of these considerations. In Bourdieusian Field Theory terms, the pharmaceutical industry has adhered to the Doxa supposedly established by the Catholic Church, thereby acting as an orthodoxy, rather than attempting to alter this, acting as a heterodoxy similar to the scientific community. This veritable silence could be interpreted in one of several ways. First, it could be the case that the pharmaceutical industry has removed itself from a visible position in the stem cell debate because, given the challenges directed toward the field by actors like the Catholic Church and others, stem cell research is a victim of an uncertain fate, and the industry would rather direct its attention to fields of

biomedical research that are less questionable. In this case, the pharmaceutical industry could be seen as simply operating within a social discourse or *Doxa* commanded by another entity. Evidence for this interpretation can be found in corporations like Pfizer paying homage to the ethical considerations that actors like the Catholic Church have addressed. Second, it could be the case that the pharmaceutical industry is more than simply playing by a set of social rules created by the Catholic Church but, instead, supports research limitations for some other reason. Some experts in the stem cell field have suggested that one of these reasons might be that, in order to reap the benefits of this research, pharmaceutical companies would have to enact undesired changes in their business model. In this case, at minimum, the pharmaceutical industry would be uninterested in aligning with the scientific community to advance the field, as such advancements would not necessarily be in its financial interest, despite some avenues of research that might prove helpful to drug testing. Evidence for this interpretation can be found in the very same claims made on pharmaceutical companies' websites. To clarify, research conducted by the pharmaceutical industry is privately funded, and thereby largely outside of the restrictions imposed by federal stem cell policies, as these policies affect research that is funded by the government. Without the need to follow federal stem cell guidelines, the pharmaceutical industry has no reason to address the federal policy at all, whether on their websites or anywhere else. Their decision to make an acknowledgment of the ethical concerns found in the federal policy bolsters the credibility of these concerns. It is from this perspective that the pharmaceutical industry, whether purposefully or accidentally, is working in conjunction with research opponents like the Catholic Church to solidify the terms of a social *Doxa*.

Within the multidimensional space of the political field in the stem cell research debate, the *heterodoxy* is, however, comprised of more than just one force, and were this not the case, the stem cell debate may have collapsed upon itself long ago. If the stem cell research community were alone in challenging a *Doxa* that has been created by the Catholic Church and bolstered by the formidable pharmaceutical industry, it may easily have been overrun, despite the credibility that is afforded to science as predicted by World Polity Theory. Instead, the *heterodoxy* that has challenged the terms of the debate is a composite of the institution of science working in collaboration with the growing strength of the patient advocacy movement, and these two actors have influenced the field in different but equally important ways. Responding to the "culture of life" terms that institutions like the Catholic Church and conservative Christians have established, the patient advocacy movement has resorted to one of the most valuable tools at its disposal: changing the terms of the social debate, and reframing the argument in terms of the quest for cures. To emphasize precisely how intimately the scientific community and patient advocates have joined forces to challenge the existing *Doxa*, patient advocacy groups like Project ALS, The New York Stem Cell Foundation, Unite 2 Fight Paralysis, and the Juvenile Diabetes Research Foundation have scientific advisory committees that are comprised of scientists like stem cell researchers, so that they can speak

with a collaborative voice. If this issue were looked at from a perspective of division of epistemic authority, there could merely be a struggle between religion and science. But, the multidimensional nature of a political field allows for, and even necessitates, the inclusion of an actor like the advocacy community. This actor has influenced the field by shifting the terms of the debate and adding strength to the position of the scientific community.

When the US case of stem cell research is looked at from a Field Theory perspective, in addition to analyses from WPT and SSK, we are left with a much clearer picture of how the research has developed. Drori and Meyer offer insights into the rapid expansion of this scientific area, through networks and vast exchanges of information, and how state governments have crafted policies to build this research to their own economic benefit. Shapin and Latour give explanatory frameworks to understand how the scientific environment in the US has shaped advances in the field, and even who enters into it. Field theory, however, presents a multidimensional framework to understand how the stem cell policy in the US has been dominated by a “culture of life”. This perspective has been put into place by the position of the Catholic Church and Christian conservatives, and has been augmented by the Orthodoxic inactivity of the pharmaceutical industry. The political field is rounded out by the heterodox created by collaborations between the scientific community and patient advocates who are gaining skills in navigating political channels.

CHAPTER 4: THE UK
SCIENCE AS EXPERTISE

CHAPTER 4: THE UK-SCIENCE AS EXPERTISE

This chapter explores stem cell research policy in the UK. As the US case has demonstrated, the authority and autonomy afforded to science are not universally applied in some democratic social contexts, especially when the scientific question at hand involves many epistemic questions. When viewed in relation to a country like the US, the UK appears to allow expertise to play a role that is relatively more independent of external constraints and influences. This focus on the autonomy of experts, especially in the stem cell research question, has fostered the translation of expertise into authority. Among the cases evaluated in this analysis, the UK is perhaps the most emblematic of World Polity Theory, both from a scientific and economic standpoint. However, Britain's social history and context have also figured very prominently in its stem cell policymaking, calling to mind some of the principles of the Sociology of Scientific Knowledge. These two sociological frameworks provide valuable means to analyze different components of the stem cell research question, and taken with Field Theory, provide a broad understanding of how the UK stem cell policy has evolved.

The unique scientific history found in the UK has made it fertile ground for the advancement of embryology and fertility research. This cultural context has come to affect the interactions among important actors in the stem cell debate, and has altered the epistemic environment so that important collaborations could be established among these actors. The UK case brings to light how an environment that favors science in the stem cell debate, can foster new interests and possibilities to shape the public discourse. This chapter begins with a retelling of how important actors have operated in this context. The discussion closes this chapter by investigating how WPT, SSK, and Field Theory are manifest through these interactions and in this particular environment.

In May of 2002, then-Prime Minister, Tony Blair, made a policy speech about the state of science in the UK. In this speech, Blair discussed his vision for stem cell research in the UK. In this speech, Blair said:

Nowhere in the world has what one might call a community of stem cell experts yet - the science is too new. But Britain starts with a strong reputation in developmental biology and a number of institutes with worldwide reputations. I want to make the UK the best place in the world for this research, so in time our scientists, together with those we are attracting from overseas, can develop new therapies to tackle brain and spinal cord repair, Alzheimer's disease and other degenerative diseases, such as Parkinson's. (Blair, May 23, 2002)

In the early days of the stem cell research, despite—or maybe because of—the US' imposed limitations, the British government under Tony Blair was ready to stake its international claim on this research. Such a claim, however, could not be so easily made, were it not for a set of cultural and historical circumstances already in existence in Britain that allowed for a quicker acceptance of complex

biomedical research. The commitment that the UK made to the field of fertility and embryology made it a prime location for the development of stem cell policy.

UK POLICY

In 1990, in response to breakthroughs in the field of embryology, the UK Parliament passed the Human Fertilization and Embryology Act, designed to be a set of regulations for the newly developing research involving human embryos. This fundamental piece of legislation affected three distinct areas of embryonic research, including the licensing of fertility treatments that involved the donation of genetic material, the storage of human gametes and embryos, and any scientific research conducted thereon. It was by virtue of the Human Fertilization and Embryology Act Of 1990 that the British government created the Human Fertilization and Embryology Authority (HFEA), whose primary responsibility was to oversee and regulate all research involving human embryos, and to address the ethical concerns that surrounded the research.³⁴

The HFEA specifies under what conditions embryonic research ought to be permitted to take place, and these include efforts to promote the understanding of infertility, to increase knowledge of congenital disease, to increase knowledge of miscarriage, and to develop more effective contraceptive techniques (Hauskeller). The HFEA also issued a report, called Cloning Issues In Reproduction, Science, and Medicine, published in 1998, which made the important distinction between therapeutic cloning, also known as somatic cell nuclear transfer (SCNT) and cloning for reproductive purposes. While the former was being pursued as a potentially fruitful means to create embryos on which to

³⁴ The HFEA emerged out of work that was started in the 1970s and 80s, which established the groundwork that in vitro fertilization was built upon. This research was gaining traction in the UK, above all other countries. Following the birth of the first “test tube”, or IVF, baby in Britain in 1978, critical ethical questions were being posed by British society about the origins of life and science’s growing ability to influence it. In response to these questions, the British government established the Committee of Inquiry into Human Fertilization and Embryology, a committee chaired by Mary Warnock (Hauskeller,2004), to address the ethical questions arising from this scientific achievement and the research that would follow. The report issued by the committee in 1984 argued that the human embryo was deserving of respect, but that research on embryos and IVF technologies would be permitted, given the establishment of appropriate safeguards (HFEA, 2011). This guiding principle would come to provide the basis for all other embryonic research legislation in Britain. As was proposed in the Warnock report, HFEA became a regulatory agency in Britain in 1990, to establish a separate institution responsible for the oversight of embryonic research. This agency was the first of its kind seen anywhere in the world is, and marked the establishment of a non-departmental public body that would oversee the creation of embryos for treatment and research, the use of donated gametes and embryos, and the storage of these biological materials. What is noteworthy is that, among the early important accomplishments of this institution was the acknowledgment of the unique moral status of the human embryo, a moral status that superseded animal or cadaveric tissue but did not have the full moral status of a human being.

conduct research, the latter was expressly banned.³⁵

While the HFEA was initially designed to oversee fertility and embryonic research, the establishment of this public Authority would come to be a tremendous benefit to future research unpredicted at the time, namely embryonic stem cell research. The existence and structure of the HFEA was an asset to Britain's future work and policymaking in the embryonic stem cell field. This public authority was characterized by its commitment to public transparency, its nimble nature, and its readiness to address new bioethical questions as they arose on the research horizon.

The HFEA brought the issue of fertility and reproduction into full public view, along with the ethical questions they introduced. To this end, the British government solicited input to address ethical quandaries found in this work. For example, the Warnock Report, which was issued to support the creation of HFEA, made the critical argument that the human embryo was deserving of respect, but that embryonic research technologies ought to be permitted. This central argument was pivotal to future stem cell policy making in Britain. At the time of the first derivation of human embryonic stem cells in 1998, British society had already spent years grappling with the moral questions of embryonic research. In a way that was considerably different from the US approach, the British government addressed this policy question from a utilitarian, *public good* ethical perspective, rather than the moral questions it raised. This guiding philosophical perspective was part of British culture long before human embryonic stem cell research became such a broadly contested social question.

The degree to which policymakers in Britain rely on expert testimony is prevalent in the dynamics of the stem cell debate. In order to disentangle ethical questions found in embryonic stem cell research, a team of British experts issued a report, entitled Stem Cell Research: Medical Progress with Responsibility, also commonly referred to as "The Donaldson Report"³⁶, which argued that this new

³⁵ HFEA a regulatory committee with the charge of reviewing information about embryos utilized in treatment services, publicizing fertility services provided to the public, providing advice and information to individuals seeking treatment or providing embryos and gametes for others, and performing other tasks that might be necessary in embryo research (Department Of Health, 1990). As the UK government writes in regard to the HFEA, " its purposes are those of increasing knowledge about the development of embryos, or about serious disease, and enabling knowledge can be applied" (Legislation.gov.UK, 2011). Other important initiatives undertaken by the HFEA included the prohibition of implantation of research embryos, and the similar prohibition of research on embryos 14-days or more following fertilization.

³⁶ The British Donaldson Report, issued in 2000 and crafted by chief medical officer, Liam Donaldson (Richards, 2000), recommended that research using human embryos should be allowed to move forward in Britain and to provide the greatest number of avenues for exploration of the therapeutic potential of stem cells. The Donaldson Report used the HFEA as its basis, and sought to determine which human embryos could legitimately be used for research under this act. The Donaldson Report Re-stipulated the guidelines and provisions that had been itemized in the 1990 Human Fertilization and Embryology Act. Most pressing among these were:

1. Research on human embryos is to be limited to 14 days post fertilization.

field of biomedical science, human embryonic stem cell research, presented no new ethical questions that the British government and research community had not taken into consideration during debates on IVF years before. In many respects, the Warnock Report and the Donaldson Report go hand in hand in establishing the current British policy for embryonic stem cell research. (Appendix 10)

The recommendations of the Warnock Report and Donaldson Report, and the creation of the HFEA, have enjoyed extensive governmental support. For instance, in 2002, the House of Lords' Select Committee on Stem Cell Research wrote of the British regulatory environment, "the linchpin of the system is the HFEA. Its work is highly regarded, both at home and abroad. It appeared from the evidence we received that it has the full confidence of the scientific and medical research community, and we believe that it has also been instrumental in reassuring the public that regulation in a particularly emotive area of public policy is carried out effectively and sensitively." (The Committee on Stem Cell Research, 2002)³⁷

As some argued, despite the ethical questions that had already been addressed, a new challenge was presented in technologies that went beyond the scope of the existing HFEA, specifically nuclear transfer technology, which some believed was a precursor to human reproductive cloning. The question of the ethical challenges of therapeutic cloning was beginning to take shape in the late 1990s, following the work of Ian Wilmut, who successfully used this technique to clone a sheep. It was argued by some, and feared among many, that this

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2. Research could be permitted on supernumerary IVF embryos, as well as stem cells derived from nuclear transfer, or therapeutic cloning, given its distinction from reproductive cloning.
 3. Research would be permitted only after the pursuit of a license from the HFEA.

³⁷ The British government acted on the recommendations of the Committee on Stem Cell Research, and presented its assessment in a report issued in July of 2002. In its response, the British government acknowledged the years of work and policymaking surrounding the embryonic research question, work that began with the Warnock report of the early 1980s and continued throughout the 1990s with the Human Fertilization and Embryology Authority. The response then continued with the announcement of expanding the regulations of the HFEA to include oversight of embryonic stem cell research, a measure passed by both houses of government, making this research a continuation of already-permissible embryonic research conducted in Britain.

The British Department of Health stated decisively in their own published response to the Donaldson Report, "The Government accepts the Report's recommendations in full and will bring forward legislation where necessary to implement them as soon as the parliamentary timetable allows" (Department of Health, 2000).

The British government's response also acknowledged the social controversy, yet scientific importance, of SCNT. The government states, "We believe that CNR (SCNT) may provide researchers with a powerful means of making progress when studying the fundamental processes of cell development. The government is satisfied that embryo research that used CNR is covered by the 1990 Act, a position endorsed by the Court of Appeal in January 2002" (Department of Health, 2002).

technology would be used to clone human beings. This fear generated debate regarding the necessity of this technology to create embryos for research, and whether this would pave the way for greater ethical questions in the future.³⁸

As Member of Parliament, Ann Winterton argued in a parliamentary debate, “if we accept therapeutic cloning now, it will lead on to reproductive cloning later.” Whereas in other countries it was hESC research that presented controversy, in Britain the debate encircled the linkage between this research and somatic cell nuclear transfer. In an effort to address some of the most pressing questions regarding the ethics of SCNT, the British Parliament sought the input of field experts, including scientists in the Royal Society, The Medical Research Council, The Wellcome Trust, The Roslin Institute, and the Nuffield Council on Bioethics.

In 2005, the research landscape changed when Chancellor of the Exchequer, Gordon Brown, announced the creation of the UK Stem Cell Initiative (UKSCI), which was designed to be a 10 year strategic plan for the development of stem cell research infrastructure in the UK, including ways to address the UK’s strengths, weaknesses, opportunities and threats.³⁹

³⁸ Britain's Center for Bioethics and Human Dignity released a fairly scathing critique on the Donaldson Report and the recommendations therein, particularly as it pertained to the permissibility of SCNT as a means to obtain human embryonic stem cells. In their response, entitled “Cloning and Stem Cell Research: Wrong Motives on Both Sides of the Atlantic”, the Center stated, “Those Who Support the Donaldson report, as well as many who favor human embryonic stem cell research in the US, have succumbed to the utilitarian drive to maximize the ends without considering the means” (O'Mathuna, 2002). In response to an argument such as this involving a means versus ends controversy, drafters of the Donaldson Report countered that the creation of embryos for research purposes always results in embryos as means to a subsequent end, and in order for SCNT to be prohibited, it must raise ethical questions above and beyond those that have already been socially addressed. The drafters of the Donaldson Report addressed the SCNT question head on, providing a strong counter to the objections raised by some British bioethicists. As the original, 1990 version of the Human Fertilization and Embryology Act made no mention of embryos created through SCNT or parthenogenesis, adjustments had to be made to account for this. In 2002, the HFEA was amended to become the licensing body for all embryo research in the UK, including research on embryos that had been created through processes other than fertilization (Hauskeller, 2004). This amendment, then, included embryos created for the purposes of embryonic stem cell research, embryos created through SCNT, and embryos created through parthenogenesis. The HFEA could then regulate therapeutic cloning, as well as initiatives that were designed to increase knowledge about embryonic development, increase knowledge of disease, or enable future knowledge of treatments for disease.

³⁹ The UK Stem Cell Initiative (UKSCI) had as its purpose to create a 10 year budgetary and strategic plan for stem cell research in the UK. With a mindfulness to the lack of coordination and faltering stem cell policy in the US, this initiative was designed to provide benchmarks and goals for research in Britain, with an emphasis on establishing public and private partnerships, and ensuring viable research funding streams (Department Of Health, 2005). In a report drafted by then-Chancellor, and future Prime Minister, Gordon Brown, the state of stem cell research in the UK was evaluated with the aim of preserving the strengths of the research while remedying the weaknesses. Although it is a governmental agency, UKSCI is staffed by some of the leading experts in research, including Prof. Julia Goodfellow, the chief executive of Biotechnology and

Following this report, while still serving as Prime Minister, Tony Blair visited California in an attempt to entice US researchers to collaborate with their British colleagues. In particular Blair met with various biotechnology companies in the San Francisco area in an attempt to develop a UK-California stem cell cooperation (Hinsliff, 2006). The regulatory environment in the US was apparently providing the UK with opportunities to hone its policies and establish a competitive research edge.⁴⁰

For years, the HFEA has served the British stem cell community well, and the public support for this agency has been considerable. However, a challenge arose when, in 2010, the British government announced plans to dissolve the HFEA, and other “arms length bodies” (ALBs), by June of 2015.⁴¹ As a report issued by the Department of Health states, “over the next four years, the government is committed to reducing NHS (National Health Services) administrative costs by more than 45% and to simplifying and reducing radically the number of NHS bodies, including the department's arms length bodies” (Department of Health, 2010). While the authority and operations of the HFEA were not eliminated, nor deemed unnecessary, the British government proposed “that [the HFEA] will remain as an independent arms length body in the short term, with the aim that their functions will be transferred by the end of the current Parliament”.

Biological Sciences Research Council, Diana Graham, chief executive of the Association of Medical Research Charities, Sir Christopher Evans of the UK Stem Cell Foundation, Dr. Peter Mountford, chief executive of Stem Cell Science UK, and Sir Keith Peters of the Academy of Medical Sciences. The UKSCI report begins by acknowledging the duration and extent of scientific research, particularly the avenues of scientific research designed to bring about medical therapies. The UKSCI report recommended that the British government continue funding all levels of stem cell research, and that this expenditure over 10 years would amount to approximately £50 million To £100 million per year. THE report cited strengths and weaknesses of the existing UK stem cell environment, and of the weaknesses, the report referenced the need for diversity in sources of research funding. Also included among the list of weaknesses facing the UK stem cell field was the need for translational research, the demand for venture capital and returns on investment, the need for big pharmaceutical investments, a smaller science base than what exists in the US, and lack of centralized coordination across science centers, and the lack of basic innovations to the US for commercialization. The UK Stem Cell Initiative operates according to The Code of Practice for the Use of Human Stem Cell Lines, which according to the UK Stem Cell Bank, offers detailed information on ethical oversight for UK research in this field. These guidelines were most recently updated in April of 2010 and focus not only on embryonic stem cells but adult stem cells and IPS cells, as well.

⁴⁰ During the Bush administration, there was a great deal of talk among researchers and policymakers that the Bush restrictions would generate a mass exodus of US researchers to other parts of the world, like the UK, where a more favorable research environment could be found. While there were a few notable cases of researcher migration, by and large, this was not the case.

⁴¹ In Britain, an ALB is an independent national organization that undertakes executive functions under the auspices of the Department of Health (Ogbogu, 2010). According to a report issued by the British Department of Health, there was a comprehensive review of existing “arms length bodies”, and the announcement to dissolve the HFEA was an effort to streamline these agencies

The streamlining of the bureaucratic agencies in Britain's NHS has been cause for some concern, particularly as it bears upon the HFEA. The HFEA remains one of the biggest, if not the biggest, success stories for British regulatory agencies. Stem cell research advocates saw this change as a potential harbinger for future changes in policy resulting from the economic downturn, with the potential to affect the historically welcoming stem cell research environment that the UK created. It might be that, although for different reasons, the UK might begin to experience some of the same challenges that US researchers have encountered.

The British government based its stem cell policy on the input given from experts in the stem cell field, who included writers of the Warnock and Donaldson Reports. This is characteristic of the British approach to policymaking, which is often predicated on information exchange and bodies of recommendations. This reliance on experts, or “rationalized others”, gives the British stem cell policy a WPT orientation, yet the influence of experts in the British case also has an effect on other actors, as well. How British social groups and actors have interacted with one another to arrive at a national stem cell policy, then, is a product of WPT and SSK working in conjunction with Field Theory.

UK ACTORS

CLASS IN BRITISH SOCIETY

When it comes to assessing questions in British society, any analysis would be incomplete without an inclusion of social class. This is especially the case for a Field Theory analysis, as Bourdieu was centrally interested in cultural symbols and structures as a product of class differentiation. Though his views evolved throughout his intellectual career, Bourdieu theorized under the premise that cultural productions are likewise productions of positions within the social structure, and how these influence access to economic and social capital. Of the factors affecting one's position in the social structure, class and socioeconomic status are critical (Gartmann, 2011). There might not be any society more keenly attuned to class structure than the UK.

In the context of social inequality, Bourdieu argued that different classes are endowed with different proportions of economic and cultural capital, with members of the upper, or “professional” class enjoying a dominant position in a social space. Members of this class have the ability to oppress or oppose members of the lower classes, in a cascading fashion. Members of the working classes must rely on cultural, as opposed to economic, sources of capital, as a means of social identification. The class structure implicit in society, then, generates very different interests for different social groups, and these interests present themselves in the negotiation of social questions. As stem cell research grows in social significance, its relation to British society is as much a function of the class structure as it is a function of more formal actors operating in their own

fields. When it comes to the stem cell question, different social classes no doubt have a different set of interests and concerns that influence their position in the social field.

The stem cell debate can be cut along many social lines, and the concerns based on class position are only starting to be brought to light. In 2011, the British Market Research Bureau (BMRB), the Biotechnology and Biological Sciences Research Council (BBSRC), the Medical Research Council (MRC), and the Sciencewise Program published a report on a series of workshops and stakeholder interviews about the issues surrounding stem cell research. Though “social class” was not an itemized outcome measure in this comprehensive report, several of its findings have a great deal of relevance to concerns based on a social class framework.

In general, funding for human embryonic stem cell research in Britain enjoys widespread support. By many accounts, about 70% of British citizens support this research and the UK's strong presence in the field. The extensive support for stem cell research funding in the UK likely does cut across socioeconomic lines, as the diseases and conditions for which stem cell research might provide a cure also cut across socioeconomic lines. The classification of “seriousness of the disease”, which is the primary criterion by which British citizens have prioritized which diseases ought to command the greatest research attention, is a characteristic of disease irrespective of class. For this reason, it seems unlikely that there is a class component to stem cell research support in the UK. This is not, however, without some reservation, and there are concerns to be drawn along class lines.

As a result of the economic downturn of the first decade of the 21st century, austerity measures and government cutbacks have become an increasing concern. This is especially the case in European countries that rely on Keynesian economics to underlie governmental support for many social services. It is these services that members of the working class depend upon, and which may be at risk through reallocation of governmental funds. As a result, members of the working class might be more concerned with securing these goods and services than providing funds to new research that may or may not ever affect their lives.

In a similar vein, there has been concern expressed by some that funds directed to human embryonic stem cell research deny funds directed to the broader British health care system, the NHS. For those who have fewer resources to spend on healthcare costs, the security of the public health system is critical, and there might be less concern over biomedical research than there is concern for basic healthcare provisions. This, too, presents itself as a class-based concern (BMRB, 2011). Finally, as with many other areas of medical research, there is concern for distributive justice in the outcome of stem cell advancement. In Britain perhaps more than anywhere, the utilitarian social perspective places concern on ensuring that people of differing socioeconomic backgrounds have equal access to medical treatments that emerge out of stem

cell science: treatments that will, no doubt, be costly. There has been a feeling of uncertainty that medical breakthroughs might disproportionately favor those of considerable economic means.

Nevertheless, according to many, the outcomes of science are viewed as important social goods, which, especially in the UK, take precedence over more provincial concerns. With these factors in mind, the stem cell research debate incorporates the positions and interests of powerful social actors. However in Britain more than anywhere else, the issue might take on a socioeconomic dimension, as well. Public concerns about stem cell research, as itemized in various reports, include an economic framing that lays the groundwork for similar concerns in other countries.

CATHOLIC CHURCH

With an estimated 71% of British citizens considering themselves Christian, nominally speaking, the UK can be viewed as a “Christian nation” (Barrow, 2007). However, such an assertion masks a more complex and secularly-oriented understanding that British citizens have of religion in social life. The meaning and role of Christianity in the UK is different than those found in many other countries around the world, and this begins with the relationship between religion and the State in the UK. The Church of England, a Christian Church and the largest church in the UK, is an institution of the State.⁴²

The British monarch is referred to as, “the defender of the faith”. Despite the strength of the Church of England as an institution under the leadership of the British monarch, the role of religion in British life is significantly less pronounced than it is in countries like the US. Since 1983, the British National Center for Social Research has conducted the British Social Attitudes Survey (BSA), to research trends in British social life. In the most recent versions of the study, in British society, those who claim to have no religion has risen to 51% of

⁴² As a religion, Anglicanism has its origins in the first centuries AD, when Christianity first arrived on the British Isles. The first Archbishop of Canterbury, St. Augustine, presided over the Anglicans at the end of the sixth century, when early Christianity joined the pagan traditions of the Anglo-Saxons. The union of the Church of England and the British monarch took place under King Henry VIII who repudiated the authority of the Pope. After years of tension, the Christian Church in England severed ties with Rome and then fell under the auspices of the British Crown. The Church of England in its present form has its origins under the reign of Elizabeth I, who served as Queen from 1558-1603. It was under Elizabeth I's reign that the British Parliament made the monarch the effective head of the Church of England. This concentration of the authority of the British monarch was the result of the second Act of Supremacy, which essentially achieved two goals: it established the monarch as the Church of England's supreme governor; and it created a single national Church to unify British citizens. After centuries of tension between the British monarchy and the papacy, the Act of Supremacy under Elizabeth I finally severed all connections between the two.

the population. Similarly, though the UK is by name a Christian nation, only 43% of the population identifies itself as such (British Social Attitudes Survey, 2011). Finally, signaling the diminishing role of religion in British social life, 62% of British citizens indicate that they have never attended a religious service. The role of religion in British social life extends beyond individual practice to include the relationship between religion and politics. Without question, there is a very strong condemnation of the influence of religion on politics, with 75% of respondents indicating that religious leaders should not try to influence legislators. As a result, there is a growing secular presence in Britain that exists even despite the leadership role played by the monarch in British religion. As a result of these figures, it can be demonstrated that, though religion has an important role to play in the UK, the British have a very defined understanding of what this role should be.

The fact that the British monarch serves as the titular head of the Church of England perhaps says less about the power of the religious institution than it does about the power of the British government. The monarch has jurisdiction over the operations of the Church, but does not serve as its spiritual authority in a way that the Pope does over the Catholic Church (Bennett, 2009). Importantly, however, as the British Established Church, the Church of England has laws that are part of the British legal system. This provides the British Parliament with the ability to block changes to Church doctrine. This differs from what is often seen in the US, where the State has influence over the Church's policies, rather than the reverse.

This relationship between Parliament and the Church of England has bearing on stem cell research legislation, as this matter can be seen from the perspective of powerful religious institutions. In 2004 the Church of England released a series of statements about its position on human embryonic stem cell research. The document that was released by the Church of England Investments Advisory Group begins with a series of explanatory statements, giving basic information about the nature of embryonic and adult stem cells and what their impact on medicine might be. To the direct question, "What makes human embryonic stem cells so important to scientific research?" The advisory group offered the following response:

Human [embryonic] stem cell research is stated to promise new life-changing treatments and possible cures for many debilitating diseases and injuries, Parkinson's disease, diabetes, heart disease, multiple sclerosis, burns, and spinal cord injuries. This comes from the ability of stem cells to replicate new stem cells, as well as giving rise to more specialized daughter cells, whereby banks of tissues and cells could be created for use in medical treatment.

This non-sensationalized and straightforward explanation of embryonic stem cells and how they might be used in medical treatment presents the very type of factual information that many people desire from authority figures. Whether or not the Church of England is fundamentally in favor of, opposed to, or

neutral about human embryonic stem cell research, in this particular document, the institution bears no evidence of any persuasive position. However, the House of Lords Select Committee on Stem Cell Research did solicit the input of the Church Of England Board for Social Responsibility in crafting their stem cell policy. In June of 2001, the Board issued a response to the Committee's consultation. The Board prefaced its response by stating, "the Board believes that any decisions made with regard to stem cell research need to be taken in recognition of the value of all life and of the special significance of humans in God's creation." (Board For Social Responsibility of the Church of England, 2001).

In response to the question regarding the moral acceptability of human embryonic stem cell research, the Church of England Board for Social Responsibility highlighted two important features of British culture that, in SSK argumentation, have come to define the epistemic environment in the UK. First, the Board acknowledged the 1990 Human Fertilization and Embryology Act, which established the moral justification for the use of embryos in research. This Act has been a defining feature in British thought and has come to be taken by many British institutions as fact. Secondly, the Board referenced the utilitarian principles on which the justification for embryonic research was based, another defining feature of British thought. The Board claimed that the moral justification for the use of embryos in embryonic stem cell research was, in fact, even more compelling and might produce an even greater social outcome, thereby emphasizing its moral justification (Board for Social Responsibility of the Church of England).

In another surprisingly supportive claim made by the Church of England, the Board stated, "if stem cell research lives up to its billing, the benefits in terms of novel medical treatments will be phenomenal", but, taking a globalized perspective, the Board also cautioned, "one risk is that humankind loses touch with deeper values, a dignified sense of proportion about the whole issue, and that wealthy economies pour resources into the research at the expense of other pressing global needs". The position taken by the Church of England, then, is considerably more nuanced and not based on the more reactionary "pro-life" perspective taken by other powerful religious institutions like the Catholic Church.

Finally, another important claim that was made by the Church of England regarding the ethics of embryonic stem cell research was in regard to the effectiveness of the HFEA in safeguarding embryonic research. The Board for Social Responsibility stated, "Yes, the Human Fertilization and Embryology Authority has been effective in ensuring that the regulatory framework established by the 1990 Act has been adhered to, and has worked successfully to protect both the public and patients". It is from this standpoint that the Church Of England has framed its response to human embryonic stem cell research ethics in a manner that is specific to the British context, taking into consideration such defining features of British culture as a utilitarian moral perspective and the efficacy of the HFEA in embryonic research oversight.

The fact that the Church of England has been notably supportive of the UK's efforts at human embryonic stem cell research advancement is incongruous with the position of the other major religious institution in the UK: the Catholic Church. As a religion, Catholicism has a small presence in British society, but one that is backed by a powerful institution with a strong hierarchy. The Catholic Church in the UK, then, sits between the strength of the British monarchy and the strength of the Papacy. The circumstances are difficult for the Catholic Church for several reasons, not least of which is the diminished role that religion plays in matters of science in British life. The UK is among the most secular countries in the world, however, any analysis of stem cell research cannot be separated from an analysis of the role of the Catholic Church, regardless of how secular the context might be. The British context poses no exception.

In Anglicanism, there is a professed complementary nature between science and religion. The standard Anglican position on science is that, "science is a self-correcting method of finding truths about the universe" (St. John's Roslyn, 2012). In this faith, there is less tension between religion and science, and the understandings established through scientific reasoning are given greater weight. This holds true for the stem cell research question. In August of 2008, the Church of England's Ethical Investment Advisory Group issued a set of recommendations regarding this research, which began with acknowledging the, "significant potential of human embryonic stem cell research in the development of new knowledge, life-changing treatments, and possible cures for many debilitating diseases and injuries" (Church of England, 2008). The Church of England freely acknowledged the ethical considerations of the research, but made the claim that this work ought to be pursued.

The limited influence that the Catholic Church has on British society is felt in the dynamics of many social issues, including the origins of life. As Scott Gilbert has written, in England, it is generally accepted that the human embryo does not have a full moral status until 14 days into development, at which time the primitive neurological streak has formed and there is no possibility of the embryo becoming a twin. This cultural determination allows for the research on embryonic material that is less than 14 days old, and includes research on embryos created through somatic cell nuclear transfer (Gilbert, 2005). This position is at odds with the position established by the Catholic Church hierarchy, and is fundamental to the stem cell debate. Without gaining traction on this central issue, the Catholic Church's ability to influence the broader debate on research is significantly limited. Similarly, without a strong Catholic representation across England, the Church's ability to mobilize large numbers of followers is likewise limited.

The fact that the Catholic Church in Britain is more limited than that found in the US does not imply that it is an irrelevant entity. In fact, there are many similar features to be found in the US and UK when it comes to the composition of the Catholic Church. As an institution, the Catholic Church in England is comprised of the official entity, The Catholic Church in England and Wales

(CCEW). On their website, the CCEW has a webpage entitled, “legislation and public policy” similar in nature to the United States Catholic Conference of Bishops’ Government Relations department. As a rule The Catholic Bishop’s Conference of England and Wales writes on its legislative page, “the engagement of the Catholic Church in public policy and public life is first and foremost the task of the lay members of the church, active and engaged as citizens in all walks of life” (CBCEW, 2011). This is a telling statement about the responsibility that the British CBCEW feels it should have in society and policymaking. Similarly, on the same page, the CBCEW has a list of issues on which it seeks to voice an opinion, and these include consultation on assisted suicide, matters of equality, social justice, the Human Fertilization and Embryology Act, Catholic adoption agencies, and living wills. Of these listed, the Human Fertilization and Embryology Act⁴³ is the issue most relevant and closely aligned with human embryonic stem cell research.

The Human Fertilization and Embryology Act touches upon the issue that, as of 2005, Pope John Paul II declared as the most critical issue facing the world—the degradation of embryonic human life. The HFEA directly addresses many of the life-related issues on which the papacy takes exception. Therefore, in response to this Act, the Bishops Conference in England and Wales issued a statement and published a pamphlet to highlight their concerns. In opposition to the tactic taken by the United States Conference of Catholic Bishops, however, the British counterpart decided to leave the lobbying effort to the British people in a grassroots fashion. Additionally, in their pamphlet regarding the Human Fertilization and Embryology Act, the CBCEW shied away from inflammatory statements or pictures, and wrote their testimony in a straightforward tone.

On the Catholic Bishops Conference in England and Wales webpage dedicated to “life issues”, the bishops state that they believe that “all life is sacred, a gift from God”, however they also state that “this is why the Church opposes abortion (ending life in the womb) and euthanasia (ending life before natural death)” (CBCEW, 2011). Interestingly, the bishops make no mention of human embryonic stem cell research as a fundamental issue they oppose within the pro-life debate. That is not to say, however, that the bishops have made no attempt to have an effect on the human embryonic stem cell research debate in

⁴³ Britain’s 1990 Human Fertilization and Embryology Act was enacted by the British Parliament as a means to regulate human fertility treatments and assisted reproduction. The act also stipulates the conditions under which an abortion can legally take place, which include threat to the mother’s life, risk to the mother’s mental and physical health, risk to the health of existing children, or the likelihood of extreme abnormalities for the baby (www.legislation.co.uk, 2011). In 2008, the British Parliament amended the Human Fertilization and Embryology Act to include provisions more directly relevant to human embryonic stem cell research, including “to ensure that all human embryos outside the body—whatever the process used in their creation—are subject to regulation” and “to ensure regulation of ‘human-mixed’ embryos created from a combination of human and animal genetic material for research”.

England. To the contrary, members of the Catholic Bishops Conference in England and Wales met with scientists and ethicists to discuss the ethics of embryonic stem cell research and the Human Fertilization and Embryology Bill. The concerns of the Catholic Church regarding this research were itemized in a subsequent press release. What this does suggest, though, is the hesitation that the CBCEW might have in challenging a life-related issue when this issue is backed by the scientific community.

The fact that the Catholic Church in the UK plays such a different role in the stem cell debate than does the Catholic Church in the US raises two important questions: first, how does a social actor establish a position of authority in one nation over another; and second, how does a social actor establish this authority when it comes to adjudicating specific epistemological questions. These questions have been approached from several sociological theorists on epistemological questions. As some have argued, the social ability to properly attribute authority to expertise is a function of a well-educated society. Anderegg makes the claim, "in a democracy, the vigilance of a well educated citizenry provides the best defense against active campaigns to sow confusion and uncertainty." (Anderegg, 2010). This assertion by Anderegg supports the deficit model of public understanding of scientific questions. In order to balance a dyadic wrote of epistemic authority and political actor in the stem cell debate, the Catholic Church in the UK has tempered its unpopular position on the question of life while concurrently operating as a force in the political field.

As Beronzi indicates, the Catholic Church has a tenuous status in the UK, particularly in the urban parts of England. The Catholic Church, as an international institution, generates a considerable amount of its authority from the role that the Pope plays as the infallible, and that the bishops and clergy play as mediator between man and God. In Britain, this infallibility is juxtaposed with the authority of the monarch and the Church of England. It is, however, one claim to make that the Catholic Church does not command as much authority in England as it does in the United States, but a different argument to make that it does not command as much authority in the issue of stem cell research, in particular. The prevailing British opinion on the origins of life and the use of embryos in research is one proxy measurement to indicate the influence of the church on this matter. However, this is not the only measure, and there are others that speak more directly to the British identity.

As Hauskeller argues, when it comes to philosophical frameworks driving public policy decisions, Britain is much more likely to rely on utilitarian ethics rather than deontological ethics. In this way, the British pay greater attention to maximizing the overall public good than to the moralistic claims pursuant to individual actions. What is more, the British place particular emphasis on this when it comes to matters of public health. For instance, the British National Health Service is based upon the notion of the common good, as Hauskeller writes, "the National Health Service is organized around the social idea of providing universally available comprehensive healthcare based on equality and

fair financing” (Hauskeller, 2004, page 510).

The utilitarian perspective has become institutionalized in British social and political thought. The deontological argument advanced by the Catholic Church that embryos used for research were “means to ends” was countered by the utilitarian argument, issued years before, that all embryos used for any kind of research were “means to ends” in some capacity. As argued by the Warnock report and others, embryonic research, including human embryonic stem cell research, was permissible if the potential benefits for humanity were greater than the moral significance of the embryo. This utilitarian logic was at the heart of British political thought, and undergirded their stem cell research decision-making. With this in mind, the Catholic Church’s position, which openly challenged a utilitarian ethical framework, had little influence on stem cell research.

When it comes to the stem cell research question, however, the British utilitarian philosophical orientation is coupled with a secular and pro-science culture. Given the “pro-science” perspective already taken by British citizens, and given the success of embryonic and fertility research in the decades preceding the hESC derivation, raising fundamental challenges to embryonic stem cell research would have been a tall order for any institution, let alone one like the Catholic Church that has diminished authority in Britain. It is perhaps for this reason that the strategy of influence utilized by the Catholic Church in Britain is so different than the strategy utilized by the US counterpart in the stem cell debate. If the British policymaking structure is reliant on sources of authority in policy matters, and the Catholic Church does not command this authority in questions regarding the issue of life, a different approach must be taken. Contrary to the top down approach used by the USCCB in the US, the Catholic Church in Britain has had to adopt a more grassroots approach, while acknowledging that the sphere of influence in Britain is significantly reduced.

In a cacophony of “purported experts” seeking to influence any policy discussion, there is a gap to be bridged between the information that ordinary citizens can integrate, and from whom this information comes. Collins and Evans have introduced the idea of “downward discrimination” as a means to adjudicate which positions are, in fact, credible, which are not. By “downward discrimination” Collins and Evans suggest that one person’s expertise can only be judged internally or directly by another who has more expertise (Collins and Evans, 2007). When discussing “ordinary citizens” who do not have a superior level of expertise, the challenge becomes that much greater. Goodwin quotes philosopher, Sextus Empiricus, explaining the conundrum, stating:

Who is to be the judge of skill? Presumably, these are the expert or the non-expert. But it cannot be the non-expert, for he does not know what constitutes skill (otherwise he would be an expert). Nor can it be the expert, because that would make him a party to the dispute, and hence untrustworthy to be a judge in his own case. Therefore, nobody can be the judge of skills.

However, in an attempt to reconcile this challenge, recent scholars have argued that, when it is impossible to disentangle the perspectives of expertise, “citizens can proceed indirectly, assessing the external features or signs the purported experts display” (Goodwin). In so doing, non-experts, like ordinary citizens making policy judgments or shaping the social Doxa, can base their knowledge-claim decisions not simply on scientific knowledge but social knowledge. In this way, assessments of expertise “do not depend on the understanding of the expertise being judged but upon an understanding of the experts” (Collins and Evans, 2007, page 51). The practical implication of this is that, when citizens are judging a level of expertise of those influencing policy matters, they are, in fact, making social judgments about who is to be agreed with, not scientific judgments about what ought to be believed.

This lies squarely in how the British have come to view levels of expertise directed towards the stem cell debate. Whereas in the US, the scientific question of life has dominated much of the policy discussion, in the UK social evaluations have been made surrounding the capacity of different actors to offer their input. In a country where the Catholic Church is viewed with skepticism, and certainly outside the realm of the scientific, this social actor has not been accredited with associated expertise to contribute significantly to this debate.

Where this fits into the struggle between science and the Catholic Church lies in how the British have come to evaluate “expertise” versus “authority”. The British tradition is one that places a particular value on the role that experts play in public discussion, and the creation of expertise is not analogous to social authority. Whereas an institution like the Catholic Church generates its influence from its position of social authority, it is not necessarily likewise implied that this authority has any bearing on the public discussion for scientific issues. This, coupled with the emphasis of utilitarian logic, has made the Catholic Church's influence on the stem cell research question in Britain a marginal one.

The presence of the Catholic Church in the UK is significantly smaller than that found in the US. This fact weakens the position that the Catholic Church has held in the stem cell debate in the UK. However, this is not the only reason for its struggles. From an SSK standpoint, the context in Britain is likewise very different than that of the US, and these differences begin with the existence of the Church of England. The Church of England, with its large demographic size and authority from the British monarch, presents a pressing problem for the Catholic Church in the UK. Were these two religious institutions to have similar perspectives on embryonic stem cell research, they likely could have developed a strong collaborative force, similar to that created by the Catholic Church and conservative Christians in the US. However, they have opposing points of view on this work, creating a tenuous position for the smaller and less socially-influential Catholic Church. This is coupled with a society that respects religion but bases policy on secular principles.

Creating a moral framework that is based on religious principles in a decidedly secular nation would be a lofty feat in any regard, but significantly so when it comes to the question of life. To be sure, the Catholic Church in England has been ineffective at defining this issue as it pertains to such questions as abortion and reproductive rights. At least in part, this is the result of Britain's groundbreaking success in assisted reproductive technologies like *in vitro* fertilization. The birth of the first "test tube" baby, Louise Brown, stands as a profound scientific achievement in British history—an accomplishment for which British physician, Edwards, received a Nobel Prize in 2010. While the papacy's official position on this scientific achievement was, and is, one of opposition, the British Council of Bishops had a much more difficult time condemning the breakthrough or influencing the public policy. This event, in SSK terms, has helped to define the cultural atmosphere in which science is conducted in Britain.

Much the same can be said for the Catholic Church's predicament in the stem cell debate in the UK. Though the first derivation of human embryonic stem cells did not take place in Britain, this research did grow out of groundwork that was done in Britain: groundwork in reproductive technologies, embryology, and cloning. For this reason, the scientific community in Britain can claim ownership over this scientific field. However, the argument can be taken further. While the US was, in essence, floundering on the stem cell research question, with a restrictive policy put into place by President Bush, Britain was presented with a valuable opportunity to surge ahead in this field, possibly creating a dramatic economic boon for a country often in the US' shadow. Rather than adopt a similar policy to that found in the US, the UK had the chance to establish itself as different, more progressive, and more scientifically friendly than the US. Were the British to have adopted the Catholic Church's standard position, this window might never have been opened.

It was because of this confluence of circumstances that, unlike in other countries, the Catholic Church in the UK has not been able to define the terms of the social debate, either implicitly or in actuality (Appendix 11). However, when these conditions are slightly shifted, a somewhat different picture is created. The Catholic Church has made more headway in influencing the permissibility of research like SCNT, an issue whose ethics is less reliant on the question of life than it is on questions of "natural law" and the potential dangers of unfettered scientific advancement. The cultural atmosphere, in SSK terms, is much less friendly to this work than it is to the question of life. The framework of this argument, then, is not a matter of disputing epistemic authority as it pertains to the meaning of life, but instead raising questions about how far science can legitimately go before creating unanticipated negative consequences. In short, the fundamental argument in Britain's SCNT debate is not a dispute for epistemic authority but rather the questioning of where these epistemic boundaries are to be drawn.

It is with this in mind that it becomes evident that the Catholic Church is not operating in a social debate of its own creation but rather a debate in which it

is challenging some otherwise-established framework, namely the justifiable ends of scientific advancement. Otherwise stated, in the SCNT debate, the Catholic Church is much better poised to question how far scientific experimentation should be taken, rather than question its authority as epistemic actor. The Catholic Church in Britain has not won the epistemic battle on the question of life, and without this entry point, the Catholic Church has had limited ability to claim some degree of authority in the stem cell debate. There has been, then, essentially no clear way for the Church to attempt to establish the Doxa or define the terms of the social discourse.

This is not to argue, however, that the Catholic Church in Britain neither has anything at stake in stem cell research policymaking nor any social capital to pursue. Were this the case, the Catholic Church would have no visible presence in this debate in Britain whatsoever, and by the actions taken by the Catholic Church, it is clear that this is not true. The hierarchy of the Catholic Church, irrespective of location, is bound by a policy of “infallibility” from the papacy. In this framework, whatever it is that the Pope demands, the Church hierarchy around the world must support and adopt. The Pope's policy is, then, an international policy that runs through the channels and structure of the Church, representing the very type of institutionalized and international channels for which World Polity Theory advocates for science. This fact puts the British bishops in a nearly untenable position in the confines of the stem cell question: a position of either entering a social debate in which it has little social credibility or failing to adhere to a fundamental principle of Catholicism. To this end, the British bishops have had to walk a delicate line.

Given the challenging position the British bishops have found themselves, they have played this position to the best of their ability. Adopting the standard Catholic position, the British bishops have expressed their concern over the use of embryos in stem cell research but have steered clear of making blanket or sweeping statements about the origins of life. Similarly, given the British focus on sources of authority and how they relate to epistemic questions, the British Catholic Church has remained relatively removed from influencing British legislators, instead taking their case to a more grassroots level. The result is a tepid, yet certainly Heterodox, status in the stem cell debate, with the Catholic Church balancing its role as a Catholic institution operating in a secular domain.

SCIENTIFIC COMMUNITY

The code of conduct governing stem cell research in the UK was the product of input from a wide range of stakeholders, of whom the scientific community played a central role. As the code states, “this code should provide confidence and reassurance to professionals and the public alike that stem cell research in the UK is performed to best practice and is conducted within a

transparent and ethical framework” (Code of Practice, 2010, page 6).⁴⁴ The British Department of Health seeks input from the “Advisory Non-Departmental Public Bodies” (ANDPBs), which the British government describes as an integral part of policymaking and central to providing expert advice. Of the ANDPBs that consistently advise the Department of Health, the department lists such organizations as the Commission on Human Medicines, Medical Education England, Human Genetics Commission, and the Advisory Committee on Borderline Substances (Department of Health, 2011).

That the British government has relied on the scientific community for guidance on the stem cell matter is unsurprising, given the history of science in Britain. In particular, Britain's Royal Society is a fellowship of scientists, the oldest scientific Academy in existence, which fosters the development of science, mathematics, engineering, and medicine. Members are elected for life on the basis of their scientific excellence, and have included such luminaries as Isaac Newton, Charles Darwin, Ernest Rutherford, Dorothy Hodgkin, Francis Crick, James Watson, and Stephen Hawking. At present, there are about 1500 members of the Royal Society, with Sir Paul Nurse acting as current president.⁴⁵

The Royal Society influences policy through its Science Policy Center, which works, “to ensure that policies on key issues are influenced by the best independent science” (Royal Society, 2011). The Royal Society specifies the areas of science on which it will focus its policy-relevant influence, and these are climate change, energy and environment; new and emerging technologies; biosciences and health; science base and innovation; and international security.⁴⁶ The Royal Society places attention on broadening the channels of

⁴⁴ The British Department Of Health has a set group of organizations with which it works when creating policies, or “stakeholders”, which include “patients and the public, local and regional NHS organizations, local authorities and social care providers, charities, the voluntary and community sector, and many others” (Department of Health, 2011).

⁴⁵ Founded in November of 1660 by Christopher Wren, the Royal Society gained a great deal of social stature among British nobility. It wasn't until the mid-19th century, however, that the patronage of the Royal Society translated into some degree of governmental recognition. In 1850, the Royal Society was, for the first time, officially recognized by the British government, when it was awarded a federal grant in the amount of £1000 to allow the scientists to move forward with their research and purchase equipment (Royal Society, 2011). Following this first governmental grant, an intimate relationship was forged between the British government and the Royal Society, while still allowing the Society the ability to maintain its autonomy.

The Royal Society has five strategic priorities:

1. Invest in future scientific leaders and innovation
2. Influence policymaking with the best scientific advice
3. Invigorate science and mathematics education
4. Increase access to the best science internationally
5. Inspire an interest in the joy, wonder, and excitement of scientific discovery

⁴⁶The strategies that the Royal Society's Science Policy Center employs to influence policymaking include:

communication between the scientific community and policymakers, as well as the scientific community and the public. The purpose of this is to keep the information about science in the hands of those who create the science, lest it be misrepresented by other social entities.

The Royal Society's Science Policy Center has issued a series of policy publications in response to members of the British House of Commons and House of Lords' science-related inquiries. These policy publications play a prominent role in the creation of science policy matters, and the advice and expertise of members of the Royal Society are taken very seriously. Over the years, the Royal Society has issued 11 policy publications indicating its support for human embryonic stem cell research.⁴⁷

The initial UK stem cell policy took the form of amendments to the already-existing Human Fertilization and Embryology Act, and incorporated the viewpoints of several groups, most of which enjoyed some degree of authority in some relevant area, such as science, law, ethics, or religion. Stephen Minger, a prominent British stem cell biologist and US expatriate, has recounted the effect that the scientific community has had on the legislation in the UK. As Minger argues, as a result of this arrangement, the HFEA is an “independent statutory agency that strictly regulated all reproductive medical practices and research. Unlike the United States, where regulation of embryonic research is found in multiple agencies and sometimes does not exist, in the United Kingdom, “everything related to reproductive medicine is very, very tightly regulated and controlled” (Minger quoted in Tambra and Matthews, 2010). In addition, Minger has celebrated the UK’s stem cell bank that grew out of the HFEA as an

Providing more extensive coverage of key themes

Identifying emerging issues

Engaging more actively at all stages with those we seek to influence, create stronger links with government, Parliament, European policymaking bodies, multilateral organizations, industry, and NGOs

Systematically conducting structured dialogue with public groups and stakeholders over policy issues, and building on our reputation as a pioneer in incorporating dialogue into policy studies by continuing to be innovative in this area

Interacting more vigorously with other organizations and world scientific bodies, ensuring we play a leading role

Stepping up our work with the media to ensure science is accurately represented

⁴⁷ The first policy publication issued by the Royal Society in response to stem cell research inquiries was a response to the Department of Health's review of the Human Fertilization and Embryology Act as an appropriate means to oversee stem cell research in the UK. With some concern about the joining of the HFEA and the Human Tissue Authority, the Royal Society was supportive of the existing legislation to make the derivation of human embryonic stem cells under the auspices of the HFEA, to be followed by oversight by a special steering committee. The Royal Society did, however, reject the need for the creation of human/animal hybrids through stem cell technologies, but supported research on inter-specific chimeras through the introduction of human embryonic stem cells into animal embryos (RS policy document 25/05, 2005).

important means to standardize the opportunities for British researchers to gain access to embryonic stem cell lines. The UK's stem cell bank provides embryonic stem cells to researchers without cost, thereby eliminating the need for these researchers to have substantial economic resources at their disposal in order to conduct this work (Minger, cited in Rosenthal, 2004). This has provided a more egalitarian approach to this research than what is found in the US.

As a result of the dedication that members of the scientific community in Britain have demonstrated toward public policy making, many of these researchers have been described as “civic scientists”. Former science advisor for President Clinton, Neal Lane, described a civic scientist, as, “someone who uses his or her knowledge, accomplishments, and skills to help bridge the gap between science and society” (Lane, quoted in Tamba, et al.). The British emphasis on expertise in policymaking makes for a set of social conditions that is particularly amenable to the role and the creation of civic scientists.

With this in mind, the scientific community in the UK remains strong and extensive. In 2003, scientific organizations in Britain came together to found the Science Council, a network of scientific organizations in many different scientific disciplines. Illustrating their role as “civic scientists”, members of these organizations have made statements on matters of science policy, and how these issues affect British society. For instance, the Society of Biology takes a position on embryo research, and offers public education about it. This includes information about embryonic and hybrid research, how it is conducted, and why scientists feel it is necessary (Society of Biology, 2011). Similarly, many of these organizations have taken an active role in shaping the public dialogue. For instance, the Institute of Clinical Research offers a series of panel discussions and joint conferences with such entities as The European Medical Writers Association, to broaden the base of public knowledge of science. Finally, the Institute of Biomedical Science has a series it has titled, “Out in the Open: Promoting Biomedical Science”, used as an advertisement of sorts for the public to become more fully aware of the operations of biomedical scientists, and has included such things as tours of research laboratories, biomedical science exhibits, and information about becoming involved in the science, itself (Institute of Biomedical Science, 2011).

The extent of the scientific network in Britain is a testament to the active role that the scientific community has played in British society.⁴⁸ For instance, the British Biotechnology and Biological Sciences Research Council (BBSRC) provides strategic funding for a network of bioscience research institutions (BBSRC, 2011). The Research Council has as part of its mission, to encourage institutes to work together in conjunction with partners on public engagement to

⁴⁸ The British commitment to science has had a demonstrable effect on the picture of the British labor force. Based on estimates taken in 2007, 21% of the British workforce had higher education qualifications. Of these, nearly 43% had higher education degrees in science and engineering (Department for Business Innovation and Skills, 2011).

increase the impact of science. In addition, the BBSRC has a history of coordinating with policymakers, presenting research to parliamentarians, government officials, and members of business and industry.⁴⁹

While, in the US, science plays a more limited role as a rationalized other in the stem cell debate, in the UK, science has sought to balance both its role of authority and how this role is made visible in circles of society that go beyond the confines of science, itself. Through the establishment of institutions like the Royal Society, science is a present entity unto which British society can attribute ideas, opinions, and influence.

The primary concern of the stem cell debate in the UK has not significantly surrounded the ethics of the research, itself, but instead on the ethics of more exotic scientific research like somatic cell nuclear transfer and chimeric research. Having already defined much over the course of stem cell research in the UK, the scientific community faced a challenge in how to navigate this more difficult and arguably more controversial research question. It is in this question that the scientific community has had more difficulty dominating the public discussion.

At the time of the first derivation of human embryonic stem cells in 1998, the UK was cast in the shadow of an extraordinary breakthrough in the US. This scientific breakthrough put the “world polity” on a course to adopt a dominant social script for embryonic stem cell research, despite the fact that the US under the Bush administration did not embrace this script. For a nation like the UK, which had grappled with questions involving embryonic research in general, it was not a significant intellectual, social, or ethical step to move forward on human embryonic stem cell research. A different picture, however, can be painted for somatic cell nuclear transfer and how it has been received worldwide.

For several important reasons, somatic cell nuclear transfer has not enjoyed widespread social acceptance in many countries around the world. The US National Academies of Science issued research guidelines that expressly prohibited this type of research because it only permitted research on embryos that had been created for fertility purposes and were no longer desired by the donating couple. In SCNT, this requirement is not met. Additionally, in order to conduct SCNT using human gametes, it is necessary to have unfertilized eggs. However, in order to obtain these eggs, women have to undergo a lengthy, difficult, and risky procedure that requires hormone injections and laparoscopic

⁴⁹ The BBSRC is part of a broader scientific network characteristic of the British scientific community and is part of the broad Research Councils UK, which collectively invest about £3 billion per year in a wide variety of academic and scientific disciplines. The Research Councils UK fosters such things as careers in research, public engagement with research, knowledge exchange and impact, and interactions with the media. As the Research Councils UK state, “The Research Councils are committed to continuing to work together to proactively provide a wide variety of accessible and flexible support mechanisms to generate economic and social benefits from the excellent research, people, and facilities they fund” (Research Councils UK, 2011).

egg retrieval—process that essentially no woman is willing to undergo voluntarily. As compensation for this procedure has been frowned upon among many regulatory bodies in the US, SCNT has largely stalled in the US.⁵⁰

In a World Polity sense, support for SCNT has not been uniform across members of the scientific community, and has not reached a level significant enough to generate a predominant social script. This has only been complicated by the work of disgraced Korean researcher, Woo Suk Hwang, who fraudulently reported-to much scientific acclaim-that he had created human embryos through this technique. So, while science as a unified institution represents a dominant and rational voice from an international perspective, it is difficult to gain traction on an individual issue that has not generated an international script. This argument puts some of the fundamental predictions of WPT to the test. Perhaps if the US had not implemented a policy that was so adamantly opposed to research involving SCNT, this issue may not have been so contested in the UK.

From this perspective, World Polity Theory and Field Theory are somewhat in alignment. The lack of a dominant social script surrounding SCNT has made it particularly difficult for the British scientific community to define the social Doxa in the UK. In essence, the degree of expertise afforded to even a firmly established and influential institution like the British Royal Society can only be measured so far as this expertise is accompanied by some broader international perspective.

When compared to the stem cell debate in countries like the US and Germany, the issue of “life” features less prominently in the UK. This epistemic question presents itself in some important social circles, however it has not been the dominant concern. What is more, in the UK, the most challenging aspects of the question of “life”, namely what moral status ought to be attributed to the human embryo, was debated and politically resolved decades ago during the debates surrounding the HFEA. At that time the moral status attributed to the human embryo was one of respect but not tantamount to a human being. This perspective has remained over the past twenty years. As a result, in the context of the stem cell research debate, the scientific community in Britain essentially had one primary task: how to present and advance this research in such a way that it upheld the fundamentals of research ethics. Central to this task was the need to be very public, open, and transparent about the details of this research,

⁵⁰ An important distinction between the US environment and the UK environment must be noted when it comes to SCNT. While the availability of eggs presented the biggest complication for SCNT in the US, the UK HFEA allows for an egg sharing system, by which women who are already undergoing the in vitro fertilization process, and thereby already undergoing the difficult egg retrieval process, can have their treatment costs reduced by donating some of their excess eggs either to another couple or to research. This circumvents the challenges that have plagued SCNT in the US. Nevertheless, despite the fact that there is availability for eggs in the UK, this research still was met with a great deal of skepticism, more so than the British scientific community has been able to overcome.

and what is or is not known about it. This was essentially the approach that was taken from the British scientific community, notably the Royal Society, that stem cell research was research to be supported but that it required important regulations and oversight. To protect itself from challenges that stem cell research was not adhering to research ethics, the scientific community essentially made the claim to legislators and the public, alike, that they would like to conduct this research, but it needed to be regulated so it could be conducted properly. This position gave the scientific community the opportunity to do two important things: first, they could express the importance of the research and educate members of the British community about what it entailed, and second, they could demonstrate that this research touched upon critical ethical questions that scientists were ready and willing to consider thoughtfully.

Reflective of World Polity principles, members of the British scientific community performed this task skillfully, offering a great deal of testimony and insight for British scientific policymakers and the British Parliament. However, it is more than simply because the British scientific community *wanted* to conduct embryonic stem cell research that this balance was so well struck. In addition to the commitment by the scientific community, an equally powerful motive may have come from the British government, who saw an extensive economic opportunity in the future of this research.

When President Bush implemented a very restrictive stem cell policy, an opportunity was created not only for British scientists but for also the British economy to seize upon this fertile research territory, reclaim this field, and surpass the US in a burgeoning scientific area. In fact, there were many claims being made, even by Prime Minister Blair, that the UK would be the beneficiary of scientific emigration from US stem cell researchers frustrated with the limited research policy in their home country. Ultimately, the number of US researchers who emigrated to the UK as a result of its stem cell policy is no doubt small, with some indicating it has been fewer than five (Weiss, 2005), and others claiming it could be as few as one or two (Wolinsky, 2009). Despite these small numbers, the relatively welcoming scientific environment in the UK has been a source of enticement for researchers without academic or familial ties. However, in order to make these possibilities a reality, the British scientific environment had to be friendly to this research, and needed a stem cell policy that favored the interests of the scientific community

With this desire in mind, it was in the British government's interest to act in conjunction with the scientific community. Fortunately, the British scientific community is well established and well-respected, in the form of the historical Royal Society. This is coupled with the fact that entities like the Catholic Church have not been able to characterize the debate in terms of "life". While the US does have scientific societies and academies, like the AAAS, the NAS, and more specialized organizations, the US government has been less accountable to these prolific institutions than the UK has been to the Royal Society. This is evidenced by the fact that most, and likely all, of these US-based organizations

have offered their unequivocal support for embryonic stem cell research and the US government has only partially taken this support into account. As the degree of expertise is similar across the NAS, AAAS, and the Royal Society, the difference lies in how the British have been able to translate expertise into authority on policy matters. This has made the relationship between policymakers and the scientific community, and the relationship between the scientific community and the public, friendly ones.

It was by virtue of these factors, including the institutionalization of science and an active role as “civic educator”, that the scientific community was able to establish its position as epistemic authority for the stem cell debate. The British moral tradition relies on expertise as a measure of authority in policymaking, with scrutiny given to how authority is attributed to policy matters. The resolution of science policy issues is often dominated by those who command scientific expertise. In the US, where biologically-relevant matters of science can often be a product of varied epistemic authorities, the field of dispute is very different than that found in the UK. This reliance on expertise as a measure of authority is built into the principles of rationalist thought that has come to define utilitarianism.

The UK's reliance on rationalist principles and science as authority are not the only circumstances that favor the scientific community in the stem cell debate. In addition to these factors are the types of contextual forces central to an SSK perspective. For instance, the epistemic culture in Britain as it pertains to embryonic research was defined by the successful IVF breakthrough that has since come to be a source of British pride and an example of scientific achievement. In addition, faith was restored to the scientific community by its active role in expressing the need for regulation of this research, and how bioethical considerations were central to the success of this work. Finally, the position of the scientific community was strengthened by the desire for advancement in the global stem cell field, a desire that was perpetuated by the British government.

PHARMACEUTICAL INDUSTRY

The British pharmaceutical industry is represented by the Association of the British Pharmaceutical Industry (ABPI) in a way that is similar to PhRMA's representation of the pharmaceutical industry in the US. Member organizations of ABPI are involved in the research, development, manufacturing, and supply of drugs that are prescribed to the British National Health Service (ABPI, 2011).⁵¹

⁵¹ Member organizations in ABPI typically fall into three general classes: members that market and conduct business in the UK, members that conduct business in the UK but do not have an official UK sales operation, and members who have an interest in the pharmaceutical industry but do not produce medicines, themselves. For these component members, of whom there are about 150, the ABPI is a representation entity, targeting commercial outlets, corporate affairs, and legal entities.

As ABPI describes, the organization works “at the heart of policy development and decision-making to ensure that patients are able to benefit from the latest and most advanced medicines” (ABPI). As ABPI claims, the organization also has close ties with patient and disease groups, health managers, educational and training bodies, and other professional organizations. ABPI prides itself on the well-being that it helps to create for British citizens, “both directly and indirectly”, and has as its objective to ensure that all levels of British society are fully aware of the role that the pharmaceutical industry plays in maintaining public health.

ABPI focuses its attention on four “core imperatives”: value, innovation, trust, and access. To this end, ABPI focuses on the importance of “a vibrant R&D community in helping patients in the future to combat disease” (ABPI). To achieve this, ABPI has positioned itself in a network with the British government, the National Institute for Health and Clinical Excellence (NICE), the NHS, and other stakeholders, with whom ABPI works to improve patient outcomes and direct the Pharmaceutical Price Regulation Scheme (PPRS). These agencies create a network within which ABPI can secure public understanding about drugs that are created and what their benefits might be.⁵²

Though ABPI represents the pharmaceutical sector in the British Parliament, many of the corporations under the representation of this organization either have a global presence or are headquartered in locations outside of the UK. For instance, A. Menarini Pharmaceuticals UK Limited has a British location but is headquartered in Italy. Similarly, Basilea Pharmaceutica, also represented by ABPI, is a Swiss-based corporation. From another geographical origin, Daiichi Sankyo Europe is headquartered in Tokyo, with an affiliate laboratory in England. Finally, Pfizer, also with a British presence, is a US company. The globalized nature of these companies, and the pharmaceutical industry in general, makes an important statement about how they must operate in the stem cell debate and the political field. Depending upon the location in which the company is currently operating, there are different social conditions and sources of concern. For instance, the regulatory environment and public opinion surrounding stem cell research in Switzerland are very different than those found in the UK, Germany, or Japan. Members of the pharmaceutical industry have become adept at navigating the regulatory and political channels of the countries in which they have a presence. In this case, the central companies have had to play all sides of the stem cell issue, from expressing support for the research as a scientific enterprise to expressing reservation over it. In the UK, this is no different. Until there is greater certainty about how embryonic stem cell research might impact the pharmaceutical sector, companies within this sector will appear to operate according to local regulations while remaining undecided

⁵² ABPI divides itself into four departments: commercial, corporate affairs, legal, and medical innovation. In terms of the commercial department, ABPI is responsible for all aspects of a medicine's marketization, including pricing, health technology appraisals of cost-effectiveness, and quality control.

about the future of the research.

The ABPI Corporate Affairs Team plays the role of government liaison and facilitator with the media. Operating underneath the Corporate Affairs Department is ABPI's government affairs division, which as ABPI describes, "seeks to ensure that the industry's position on relevant policy issues is communicated to government and other stakeholders in the most effective manner" (ABPI). Similar to PhRMA, ABPI provides briefing papers in response to policy matters. Among the recent and important policy matters for which ABPI has expressed its views was an initiative to provide a tax credit for research and development for smaller pharmaceutical companies. To this initiative, the ABPI Director of Science and Technology, Philip Wright, stated, "we are delighted to hear that the government has recognized the R&D tax credit gap for growing biopharmaceutical companies, and that it is going to see how best it can help the midsized firms that are often lagging behind their US counterparts" (Pharmaceutical Field, 2005). Small biotech companies have served as one of the primary drivers of the stem cell field, so this tax credit has direct relevance to this research. In a similar vein, ABPI has focused its attention on the strengthening of ties between the British government, the business sector, academia, and other stakeholders. The pharmaceutical industry has generated a positive response in terms of the biomedical field's future, with Wright stating, "We must have the right environment to encourage young people to take up and pursue science..." (Pharmaceutical Field).

A concern that has been expressed in the UK is that, with the introduction of the pharmaceutical industry and business sector into the stem cell field, medical advances would be driven by profit rather than by social need. In addition, though, this establishment of "social need", according to many in Britain, ought to be established by public opinion rather than simply by the government. There is an embedded mistrust of the pharmaceutical industry and other commercial enterprises as they relate to the quest for medical treatments, as British citizens have expressed a hesitation to "medicalize" the aging process, implying that those who are in their senior years need to be "fixed" (BMRB). The public relationship with pharmaceutical organizations in Britain is, then, not a wholly trusted one, and when it comes to the complex issue of stem cell research, this is even more significantly the case.

In contrast to many of the firms in the US pharmaceutical industry, the British counterparts freely acknowledge the importance of R&D streamlining and the role that stem cell research plays in this. Pharmaceutical companies in the UK have given attention to creating an environment that is supportive of science, from a research and economic development standpoint. Major corporations in this industry, like GlaxoSmithKline and Lilly & Co., join smaller biotech firms who are beneficiaries of the favorable British tax credit system, to create a voice that is largely supportive of human embryonic stem cell research. The question lies in to what degree the British pharmaceutical industry can effectively operate in the political field.

These two factors of R&D maximization and fostering an environment that builds a scientific future are important for generating a pharmaceutical field that is supportive of stem cell research, and this is the case for several reasons. First, one of the most immediate applications for the evolution of stem cell research is the development of disease-specific stem cell lines, or stem cell lines that carry genes for specific diseases, on which to test pharmacological therapies. As previously discussed, this research application would allow for research and development to take place in a much more streamlined and efficient manner—one that is less reliant on human trials to assess safety. With a governmental acknowledgment of the necessity of strong research and development, as acknowledged through the R&D tax credit system, the British government can be thought to be providing a greater opportunity for smaller biopharmaceutical companies to engage in this research, and to support the work of companies driving the stem cell field. Additionally, ABPI has acknowledged the importance of a governmental contribution to creating a regulatory atmosphere that is encouraging of new researchers and minds. ABPI has ostensibly made the claim that an environment that encourages new scientific researchers is one that is favorable to the pharmaceutical industry, and having regulatory policies that foster such an environment is created through broad-based scientific funding.

With this in mind, ABPI has offered at least tacit support for stem cell research. For instance, ABPI has embarked on work involving stem cell treatments for heart disease, in reference to which the Director General of ABPI has stated, “the UK is a world leader in the development of stem cell research...” (Pharmaceutical Field). However, similar to PhRMA, ABPI is a representative force for 75 of British pharmaceutical companies and other stakeholders, including such notable and powerful entities as Bausch & Lomb, Bristol-Myers Squibb, GlaxoSmithKline, Pfizer, and Siemens, and these entities have made their own idiosyncratic statements regarding stem cell research policy. For instance, ABPI member, Lilly & Co., has acknowledged its role in influencing UK policy, and has offered as one of its goals, “to develop and deliver the most effective healthcare solutions to our customers and patients” (Lily and Company, 2010). With this in mind, Eli Lilly & Co. has a bioethics division, in which the company “strives to maintain the highest standards of ethical behavior in all aspects of the company’s business” (Lilly & Co.). Of the bioethical issues which Lilly & Co. addresses is stem cell research.

Organizations like ABPI and individual pharmaceutical companies have expressed their support for embryonic stem cell research at least on some of their public information. However, this measure is not a particularly informative or helpful metric by which to gauge the pharmaceutical industry's true level of support for this work. A more indicative measure lies in the fact that ABPI has strongly indicated its concern over the “rigidity of the conventional view of the development process” (ABPI, 2012), and as a remedy for this, the organization states, “we need to have a wider variety of methods that we can use to develop new medicines as well as a more flexible regulatory framework”. The four methods by which ABPI has argued that this remedy can be achieved include: a

flexible drug development process, increased collaboration, value and outcomes evaluation and trial design, and personalized medicines. All of these speak directly to the future of embryonic stem cell research and its use in pharmaceutical testing. In fact, contrary to the US' PhRMA, ABPI stresses the relevance of personalized medicine to the future of the industry, indicating that a new approach to medicine must be established.

Highlighting one of the most visible benefits for embryonic stem cell research in the pharmaceutical field, ABPI has noted the need for “increased collaboration” with stem cell-related organizations, “to achieve a reduction in the time it takes to develop new medications for patients” (ABPI). The efforts at collaboration make a much stronger case for the attractiveness that ABPI finds in stem cell research. One of the noted organizations with which ABPI has collaborated is The Stem Cells for Safer Medicines, a public-private partnership that specializes in stem cell lines derived for toxicology testing. As Stem Cells for Safer Medicines describes of its collaborative nature, “[this] collaboration will draw upon scientific expertise within pharmaceutical companies—especially in relation to safety assessment of new medicines—academic stem cell experts in UK and seek engagement with third parties including biotechnology companies” (Stem Cells for Safer Medicines, 2012). The primary members of this collaborative initiative are the pharmaceutical companies, GlaxoSmithKline, AstraZeneca, and Roche, and the public entities, the Department Of Health, Department for Business, Innovation, and Skills, The Medical Research Council, and the Biological Sciences Research Council. From this standpoint, the pharmaceutical industry has taken a particularly active role in the advancement of this research and, more importantly, how it is relevant to the future of medicine.

Members of the pharmaceutical industry, as represented by the ABPI, do, in fact, provide guidance on policy measures relevant to their work. In World Polity terms, the broad reach of the pharmaceutical industry and the knowledge that only members of this industry hold, puts them in a position of a modified rationalized other. By “modified”, it can be understood that this industry does not represent the rationalizing effects of science, per se, but a socially-applied iteration of science. To the extent that science is costly and often dependent on investment from members of the private sector like pharmaceutical industry, these two often go hand-in-hand.

ABPI serves as advisor to several “All Party Parliamentary Groups” (APPG), the APPG on the Pharmaceutical Industry and the APPG on Life Sciences.⁵³ The advisory role that ABPI plays for the APPGs on Life Science and

⁵³ Similar to congressional subcommittees, APPGs are groups of British parliamentarians from all parties, who are joined to delve into specific matters of policy. However, APPGs are not official institutions of the British Parliament and are likewise not afforded any official powers, APPGs, according to the Parliament's official guide to rules on APPGs, are among the members of the House Of Commons and House Of Lords, and many of these groups involve the input of other, outside organizations, such as ABPI. ABPI has worked as the Secretariat of the British APPG on the pharmaceutical history and the life sciences. The All-Party Parliamentary Group on Life

the Pharmaceutical Industry is, however, more limited than the role that an organization like PhRMA plays when it comes to influencing policy and legislators. Contrary to the US, campaign finance rules in the UK are legislatively designed to, “prevent excessive spending by electoral candidates” by limiting the campaign expenditures of political parties and individual candidates. This regulation was put into place in the centuries-old Corrupt and Illegal Practices Prevention Act Of 1883, in addition to the more recent Representation of the People Act Of 1983 and the Political Parties Elections and Referendums Act of 2000 (Library of Congress, 2011).⁵⁴

In the US, the greatest source of capital for the pharmaceutical industry is in its ability to exert an influence on the social Doxa. Though largely not able to dominate the Doxa, an institution like the pharmaceutical industry can serve as an Orthodoxic force, strengthening a position taken by, for instance, the scientific community. While affecting the policy, itself, might be beyond the scope of what

Sciences is chaired by Penny Mordaunt, a member of the House of Commons and Conservative Party. The purpose of the APPG, as the group's registry states, is “to investigate how life science can improve quality of life in the United Kingdom” (Register of All Party Groups, 2011). Within the context of this group, the benefits received from organizations outside of the parliament include ABPI serving as the group's secretariat, along with the Association of British Healthcare Industries and the Bio Industry Association and In Vitro Diagnostics Association, who together help arrange speakers and draft reports for the group (Register of All Party Groups). In a similar fashion, the APPG on The Pharmaceutical Industry has as its express purpose, “to discuss issues to deal with the operation of the pharmaceutical industry in the UK; to debate pharmaceutical developments and their impact on patients and UK healthcare; and to exchange information and views with the pharmaceutical industries” (Registrar of All Party Groups).

⁵⁴ As a result of the political system in Britain, wherein the Parliament is dissolved by decree in the form of a Royal Proclamation issued through counsel by the Prime Minister on an irregular basis, the campaign cycle is particularly short, lasting about six or seven weeks. Expenditures can be made by political parties, which are held to rigorous standards through the Political Parties Elections and Referendums Act in terms of transparency. Expenditures can be made on, “political party broadcasts, advertising, unsolicited material to electors, manifesto or other policy documents, market research and canvassing, media/publicity, transport, and rallies or other events” (Political Parties Elections and Referendums Act, 2000). Spending limits imposed on political parties in Britain are considerably higher than those imposed upon individual candidates, and even so, in the 2005 general election, the national campaign expenditure limit for political parties was £30,000 (\$42,000) per constituency contested, amounting to a total of £19 million, or \$26 million. What is more, political parties can only accept donations greater than £200 (\$280) from what the Act deems “permissible donors”, which are defined as “an individual registered on a UK electoral register; a UK registered political party; a UK registered company; a UK registered trade union; a UK registered building society; a UK registered limited liability partnership; a UK registered friendly/building society; or a UK-based unincorporated association” (Political Parties Elections and Referendums Act). In a vein similar to the expenditure limits placed on parties, there are similar regulations placed on individual candidates, as well. Imposed by British Secretary of State, and upon recommendation from the Electoral Commission, the limits for campaign expenditures for individual candidates are, as of the 2005 general election, £7150, or about \$10,000, plus an additional £0.05 (about \$0.07), per Elector in an urban district, and £0.07 (about \$0.10) in a less-densely populated county. Taking these figures into account, according to the British Electoral Commission, the average amount spent by an electoral candidate in the 2005 general election was about £4000, or \$5600.

the pharmaceutical industry can legitimately do in the UK, it can direct its resources toward a public campaign, much in the way that the Catholic Church has done in both the US and UK. In this way, the position of the pharmaceutical industry is given added weight by aligning itself with the strong voice of the scientific community.

Perhaps the reason for this difference in circumstances between PhRMA and ABPI is that there is a favorable stem cell policy in the UK already, one that allows for extensive avenues of research. However, in a field that is so costly and research intensive, the limitations placed on SCNT would seemingly be a considerable obstacle. To clarify, embryonic stem cell search is expensive, with future therapeutic applications that are equally as expensive and beyond the typical pharmaceutical industry business model. However, the benefits of SCNT—the avenue of stem cell research that is of particular controversy in Britain—have relevance for the pharmaceutical industry, most immediately. As SCNT might provide one of the most direct benefits to the pharmaceutical industry, it would stand to reason that the industry would desire to see this form of research supported. If the pharmaceutical industry is limited in its ability to affect policy through financial means, then it might explore another avenue by which to assert its influence. Similar to the British Catholic Church, a public campaign would be a promising second choice.

Why this is relevant is that, when compared to the influence that the US' PhRMA has on legislators, legislation, and the legislative process, the British ABPI has fewer tools at its disposal. While there are no limits placed on the donations that candidates can receive, the marginal value of these donations is far less when there is a limit on how much money can be spent. This fact levels the field across candidates, and makes the accumulation of campaign funds a veritable nonissue. With this, the influence of funds and potential donations from persuasive or special-interest groups is substantially diminished. To what extent organizations like ABPI can have an effect on policy matters, then, must come from other channels, or perhaps not at all.

Taking its lead from the US pharmaceutical industry, the British counterpart has remained distanced from the type of advocacy work that would be most beneficial to its cause. Rather than emulating the US industry, the British pharmaceuticals could follow the British scientific community in mobilizing citizens through civic grassroots work. This is especially the case for SCNT, the type of research most relevant to the industry, yet receives the greatest public skepticism. It is not this type of advertising or campaigning that the pharmaceutical industry has engaged in. The industry advertises already-marketed drugs, but not the research that brings about these drugs. In this way, a profitable industry like the pharmaceutical industry is making use of one avenue to affect the field in which it operates, an avenue that might not be most effective.

In Britain, with a stem cell policy that has traditionally been more favorable to research, and a public opinion that mirrors this policy, the British

pharmaceutical industry is in much safer waters when it comes to the future support of this work. This fact, alone, might help to explain the more outwardly favorable stance taken by the British pharmaceutical industry versus that in the US. From a policy standpoint, there are fewer questions surrounding how embryonic stem cell research might be perpetuated in Britain, and the UK pharmaceutical industry has acted in accordance with this, with stated support for utilizing embryonic stem cells in the pharmaceutical R&D work. What is more, international pharmaceutical powerhouses, like Pfizer and GlaxoSmithKline, have set up operations in the UK, where hESC research is more readily embraced. With this in mind, the social acceptance of a field like embryonic stem cell research has an important effect on what social groups might then express support for it. In Field Theory terms, the composition of the social Doxa dictates who enters the field and for what reasons.

However, this argument might not explain the entire set of circumstances. As recent events, like the takeover of the HFEA and the EU court ruling on research patentability, indicate, the future of embryonic stem cell research in Britain is just as questionable as it is in the US. Though the policy and public support for this research might not change, the circumstances by which the research is carried out might change. This creates the same degree of uncertainty that the pharmaceutical industry in the US has experienced. Despite this, there is continued support for this research, as expressed by pharmaceutical companies, implying that there may be issues other than a questionable regulatory future that influence the levels of support offered by these companies. Some of this might be found in the tools afforded to the industry in Britain versus the US.

The political system in Britain is arranged in such a way as to limit the influence of corporate expenditures in policymaking. This arrangement is achieved by the campaign finance laws that have played an integral role in defining the British political culture. The result is a pharmaceutical industry, organized and represented by the ABPI, that is limited in its ability to exercise one of its primary means of influence: persuasion through economic capital. This draws a distinction between the pharmaceutical industry in the US, as represented by PhRMA, which uses this avenue of political influence to an extensive degree. Without a forceful means to effectuate policy change, whatever the change might be, it makes sense that an industry like the pharmaceutical industry would align itself with the dominant voice in this debate, the scientific community. This is the case because, without acting collaboratively with the scientific community, the pharmaceutical industry puts its future at even greater risk. The argument can be made, then, that when a social actor is reduced in its available capital, the position it takes will change in relation to the prevalent discourse.

PATIENT ADVOCACY GROUPS

The European patient advocacy community is characterized by an extensive network of “health campaigners”. As described by the international group, Health Equality Europe (HEE), a “health campaigner” is a group of advocates that provides services, like patient support, networking, and sometimes even healthcare, which are thought to be somewhat scarce in European national healthcare systems (Health Equality Europe, 2006). Many of these groups provide assistance directly to patients and members of the public, in an attempt to “make the patient voice audible to doctors, the media, healthcare systems, or government”. Health campaigners take a proactive and methodical approach to developing campaigns and policy issues, and often these priority agendas are built from the concerns raised in response to external events.

As a result of limited resources, many European health campaigners rely on less costly strategies to effectuate the changes they wish to see. Based on a study conducted by HEE on some 250 health campaigners, about 66% of these groups have utilized the placing of stories in the media as an effective strategy, and about half of these groups report having relied on the lobbying of politicians. Unfortunately, many of these health campaigners report receiving little-to-no support from European governments, though many do receive funding and support from outside sources (Health Equality Europe). With this in mind, many health campaigners argue that financing and visibility posed the greatest challenge to the perpetuation of these groups in European society.

Similar to patient advocacy groups in the US, about 30% of European health campaigners report having raised money for or have actually conducted medical research (HEE, 2006). Many more health campaigners reported wanting to conduct this kind of research if they had the means to do so. In a manner that is, likewise, similar to patient advocacy groups in the US, health campaigners in Europe also believe that their degree of influence and legitimacy is correlated to their size and notoriety, with many reporting that members of the media and government do not necessarily take their positions seriously.

In a manner that is somewhat different from strategies employed by patient advocacy groups in the US, many groups in Europe do not rely on grassroots efforts or public mobilization as a means of “campaigning” (HEE). Rather, European health campaigners often resort to direct lobbying efforts done by the organization hierarchy, as well as media stories and other low-cost initiatives. In a corresponding report issued by Health Equality Europe, the organization looked at the role that the media and policymakers play in health advocacy. In this report, which was based on interviews and data obtained from policymakers and members of the media, many legislators argue that these groups play an important role in public debate (Health Equality Europe, 2006).

The British think tank, PatientView, issued a report addressing the most central concerns facing the patient community in Britain. As PatientView argues, “The growing number of older people in the population, coupled with a gradual

rise in the incidence of chronic disease, have elevated both costs and demand to the point at which policymakers are having to ration health care services..” (PatientView, 2005). For this reason, the concerns of the patient population have been growing, in particular how their rights as individuals will be protected. From this perspective, in ways that are perhaps reflective of an inter-play between SSK and Field Theory, the scientifically-friendly social context in the UK has driven the concerns and position of the patient advocacy community. The green light that has been given to human embryonic stem cell research has emphasized the need for protections by virtue of advancements in this work.

Particularly with patient advocacy groups in the UK, health campaigners cited “patient’s rights in medical research” as a primary concern. In 2005, members of the patient advocacy community met with academics, administrators, health professionals, and policymakers to discuss how members of the public and members of the research community can work together to ensure that medical research benefits both communities (PatientView, 2005). Patient advocates have expressed concern over the disparities and sense of goals between patients and researchers. As was acknowledged, clinical research concentrates on the goal of determining whether an intervention has greater benefits or risks. However, from the perspective of a patient, this determination has a far greater and pressing impact (PatientView). As a result, patients have requested a more holistic perspective of the patient, one that acknowledges an increase in quality of life rather than simply a longer life expectancy.

With this in mind, there is a delicate and symbiotic relationship to be found between scientists conducting human embryonic stem cell research and the patient advocacy community that might benefit from this research. The “purification” or “autonomy” afforded to science has existed as a central means of establishing its authority, both from a World Polity and SSK perspective. However, when lines of epistemic division are drawn at the expense of those who, in the case of stem cell research, benefit from scientific advances, the interactive nature of Field Theory-relationships can be undermined. In other words, when the epistemic boundaries around science prevent it from creating alliances with other actors, its position in the social field can be reduced. This makes an important claim about how WPT, SSK, and Field Theory work together. The authority of an institution like science, and the epistemic boundary work that is conducted between science and society, can have a negative impact on its ability to maximize its social capital.

A lack of collaboration and communication between similarly-minded social actors can create inconsistency in centralizing a message. To a certain degree, this has been the case between the scientific community and patient advocates in Britain. As stem cell research enjoys broad support in the UK, it is not necessarily stem cell research funding or support that British advocates are looking for, but rather protections for when research translates into therapies and treatments. With this in mind, according to a survey of patient advocacy groups conducted in the UK, many disease advocacy organizations include information

about research and clinical trials on their websites.

How the patient perspective has influenced policy and public opinion is noteworthy in the UK, and is reminiscent of similar effects found in the US. Jensen conducted a full text literature review of newspapers and periodicals in the US and UK, assembled from January 1997 to February 2006, on news episodes related to embryonic stem cell research and cloning technologies, with the aim of ascertaining the degree to which patients have influenced media coverage on therapeutic cloning. Utilizing a concept which Giddens refers to as, “life politics”, patient advocates help frame complex political and social issues into a source of sympathetic concern—human suffering—which generate journalistic interest (Giddens, 1991; Hughes 1981). It is these types of appeals that seem to have a significant impact on members of Parliament and Congress.

According to Jensen, the impact of “celebrity patients” like Michael J Fox and Christopher Reeve has played a large role in shaping the debate on therapeutic cloning, and has played an equally large role in the construction of “life politics” as a lens through which to understand the social debate. It is this perspective that the scientific community lacks when addressing stem cell research from a solely scientific point of view. According to Jensen's data collection, working with patients around the UK, advocates of therapeutic cloning were able to place many opinion pieces in newspapers. To be sure, Reeve embodied the political concerns of the therapeutic cloning and larger stem cell research debate, and he captured the attention of the elite British media more than any other political activist (Jensen). In a statement made by Reeve about therapeutic cloning and stem cell research, a statement documented by the Guardian, Reeve argued, “I am disappointed. When I was first injured, I thought hope would be a product of adequate funding, and bringing enough scientific expertise to the problem... what I did not expect was that hope would be influenced by politics” (Guardian, 17 September 2002). It is likely that Reeve, as a long time political activist, did, in fact, expect that the progress of science would be influenced by politics. However, the idea that “politics” might have an effect on important social issues, especially science, is an idea with which many people might feel uncomfortable. This is the concern that Reeve was bringing to light, in an effort to mobilize public opinion. Though matters of science are increasingly being negotiated in the political field, this is not necessarily a set of circumstances that many people, in general, fully support, as there is more trust in scientists than there is in politicians. To highlight the belief in the scientific community over the demand for politics or regulation in science, the BMRB report quotes a British citizen, stating:

Well, we as a population have to have faith in the people who are doing this research on our behalf. If we don't have faith in them then there is no point is there? We have to, it's almost an institutional thing. We have to say they're there, they're there for our benefit. We have to let them get on with it.

Though this is an isolated quote, it is reflective of a general trend in British

society that prioritizes the scientific institution as a self regulating and socially beneficial enterprise.

When it comes to the tabloid sector of the British media, patient advocate, Jimmy Johnstone, has received a great deal of attention. Johnstone, a Celtic football player who was stricken with a neurological disorder, has become a prominent stem cell research advocate in Britain. Diagnosed in November of 2001, Johnstone has been particularly vocal in British media outlets, making statements in favor of stem cell research like, “to those opposing this, I say, ‘if one of your loved ones had [ALS] and knew that using stem cells could lead to the cure, what would you do?’” (Johnstone quoted in Jensen).

Large patient advocacy organizations in the UK have mirrored some of the strategies employed by US organizations to affect the stem cell issue, in a way that is emblematic of the international connections and isomorphism found in WPT. For instance, British patient advocacy groups and charities, like Diabetes UK, have issued position statements on stem cell research without expressly looking to recruit additional supporters and advocates to change federal policy. Diabetes UK has provided a position statement on stem cell research and diabetes, located on its website, as a means to inform visitors about the basics of the research and why it is important (Diabetes UK, 2010). In this statement, Diabetes UK claimed, “Following a member and stakeholder consultation in 2001 and a survey of members in late 2009, Diabetes UK has committed to support stem cell research both publicly and financially through our research grant program....”(Diabetes UK).

In terms of the research that Diabetes UK funds, the charity states that it must be in compliance with the Human Fertilization and Embryology Act in relation to the ethical criteria. Diabetes UK is a member of the larger British Association of Medical Research Charities, a conglomeration of medical research and patient advocacy charities similar in nature to the US' CAMR. The Association of Medical Research Charities (AMRC), is a membership organization with the, “aim to support the sector's effectiveness and advance medical research by developing best practice, providing information and guidance, improving public dialogue about research and science, and influencing government” (AMRC, 2011). This 126-member organization, created in 1987, has contributed more than £1 billion to medical research, in 2010-2011 alone, to combat such diseases as heart disease, cancer, diabetes, cystic fibrosis, and others.⁵⁵

⁵⁵ Through its mission to help create a vibrant and robust medical and health research sector for the benefit of the patient, AMRC has provided member organizations with support to become better research funders, and to develop collaboration across members. AMRC works in conjunction with a lengthy list of influential groups, such as the Campaign for Science and Engineering In the UK, Science Media Center, and Stempra, which help disseminate the message of needed medical research. AMRC's staff members sit on many influential research boards, including Academy of Medical Sciences Industry Forum, The Chief Scientist Committee, Medical Research Charities Group/Health Research Board, UK Clinical Research Collaboration,

AMRC includes as one of its primary roles the responsibility of being alert to legislation, regulation, and other developments that have an effect on medical research. AMRC is particularly mindful and responsive to the UK government when it comes to matters of policy and new legislation, in an effort to monitor the developments through consultation with member organizations and the government, itself. AMRC has developed a series of policy positions and statements on a number of issues, including stem cell research. In 2003, AMRC issued its statement on human embryos and stem cell research, and in this statement, argued the following:

AMRC supported the Donaldson Report's recommendation that the legislation should now be amended to permit research into human embryos and to allow that knowledge to be used to develop treatments for serious disease –AMRC, 2003

AMRC has also been asked to provide consultation to diverse inquiries from external bodies across the medical, health, science, and charity sectors. AMRC drafted a response on behalf of its membership organizations, and issued a consultation response to an inquiry on stem cell research from the House Of Commons Science and Technology Committee Inquiry into the Regulation of Hybrid and Chimera Embryos. The inquiry came in response to a request for research funding from two British researchers who sought to conduct work involving hybrid embryos, to which members of the HFEA stated they would need to collect more information before granting a decision. In order to help in these deliberations, AMRC was offered an opportunity to provide evidence, and conducted a survey of its then-112 member charities and patient organizations. Many felt that a prohibition, or even delay, in funding research on hybrid embryos would have a negative impact on their ability to research treatments in their respective fields. AMRC, as a collective entity, shared that concern, stating “we believe that any ban would limit a potentially vital avenue for research which could greatly increase our understanding of serious mental conditions which may ultimately lead to new treatments and cures” (AMRC, 2007).

The effect of this consultation from the House Of Commons Science and Technology Committee is not to be underestimated. Following the inquiry, in 2007, the British government issued a report and set of conclusions and recommendations. Based on testimony and evidence received from such organizations like AMRC and the Wellcome Trust, the House Of Commons Science and Technology Committee recommended that, “we regard the current Government proposals as overly prohibitive...The new legislative structure should permit the creation of animal-human hybrid and chimera embryos for research purposes, subject to regulation, and should aim to reduce the risk of litigation of borderline cases” (House of Commons Science and Technology

and the Stem Cells Communication Coalition.

Committee, 2007).⁵⁶

In the British, as well as the US, context, what has become central is that patient advocacy groups have seen a position for themselves in the stem cell debate. This is central when looking at stem cell research from a Field Theory perspective, and has centrality to public policy. In his book, *The Power of Public Ideas*, political scientist and presidential adviser, Robert Reich, has discussed the ways in which legitimacy is afforded to policy decisions and ways in which policy comes about. The impetus behind acts of policymaking lie in social movements, the communication of effective legislators, and the raising of a salient public question. Reich presents this by stating, “rather than responding to pre-existing public wants, the art of policymaking has lain in giving voice to these half-articulated fears and hopes, and embodying them in convincing stories about their sources and the choices they represent”(page 5). When viewed in the context of stem cell research, the members of the public most fully embodying the ability to raise the social question and provide context or stories to this question, are members of the patient advocacy community.

In the UK, the marriage of the concept of “patient” and “advocate” is a tight one. As exemplified by such notable and prolific disabled individuals in Britain as Stephen Hawking, there is an important place for the patient advocacy community in British civil society. In Habermasian terms, there is a belongingness for members of the British patient community that allows them to take part in the public sphere. Similarly, in a Bourdieusian sense, the cultural meaning attached to “patient” as advocate influences how we as individuals can be considered a part of the national polity. In the case of the patient community in Britain, a nation whose political and social culture is defined by equal opportunity, it makes sense that these individuals can engage in the political discourse.

When it comes to those in the best position to mobilize people and resources around an idea or issue, advocacy plays a critical role. While an idea can be brought to light by members of academia or social authorities, how this

⁵⁶ The recommendations provided by the Committee were offered to the government in response to proposals to ban all forms of hybrid research. Based on inquiries and evidence provided by many patient advocacy groups, this ban was not supported by the Committee, and the Committee advocated for greater definition and clarity when discussing the complexity of this research. While the Government did not wholeheartedly embrace all of the recommendations offered by the Science and Technology Committee, it did accept several important ones, including the recommendation to differentiate what types of hybrid research should be permitted and what should not. In a subsequent report issued by the Government, they recommended: “in regard to the scientific evidence produced during the Committee's inquiry, and acknowledging that the recommendations are a consensus view of the Committee, we intend to accept the principle that legislation should provide for the following interspecies entities... to be created for research purposes, subject to the usual requirements for embryo research in the 1990 Act: cytoplasmic hybrid,... human transgenic embryos,... human-animal chimera (British Parliament, 2007).

idea gains traction and becomes part of a public debate relies on advocacy. In turn, contrary to the essential premise of World Polity Theory, that legislators act with a desire for rationality or economic development, from a Field Theory and social movements perspective, governments act when they are forced by public sentiment to act. As political scientist, Philip Heymann has argued, “widely shared beliefs about the way social reality works are a powerful determinant of what is accepted, expected, and done in the relations among individuals, groups, institutions, and nations. So are the mandates and the suggestions of government. The two interact. Widely shared, well-defined beliefs shape the actions of governments.” (Heymann in Reich, 1998). In this way, the social Doxa, which lies at the heart of Field Theory, has a direct effect on matters of public policy. In the realm of stem cell research, the Doxa, or the shared belief, is fostered by the Orthodoxic role, or mobilization, perpetuated by patient advocacy groups.

With this in mind, what is the real, more adaptive challenge that members of the patient advocacy community are seeking to take on by their activism in the stem cell debate? In Britain, there has been a great deal of headway made in advancing this research, and it is possible that some of the next advances in bringing the research to market through translational research will take place in the UK, beginning with clinical trials that move to marketable products. Given the path that this research has taken in the UK, it seems likely that this translational research will take place with or without the input of the patient advocacy community. Given the choice, it seems likely that those very individuals who may be denied access to taking part in other social issues, might very well desire to be a part of *this* social issue that affects them so directly.

In addition, though, there is safety in entering the social debate on an issue that is already widely supported, especially when this issue might, in other circumstances, encompass a degree of controversy or social backlash. This is to say that, when speaking out on behalf of an issue that might significantly benefit one's life, there is little opportunity cost in entering a cause that already has support. When it comes to the stem cell research question, then, the patient advocacy community in the UK is part of an even broader *societal* community that similarly supports this research. While in the US, patient advocacy groups have subjected themselves to some degree of social criticism as a result of their support for embryonic stem cell research, similar groups in the UK might be less at risk of this alienation. There is, then, a greater degree of belongingness, or less anomie in Durkheimian terms, to be found in this issue in the UK.⁵⁷ When there are limited resources to expend on any particular cause, it might make social sense to be a part of one that can generate attention while not demanding much expense.

How this applies to stem cell policymaking, too, is of relevance. As

⁵⁷ See Chapter 3, Patient Advocacy, for more about alienation of patient advocacy groups in the US due to support for embryonic stem cell research.

opposed to the US, where agenda-setting in social groups often relies on membership support and member votes, the structure of advocacy groups in the UK is such that there are “spokespersons” or loci of authority who have influence on the advocacy agenda for the groups of which they are a part. The more generalized agenda for these groups, then, is the product of what a more limited group of advocates might desire. As such, there is a more limited yet concentrated emphasis on a select number of important issues. Gaining access to the most cutting edge and innovative therapies is one of these important issues.

DISCUSSION

Despite the fact that the US and UK are both “core” countries in Wallersteinian terms, the UK presents a case of stem cell research policymaking and social debate that is different than that seen in the US. The *interests* of social groups and actors in the UK are not largely different than their counterparts in the US. However the UK is home to a considerably different set of political and cultural ideals that implicitly shift the power dynamics of these actors, the sources of capital for which they strive, and the actions they take in order to obtain this capital. For these reasons, when looking at human embryonic stem cell research policymaking from a Field Theory point of view, the UK presents an important case of how this issue can be, and has been, approached in a political system that favors transparency, deliberation, and expertise.

Demonstrated by the extensive exchanges between the British Parliament and bodies of research experts, the British government is characterized by the reliance on and input from epistemic authority figures when it comes to matters of policy. What is more, British society is more discriminating when it comes to how it attributes “expertise” and “authority”, such that input on a matter of science is solicited from members of the scientific community. However, this claim can only be made to the extent that the British policymakers and society do, in fact, view stem cell research as a fundamentally scientific issue, and this has only been the case through the social debate surrounding this issue that has been established by the scientific community.

The results of these circumstances, predicated on a moral tradition based on rationality and utilitarian principles, have led to a policymaking framework that has the scientific community's voice as the dominant voice. This is not to argue that the British approach is the correct approach, to whatever extent an approach can be considered “correct”. What can be said, though, is that this arrangement of social actors has brought about a stem cell policy that is known for its liberal stance.

The UK is home to one of the most liberal stem cell policies to be found in the world. In a way that is distinctly different from the US, the story of stem cell research policymaking in Britain adheres especially closely to some of the most prominent features of World Polity Theory and the Sociology of Scientific

Knowledge. These two ideas, that the UK has a liberal stem cell policy and that stem cell science in Britain follows the predictions of WPT and SSK, are not necessarily related, as there are other countries around the world with liberal policies that may not have evolved in the same way. Nevertheless, when looking through the lens of WPT and SSK, the addition of Field Theory helps to explain a considerable degree of variation in science policymaking in Britain.

Meyer and Drori's notion of a "world polity" grows out of globalization theory, where the actions of individual nation-states transcend national borders and occur in an increasingly-interconnected, transnational space. It is the exchange of information across national borders that allows for institutions like science to develop on a global scale, not adherent to local sensitivities or "primitive superstitions". How the first derivation of human embryonic stem cells took place is very much the result of this idea: that a scientific breakthrough that took place in Madison, Wisconsin could quickly become an international scientific pursuit. The field of embryology and, as a result, stem cell research, is the product of extensive interactions and connectedness between work taking place in the US and work originating in the UK. The biomedical breakthroughs of the first successful IVF pregnancy, followed 18 years later by the cloning of Dolly the sheep, were both significant scientific milestones that provided basic understandings about embryonic development. Were it not for the exchange of information across national borders, from the UK to the US and back again, the progression of this scientific field would have been severely stalled. It has been the benefits of globalization and the transnational institution of science, fundamental to World Polity Theory, that have served as the impetus behind this field.

Evidence of World Polity Theory can be found in Britain's stem cell policymaking, as well. At the heart of WPT is the idea that matters of science have a rationalizing and modernizing effect on society, and that investments in science help to build a country's "knowledge economy". Further, WPT argues that the benefits of a knowledge economy are preferable to economies based on other sources of wealth, as knowledge is the foundation upon which modern societies are built. In order to maximize scientific opportunities, Meyer and others advocate that it is within a government's interest to follow the guidance of scientific experts who act as "rationalized others". The history of British policymaking demonstrates the tendency for governments to act in this very way. The extensive exchanges between special committees in the British Parliament and scientific experts like members of the Royal Society indicate how heavily the British government relied on members of the scientific community to provide guidance and expertise on its final stem cell policy. The British HFEA and UKSCI were the result of a rationalized and expert-driven approach to a system of research oversight that has served as a model for other important social issues. The product of Britain's reliance on stem cell research and scientific experts to create a piece of science policy speaks directly to the heart of WPT.

However, how Britain's stem cell research policy reflects more generalized

World Polity argumentation is not to be underestimated either. Although the UK's stem cell policy was the product of a great deal of expert input, it would not have been pursued quite so aggressively, were it not for the policy failure in the US and the opportunity for the UK to surge ahead as a result. This set of circumstances calls to mind the central line of thought in WPT, that countries that fail to embrace progressive science policies run the risk of falling behind other, more modernized countries. During the early years of the Bush administration's stem cell limitations, the British government touted the more scientifically-friendly research environment in the UK, in an attempt to lure US researchers. Though this took place to only a limited degree, the potential remained of a scientific brain drain resulting from a backwards US policy vis-à-vis a broader UK policy.

How the UK stem cell policy has evolved, however, cannot be stripped away from the cultural circumstances found in Britain, and this is where the work of SSK becomes so prominent in the UK case. The progressive nature of the British stem cell policy is not only the result of a reliance on scientific expertise in policymaking, but also the British history of comfort with scientific questions that touch upon the notion of life. The successful birth of Louise Brown in 1978, the first IVF baby, helped to create a cultural environment in Britain that was far more accepting of research like embryonic stem cell research. At the time of the first derivation of human embryonic stem cells in 1998, members of British society had already debated ethical questions of embryonic research for over 20 years, and had already implemented a regulatory agency, the HFEA, that could oversee this type of work. To a large extent, questions of embryonic research have been embedded within British culture for decades, creating a research environment that was not subject to many of the same questions that could be found in countries like the US and others. This might be one of the greatest benefits afforded to human embryonic stem cell research in Britain, and it cuts right to the heart of SSK. As SSK investigates the events in a country's history, as well as the epistemic values found within a society, the human embryonic stem cell research question in Britain is reflective of both of these ideas. The pivotal breakthrough of IVF technologies found in Britain was a culturally-transformative event that has shaped British thinking over the past 33 years.

The predominant sociology of science theories, WPT and SSK, shed considerable light on the UK case. However, there are important gaps in this case that are left unexplained through these theories alone. First, the British stem cell policy did not demonstrate the cultural isomorphism that one would expect to see from a World Polity point of view. The US policy that preceded the UK stem cell policy did not serve as the template or social script that WPT might predict. Instead, there has been a more delicate interplay of circumstances that led to a policy beyond that seen in the US. The contextual and historical circumstances found in the UK have not brought about changes in the work that is conducted in Britain, contrary to SSK. For instance, the liberal policy measures in Britain did not have any demonstrable effect on enticing US researchers to relocate to this more scientifically-friendly environment. This suggests that there are more dynamics at play that affect who enters a field and creates the knowledge. With

these lapses in mind, there is room for greater analysis provided by Field Theory.

Despite the effect that sociological frameworks like WPT and SSK have had on explaining the case of stem cell research policy in the UK, there are important interactions among social actors that are missed in these perspectives, alone. When considering some of the most influential and powerful actors who have contributed to the stem cell research debate, the Catholic Church, the scientific community, the pharmaceutical industry, and patient advocates, the interactions are caught within cultural forces that have produced an outcome particular to the UK context. In Field Theory representation, the constellation of social actors impacting the British stem cell research question can be depicted in the following way:

United Kingdom



Doxa based on expertise, authority, and Utilitarianism

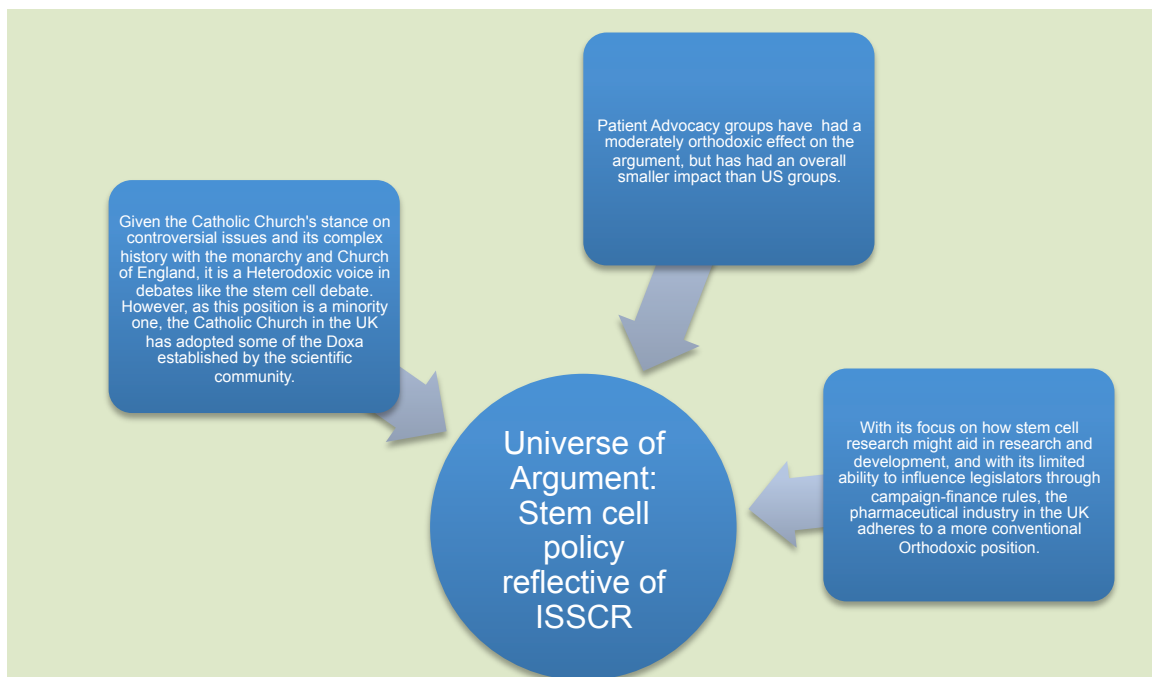


Figure 2: Field Theory Diagram of UK Stem Cell Policy

The stem cell research debate in Britain has resulted in a policy that allows for a broad array of activities in the stem cell field, including the derivation of embryonic stem cells from such techniques as SCNT and parthenogenesis. To arrive at such a policy, the scientific community has had a Doxic position in this debate. The position that members of the scientific community hold is reflective of the research guidelines recommended by such international institutions as the International Society Stem Cell Research. The reliance on experts like those found in the scientific community is to such a considerable extent that science' ability to define the terms of the debate has been difficult to challenge. The command that the scientific community has had on the stem cell question has presented itself not just in the form of policy but also in its ability to shape public opinion and discourse. British scientists' role as "civic scientists" has brought these researchers in intimate contact with members of the public who elect legislators to Parliament. The result has been a dual effect put into place by the scientific community, an effort that operates at the policy level and an effort that operates at a broader societal level.

Despite the fact that the scientific community in Britain is so formidable, the success that it has had is in no small part the result of the relationship that science has with government, and the desire that the British government has had to make a strong presence in the stem cell field. Were it not for this desire to make profound strides in an area of scientific inquiry, it is possible that the scientific community would not have had such a simple time in establishing the dominant position. In this way, the fundamentals of Field Theory have had an interactive relationship with the fundamentals of World Polity Theory.

The position enjoyed by the scientific community has a cascading effect on how other social actors have influenced the resulting debate. As to be expected, the Catholic Church in the UK has frowned upon the perpetuation of embryonic stem cell research, just as it did on the perpetuation of fertility research. However, given the reliance on the scientific community and given the cultural history found in Britain, the perspective of the Church has not been nearly as influential as it has been in the US. The Catholic Church in Britain has had to promote the doctrine of the Catholic Church hierarchy, but within a social space that favors the dominant position of the scientific community, and a competing religion that has taken a less condemning position on stem cell research. As a result, how much this position has resonated at the policy level is considerably less. This is coupled with the fact that, central to British culture, there is greater discernment in which actors can claim legitimate authority over what issues. The result has been a more tacit and grassroots approach to affecting the stem cell debate, one that is Heterodox to the dominant scientific perspective. The strategies of the Catholic Church in Britain, then, have been different than those used in the United States, as the British entity does not maintain as strong ties to the policymaking structure, and especially not in a matter of science. The Catholic Church in the UK has a position that is at odds

with that of the Church of England, which enjoys much broader public and governmental support, as it is far more widely practiced and is under the oversight of the British monarchy. What is of note is that the Church of England's position on the ethics of embryonic stem cell research is in alignment with, from an SSK perspective, some of the most defining features of the British stem cell context: the existence of the HFEA as a cultural icon in the UK, and the British moral tradition based on utilitarian principles. With the gradual phasing out of the HFEA in the years to come, it will be interesting to see if and, if so, how the Church of England's perspective might similarly evolve. If, at that time, the Church of England alters its view to be less favorable to embryonic stem cell research, the Catholic Church might find a formidable ally.

In relation to the US, Britain has a more progressive stem cell policy and has adopted the position of the scientific community. As a result, influential actors like the pharmaceutical industry and the patient advocacy community are given greater discretion to adopt positions that are in better alignment with the prevailing social discourse. The British pharmaceutical industry, in relation to that of the US, has been much more supportive of and committed to the benefits that embryonic stem cell research affords to its future. Not simply expressing support in electronic media, corporations like Pfizer and GlaxoSmithKline have established research centers in areas like Cambridge, England, where public opinion on this research is more welcoming.

The progressive stem cell policy and social debate established by the scientific community has created a set of circumstances where the pharmaceutical industry has been able to develop connections with research institutions, academia, and biotechnology to advance this work. The implications of this are manifold. First, the British government that prioritizes science in the stem cell debate has made the entrance of the private sector less uncertain in the UK versus the US. For over a decade, the permissibility of embryonic stem cell research in Britain has been relatively unquestioned, likely alleviating many of the concerns that the US counterparts exhibited towards this research. In years to come, with the consolidation of the HFEA, the pharmaceutical industry's commitment to this work will surely be tested. In addition, however, the Doxa established by the scientific community has encouraged collaboration between the pharmaceutical sector and the research infrastructure in a way that has been absent in the US. The interconnectedness between the pharmaceutical industry and scientific community, fostered by such organizations as Stem Cells for Safer Medicines, likely has helped establish a friendlier relationship between these two actors. With these connections already in place, the pharmaceutical industry in the UK, then, is in a better position to embrace or even promote the benefits of embryonic stem cell advances to their work. This is a position that has not yet been fully emphasized by the pharmaceutical industry in the US.

How members of the patient advocacy community have negotiated the multidimensional space of stem cell policy in Britain is a bit more complex and multifaceted. To a large extent, members of patient advocacy groups have rallied

around human embryonic stem cell research as a means to alleviate human suffering. While many of these groups operate on limited funding, the social environment created by a Doxa established by the scientific community allows members of these groups to support this research without great expense. In the US, a great deal of funds is directed towards lobbying efforts and altering public opinion. However, in a country like England where the policy is more liberal, these expenses are not necessary. Efforts, then, can be made to bolster the position of the scientific community in a way that provides human testimony to scientific work. Additionally, the environment created by the scientific community makes the resistance and fears of backlash more reduced, allowing for more patient advocates to be a part of the field without risk. However, this does not remove some of the fears about the future of this research, and protecting patients from abusive trial processes that may result from this work. For this reason, the support for stem cell research policy extension is reserved, with a promotion of the science but with concerns about how translational efforts might be carried out.

The result is a social space that has been dominated by the position of the scientific community, allowing for similar support to be expressed by diverse actors like the pharmaceutical industry and patient advocates. The focus on the science has given free reign to others to enter the debate with less reservation, despite the fewer resources afforded to these groups in the UK versus the US. The Doxa established by the scientific community has given way to an even stronger orthodoxy, supporting a more liberal policy than seen in many other parts of the world.

CHAPTER 5: GERMANY
**SCIENCE THROUGH COLLECTIVE
MEMORY**

CHAPTER 5: GERMANY-SCIENCE THROUGH COLLECTIVE MEMORY

As World Polity Theory argues, science has a modernizing effect, and it is within federal governments' interest to embrace the recommendations of experts in science, so as to bring about a rational and economically competitive society. However, when countries choose not to embrace the rationalizing effects of science, it is not always the result of a rejection of the “rational” in favor of some more traditional or religiously-based belief structure. In World Polity Theory, there is an implicit assumption that “rationality” is an attainable status, and that this is achieved through a reliance on secular principles. Some social theorists, including many in the Sociology of Scientific Knowledge school of thought, might argue that such a pursuit of rationality is a social myth. Science, according to this line of reasoning, is no more a culturally-neutral construct than any other social artifact, and it is not necessarily a normatively-neutral vehicle to rational thinking. The complex history embedded within a culture—to a degree that reflects or even surpasses the social factors highlighted in the Sociology Of Scientific Knowledge—plays a measurable and even decisive role in how a country relates to and internalizes a matter of science policy. How human embryonic stem cell research has taken shape in Germany highlights this very idea, with a complex social history and populace keenly tuned into its history. The path-dependent nature of stem cell research legislation in Germany implies a new set of social considerations that exists beyond many of the cultural, economic, or religious concerns that have shaped policy in other countries.

Germany, by its nature, is economically sound and capable of investing in science. In fact, Germany has quite a rich history of science, and has invested heavily into areas of scientific inquiry like climate research. It is stem cell research and issues of bioethics that Germany bristles against, highlighting a complex relationship with this scientific question above all others. Germany has one of the most restrictive stem cell research policies in the world, and certainly within Europe. Whereas many other countries that reject this research do so from a religious perspective, Germany takes a different approach, one that comes from ethical principles rather than religious prohibitions. Germany's complex social history makes for a particularly fascinating case study in scientific policymaking for new avenues of scientific research. Stem cell research in Germany is a product of cultural context and historical memory operating both to influence the epistemic environment and interactions among social actors.

As with all cases included in this analysis, the German case has been included because it offers a valuable insight into how scientific policymaking can adhere to unanticipated social forces. Germany is a valuable case to illustrate how the authority afforded to science can be divided according to salient cultural and historical events that drastically alter how science is prioritized in relation to other important social ideals. In German history, the Holocaust and societal concerns that have grown out of this event have framed nearly all facets of social debate, including one of a scientific nature like stem cell research. How actors in this case have affected the stem cell question can only be understood with this

culturally-defining event in mind. This case illustrates how a political field and social Doxa can be built around important ideas and events. These are the same ideas and events that SSK draws upon when describing an epistemic environment. However, Field Theory takes this argument even further by including how historical memory and cultural context can define a social reality and what relationships are possible to bring about a policy outcome.

GERMAN POLICY

According to some in Germany, human embryonic stem cell research is fundamentally “evil” (Takala and Hayry, 2007). The guiding principal behind any stem cell policy in Germany has been how to derive the greatest benefit from an area of science that is inherently evil. Although the first derivation of human stem cells took place in 1998, legislation surrounding embryonic research in Germany existed years prior to that. The German Basic Law, which dates back to 1949, emphasizes that “the dignity of the human person is inviolable”, (Banchoff, 2004). The Basic Law, which was invoked numerous times since 1949, was a means to protect the rights of developing fetuses throughout gestation.⁵⁸

Germany’s Basic Law, which is tantamount to its Constitution, was passed following the atrocities of World War II. Article 1 of The Basic Law, directly addresses the notion of Human Dignity as the most important issue to be addressed in the newly recreated country. The prominent position that the norm of human dignity enjoys in the German Basic Law is a direct response to the absence of such dignity during the Nazi regime. As Mahlmann describes, “Nazism still legitimizes the guarantee of human dignity today by the abominable, vivid barbarism of its negation” (Mahlmann, 2010, p. 10). The inclusion of human dignity as the defining feature of the German Basic Law stands as an indictment of misdeeds in the past but in addition, a legally institutionalized promise to create a culture of respect in Germany moving forward. The guarantee of human dignity and respect laid the groundwork for an international human rights discourse that began in Germany, has undergirded German policies since 1949, and has diffused internationally in an institutionalization of human rights culture.

⁵⁸ It was not until the birth of the first IVF baby in Germany in 1982 that Germany began to look at the questions and eugenic implications that these technologies demanded. As a result, the German government established the Benda Group, led by the former head of The Constitutional Court, Ernst Benda, which published a report in 1985. The report recommended the establishment of criminal sanctions for embryos created for research purposes, (Banchoff), but allowed the use of surplus embryos from IVF procedures. The political parties, after this report had been issued, took a more restrictive position, and the Christian Democrats, the social Democrats, and the Green party aligned themselves against the small liberal faction, the free Democrats. By a vote of 340/265, the Bundestag endorsed the compromise position that allowed for the importation of embryonic stem cell lines while prohibiting the derivation of lines in Germany.

The centrality of human dignity in German policymaking can be seen in legislative issues like those regulating biomedical technologies. In 1988, as Augst summarizes, the German Parliament addressed legislation to regulate assisted fertilization and embryo research, in a way that is both very similar to and very different from the British Human Fertilization and Embryology Act of 1990. The German Embryo Protection Act is a piece of criminal law, one of the strictest of its kind around the world. The German EPA criminalizes gamete and embryo transfer and surrogacy of any kind, and only permits fertility treatment for married couples (Augst, 2000). Similarly, according to the German EPA, most research conducted on embryos has also been prohibited. However, among those avenues of research that are permitted, there is very little in the way of supervision or regulation, and medical professionals are often given the opportunity to supervise themselves. This dual nature of German regulations, with criminalized restrictions on one side and little supervision on the other, has created a tense environment for the state of embryo research in Germany.

This issue of how to regulate questions pertaining to the dignity of human life is one that presents itself repeatedly in the German stem cell debate. For instance, one of the central challenges to establishing guidelines for embryonic research in Germany involved defining precisely what constitutes “an embryo” and what does not. The German EPA defined the human embryo as, “any fertilized egg capable of developing from the time of fusion of the nuclei, and each totipotent cell removed from an embryo that is capable of dividing or developing into an individual human being as the necessary conditions prevail” (Genetics and Public Policy Center, 2011). The EPA continues by stating that the use of embryos for any purpose other than to protect or preserve it will be punished by imprisonment. What is noteworthy about the definition of a human embryo in the German EPA is that it almost certainly includes human embryonic stem cells as embryos, as these cells have been “removed from an embryo” and are “capable of dividing”.

Perspectives on the embryonic and fertility research debate in Germany largely have fallen along partisan, though possibly not ideological, lines,⁵⁹ The provisions and prohibitions set out in the 1990 German EPA laid the groundwork for future issues regarding embryonic research, and the guiding principle for all of these was the reticence against conducting research that questioned human dignity or approached the border of eugenics and human manipulation. This was

⁵⁹ The Conservative and Liberal parties supporting the already-restrictive legislation as it was passed. The Green party, however, rejected all forms of reproductive technology, fearing the outcome of eugenic practices, and thus demanded the prohibition of any form of embryonic research, altogether. The Social Democrats took a stance that was similar to the Green Party, however they also alleged that such research could be conducted responsibly in instances designed to help those who were infertile. All parties and even experts called in to testify before the Bundestag, that when it comes to matters of reproductive and embryonic research, it is unacceptable to use these technologies in a setting outside of the “family”.

the basic concern for all types of embryonic and fertility research, and served as the fundamental question implicit in embryonic stem cell research legislation.

How regulations on embryonic research grew into regulations on human embryonic stem cell research is a story that casts light on interactions among key actors in German society. The human embryonic stem cell research question was first brought to light in Germany in 2000, when German researcher, Oliver Brustle, applied for funding from the German research foundation (DFG) for a research project involving human embryonic stem cells that had been derived outside of the German border. The prohibition on research conducted on the human embryo, as put into place in the EPA of 1990, created a potentially unanticipated loophole that allowed for the importation of human embryonic stem cells that had been derived in other countries.

In response to Brustle's request to the DFG, decision-makers were asked to delay their decision until the German Parliament had the opportunity to debate the ethics of the research and establish a coherent policy (Taupitz, 2010). To this end, two separate committees were established to investigate the ethical considerations of this funding request, and of embryonic stem cell research in general: the Committee of Inquiry On Law and Ethics of Modern Medicine, established by the Bundestag in March of 2001, and the National Ethics Council, established by the German Government in May of 2001. The first committee recommended a rejection of the importation of human embryonic stem cell lines from other countries, thereby closing the loophole created in the Embryo Protection Act. The National Ethics Council, however, decided that the government should allow a time-limited and highly regulated window in which the importation of embryonic stem cells could take place.

Given the discrepancy in recommendations, starting in January of 2002, the German Bundestag debated three different proposals regarding how to develop a piece of stem cell legislation:

1. "In light of the protection of the dignity of embryos and the Embryo Protection Act", there ought to be a prohibition of the importation of embryonic stem cells altogether.
2. The possibility of importation of hESC, so long as the imported cells were derived from supernumerary embryos that were donated for critical scientific research. A committee will be established to approve any stem cell importation.
3. The prohibition of the utilization of additional embryos in order to derive embryonic stem cells, however stem cells that were already derived and met strict regulations could be imported into Germany.

These three proposals adopt an idiosyncratically German tone. Proposal 1 illuminates the path-dependent nature of policy choices that have grown out of events in historical memory. The notion of dignity and human protections central to the first proposal calls to mind the "human dignity" established in the Basic Law. During the human rights abuses of the Holocaust, unethical and inhuman

experimentation was perpetrated on unwilling subjects in the name of scientific and medical advancement. Fears that similar practices could be carried out on the human embryo lie at the center of the German context. The historical concerns over the need to protect humans from abuses were extrapolated through the EPA to regulations on embryonic stem cell research. Proposal 2, which was the most progressive of the three, allowed for newly derived embryonic stem cell lines to be imported from other countries. The importation caveat retained a barrier between the actions of German researchers and the future of scientific advancement so that Germany could remain beyond the threat of perpetrating acts that might be deemed contrary to the preservation of human dignity. Proposal 3, which represented a centrist position between the two other extremes, addressed the same cultural concerns embedded in historical memory relating to human dignity as a proxy for the larger human rights discourse. This was the proposal that ultimately generated the greatest parliamentary support and became the foundation of the German Stem Cell Act of 2002 (Taupitz, 2010). Parliamentary coalitions that were formed to either support or oppose the permissibility of embryonic stem cell research in Germany cut along unpredictable and non-ideological lines, with alliances created across the political spectrum. During votes, coalitions were created based on dissimilar points of view, for instance an opposition to embryonic research from the political left based on concerns over eugenics and opposition from the political right based on religious beliefs.

As these three proposals highlight, the link between historical events and contemporary actions is of sociological concern. The phenomenon of historical memory bears particular relevance to many issues in German culture, and particularly an issue like human embryonic stem cell research. In fact, when discussing a sociological theory like historical memory, the Holocaust is often cited as a paradigmatic example of how memories can create public anxieties that can dominate cultural identity (Healy and Tumarkin, 2011). Central to a theory of historical memory is the idea that individual memories are often incomplete, distorted, and partial, but each carries with it a distinct social significance (Mize, 2009). This sociological framework is particularly useful for understanding how events in the past affect understandings in the present, and how “remembering” can be a social process.

At the time that the stem cell debate was fermenting in Germany, the DFG began to take an advisory role in how legislation ought to evolve. The DFG recommended that a Federal Commission should be created to verify that research requiring embryonic stem cells was scientifically valuable, and that the stem cells were derived using supernumerary IVF embryos donated without any financial compensation (Beckmann, 2010). Interestingly, the DFG recommended that, above all, researchers requesting the use of embryonic stem cells demonstrate that these cells were the only means to bring about the desired medical advancement and could not be achieved through the use of any other medium. Curiously, in a break from the scientific ranks, the DFG stated that research using adult stem cells was preferable to research using embryonic stem

cells (Beckmann). The DFG similarly made the statement that a human life begins at the final fusion of the gametes, or essentially at conception, however the protection of this life is on a variable scale, with the necessity to protect life increasing according to the stage of embryonic development.⁶⁰

The German Stem Cell Act was passed on April 25, 2002 (Heinemann and Honnefelder, 2002). This Act stated that the importation and use of embryonic stem cells are, in theory, prohibited. A caveat to this position was that embryos could be imported into Germany under very particular circumstances.⁶¹ In a deviation from the definition of “embryo” established in the Embryo Protection Act, the German Stem Cell Act defined “embryonic stem cell” as “all human cells which have the potential to multiply by cell division if in a suitable environment and which by themselves or through their daughter cells are capable, under favorable conditions, of developing into specialized cells, but not into a human being” (Stem Cell Act, 2002). This definition created a necessary and important distinction between an embryo, which Germany describes as having the ability to develop into a fully functioning human being, and an embryonic stem cell, which has the ability to develop into specialized cell types.

The German Stem Cell Act stipulates conditions under which human embryonic stem cell lines can be imported into Germany. Similar to the policy implemented by President Bush in 2001, the German Parliament declared that human embryonic stem cells entering Germany could not have been derived at any point later than January 1, 2002, and must have been derived according to legislation relevant to the country of origin. This provision took a traditionally German ethical perspective, based on the Kantian rejection of using persons, in this case human embryos, as means. What is especially interesting about this policy provision is that the first country from which Germany imported human embryonic stem cell lines was Israel, home to many of the Jews who left Germany after World War II.

The German Stem Cell Act also required that embryos from which stem cells had been derived were created through medically-assisted *in vitro* fertilization, and were created for the purposes of a pregnancy. This rejects embryos created for research purposes, as well as embryos created through somatic cell nuclear transfer (SCNT). Additionally, in a prohibition that, from an SSK perspective, speaks directly to Germany's concern over eugenic practices,

⁶⁰ The DFG, requested that the German policymaking authority, the Bundestag, examine whether research using human embryos could be exempted from criminal prosecution (Beckmann). In response to this request, the Bundestag created a special committee, called the Inquest-Commission, comprised of seven delegates from the four parties represented in the Bundestag, and seven experts from the fields of philosophy, medicine, law and science. The Inquest-Commission presented two perhaps contradictory proposals on how to proceed with human embryonic stem cell research in Germany, one that expressed support for permitting the importation of human embryonic stem cells from other countries and one that rejected that position.

⁶¹ In an interesting twist, many of the stem cell lines are imported from Israel, Haifa University.

the rejection of the IVF embryo must have been for some reason other than the quality of the embryo, itself. In other words, the decision to discard the embryo must not have been because society felt this embryo was “inadequate”. Finally, there must have been no financial transaction or benefit derived from the decision to donate the embryos to research.⁶²

German policymakers have given significant attention to crafting a policy that takes into consideration important protections for human life and human dignity. Possibly more than any other country, Germany has been particular in limiting the extent to which scientific advancement can breach upon people’s lives. When it comes to issues regarding challenging bioethical questions, Germany’s history cannot be stripped away from its policymaking. The questions that arose as a result of the Nazi atrocities have generated fears about the intersection of science and humanity. Sociological luminaries, like Ulrich Beck, have delved into the ways in which countries have come to fear or reject matters of science. Beck’s theory of World Risk bears significant relevance to some of the ways in which Germany has dealt with, or better said, shied away from embryonic stem cell research. Why the notion of risk features so prominently in German social thought and public opinion grows out of the complex German history, where catastrophic consequences were the result of unfettered human actions. In this way, the behaviors of individuals in positions of power or authority cannot be looked at as virtuous in themselves, but must be subject to scrutiny on the social level. This holds not only for the actions of politicians but also for the actions of other social authorities, like scientists. Beck argues that the progression of scientific, economic, and militaristic interconnectedness is such that the threats to modern society cannot be anticipated but are shared around the world. It is, then, government’s role to protect its citizens from the fallout of these risks through matters of policy, though these can oftentimes fall short.

As has been the case with other national stem cell policies, Germany’s has not been without its logistical challenge. For instance, some have argued that the restrictions put into place in the German Stem Cell Act are

⁶² In addition to these prohibitions, the German policy requires that any research project requesting the use of embryonic stem cells must be scientifically valid and demonstrably necessary. The Stem Cell Act outlines several criteria by which to establish whether or not a research project is worthy of the use of embryonic stem cells, and they include: “if it has been shown by scientific reasons that such research serves and research aims to gain scientific knowledge in basic research or to extend diagnostic, preventive, or therapeutic methods to be applied to humans” (Stem Cell Act, 2002). Secondly, the Act requires that the research must have been shown by demonstrated state-of-the-art scientific reasoning that the questions being studied have been clarified as far as possible in animal models, and that the scientific knowledge to be gained from the project can only be generated through the use of embryonic stem cells. As part of the Stem Cell Act, Germany has appointed an overseeing body designed to issue approval of stem cell lines, and this body is comprised of members of the Robert Koch Institute. In addition, the approval must be given by the Central Ethics Commission for Stem Cell Research, which is a committee comprised of specialists in biology, medicine, and ethics.

unconstitutional, because the restrictions would be applied to actions taken outside of the country (Taupitz, 2010). While issues of morality and ethics can justifiably be considered beyond the determinations of any national perspective, restrictions based on law are confined to the State within which they have been created. Additionally, and perhaps more significantly, some have argued that the German policy creates an ethical double standard by prohibiting the actual derivation of stem cell lines but allowing the importation and use of stem cells. In an effort to, at least ostensibly, “keep their hands clean”, Germany has taken a highly unusual middle-of-the-road position designed to keep German researchers, and thus Germany, out of the ethical quandary of embryo destruction.

What is a pragmatic problem for Germany, given its stem cell policy and, in specific, its January 1, 2002 chronological benchmark, is that the embryos with which German researchers are permitted to work are of poor and antiquated quality. Embryonic stem cell lines that were derived prior to January 1, 2002, were derived using techniques that have since been improved upon. What is more, the number of human embryonic stem cell lines that were created prior to January 1, 2002 is small, and these stem cell lines are not broad in their genetic composition. This has placed German stem cell researchers in a position of international disadvantage.

An additional problem that has presented itself in Germany results from the importation stipulation in their hESC regulation. As Taupitz acknowledges, the dependence on imported human embryonic stem cell lines makes Germany reliant on other countries for patented materials. This forces Germany into detailed material transfer agreements that stipulate that research results obtained on imported materials are partially owned by the creators of the stem cell lines. With scientific activity like embryonic stem cell research existing as such a potentially broad economic boon, the cross-national patenting agreements that generate funds for other countries likewise keeps Germany in a position of disadvantage. And, finally, the policy implemented by Germany made international collaborative efforts with German researchers especially difficult, as it was unclear how projects using more recently derived stem cell lines might be punishable in Germany.

Given these reasons, among others, in the spring of 2008, five bills were introduced to the Bundestag, designed to amend the existing Stem Cell Act. The five proposals were:

1. The repeal of the January 1, 2002 target date, and the criminal provision of the Stem Cell Act
2. A change of the target date to May 1, 2007, and a change to the criminality of stem cell lines derived in Germany
3. A change in the criminality of stem cell lines derived in Germany
4. The maintenance of the existing stem cell regulations, however with an emphasis on perpetuating adult stem cell research
5. Complete prohibition of the importation and use of embryonic stem cells

In April of 2008, the German Parliament voted by a decisive majority in favor of a change of the target date to May 1, 2007. The fact that a country that previously expressed such vehement opposition to the pursuit of human embryonic stem cell research was willing to revisit and broaden its restrictive stem cell policy is noteworthy. It is at this point in the German stem cell policy evolution that tenets of World Polity Theory, Sociology of Scientific Knowledge, and Field Theory begin to converge.

The notion of human dignity and the need to protect the embryo from potential human rights abuses are central to the German stem cell policy. These regulations are based on haunting and lingering concerns from events in Germany's past. However, by 2008, other countries outside of Germany had begun to make important advances in this research. Even countries like the US, with similarly restrictive policies, were the home to researchers who made strides through the recruitment of philanthropic, private, and local funding. These international advances, in WPT terms, put pressure on the German Parliament to reconsider its initial hesitation. The balance between the desire to remain true to cultural and historical concerns, and the sense of disadvantage that was being created in Germany by virtue of these concerns, began to shift in favor of research liberalization. The updated target date passed by the German Parliament was a veritable nod to the legitimacy of embryonic stem cell research as an economic and competitive imperative.⁶³ The events of Germany's past remain at odds with advances in the future.

It is Germany's history that influences how this piece of scientific legislation has been approached in ways unlike anywhere else. As Olick and Levy argue, "from the immediate postwar period to the present, powerful images of the Nazi past have shaped West Germany. Virtually every institutional arrangement and substantive policy is a response, in some sense, to Germany's memory of those fateful years. The Holocaust, moreover, has long been the standard for evaluating German political activity: indeed as some critics have complained, Germany has a past that, for whatever reason, will not pass away" (Olick and Levy, 1997, p. 921). With this in mind, it is not simply the stem cell debate, per se, that must be viewed with the Holocaust as a factor, but also how individual social actors may have been involved in this pivotal event. Not only does this context frame the stem cell debate in Germany, it operates through important social actors and influences how these actors relate to one another. The following is an analysis of how social actors have engaged in the stem cell question, taking into consideration the dynamics that Germany's history introduces.

⁶³ Members of the scientific community heralded the decision. The scientist who initially brought this issue to the forefront of German debate, Oliver Brustle, stated "we are relieved that this compromise has been reached. This will make cooperating on international projects—especially within Europe—much easier" (Spiegel, 2008).

GERMAN ACTORS

CATHOLIC CHURCH

The role that religion plays in German society is more complex and contentious than that seen in many other Western countries. The notion of religious difference was the defining feature of the Nazi atrocities, in a way that shamed German history. For this reason, how Germany negotiates the role of powerful religious institutions in society and policymaking must be handled with caution. As stem cell research policy is repeatedly carried out in the political field, the Catholic Church consistently is a prominent actor. Germany poses no exception to this trend, however circumstances particular to Germany have influenced how this has been carried out.

German Catholics obtain their influence not purely from the demographic size of their constituency⁶⁴ but also from the Christian Democratic Union, which, in essence, operates as a Catholic political party. The CDU is a visible manifestation of the Church's actions in the political field, which applies Catholic or Christian principles to solving modern political, social, and economic challenges. Although the CDU and the Catholic Church cannot be looked at as synonymous entities, the establishment of the CDU implicitly brought the Catholic Church into the political field with an ability to exercise influence on policy matters. The extent of the Church's attempts at social influence can be read in one of two ways: first, that the Church maintains a significant and dominant role in German society; or second, that the Church feels as though its influence is waning and is working to centralize the influence it does have. The actions of the Church in the stem cell debate might indicate that the latter of these two possibilities is the likely scenario.

An entrance into the public sphere results when more standard symbols, practices, objects, and forms of communication are not having the desired effect on some social issue. From a Bourdieusian perspective, the Church's actorhood in the political field implies that it has something to lose, some social capital at stake that has forced its participation in this field. When it comes to the stem cell research policy question, there has been a contentious relationship between the CDU and the Catholic Church that may highlight the Church's diminishing influence in German society. Despite its platform based on Christian and Catholic values, the Christian Democratic Union has rejected the dogma of the Roman Catholic Church in its stem cell stance. It was under the leadership of Chancellor

⁶⁴ With about one third of its population belonging to the Catholic faith, Germany has a particularly interesting and unique relationship with the Church. Presently, there are about 28 million Catholics in Germany. The Catholic Church in Germany is the wealthiest Catholic Church in Europe, due to the fact that German religious groups have levied a compulsory tax on German citizens. This tax, instituted in 1949, amounts to a 9% personal income tax (German Bishops conference, 2010) and is collected through the state tax office. The existence of this tax is partly to blame for some German citizens' abandonment of religious practice.

Angela Merkel that human embryonic stem cell research in Germany began to gain traction⁶⁵. What is noteworthy, is that, Merkel is a representative of the CDU, daughter of a Protestant minister from East Germany, and a scientist herself. In response to Merkel's attempts at liberalizing the stem cell policy, members of the German government received strong backlash from the Catholic Church hierarchy who claimed that this change in policy represented a betrayal of the Christian principles that were at the foundation of the party.

For quite some time, the German Bishops Conference has been vocal about its position on biomedicine, in general, and embryonic stem cell research, in specific. In a statement issued by the German Bishops Conference, the bishops articulated their stance on aspects of this research: research to which they referred as, "cloning". In their statement, the bishops argued the following, "apart from the fact that we do not yet know whether at all and, if yes, when this method can be used to cure diseases, the road along which this goal is being pursued is ethically unacceptable.... Human life, which is always at the same time a personal life approved by God, is downgraded to being a source of spare parts" (German Bishops Conference, 2001). In the same document, the bishops argue, "it must be clearly understood that economic reasons do not suffice to help certain ethically irresponsible research or ethically problematic processes assert themselves. Behind some genetic research and development occasionally also lie hidden massive economic interests which can lead to the industrial exploitation and utilization of man" (2001). In this statement, and in its actions, the German Catholic Church makes a direct target at the creation of a knowledge economy that WPT proposes for science.

Cardinal Meisner, in fact, joined Germany's Bishop Lehman's condemnation of the German movement to relax restrictions on embryonic research following the 2007 breakthrough in iPS technology⁶⁶. According to both of these religious figures, this new technology would provide the same scientific

⁶⁵ The sentiment expressed by the bishops collectively was also expressed quite vehemently by several, prominent bishops in Germany, like the Bishop Lehmann of Mainz and Bishop Meisner of Cologne. The arguments presented by both of these religious leaders were directed, however, specifically to the German government, and this is noteworthy for several reasons. The German government, at present, is in the hands of the CDU, or the Christian Democratic Union. The current Chancellor of Germany, Angela Merkel, is also the leader of the CDU. In 2007, German Cardinal Meisner issued a statement to the German research minister, Annette Schavan, herself a member of the CDU, in scathing criticism of her request for a relaxation of notoriously restrictive stem cell research regulations in Germany. In response to Minister Schavan's request, the Cardinal accused her of abandoning her Christian principles.

⁶⁶ As has been the case many times throughout the course of the five year history of iPS research, anti-human embryonic stem cell research advocates, like members of the Catholic Church hierarchy, have used this scientific breakthrough as a vindication of their oppositional stance. For instance, in response to this breakthrough, the German Bishop Lehmann made the following statement: "the notable new successes in adult stem cell research and the reprogramming of cells are an additional argument against expanding stem cell research... so we call for a significant restructuring of European and German research funding from embryonic to adult stem cell research" (Henneghan, 2007).

and therapeutic potential without the ethical questions. While iPS technology first arrived on the scientific scene in November of 2007, Cardinal Meisner and Bishop Lehmann were already making this assertion only one month later, long before any scientist would make the same. This calls into question the degree to which the Catholic Church feels that it has epistemic jurisdiction over the stem cell research debate. Framing this issue as a matter of bioethical challenges, not necessarily based on the notion of “life” but instead the very German notion of “exploitation and utilization of man”, the Catholic Church in Germany sought to find its entry point into the stem cell debate.

In some respects, the political infrastructure of the Catholic Church in Germany is reminiscent of that found in the United States. In Germany, however, there are fewer opportunities to influence legislators, given the construction of the political system. As an alternative, the Church has attempted to seek influence through legislators who are members of its own political party. However, this claim cannot be made with great certainty when it comes to the stem cell research issue. Although the German policy on human embryonic stem cell research is among the most restrictive, it does not imply that this is the result of the Catholic influence.⁶⁷ This is perhaps the result of the fact that the institution of the Catholic Church has seen a reduction in its authority as a social actor, and does not command the social debate when it comes to matters of “life”.

The Holocaust and the Nazi era are iconic events in German history. These events have shaped the discourse in Germany, and nearly any analysis of German culture—whether from a Field Theory perspective or any other perspective—must be conducted with this issue in mind. It was during these events that religiously-based determinations of the value of life and morality went grievously awry. The modern German moral tradition, as seen in the text of the Basic Law, is based on secular principles that emphasize the value of human dignity. This is a secularly oriented concept, not necessarily based on any one particular religion. As a result, when it comes to establishing a position on salient bioethical questions, the likes of which have grown out of events like the Holocaust, German citizens might give greater value to secular ideals than to religious principles. The Catholic Church, then, might have had its authority diminished in the domain of bioethical questions. In fact, as the Church played a

⁶⁷ Despite its Catholic leanings, the CDU in Germany has yet to be persuaded by the arguments of the Bishop and Cardinal. In fact, in some ways, human embryonic stem cell research has seen a growth in Germany despite this position. According to an article in *Nature News*, in 2009, the German government under CDU leadership was planning to make very few changes to its revised research strategy, and was intent on infusing more money into its research budget (Abbott, 2009). The Excellence Initiative, implemented by the German government as a means for German research institutions and universities to compete for “elite status”, was expanded to include efforts to broaden the public dialogue surrounding human embryonic stem cell research. This expansion took place at the hands of the CDU, despite the fact that the German Catholic hierarchy was advocating for the opposite.

memorable and accomodationist role in the German Holocaust, the German policy can be looked at as an indictment of these actions rather than an embrace of the Church's position. In this way, the cultural context on which SSK places its attention has had a strong influence both on the German policy and how prominent actors have shaped it.

The Church's diminishing credibility on issues pertaining to bioethical questions is one significant part of an even more complex credibility problem that the Catholic Church in Germany faces. Bioethical questions notwithstanding, the Catholic Church in Germany has experienced a precipitous decline in its social status in recent years, in a way that may have caused some legislators in public office to distance themselves from the Church. Perhaps much more so than nearly any other country, the Catholic Church in Germany has been rocked by scandal and allegations of sexual abuse⁶⁸. Recently, in March of 2011, the German Catholic Church agreed to a pay out of €5000 to abuse victims as compensation for previous misdeeds. This is coupled with the fact that the current Catholic Pope, Pope Benedict XVI, is German by ancestry and was, to a significant degree culpable for much of the attempts to hide these instances of sexual abuse. In response to this scandal and lack of transparency in addressing it, the Catholic Church in Germany has seen a significant decline in its congregation size. As tens of thousands of practitioners have left the German Catholic Church, its authority within the country has been severely subverted.

To this end, the Catholic Church in Germany has lost a great deal of its persuasive power and social capital. The Church's ability to influence policy decisions is offset by the loss of authority it has experienced as a result of the scandals that have plagued the institution. However, what is more, within the confines of the CDU, to whatever extent the union is able to distance itself from the Catholic Church, particularly on controversial issues, it is likely to benefit. This might illuminate some degree of explanation in terms of why the Catholic Church has been relatively unable to affect the stem cell research dialogue and policy.

Despite the fact that Germany's stem cell limitations are based on a secular framework of morality, the Church's position has been a bolstering, or

⁶⁸ When it comes to issues that are particularly important to German Catholics, the scandal within the Catholic Church regarding child sexual abuse ranks very high. A recent poll conducted by the Forcra Institute (The local, 2010) indicated that nearly one quarter of German Catholics were considering leaving the church altogether because of the scandal. Similarly, within the same poll, only 16% of Catholics in Germany believed that the Catholic Church was handling the child abuse scandal effectively, while 77% believed that it wasn't. These numbers were most predominant in younger Catholics, between the age of 18 and 29 years. Similar to some of the disillusionment with the Catholic Church in the United States, younger Catholics in Germany are likewise relatively alienated from the institution.

Orthodoxic, force. Given the role that religion played in the Holocaust, many German interpretations of human dignity and even “life” are based on a human rights ethic. This is not to argue that the German Catholic Church has not contributed to a human rights discourse or attempted to promote its own values, but it is far less certain to what extent it has been persuasive in defining the stem cell debate. This can be seen from the language used in the German policy, which is reflective of secular bioethical principles, like human rights or the necessity of informed consent.

The fact that the Church has not demonstrated a more influential position might be the result of the credibility it has lost through allegations of child molestation, sexual abuse, an inconsistent position on the question of life, and its theological interpretation of morality. This gives the Church a supportive yet not dominant voice in the dynamics of this debate. However, there is a way that the position of the Church must be disentangled, such that a better light can be cast on the capital that the German Catholic Church is trying to secure its participation in this debate. What is at stake for the German Catholic Church and why has it held so strongly to this position?

For certain, the outreach of the Catholic Church is strong and not to be underestimated, however there might be some other, more context-specific reason behind how this social actor has sought to influence the German stem cell debate. Were it not for the Catholic Church's unfortunate silence during the Nazi era, followed by an equally unfortunate reputation of sexual malfeasance, the Church might not have felt the need to be quite as visible in this issue, and might not have felt as though there was a public image to rebuild. These circumstances work in conjunction with the social capital that the Church is seeking: social capital necessary to rebuild a tarnished reputation. Failing to take a firm stand on an issue that is socially questionable might further reduce this image. Germany, then, presents a set of circumstances not entirely unlike the US. As there is no established social Doxa for stem cell research, there is a reliance on an already established social Doxa, in this case that of the bioethical constraints put on science, that serves as a proxy for this newer social question.

SCIENTIFIC COMMUNITY

Science holds an undoubtedly prestigious position in German society. The institution of science, as World Polity Theory might predict, has had a great impact on German policymaking and development. It has been through a scientific infrastructure that Germany has excelled in the post-World War II era, growing from a position of enforced limitation to pronounced development. When envisioning some of the most notable individuals in scientific history, Germany has been home to many of them. Just as notably, even in recent years with issues like environmental science and particle physics, Germany has been a world leader. It has been through a reliance on science that Germany has become a rationalized and highly modernized society.

Much of the scientific research that takes place in Germany is supported

by the network of German universities, private industry, or state institutions. One of the most prominent scientific organizations in Germany is the Deutsche Forschungsgemeinschaft (DFG), or the German Research Foundation. The DFG is Germany's largest research funding organization, and as the Foundation describes itself, it is, "the central self governing research funding organization in Germany. Its mission is to fund and promote all fields of science and the humanities... by relying on its statutory bodies and its Head Office, which shape the work and structure of the DFG" (Deutsche Forschungsgemeinschaft, 2011).

The DFG, as the organization describes, is charged with promoting science and research in all its branches, coordinating research projects from all disciplines. In addition, it works to provide guidance to members of the German Parliament and public authorities about science and research-related issues. The DFG is organized in such a way that it incorporates a Senate of scientists who are, "responsible for questions relating to science and research. It represents the interests and concerns of scientific and academic research, promotes cooperation and advises governments, parliaments, and public authorities by showing scientifically founded statements. The DFG sets priorities and research by establishing thematic Priority Programs and Research Units" (DFG).

The DFG has issued reports on numerous science policy matters, and within the context of genetics, members of the DFG Senate have issued statements on stem cell research. In 2001, the DFG issued its first of several reports on stem cell research, entitled "Recommendations From the German Research Foundation concerning Research on Human Embryonic Stem Cells". In this publication, the DFG stressed the necessity to move research forward in Germany under "strictly controlled conditions" (Appendix 12) (DFG, 2001). Even as the German policymakers were negotiating the various iterations of the stem cell policy, the DFG had a lukewarm position. Initially, the DFG expressed its concerns over the research, and though this position evolved, it did so slowly and with caution. The reason for this is uncertain, but can be explained in several ways. First, it could be the case that, true to SSK thought, scientists in Germany evaluate scientific knowledge based on cultural conditions and, as a result, broke from dominant scientific thought in prioritizing adult stem cell research over embryonic stem cell research. Second, it could be the case that the DFG recognized the importance of both avenues of scientific investigation, but was hesitant to make this known widely. In either case, it demonstrates a degree of uncertainty in securing a dominant position in this scientific debate.⁶⁹

⁶⁹The DFG invests heavily into the life sciences, of which embryonic stem cell research is a clear part. In fact, since 2003, the DFG's investments into the life sciences has increased as a share of its overall investment in science, and remains the field of science most heavily funded by the organization. In 2003, of a total of 171 research units connected in the DFG, 65 were in the life sciences. In 2010, of a total of 242 research units conducted in the DFG, 118 were in the life sciences. Every year in the past decade, the life sciences has led the way for the research conducted by the DFG. Furthermore, when it comes to research fellowships funded by the DFG, fellowships in the life sciences also lead the way. In 2010, the DFG funded 532 research fellowships in the life sciences, far outpacing all other fields of science

Though the initial attempt to bring embryonic stem cell research to Germany was the result of one prominent scientist, in 2001 the DFG was not fully behind this research. This lack of unity, which can be seen in the differing opinions across scientists in Germany, has diminished the persuasiveness of the scientific community. Though members of the DFG advise on policy issues, as an institution the DFG is supported by federal funds, creating a potential conflict of interest between this organization and Legislators who provide the funds. In a way that might be similar to the NIH's role in the US, the DFG's participation in the German stem cell debate cannot be stripped from its governmental funding source.

The DFG has, at minimum, tacit support for the expansion of the human embryonic stem cell research in Germany. Such a supposition is bolstered by the fact that a significant number of DFG-funded researchers make their career in the Max Planck Society's Institute of Molecular Bioscience, one of Germany's most distinguished research centers which houses much of the embryonic stem cell related work in Germany.⁷⁰

The Max Planck Society's Institute of Molecular Bioscience has a commitment to public affairs, through the presentation of public lectures, progress reports: and international conferences. The Institute is a member of the larger Münster chapter of the Stem Cell Network North Rhine Westphalia. Existing as a relative anomaly in Germany, the state of North Rhine Westphalia (NRW)⁷¹ has an impressive legacy of commitment to stem cell research, both adult and embryonic. Within NRW, there is a broad network of research institutions that focus on cutting-edge biomedical research, including "virtually the whole spectrum of scientific issues in the field of adult and embryonic stem cell research" (Stem Cell Network North Rhine Westphalia, 2011)⁷². This puts the state of NRW in a particularly advantageous spot, allowing it "to coordinate and

⁷⁰ Germany's Max Planck Society is a prestigious network of scientific institutions. As the society describes, "the Max Planck Society is Germany's most successful research organization... Max Planck institutes are built up solely around the world's leading researchers". Involving 80 research institutions focusing on the most cutting-edge, yet high risk, research, the Max Planck Society offers an infrastructure of leading scientific research and promotes the perpetuation of scientific research not only throughout Germany but collaboratively throughout the world.

⁷¹ NRW is the most populous and most economically powerful state in Germany and, with a total population of about 17,850,000. Policy making in NRW, as in the other German states, is split between the NRW Landtag, or state government, and the Bundestag, or federal government. The history of NRW's economic strength has its origins in the "economic miracle" created by the postwar coal and steel industries (Waggener, 2009), however now the economic prowess of the region depends upon the cities along the Rhine River, which include Düsseldorf, Cologne, and Bonn. The state also enjoys a significant amount of political capital, with 25-30% of Bundestag representatives coming from NRW, and 25% of the top German companies having their quarters within the NRW state borders

⁷² Research institutions include universities in Aachen, Bielefeld, Bochum, Bonn, Cologne, Düsseldorf, Essen, Münster, and Witten

optimize statewide activities in stem cell research”.⁷³

In ways that are similar to some of the state-based stem cell policies in the US, the stem cell work conducted in North Rhine Westphalia emphasizes the desire for governments to embrace the economic advantages and rationalizing benefits of science that World Polity Theory addresses. In addition, it demonstrates how, under certain social conditions like the favorable conditions found in North Rhine Westphalia, scientists in Germany, in fact, do embrace the benefits that human embryonic stem cell research has for the future of medicine. The existence of a prominent stem cell network in Germany, and the demonstrable impact that scientific research has had on the NRW economy, makes the voice of the scientific community not an insignificant one⁷⁴. In the early days of the stem cell research debate, German researchers demonstrated a growing concern about the research environment in Germany versus the rest of the world.

The restrictions put into place in Germany, representing one of the most regressive stem cell policies in all of Europe, was met with increasing frustration among members of the scientific community. As of the 2002 policy, the notoriously few available stem cell lines were poor in quality (Banchoff) and inadequate in number, forcing the DFG to abandon its former position. In 2006, the DFG issued a press release stating that, “as a result of the legal framework conditions, science in Germany can only make a limited contribution to this field” (DFG, 2006).

From 2006-2008, the DFG expressed an increasingly vocal attitude toward the relaxation of stem cell regulations. This could have been the result of changing attitudes toward the research across the population, the result of scientific advances being made in other parts of the world that put Germany at a disadvantage, or a shift in the political makeup of the Bundestag that made it more favorable to this research. After a change in policy in 2008, the DFG stated, “the Deutsches Forschungsgemeinschaft is pleased and grateful for the decision taken by Parliament. We are especially grateful to those members of

⁷³ The Stem Cell Network North Rhine Westphalia offers membership to any situation involved in stem cell research or its bioethical and legal impacts. The Network is affiliated with the Ministry of Innovation, Science, Research, and Technology in NRW. As a result, the German state is one of the most prolific and extensive scientific hubs in all of Germany. As the DFG indicates, NRW is home to about 300 research institutions with an extensive focus on biomedical research.

⁷⁴ It was the research infrastructure in NRW that prompted then-Premier of NRW, Wolfgang Clement, to negotiate a deal with the University of Haifa and Bonn, for the importation of stem cell lines. Then-Chancellor, Gerhard Schroeder, a political ally of Clement, advocated for the politics of scientific ethics to be shepherded through the German National Ethics Council at the time that the deal between Bonn and Haifa was negotiated. This was at least partially in response to the opposition expressed by members of The Greens, a minority party/junior coalition in the North Rhine Westphalia and national governments, which historically sides with religious conservatives and opposes stem cell research (Brookman, 2001).

Parliament who contributed towards the critical debate of the issue. The decision taken to move the qualifying date for important human embryonic stem cell lines is a good and important step forward for German science and for German stem cell researchers.” (DFG, April, 2008).

The “qualifying date” of January 1, 2002, for quite some time, came to define the German policy in a way that was similar to how the August 9, 2001 “qualifying date” came to define the US policy. Echoing the condemnation expressed by members of the US scientific community, German researchers likewise expressed concern about the qualifying date limiting the scope of their research, however possibly to a less visible degree. It was only with time following the initial policymaking debates that German researchers developed and seized upon their position of authority and capital to express their disapproval. In April of 2008, the DFG issued a press release which stated, “the current qualifying date rule, in particular, strongly impedes German stem cell research... the best thing for basic research would be if this qualifying date rule, a deadline which restricts the period in which embryonic stem cell lines are allowed to be imported, were to be abolished altogether” (DFG, 2008). The DFG also called for the end of the criminalization of German researchers, taking a stance that was much more emboldened than stances taken in the past. For instance, in opposition to the DFG's previous declaration that adult stem cells ought to be viewed as preferable to embryonic stem cells, in their 2008 press release, the DFG quotes German researcher, Jorg Hacker, stating, “embryonic stem cell lines are more or less the gold standard for studies of this kind”.

The 2008 change in the German stem cell policy parallels the changes in position of the German scientific community, in a way that brings together the ideas of WPT, SSK, and Field Theory. In the early days of the research, the DFG and many other German scientists had a hesitant attitude toward embryonic research, reflecting broad public concerns about ethically questionable biomedical research. This level of concern is illustrative of the types of cultural factors that influence the nature of scientific production found in SSK. However, as embryonic stem cell research has become globalized and other countries around the world have made economic strides as a result, the position of the German scientific community has shifted in favor of a broader international script, in a way that is reflective of WPT argumentation. Within the context of the policy debate, the position and sources of capital that the scientific community has been able to draw upon have changed in relation to other forces, allowing for the benefits of Field Theory to come to light.

The story does not conclude there, and the German research community has still experienced instances of frustration despite the relaxation of the stem cell regulation. In a recent turn of events, the authority of the scientific community in Germany, and even the larger EU, has been brought into question. In October of 2011, the European Court of Justice issued a ruling on the case, *Brustle versus Greenpeace*, a court case that has legal ramifications for stem cell research throughout Europe.

Oliver Brustle, one of Germany's preeminent stem cell researchers, obtained a patent on his technique that differentiated human stem cells into neural precursor cells to treat neurological diseases. The patent, issued in December of 1997, was thought to be invalid, given that Brustle's work pertained to human embryos which, according to European law, involves human life and is, therefore, beyond the scope of patentability in Europe (Court of Justice of the European Union, 2011). It was unclear, however, whether the definition of the "human embryo" pertained to all stages of embryonic development from the point of fertilization, or if some other developmental criterion needed to be reached before an embryo could be considered "life".

The resulting EU opinion⁷⁵ was that the removal of human embryonic stem cells necessarily results in the destruction of an embryo, and failure to exclude this research from patentability would likewise fail to meet the non-patentability criterion of work that destroys the embryo or uses it as base material (Court of Justice Of the European Union). This ruling has sparked concern in researchers around the world.

The practical implications of the EU Court's decision were that the intellectual property of scientific discoveries made by Brustle and others to follow would not belong to the researcher who made the discovery. This creates a disincentive for new researchers to enter the field, who would now be unable to claim ownership of their discoveries. Additionally, in a manner similar to the conditions under the restrictive Bush administration, there were fears that this EU decision would force European researchers to pursue research opportunities in other, more welcoming environments. As Dr. Brustle describes of the decision, this was, "an unbelievable setback for biomedical stem cell research". Similarly, the decision serves to spark fear in potential research investors who will be unable to see a return on their investment.⁷⁶

⁷⁵ In examining this question, the European Court focused not on the medical or ethical implications of Brustle's work, but rather on a strict legal definition of "embryo". As a press release from the Court of Justice of the European Union stated, "the European Union legislature intended to exclude any possibility of patentability where respect for human dignity could thereby be affected." To this end, the Court decided that the term, "human embryo", applied to all stages of development, including the blastocyst which Brustle was to use in his research and sought to patent.⁷⁵ The European Court made the argument that, as uses of human embryos for industrial or commercial purposes are not permitted to be patented under European law, scientific work like Brustle's would inevitably lead to this industrialization or commercialization, and therefore could not be patented.

⁷⁶ Others have claimed that the result of this decision is not nearly as negative as some researchers have suggested. For instance, Julian Hitchcock, founder of CellFate, former director of the East of England Stem Cell Network, and intellectual property lawyer specializing in life sciences, has argued that, in a globalized world, the relevant market for research advances will be, in fact, the world (Hitchcock, 2011). Any net effect of this decision will not be exclusive to Europe but will, instead, be across the board. Additionally, Hitchcock suggests that it is not the research, itself, that is enticing for intellectual property but how this research is translated using other materials that are fully open for patentability. Finally, as Hitchcock claims, patents have a stifling effect on researchers who do not have the means to pay royalties for intellectual property,

The practical fallout of the Brüstle decision will only be determined in the coming years. However, there is more to this decision than just technical effects. The more academic result of this decision—the result praised by many research opponents, most notably the Catholic Church—was that it defined the start of life to be at the moment of conception, creating a legal precedent for a highly complex issue not previously agreed-upon. While the question of life has, historically, been decided in the personal domain when it comes to matters of belief, this interpretation has not been applied in scientific questions. This, once again, throws the question of the origins of life into epistemic limbo.

Even to this day, German researchers have been hesitant to express support for particularly controversial areas of embryonic stem cell research, including therapeutic cloning and the creation of embryos for research purposes. It is perhaps the case that members of the scientific community do not, in fact, reject these lines of investigation but, instead, do not feel that the German public is ready to accept these avenues of research. As advances are made, and as the German Society has time to grapple with these complex issues, it is likely that the German scientific community will play a more vocal and central role.

It is with this in mind that the scientific community's influence, or lack thereof, on stem cell research policy in Germany is so evidently tied to events in Germany's past. Of the four countries under investigation in this analysis, it might be in Germany that the scientific community has had the most difficult and complex role in the stem cell debate. Germany's long tradition of commitment to science, and its current emphasis on secular principles, would seem to put it in a position comparable to that found in the UK. However, given the events in Germany's history, when it comes to stem cell research, a very different picture comes to light. The social circumstances and nature of public opinion are such that, in Germany, the emphasis has been on the misuses of science and human rights abuses that have come about as a result. This has been at the expense of the authority of the scientific community. As many of the Holocaust atrocities revolved around medical experimentation and gross violations in medical research ethics, it is avenues of science that touch upon this highly sensitive and emotionally charged issue that generate concern. How salient historical events come to affect future policy measures can be found in work that intersects collective memory and path dependence.

The concept of path dependence has been used to explain a wide variety of choices and policies, outcomes and institutions found in many different cultural contexts, in a way that implies that the realities we experience today are, in no small part, the result of events we have experienced in the past. The Holocaust is such an enormous and socially-defining event in Germany that it would be shortsighted to omit it in an analysis of the complex stem cell issue. When it comes to pressing science policy questions, like climate change and nuclear

thereby putting an implicit brake on research opportunities. Without this limitation, Hitchcock suggests, Europe will be even more enticing for researchers.

proliferation, Germany has placed much greater attention on the international fallout of action or inaction on these issues, emphasizing the consequences that will be felt on a global scale if the authority and recommendations of scientific experts are not followed. However, in the domain of stem cell research, Germany has approached this question from a far more provincial perspective, with a largely German orientation to the concerns that have been codified in its policy. The degree of autonomy and expertise that may have come about from the input of the scientific community, then, has nearly been eclipsed by the effects of historically-defined ideals and concerns.

Why events in German history have so significantly affected stem cell research policy as opposed to other questions of science policy is central to the nature of the stem cell debate in Germany. In Germany's past, when the progression of science trumped bioethical questions, Germany was faced with disastrous outcomes. In this regard, the push for "scientific understanding" was at the expense of grossly unethical and devastating human loss. Science, in this case, acted in collusion with a regulatory environment that allowed, and even encouraged, manipulation of and experimentation on human life without any consent. During the Holocaust, abusive scientific practices were only accomplished because of the political atmosphere that allowed them to take place. The logical fallout of these circumstances is that, when science involves matters of human life and is given free rein to proceed as it wishes, the very risk that, as Beck describes, might come to fruition. The result is a set of social concerns that focuses particularly on life as a pursuit of science, and regulation to control this pursuit.

It is within this framework of "risk" that science in Germany can better be understood, presenting a direct challenge to the authority given to science in World Polity Theory. Science in Germany, as it pertains to matters of modern policy, is not a monolithic and unified entity, but rather is approached on a case-by-case basis. The basis of judgment depends less on the authority of the scientific question at hand and more on how the scientific pursuit might either circumvent risk or generate risk. This framework provides a very useful rubric from which to look at matters of science policy in Germany, and whether these science policies are afforded relative autonomy or regulation. For instance, in the domain of climate change policy and research, a failure to act in a progressive manner might lead to global catastrophe, as predicted by climate change scientists. The nature of the risk, or realizing this risk, stems from not adhering to scientific recommendations. Conversely, when it comes to matters of science policy like nuclear technology or stem cell research, the risk is posed when society pursues these technologies aggressively. It is therein that a distinction can be drawn between how Germany embraces or rejects scientific questions.

The position, then, of the scientific community in Germany has, at least in part, acted as a heterodoxy against the social Doxa based on events in collective memory and a cultural emphasis on the principles of bioethics. Whereas the British moral tradition is one based on utilitarian philosophy, the German moral

position, growing out of work conducted by Kant, is one of a deontological nature, and this quickly pits a moral tradition and public opinion against the actions of the scientific community. This is the case, despite the fact that science—as a collective enterprise—in Germany is held in high regard, and despite the fact that the DFG offers a locus of contact on which German legislators can rely when it comes to policymaking.

Taken on a collective and not individual basis, there is general agreement from the scientific community on the value of human embryonic stem cell research, and this goes beyond the German borders. However, when looked at from a purely German context, the importance of this research is not as uniformly believed. The question is, then, why there has been a relative lack of unity among German researchers on why human embryonic stem cell research is worthy of legislative and social support. This question speaks directly to the centrality of Field Theory when it comes to investigating stem cell research policy, and how the pursuit of capital and the relationship with other social actors influence decisions.

The German scientific community is operating within a Doxa not established for stem cell research but rather for the respect of human rights and bioethical principles. Scientists, then, can make the active decision of whether to play according to these instantiated ideas or challenge them by making the claim that human embryonic stem cell research does not violate the human rights Doxa. From this perspective, scientists can either embrace and support the social Doxa or redefine the ethical questions surrounding this research, such that embryonic stem cell research is not looked at as violating any social norm. Neither of these choices is an easy or right one, and depends on how each individual scientist evaluates capital. This has created a divide among members of the German scientific community.

Whereas in countries like the US and UK, the scientific community has been largely uniform in its position on the importance of stem cell research, this same degree of consensus is not the case in Germany. A number of German researchers, in a way decidedly contrary to World Polity principles, have made the argument that adult stem cell research is superior to, rather than simply different from, human embryonic stem cell research, and that this avenue of the general field is where the German government ought to be directing its resources. Without approaching this issue with a unified voice, the magnitude of the scientific community's position is severely diminished. Without a standardized opinion on human embryonic stem cell research, the pursuit of this research can be viewed as a matter of opinion rather than a matter of scientific truth. When taking on an established social Doxa, the diluted position has little chance in swaying dominant social attitudes.

This lack of uniformity can be seen in Germany in ways that are similar to the US, in that the differences in state policies have allowed research to move forward in some areas of Germany and not in others. The most striking example is the research that is conducted, in a fairly aggressive way, in NRW through a

combination of state and federal funds. However, there is a pressing disconnect between the urgency of this work, the sense of urgency that the scientific community has collectively expressed when it comes to human embryonic stem cell research, and the impression of urgency that members of the Bundestag have gotten from the scientific community. To the extent that this research is not viewed as an urgent matter, the German government can take, and has taken, a removed stance on this research. To a large extent, this has been precisely the strategy that the German government has taken in its restrictive stem cell policy.

The consequences of the German scientific community's inability to significantly influence the stem cell research debate in Germany is felt far beyond the borders of Germany, alone, and now has had an impact on the entire global stem cell field. When Greenpeace sued, and ultimately won, in a case against the prominent German stem cell researcher, Oliver Brustle, a severe blow was dealt to the research on both stem cell research conducted in Germany, as well as research conducted in Europe, and even the entire world. What is interesting is that this case was brought up against German stem cell researchers by the environmental organization, Greenpeace. This highlights the idea that science, itself, has not been dismissed as an illegitimate authority but, rather, this particular scientific discipline. The nature of the case was built on the very same challenges that have characterized the German stem cell debate, specifically the question of the ethical use of human embryos for research purposes, with Greenpeace arguing, successfully, that patents cannot be issued on research that involves human life. This is not a religiously-based claim, although it is a claim that the Catholic Church in Germany strongly supports, but a secular claim that speaks to uniquely German concerns.

This legal case addresses another important point. In a fashion that is similar to that seen in the US, Germany has ostensibly prioritized the degree of credibility afforded to different domains of science, with stem cell science still failing to secure credible traction. This is similar to some of the very same challenges seen in the United States, where the credibility of science or scientists has not been uniformly applied. What Germany is left with, is a social perception of the stem cell research scientific community that is bound by skepticism of the work they conduct. The social Doxa surrounding this work focuses on the deontological bioethical principles that question the legitimacy of stem cell research. These ideas are rooted in an iconic and pivotal event in German history from which public policy cannot be disentangled. Members of the scientific community, no matter how prominent, have had a difficult time overcoming this social perception. When this is joined with a focus on the notion of globalized risk emerging from scientific advances, the scientific community in Germany is in a weakened position.

PHARMACEUTICAL INDUSTRY

As has been evidenced by the enormous success of the pharmaceutical industry in the US, the potential for development based on pharmaceutical advances has become a matter of international importance. Just as science,

itself, has been viewed as a critical and primary economic driver around the world, so, too, has the impact of the pharmaceutical industry. As a result, in ways that are similar to the globalization of science, advances in pharmaceutical research and industry have diffused around the world. Germany is no exception when it comes to countries to which the advances in pharmaceuticals have globalized.

If viewed from a global perspective, the pharmaceutical industry appears to be a force to be reckoned with. If modeled after a script established in a core country like the US, the power of the pharmaceutical industry would be formidable, with the ability to dominate policy discussions in matters of pharmaceutical relevance. What is more, pharmaceutical and biomedical research exist as one of the primary applications of scientific research, one of the manifestations of economic development that science is purported to provide. From a World Polity perspective, the rationalizing aspects of science would find their home in an industry like pharmaceuticals, as it provides channels by which progress is made, betterment for human welfare can be created, and broad-based economic development is established.

The German government issued a report on the state of the pharmaceutical industry in Germany (Germany Trade and Invest, 2011). According to this report, as of 2008, Germany's pharmaceutical industry was comprised of 243 companies and employed about 126,000 individuals. The market value of the drugs produced in Germany are estimated, as of 2008, to be about €27.1 billion, making Germany the fourth-largest producer of pharmaceuticals in the world, and is approximately 5% of the world's market share. As documented by the German government, more than 20% of the pharmaceutical workforce has a university degree, and the industry is one of Germany's best performing (Germany Trade and Invest). In "advertising" the environment for strengthening the pharmaceutical industry in Germany, the German government emphasizes its centers of academic and research excellence, of which it includes world renowned universities and research centers like The Max Planck Society, which maintains about 80 research institutes and 17 Nobel laureates in the fields of chemistry and medicine, the Heimholtz Association, and the Leibniz Association. All of these research institutes work closely and collaboratively with universities and industry in order to bring science from its basic research to its product on the market.⁷⁷

In 2008, Germany's influential, Hamburg Institute of International Economics published a policy report on the status and perspectives of the

⁷⁷ In statistical and data terms, the growing nature of the pharmaceutical industry in Germany is not to be overlooked. For instance, exceeding other European countries like the UK, Denmark, and Finland, Germany has about 581 resident patent filings per 1 million inhabitants, had about 12,000 patents granted in the European Patent Office in 2007, and was among the leading nations in obtaining "triadic" patents, or patents registered with the European Patent Office, the United States Patent and Trademark Office, and the Japanese Patent Office, at 75 triadic patents per million inhabitants as of 2007 (Germany Trade and Invest).

pharmaceutical industry in Germany (Hamburg Institute, 2008). As the authors argue, “for the future, it may be expected that the new technologies—such as biotechnology, nanotechnology, and genetic engineering—will lead to a surge in innovations, especially in the area of healthcare, medicine, and pharmaceuticals” (Hamburg Institute, 2008, p.3). This is underscored by expected shifts in population demographics in Germany by 2050, shifts that will grow the percentage of citizens over the age of 65, demanding greater medical treatments and disease prevention.

It is with this in mind that the Hamburg Institute sought to map the German landscape and regulatory environment to determine the likelihood of success for pharmaceutical companies to help build Germany's economy and future. The conclusions reached by the research institute were the product of how Germany is valued by key stakeholders in the pharmaceutical industries. The report claimed that, while the US leads the world in pharmaceutical research and the UK leads in pharmaceutical development, Germany has strengths as a pharmaceutical center because of the quality of its researchers, its position in areas of basic research, its experience in high-tech production, and its access to market and drug price determination. Germany also touts itself as an advantageous environment for conducting clinical trials by providing lower costs, higher expertise, and greater collaboration with research institutes and universities. However, the picture is not entirely bright for Germany's development as a pharmaceutical hub. Primary challenges to the industry in Germany have been the “high level of regulation and sometimes inefficient application of approval procedures” that has affected the environment within which the industry can operate. (Hamburg Institute). As a result, Germany has emphasized the need to promote policy measures in light of the global policy context, such that the German regulatory policy is viewed as a complementary player in an international network of similar research policies.⁷⁸

In itemizing key economic factors to pursue in the 21st century, Germany has focused on the life sciences, and has sought to finance this research at national, state, and regional levels. For instance, the German federal government invests about €4 billion a year on “high-tech strategies”, which include R&D projects in healthcare and biotechnology (Germany Trade and Invest). In a similar manner, the German Federal Ministry of Education And Research has implemented the “Pharmaceuticals Initiative for Germany”, designed to motivate

⁷⁸ The German government has emphasized long-term commitments, rather than short-term political measures, so that the pharmaceutical industry, or any other industry, feels secure in laying groundwork in Germany. Among these strategies, the Hamburg Institute has emphasized greater state promotion of privately funded research, modifications in the tax structure, promotion of centers of research excellence, focus on schools and universities, and an analysis of all policy measures that might impede growth. It is with these measures that Germany hopes to counteract its reputation of lacking transparency in regulation, the high number of regulations and inefficiency, and the protections on patents and intellectual property.

the biotech and pharmaceutical sectors. Also, the German government has created the Interdisciplinary Centers for Clinical Research and Coordinating Centers For Clinical Trials, both of which are funded by the federal government. What is of particular note is that, when it comes to emphasizing unique strengths in Germany's healthcare sector and pharmaceutical opportunities, Germany pays close attention, and directs much research into, "diseases [that] are unresponsive to therapy" (page 9), and in so doing has celebrated its advances in molecular and cellular biology.

In presenting itself as a country and location that is particularly favorable for the pharmaceutical industry⁷⁹, Germany has initiated a veritable advertising campaign, focusing on its regulatory strengths and diminishing its potential weaknesses. With advances in the pharmaceutical industry emerging as one of the most profitable, particularly in an aging Western population, failing to seize upon the benefits of a strong pharmaceutical sector puts any country at a competitive disadvantage. There are several noteworthy pharmaceutical companies that have heeded Germany's call, and primary among them are Braun Melsungen, Bayer, Bayer Schering Pharma, Merck, Roche Applied Science, and Schering AG.

The applications of science have produced a significant economic boon in countries around the world like the US, and this industry has dominated many policy discussions, including that of stem cell research. In Germany, from a historical standpoint, a similar set of circumstances may well have been the case. In fact, preceding and during World War II, the tie between biomedical science and the pharmaceutical output it created was substantial. Similarly, preceding and during World War II, the influence that an industry like pharmaceuticals had on policy measures or government actions was just as significant. However, like

⁷⁹ As of 2008, Germany ranked fourth in the world in terms of GDP health spending, with approximately €161 billion set aside for the mandated health insurance sector. Of these funds, 15% was spent on medical treatment, 33% was allocated for hospital treatment, and 18% was spent on pharmaceuticals (Germany Trade And Invest). In a manner similar to that seen in the UK, 90% of German citizens are enrolled in the statutory health insurance provider, with the remaining 10% opting for private health insurance. As a result of these broadened and extensive levels of insurance coverage, Germany has a stable market of healthcare consumers, a set of circumstances that is particularly favorable for the pharmaceutical industry.

Germany has shown a commitment to educating its students and labor force toward mathematics and science. In 2008, approximately 98,000 students entered either mathematics, natural sciences, or engineering in one of 104 universities in Germany. In attracting a greater number of pharmaceutical companies, Germany has emphasized its "social, economic, and political stability [which] provides a solid base for corporate investment projects" (page 11), as well as an open German market that is "free from regulations restricting day-to-day business." Among the conditions that Germany believes are particularly favorable to the development of industry is an overall corporate tax burden of less than 30%, and even as low as 22.83% in some municipalities, making "Germany's corporate tax system one of the most competitive tax systems among major industrialized countries." [The US corporate tax rate is at about 35%, however there are many loopholes, tax breaks, and shelters that bring the tax burden down, to an average of about 27.1%].

so much of the German discourse surrounding human embryonic stem cell research, the role that the pharmaceutical industry has played cannot be divorced from the historical events of World War II that exist in Germany's past.

Bayer, one of the crown jewels of the German pharmaceutical industry, was founded in 1863 by German researchers, Friedrich Bayer and Johann Friedrich Weskott. Following World War I, the Bayer Company came under the ownership of IG Farben, (Association of Common Interests) a conglomerate of chemical industries in Germany. This incorporation was notable for several important reasons.

IG Farben was the single largest donor to the election campaign of Adolf Hitler (Business with Disease, 2011). As has been reported, all of the explosives and combustible materials used in World War II were supplied to Hitler's Wehrmacht by IG Farben. It was through the use of these explosives that Germany was able to overtake nearby countries and their industrial sectors. As US investigations concluded, "Without IG Farben, the Second World War would simply not have been possible" (Business with Disease). What is more distressing is IG Farben's involvement in the operations of the Nazi concentration camps. Auschwitz, the largest and most infamous Nazi labor camp, was, in actuality, only a small component of the much larger main project, IG Auschwitz, a 100 % subsidiary of IG Farben. The benefits of the concentration camps to IG Farben were as direct as they were appalling. The pharmaceutical departments of the Corporation used tens of thousands of victims for drug experimentation and the testing of unknown vaccines. Further, when victims were sent to the gas chambers in Auschwitz and other camps, the chemical gas, Zyklon-B, was a product of IG Farben.⁸⁰

Given the critical role that the pharmaceutical industry played in the Nazi atrocities during World War II, it is not surprising that this industry is looked at with a keen degree of suspicion. While industries like pharmaceuticals might not have particular relevance to a social debate, it does have relevance to a political debate. On a near categorical basis, the pharmaceutical industry has made its effects most significantly known in the political field. However, in order to gain mastery in this field and secure capital within it, a social actor like the pharmaceutical industry must be able to command the attention of legislators. The pharmaceutical industry in Germany has been able to do this through its close relationship with German policymakers and its lobbying arm, Verband

⁸⁰ Following World War II, the Nuremberg War Criminal Tribunal convicted 24 IG Farben board members for murder and crimes against humanity. However, by 1951, all who had been convicted were released, and already serving as consultants to German corporations. IG Farben, itself, was disintegrated into its component parts, namely Bayer, BASF, and Hoechst, which later became Aventis. At present, the three daughter companies of IG Farben are 20 times bigger than IG Farben was in 1944 (Business with Disease). Additionally, each of these daughter companies filled its chairman of the board positions with former members of the Nazi party.

Chemische Industrie (VCI).⁸¹

The German emphasis on the pharmaceutical industry as a means of global expansion and economic development has lasted over 100 years. The VCI remains a prominent force in German political and social life. The VCI continues to issue reports and offer recommendations on matters relevant to the pharmaceutical industry, including matters of research and development, biotechnology, and the German government's role in regulating all of these. In January of 2011, the VCI issued a report entitled, "Tax Incentives for Research and Development, Messages and Demands", in which it itemized policy recommendations for the federal support of the pharmaceutical industry's research and development. As the report states, "the introduction of tax incentives for research and development (R&D) in Germany is long overdue.... Almost all major industrial countries promote R&D through tax incentives. The German government coalition agreement includes tax incentives for R&D, especially for small and midsize enterprises" (VCI, 2011). It would appear, then, that a lobbying entity like VCI would have a great interest in an avenue of research like stem cell research, which has the potential to significantly streamline research and development requirements.

Despite this, the German VCI has had little to say about stem cell research as a priority for Germany. It is not the case that the pharmaceutical industry in Germany is altogether ineffectual. In fact, when it comes to its relationship with politics, the pharmaceutical industry has been anything but ineffectual. So much, however, has failed to be the case in the instance of stem cell research policy, despite the fact that the pharmaceutical industry wields a great deal of power and many would clearly benefit from advances in this work.

Germany's biggest and most historically influential pharmaceutical company, Bayer, has similarly had relatively little to say about stem cell research, either as a research or an ethical matter. On the "Innovation and Ethics" webpage on its website, Bayer has this to say:

⁸¹ It is through the VCI that German pharmaceutical companies like Bayer and others engage with members of the German Parliament. The VCI gains its authority as a member of the lobbying community in the German political system. The Federal Republic of Germany is Germany's second attempt at a Democratic political regime, the first taking place during the failed Weimar Republic and Nazi regime (Hartmann, 2011). The Basic Law, which guided the political system in the Democratic West Germany following World War II became the governing document for all of Germany following reunification in 1990. The Basic Law specifies that Germany is a constitutional state, and that the guiding principle for Germany is one of respect for human dignity. As the Basic Law states, "Human dignity shall be inviolable. To respect and protect it shall be the duty of all state authority" (Basic Law, 1949). As Germany is also a constitutional state, all state authorities are subject to judicial control. Finally, as Germany is a federal state, the government authorities are divided into member states and a central state. As has been stipulated in the Basic Law, Germany is a direct democracy, wherein a popular initiative can gain parliamentary passage through support from a minimum number of citizens who call on the initiative's passage. Similarly, referenda demand that Parliament pass bills that have been presented to it, allowing the popular majority determine legislation.

The possibility to cultivate human stem cells allows for completely new medical therapy options... research on human stem cells is currently still in the state of fundamental research. However, it promises great possibilities for the therapy of diseases, which, today, cannot be treated sufficiently or at all. At present, Bayer does not conduct any stem cell research and we do not utilize human embryonic or adult stem cells. However, in general, we believe that research in the field of regenerative medicine should be promoted as research findings may allow the development of new therapies for serious and life-threatening diseases.”

Whereas other leading pharmaceutical companies have embarked on research using stem cells, or stem cell-derived media, Bayer has not yet seized upon this research avenue. Why they have not, however, is a far more uncertain question. What is interesting, however, is that Bayer has established strategic partnerships with a number of small and large companies and academic institutions, some of which engage extensively in stem cell research of some kind. For instance, Bayer has partnerships with Genzyme Corporation, Stanford University, Prometheus Laboratories, and GlaxoSmithKline, all of which have a noted history of work in stem cell research.

Perhaps it is because Bayer partners with other laboratories and companies that do engage in research using stem cells that it has decided not to take on this line of research in Germany. Perhaps it is precisely because Bayer can enjoy some of the benefits of this research without risking its reputation in Germany that Bayer has offered only a tacit amount of support for it. And, finally, perhaps it is because Germany's biggest and most profitable pharmaceutical company, Bayer, does not engage in this research that the VCI–Germany's pharmaceutical lobby– has not taken an aggressive stance on the issue. Although these questions cannot be answered with complete certainty, it is possible that any one of these is the case, given the controversial history of the company in German social life. As there is already a considerable degree of hesitation, uncertainty, and at times rejection of embryonic stem cell research among German citizens, and as Bayer has been aligned with organizations like IG Farben who have a legacy of highly unscrupulous acts, it would not be surprising that the Corporation, which leads much of the pharmaceutical industry in Germany, would be hesitant to engage in this work in any public manner.

The construction of the German democratic system is such that it is resistant to most attempts of manipulation or undue influence⁸². The particularly

⁸² Different from the US, yet similar to the UK, Germany has a campaign finance system that is reliant on public funding. For instance, the selection and promotion of candidates for political office are addressed in the Constitution, and funds used to finance election campaigns are reimbursed by the federal government. This provision was codified in the German Basic Law, making Germany the first among many other democracies to adopt a public campaign finance system (Hartmann, 2011). Similarly, the German party system prides itself on its commitment to transparency as essential to a well functioning democracy, a provision that has made way for a five-party system that includes the major parties of the Christian Democratic Union (CDU), Christian Social Union, the Social Democratic Party, the Greens, the Free Democratic Party, and

democratic nature of the German Bundestag makes the lobbying efforts of even powerful social actors, like the pharmaceutical industry, less effective. In the context of human embryonic stem cell research, Germans have demonstrated a discerning nature about which social actors can be credibly relied upon in different social settings, and given the historical nature through which this issue has been viewed, the pharmaceutical industry has made little headway. That the pharmaceutical industry played such a significant role in the Nazi era, and that this industry was so capriciously destructive of some of the lives it should have been improving, has given the industry little grounds on which to make claims about bioethically thorny issues. When it comes to these ethnically complex issues, stem cell research is among the most visible.

Given the skepticism through which the German pharmaceutical industry is viewed, and given the industry's uncertain stance on stem cell research, precisely how this actor has either influenced the debate or sought out sources of social capital are uncertain. There is little question that advances in stem cell research, particularly those resulting from SCNT, are beneficial for the R&D necessary for pharmaceutical advancement. To be sure, the German pharmaceutical industry has gone to great lengths to help create a welcoming environment in Germany for pharmaceutical research to take place. However, within the confines of Germany, if hESC research were to have been promoted by the pharmaceutical industry, it is quite possible that the political and social backlash could have superseded the benefit.

Germany is caught between creating an environment that is friendly to pharmaceutical advancement, and adhering to a social Doxa that rejects research that would create a pharmaceutically-friendly environment. What effect this has on the pharmaceutical industry, itself, is equally as uncertain, with an industry that is primed to grow considerably based on economic development incentives and a set of research limitations that handicap this growth. The industry, then, is simultaneously in a position of advantage so far as it serves as a primary economic driver, and a position of disadvantage so far as industry growth is dependent on research like stem cell research.

The German pharmaceutical industry can find its most strategic position by acting as an economic driver without relying heavily on the advances of stem cell research to capitalize on this role. With the favorable corporate tax burden placed on German industry, at a level of 22.8%, and the number of research

the Left party. As a result of the five-party system, the establishment of permanent alliances and government through coalition is the general rule in German Parliament.

The German Chancellor is elected by members of the Bundestag, who can similarly relieve him of his duties through a vote of no-confidence. This responsibility is one of the two primary responsibilities of members of the Bundestag. The other primary responsibility is to pass legislation, acting upon bills that have been proposed by the German federal government. The Bundestag's parliamentary committees discuss and offer expertise on bills that have been introduced, in a manner that is similar to the US Congress' committee system.

institutions with which companies can collaborate, some of this problem is circumvented, as the economic benefit is established without even engaging in any research at all. The level of enticement that the German government has offered the pharmaceutical industry is extensive, and one would be inclined to believe that the industry, then, would be in a position to set the terms of the stem cell research debate and use its position to its advantage. The problem arises, given the history of the pharmaceutical industry in Germany's difficult past.

To the extent that the German pharmaceutical industry “called the shots” in the past, the country was brought to devastation. It is quite possible that the industry has greater leverage in other matters, like strategic planning and economic consultation, but so far as specific bioethical issues are looked at through a policy framework, the industry has a weakened position. The same can be said for the German government, as well, in so far as its relationship with the pharmaceutical industry is concerned. The German government has had to be particularly sensitive to how ostensibly collusive relationships between the pharmaceutical industry and the government are perceived by German citizens, especially when these relationships involve questions like those raised in human embryonic stem cell research. For this reason, it would be unsurprising to see members of the German pharmaceutical industry, as well as, members of the German government, distancing themselves from one another when it comes to this, specific issue. Were the German government to expand its stem cell policy, it must not appear to be the result of influence from the pharmaceutical industry. Likewise, to the extent that the German pharmaceutical industry might refuse to advance this research, it would be advisable to not be from the directives of the government. This is precisely the relationship that the pharmaceutical industry and the German government have struck when it comes to stem cell research policy.

PATIENT ADVOCACY GROUPS

The German political system provides opportunities for a great deal of democratic and popular input when it comes to matters of public policy. Directly stated in the German constitution is the provision to allow for the legislative consideration of policy matters as a result of public support for them. With such a broadly democratic political system in mind, it would stand to reason that an issue like funding for and legality of stem cell research would be particularly susceptible to social influence, as this research has such direct relevance to people's lives.

In a manner that is similar to the US' CAMR and the UK's AMRC, Germany has a similar organization known as BAG SELF-HELP. The organization describes itself as, “an umbrella organization of 109 organizations of disabled and chronically ill people and their families as they develop activities nationwide [in Germany]... Our association of more than 1 million physically, mentally, and psychologically disabled and chronically ill people have joined

together at the local/regional level in support and unity. These groups have, in turn, organized into self-help associations with disease-specific orientation to national advocacy” (BAG SELF-HELP, 2011).

BAG SELF-HELP provides for its member organizations guidance on the issues particularly relevant to people facing disabilities and chronic diseases. The issues that BSH focuses on include such important matters as compensation for morbidity as a result of disease or disability, the strengthening of collective and individual patient rights under the Institute for Quality and Efficiency in Health Care, patient-oriented medical care that centers on the physician/patient relationship, adequate drug supplies, regulation of generic drugs, and the registry of drug testing (BAG SELF HELP). The umbrella organization has also issued a series of opinion statements on what it calls, “health policy emphases”, of which they include the necessity of a patients' rights law, greater transparency in the health sector, protections for patients in medical research, and the necessary coordination between inpatient and outpatient care. What is notable, though, is that, despite the fact that BSH represents a wide variety of patient interest groups, including those that historically have been primary targets for advancements in human embryonic stem cell research, the umbrella organization makes essentially no mention of advocating for or the perpetuation of this research.

In an immediate sense, the influence of the patient advocacy movement in Germany might appear to be somewhat limited. However, the German stem cell Doxa is based on historical events and protecting vulnerable populations from human rights abuses. In the confines of the stem cell debate, patient advocates might represent this very vulnerable population whose lives need to be protected from scientific exploitation. As a result, it might be the case that this social actor may have had the single most significant effect on the human rights perceptions surrounding stem cell research. At least in part, this is due to the epistemic environment that members of the patient advocacy community have helped to create.

As in many other Western countries, when it comes to patient advocacy in Germany, there is a considerable amount of attention placed on quality of life. In a manner that is even more evident than in the US and UK, the patient advocacy movement in Germany has placed a premium on establishing equality for German citizens facing disease or disability, and has made patients' rights a priority. As can be seen in the efforts taken by BSH, ensuring that citizens facing disease and disability are placed on an equal footing, and that these individuals are not taken advantage of, are of central importance.

Given Germany's complex history of unthinkable abuses carried out on vulnerable populations, like those facing disability, it is quite expected that creating policies that would prevent the recurrence of such a set of circumstances would be of highest importance. In looking at the priorities of the patient advocacy movement in Germany, even as it pertains particularly to stem cell research, there is a significant degree of uncertainty about how this research

might negatively impact the lives of Germans with disease or disability. In a report by PatientView, documenting the state of patient advocacy in Germany, the research organization made an auspicious argument about the concerns of patient advocates in Germany. The group stated, “an innate distrust born of decades of living under a health system whose administrators, providers, and suppliers have all contrived to work together to the apparent financial detriment of patients, makes most German patient groups deeply suspicious of the Pharma industry and its motives” (PatientView, 2008). This concern has been raised, while acknowledging the influential role that patients have in decision-making. They argue that, “since patients are ultimately the main source of funding of the sickness insurance system, their representatives—the patient groups—should have the right to a say in decisions on public policy” (PatientView).

This “right to a say” given to and demanded by members of the disability community in Germany represents another manifestation of the collective memory in German culture. The need for protections against unethical practices perpetrated against vulnerable populations like the patient advocacy community is a defining feature of the German thought and practice. In fact, the medical ethics movement has its origins in Germany following World War II, as it was a result of the Holocaust that the Nuremberg Code of Ethics was created (See Appendix 13). The Nuremberg Code is one of the most important, if not the most important, documents in the history of biomedical research. Each of the stipulations itemized in the Nuremberg Code was designed to address some aspect of the atrocities conducted in the concentration camps. Though these acts of alleged medical experimentation were conducted on individuals of all physical capabilities, this code of ethics was designed to protect individuals taking part in scientific research for the good of humanity in the future. Often, though not always, individuals who fall into this research demographic are those facing medical challenges and disabilities.

There is a particularly German spin on the role of patient advocates in Germany: a role that centers on the need for bioethical protections against ethical abuses. The concerns that have been generated from the patient advocacy movement in Germany apply not only to historical practices but also much more recent practices. This has particular relevance to the stem cell issue. With an emphasis on adult stem cell therapies, Germany has been the home to unproven and potentially unsafe therapies for a wide array of diseases and conditions, becoming one of the international hotspots for “stem cell tourism”. Representing the tangible risks of the globalization of stem cell research, “stem cell tourism”, like other forms of medical tourism, demonstrates some of the potential threats that arise as a result of a growing interconnectedness. One of the most notable and infamous entities conducting unproven, and demonstrably unsafe and unethical treatments, was the offshore German clinic, Xcell.

The Xcell Center was a Cologne--based stem cell therapy clinic that advertised treatments and cures to a wide range of diseases, despite the fact that there was no documentation that these therapies would be effective or even

safe. In May of 2011, the clinic was forced to shut its doors because of these safety concerns, after one child who received stem cell injections at the clinic died as a result of complications. As the UK Telegraph reported:

According to Xcell, about 25 British patients a month –including children with severe disabilities—are treated at its clinic in Düsseldorf and at another in nearby Cologne. The treatment involves taking bone marrow from patients, harvesting stem cells from the bone marrow, and then reinjecting those stem cells into other parts of the body, including the brain, the spine, and the neck.

Prior to the allegations and subsequent closing of Xcell, there was a great deal of attention directed toward this clinic as a location to pursue therapies without the ethical question of the use of embryos to obtain stem cells. However, the highly unethical practice of treating patients using unsafe therapies has since sparked a renewed concern for the manipulation of patients with diseases and disability. As a result, greater focus, once again, has been placed on ensuring that vulnerable populations, like members of the disease and disability community, are safely protected from research and medical abuses.

Many of the patient advocacy groups in Germany have addressed, in some form, either the stem cell research question, in particular, or some aspect of biomedical research that is reliant on experimentation. However, given the history of experimental research in Germany since World War II, fears about how this research might negatively affect German citizens sits at the forefront of many German citizens' concerns. For this reason, it is not the pursuit of cures through hESC research that has generated the greatest attention from the patient advocacy community, but rather how to safely protect these individuals from the risks posed by it.

When it comes to those who might be participants in stem cell research experimentation, a new concern has arisen, given work conducted in embryology. This concern lies in exactly who or what constitutes the “human subjects” which the Nuremberg Code is designed to protect. Contrary to the position taken by other countries, the German position has been a highly protectionist one, a position that is willing to err on the side of inclusivity rather than exclusivity. This position has fostered a stem cell policy that counts the embryos on which the research is conducted as veritable human subjects, protected under the same ethical guidelines as others. Based on events in Germany's past, there is a rejection of the possibility of being selective about who is entitled to protections and who is not. This critical position, which arose out of establishing human rights protections for research participants, is arguably the single greatest influence on the stem cell research policy in Germany.

Of the social actors at play in the German stem cell research debate, the actor that is in the best position to challenge the social Doxa is the patient advocacy community. Members of this group represent those most directly affected by the events of the Holocaust, and as a result, represent those with the

greatest degree of leverage to influence a Doxa on their experiences. The position that the patient advocacy community holds in Germany, then, is one that is wrought with complexity and nuance, and this has its basis in a tension between events of the past and a look to the future.

While the Holocaust most notably affected Jews in Germany, the abuses carried out on “invalids”, or those facing physical and mental disabilities, were equally as pervasive. The medical experimentation that was conducted on German citizens facing disease was executed in the name of scientific understanding. By 1945, abuses like forced sterilization and surgeries were perpetrated against some 400,000 German citizens, suffering from illnesses like epilepsy, blindness, deafness and physical deformity (Bachrach, 2004). It was these human rights abuses that laid the groundwork for the Nuremberg Code of Ethics that has come to define not only the bioethical field but also the social framework characteristic of Germany.

In a manner that is highly reflective of the predictions of SSK, the context of the research environment in Germany has directly influenced the research and knowledge that is created. The respect for life that has come to define so much of stem cell policy limitations, then, is not the result of religious argumentation but rather uniquely secular argumentation, where morality orients itself on the secular bioethical principles of beneficence, justice, autonomy, and respect. These do not emerge out of any particular theology but rather cultural beliefs that draw upon the notions of collective memory and risk.

From this standpoint, the position of the patient advocacy community is a heuristic that can also be applied to the embryos from which embryonic stem cells are derived. If it is society's responsibility to protect individuals, this protection must be categorical, without exceptions for life at any level of “validity” or viability. At the heart of the bioethical principles in Germany is the necessity of proper informed consent when it comes to medical or scientific research. Without obtaining fully informed consent, it is against bioethical principles to conduct experimentation. As embryos are not in the position to authorize consent, yet are necessary for embryonic stem cell research and are forms of human life, then they are outside of the realm of legitimate scientific media on which experimentation can take place. This echoes the protections that the German polity would desire as a result of the events of the Holocaust.

Finally, another critical point must be acknowledged. Implicit in the “quest for cures” is the idea that an individual facing disability needs to be “cured” or “improved”. A sentiment like this has great implications for the very ideas that sat at the heart of the Holocaust—that some lives are less worthy than others, and that society would be better off if these individuals were not a part of it. In this sense, the “quest for cures” might not be understood as a means to improve people's lives, but rather might be understood as making the statement that people's lives should be changed. For those in Germany who have faced unimaginable abuses because of their disability, it is not surprising why this idea would be rejected.

For this reason, the patient advocacy community in Germany not only acts as an orthodoxy, but might very well be the defining feature of the social Doxa. These individuals are most representative of the protections that underlie the German policy, protections that are put into place to offer respect to human life at all stages and levels of ability. There is no one social group that is more intimately affected by the advances of stem cell research than those for whom this research is directed.

DISCUSSION

Germany represents one of the most complex cases of human embryonic stem cell research policymaking. In ways that are similar to the United States, Germany is a cultural context where one might not expect to see a restrictive policy, as Germany is a wealthy nation with a historical commitment to science. However, the stem cell research case in Germany indicates precisely how difficult it is to view a matter like stem cell research in standard theories of the sociology of science. There are more considerations to take into account when investigating the development of human embryonic stem cell research, factors that touch upon this particular avenue of scientific research and lay the groundwork for future areas of multidisciplinary science. The case of human embryonic stem cell research in Germany represents a particularly illuminating case in which to view how the principles of World Polity Theory, Sociology of Scientific Knowledge, and Field Theory work together to explain the progression of complex scientific research.

Germany offers an important case of how the dynamics of SSK and Field Theory can operate together. Stem cell research legislation, much like nearly every other issue debated in the country, can only be looked at through the lens of events in Germany's history. The Holocaust, Nazi era, and World War II cannot be stripped away from the psyche and social understanding of German citizens, and every issue is bound by the ideas that these events have generated. The German moral tradition is one that is based on deontological principles in a historic sense, and the notion of risk in a more modern sense. Both of these theoretical frameworks have underpinnings that focus attention on the negative outcomes of individual actions. The complex German history and philosophy that is based on a sense of risk have created a social framework, or even a social Doxa, that guides thinking and creates reality.

As Germany's historical memory defines German thinking, the behaviors of social actors in any debate, especially in a controversial question like human embryonic stem cell research, can be understood in terms of their relation to the Holocaust. The focus on ethical principles and human rights, and the fear of questionable research practices have come to define the German position on embryonic stem cell research, and result from this prominent historical event. German actors in the stem cell debate not only act in relation to one another, but also in relation to this prevailing cultural context in a manner that joins SSK and

Field Theory.

Despite the particular interplay between SSK and Field Theory in Germany, all three predominant sociological frameworks come to bear on this case. When looking at stem cell research in Germany from a World Polity point of view, even despite Germany's restrictive policy, there is much to be found. Particularly in the post-World War II era, Germany has been the home of highly secular and rationalized thinking. It is this very type of secularly-oriented social thought that, according to World Polity theorists like Meyer, Drori, and Boli, lies at the heart of global modernization. To be sure, much of Germany's recent economic development has been the result of a focus on secular principles and a rejection of traditional thinking. The extensive connections and network that undergirds the scientific field in Germany speaks to the country's commitment to scientific principles as a means to grow the national economy. This has been carried out in many domains of science, and in particular, science that has an application to society.

Although the German stem cell policy rejects some of the most scientifically-supported guidelines for hESC research, as addressed by organizations like the ISSCR, the German perspective is still based on the international scripts on which WPT is built. Rather than an orientation that is centered on scientific principles as a means of rationalization, the German policy is built on human rights and bioethical principles as a means of rationalization. There has been a calculated choice made by German citizens and policymakers to prioritize the channels by which modernity and rationality are achieved in society, and in the case of hESC research, the international human rights script has emerged as preferable to a scientific approach. It is at this juncture that, in Germany, WPT fits seamlessly with an SSK framework.

The prioritization of human rights in Germany is the result of the cultural context and historical memory that is fundamental to German thinking, a historical memory that cannot be disentangled from the atrocities of the Holocaust. This is where SSK fits so prominently into the German stem cell case. The unfortunate legacy of the Holocaust has come to define nearly every aspect of German social life, in a way that speaks directly to the principles of SSK, and this provides context to the ways in which science has been approached. The Holocaust lies as a framework for understanding many social issues, was the impetus behind the Nuremberg Code, and is the starting point for the German stem cell policy. This is the globalized script around which Germany has oriented itself, and is the product of the unique German culture.

Germany has not, however, rejected the importance of hESC research altogether, and true to WPT, has viewed some of this as important to building the German economy. The hESC research that is being conducted in the state of North Rhine-Westphalia has served to expand the economy of the state in a pronounced way, making NRW one of the most economically sound regions in the country. The permissibility of conducting hESC research in North Rhine-Westphalia was a result of the economic benefit that this research could

generate.

The biggest shortfall of the German case as it pertains to WPT lies in the rejection of the input from prominent German researchers like Oliver Brustle, whose work initiated the debate. The restrictive stem cell policy that has resulted, though, provides one of the greatest examples of SSK in practice, as the research limitations have directly influenced the perceptions that German scientists have on stem cell research. Whereas many among the scientific community feel that human embryonic stem cells represent the “gold standard” in research media, German scientists have been far more wary, and have celebrated the potential of adult stem cells. The social context in which this research is being conducted, then, has had a direct effect on the knowledge that is created.

While WPT and SSK help to illuminate some of the German stem cell case, they do not explain all of it. The context created by the cultural history of Germany offers insight into how actors have behaved on an individual basis, but not how they have responded in relation to one another. This is where the value of Field Theory comes into light. Though the social actors in Germany contributing to the stem cell debate might remain the same, how these actors operate is highly reflective of the greater social context, so much so that the dynamics of this context can be viewed as actors, themselves. A preliminary Field Theory representation of the relevant actors in the German case can be represented in the following way:

Germany



Doxa based on events in historical memory and bioethical concerns

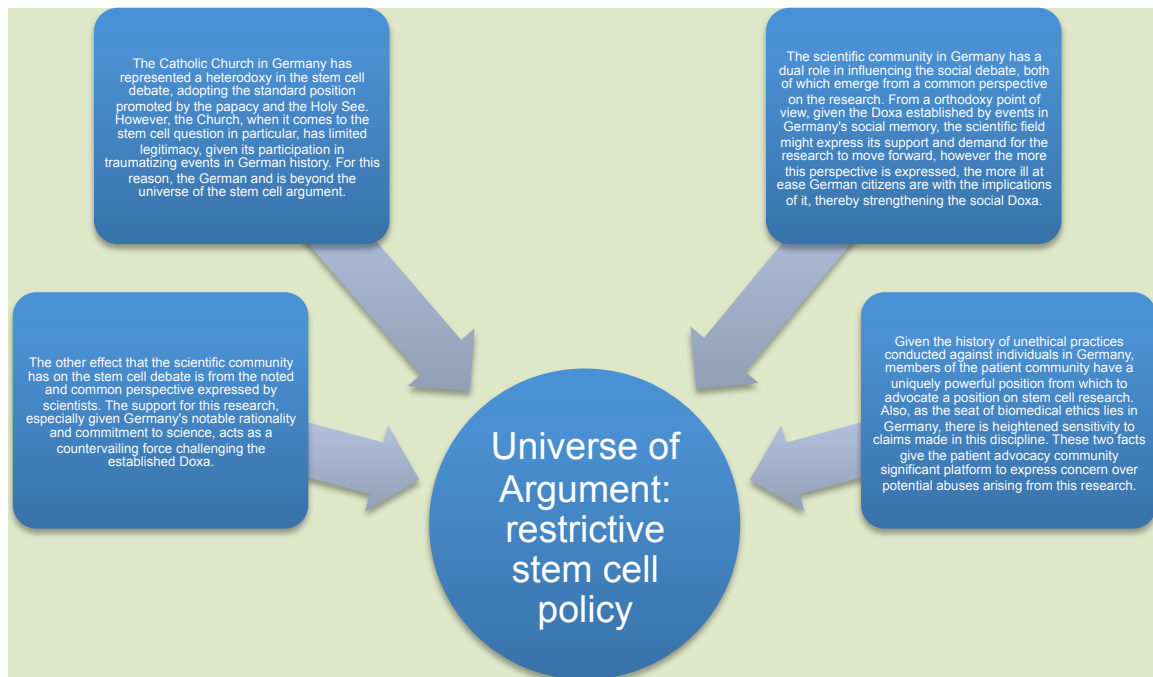


Figure 3: Field Theory Diagram of German Stem Sell Policy

All of the German actors can be looked at from the context of a social history centered on the Holocaust. This fact makes the actions, influence, and capital of the individual actors different than what might be expected in other contexts. In fact, it is quite arguable that this context makes the German case as unpredictable as it is. The impact of the Holocaust joins more modern German sociological and philosophical thought, most significantly that of Ulrich Beck, whose work on World Risk reflects the years of human degradation as a result of scientific and technological activity or inactivity. The fears that grow out of work on human embryonic stem cells put the rights of individuals at the forefront, and by “individuals”, the German policy implies both patients who might benefit from advancements in stem cell research and the embryos from which human embryonic stem cells are derived. As a result, along with protecting the rights of the embryo, protecting the rights of members of patients groups is critical to the German context.

To the extent that there is a social Doxa in Germany that relates to human embryonic stem cell research, it is possible to take a proxy from a Doxa based on bioethical reasoning and human rights discourse. Actors involved in these circumstances either strengthen such a social perspective or, whether intentionally or inadvertently, serve to reduce it. Whereas in the US, the scientific community and patient advocates work together to create a heterodoxy to counterbalance a Doxa based on a “culture of life” and a restrictive stem cell policy, in Germany, the scientific community and patient advocates work together to create an orthodoxy that strengthens a restrictive stem cell policy.

From the standpoint of the abuses perpetrated on vulnerable populations in Germany, the patients' rights groups speak from a position of power and credibility. To the extent that the products of stem cell research are viewed as something to be feared or rejected, it calls to mind events of the past. Given some of the unethical practices that have taken place in the German stem cell enterprise, practices that led to the closing of the clinics like Germany's Xcell, there are still lingering concerns. This works collaboratively with the position of some members of the German scientific community who have pushed for embryonic stem cell research permissibility to be expanded. While some regulations have been relaxed in Germany, specifically with the change of the “cutoff date” for embryonic stem cell line importation, on a more societal level, the harder scientists push to make changes, the more resistance they might receive. This set of circumstances makes for an inadvertently interactive relationship between scientists and patients, which interestingly strengthens the terms of the social debate.

Actors like the Catholic Church and the pharmaceutical industry, too, must be looked at from the perspective of the influence they have had throughout history. The current structure of the Catholic Church hierarchy is especially conservative and promotes religiously based moral principles. As seen in the German Basic Law, Germany has a moral position that is based on secular

human rights ideals that rebuff some of the authority that religious institutions like the Catholic Church seek to establish. The particularly conservative Church, coupled with a secularly based morality that has grown out of Germany's history, makes this social actor orthodox to the Germany's stem cell policy position but not a leading voice in its creation.

Finally, the pharmaceutical industry has had a noteworthy role in both German history and the stem cell debate, in particular. In a way that is reflective of WPT, Germany has tried to lure industry in the form of pharmaceutical companies to their economy, noting the vast benefit that this industry has for economic development. However, Germany's drive to build upon this is tempered by the ethical concerns that this research raises. To the extent that this involves the pharmaceutical industry lies in the uncertainty about the pace of biomedical technologies and the industry's unfortunate past. For certain, the role that the pharmaceutical industry played in the World War II atrocities should not be overstated, and Germany has moved to establishing an enticing environment for this industry to grow. However, to the extent that the pharmaceutical industry in Germany is able to call the shots or be demonstrative in public policy formation, there is reason for concern. This legacy forces a sharp reduction in the social capital that the industry holds, and how much trust is afforded in the domain of bioethical matters. Though the pharmaceutical industry might have greater leverage in other matters, like strategic planning and economic consultation, its role in specific bioethical issues that are looked at through a policy framework puts the industry in a weakened position.

There is an important, interactive relationship, then, among these social actors that comes to light through Field Theory analysis. The social Doxa within which all of these actors operate is defined by the collective memory of the Holocaust. The patient advocacy community responds to and pushes against the advances of science, and the scientific community, in turn, speaks from a fragmented perspective as a result. It has only been through the growing status of embryonic stem cell research on a global scale that unity among the German scientific community has been approached. Without a firm backing from the scientific community, the position of the pharmaceutical industry is, likewise, diminished. This is especially the case, given the industry's complex history in German culture. Without a clear ally with which to align itself, the pharmaceutical industry in Germany has either remained relatively silent on the embryonic stem cell research issue or has sought opportunities elsewhere. The Catholic Church is in an unusual position, as its credibility as an authoritative institution has been eroded. By seeming to support the German policy, the Church bolsters its social standing.

It is with this in mind that the complementary nature of these three sociological theories comes into play. It is from an SSK point of view that the events in German collective memory have a dominant effect on German social thought and culture. The impact of this context cannot be stripped away from nearly any issue discussed in German policy, especially one that is plagued with

bioethical questions like those found in human embryonic stem cell research. This context has a tremendous effect on how important actors subsequently influence a policy matter like stem cell research, and alters the way that a country like Germany prioritizes international discourses. The result is a policymaking framework that is reliant on an international script, but a script based on human rights rather than science.

CHAPTER 6: CHINA

POLICY WITHOUT A POLITICAL FIELD

CHAPTER 6: CHINA-POLICY WITHOUT A POLITICAL FIELD

When it comes to policymaking, particularly stem cell policymaking, China represents a “control” case against which to compare the US, UK, and Germany. This is so because, in the Chinese political system, the State exerts monopolistic control over policymaking, (Peng in Jones Finer, 2003) and there is little room for the influence of social actors, unless these actors operate in accordance with the demands of the State. With this in mind, it is through the Chinese case that we can see how policy is developed and what outcomes arise when sources of capital are not pursued and the State is the primary generator of social context and culture.

China, then, exists as an exemplary case of the powerful State of which Bourdieu was so critical. According to Bourdieu's analysis of the State, citizens are bound by the thinking and reality of the State, as it defines the possibilities of thought and what should be considered “unthinkable”. As Bourdieu argues, it is the State's bureaucratic entities that place a framework around a society's quest for knowledge and how autonomous the educational and scientific fields might be. In an analysis of the power of the hyperbolic State, the State can claim to have a monopoly on sources of symbolic and physical capital, as it pervades social structures and mental constructs. In an authoritarian regime like China's, the ideas addressed by Bourdieu are brought to the highest degree, with the Chinese government exerting totalitarian control. However, the monopolistic nature of the Chinese autocratic State and the policies it implements must adhere to its own internal institutions and international scrutiny (Lin & Kangas, 2006) It is from this point of view that the actors relevant to the stem cell “debate” in China must be addressed.

CHINESE POLICY

China is known for its liberal and permissive stem cell research policy, possibly the most liberal in the world. However, this policy emerged from a far different set of social conditions than those seen in the UK. Though it is considered a “developing country”, China, in recent decades, has made an attempt to modernize and become a leading player on the world stage. Distancing itself from policy based on ideological principles, the Chinese government has made a firm commitment to funding science as a primary means to reach this goal. In a way that is reflective of the heart of WPT argumentation, in 2006, Chinese President Hu Jintao stated his commitment to modernizing China, and focused on biotechnology as a central priority, “by which China will try to catch up with the developed countries” (cited in Chen, 2007). Among areas of biotechnological advancement, President Hu emphasized a focus on stem cell research.

Hu Jintao took office in 2002, at which time “scientific development” became the predominant policy in his overall ideology (Klein, 2010). Hu's rationale for this commitment was to strengthen the Chinese position in the world

economy and boost its economic development. While unable to invest financially in every aspect of scientific development, the Chinese government chose several key areas in which it could make particularly significant strides. Due in large part to the ongoing international controversy surrounding stem cell research, and other countries' hesitation to embrace sweeping stem cell policies, Hu itemized human embryonic stem cell research as one key area in which to excel internationally. While it is in any country's economic interests to invest in science, China has emphasized this particular scientific field that other countries have neglected for a host of cultural reasons.

The social conditions in Chinese society have been particularly amenable to advances in stem cell research. The Chinese moral philosophy is based on Confucian ethics, and this ethical framework places little or no moral question on the status of the embryo. According to Confucian philosophy, personhood is a characteristic only acquired through social interactions, and an embryo without such meaningful relationships, does not have value (Klein in Yorke, 2010). Similarly, this philosophy places greater value on maximizing the human experience, and a primary means to do this is through medical treatment. The one-party Communist Chinese government embraces this philosophy, and as a result, it is the guiding policy and ideology throughout China. This singular philosophical belief puts China in a somewhat unique category in relation to many democratic countries, as the Chinese stem cell policy is resistant to a diversity of social thought on the ethical usage of embryos in research. In fact, in a Bourdieusian sense, the public opinion surrounding the ethics of this research might very well be the product of the Chinese State's propaganda, which readily resorts to media and educational outlets to promote its policies (Peng).

World Polity Theory advocates for a modernizing role played by science in society. True to this idea, China's commitment to science and technology has been in evolution for several decades. In the late 1970s, Deng Xiaoping unveiled a new role for science and technology in China when he stated, "without the rapid development of S&T, there can be no rapid development of the country" (Deng quoted in Klein, 2010). Later in the Deng era, in 1986, the Chinese President unveiled the "national High-Tech Research and Development program", which highlighted the importance of applied research as a means to drive the commercial and clinical aspects of scientific research. Biotechnology took center stage, with an emphasis on high-tech medical research emerging on the 21st century horizon. This focus on biotechnology provided the necessary infrastructure to seize upon the potential of human embryonic stem cell research when it arrived in 1998.

There has been increasing interest in understanding the rapid changes occurring in China in the stem cell field. As McMahon notes, in 2000, China had only 37 publications in stem cell journals but dramatically increased this number to 1109 publications by 2008 (McMahon, 2010). It has been through the quest for journal publications that China has attempted to shift its local stem cell-related work to a broader international audience. China has mirrored the path by which

countries like the US have made an international presence in the stem cell field. However, China's growing role in the international stem cell field is the result of an interplay between scientific advancement *and* the unusually permissive policies that allow this science to take place at a nearly unfettered pace.

China exists as a case against which to draw comparisons about how social actors influence policy when they are afforded the opportunity to do so, versus how policy is developed when, as in China, the social conditions prevent these opportunities. Field Theory is reliant on the establishment of a social Doxa and the pursuit of capital by actors operating within social disciplines. The challenge is that, in an authoritarian country like China, those who are able to express a “competing discourse”, or in other words, operate in the “field of opinion”, are heavily regulated by the creator of the social Doxa, itself, namely, the Chinese government. This makes the opportunity for struggles for capital or a socially heterodox position fundamentally anathema. The “political field” in China, then, operates by a different logic, with actors positioning themselves within the organization of the state structure.

This is not to argue, however, that the Chinese government has been able to act in whatever way it so chooses. China's efforts to participate in an international community prevent this from happening. Adhering to the format established in core countries like the US and UK, China's stem cell science is bound by policy. In order to craft a set of research guidelines that was, at least on the outside, built around ethical principles, the Chinese government created two bioethics workgroups, one based in Beijing and one based in Shanghai. The former of these two groups developed a report entitled, “Ethical Principles and Management Proposals on Human Embryonic Stem Cell Research”, which was submitted to the Chinese government in 2001. The Shanghai workgroup similarly created a set of proposed guidelines, entitled “Ethical Guidelines For Human Embryonic Stem Cell Research”, submitted the following month (McMahon). Many of the concerns that were initially brought to light by the ethics workgroups were, however, dismissed by the Chinese government who argued that ethical concerns were too limiting to the research that needed to be done. Within this structure, bioethicists in China found themselves caught between a desire to establish comprehensive ethical guidelines and a Chinese governmental policy more centrally interested in strategic advantage in international competition (O'Doring, 2003). According to tenets of WPT thought, China has exhibited a degree of *decoupling*, in terms of emphasizing ethical and regulatory guidelines that it may have no intention of implementing.⁸³ In essence, as a member of the international research community, China needed to indicate a commitment to research ethics without necessarily having any interest in this commitment.

The relative inability of the bioethical community to make headway in

⁸³ In World Polity thought, “decoupling” refers to the tendency for governments to implement policies that they have neither the means nor the intention of fulfilling. This is done to obtain international legitimacy.

establishing a set of agreed-upon stem cell research guidelines is due, in large part, to the Chinese government's ability to solicit policy input from only those experts whose opinions support its desires (Peng). However, that is not the sole reason. In order for a discipline like bioethics to have some notable effect on policymaking, it must also have some degree of authority within the society and policymaking structure. As Salter, et al. assert, the discipline of bioethics did not exist in China until very recently, partly because of the Chinese emphasis on communitarian rather than individualistic values (Salter, Cooper, Dickens, 2006; Fox & Swazey, 1981). In order for China to gain traction in the international stem cell community, it had to take part in some of the ethical agreements that were taking place around the world to provide a framework for the research.⁸⁴

The policy provision that was common in both recommended guidelines, which stated the imperative prohibition of human reproductive cloning, led the Chinese government to adopt a prohibitive policy, known as "a policy of four 'no's" (McMahon, 2010). This policy states, "under no situation, under no circumstances, will human reproductive cloning experiments be endorsed, permitted, supported, or accepted". This regulation is, interestingly, among the only in China that is negatively worded, as the remainder of the Chinese policy is particularly permissive and progressive. On its single-paged series of research guidelines, the Chinese government regulates as follows:

1. China permits stem cell lines derived from parthenogenesis and SCNT
2. China permits the creation of embryos that join genetic material from humans and non-human oocytes
3. China requires informed consent from the embryo and gamete donors
4. China requires that embryos more than 14 days post-fertilization cannot be used for research
5. China prohibits the fusion of human and non-human gametes, and the implantation of research embryos into a uterus

In many respects, these guidelines are similar to those found in the UK, however with one notable exception. While in the UK there is an implemented oversight body that regulates this research, in China there is no such overseeing entity. In fact, as McMahon documents, the implementation of the research guidelines is left to the institutions, themselves. What is more, there is no recourse or consequence should researchers neglect to follow the research guidelines. Finally, these research guidelines are not law, and therefore cannot

⁸⁴ In 2001, China helped to craft UNESCO's International Bioethics Committee's statement on "human and fetal research and international solidarity and cooperation" (O'Doring, 2003), and then hosted the 2006 World Congress of Bioethics, coordinated with the International Association of Bioethics. In many nations, in order to gain international credibility as a "player" in this field of research, China needed to adopt some set of guidelines.

be enforced unless the research is government-funded.⁸⁵

While China's stem cell policy has applied to basic research, the strategic goals of Hu lie in the application and translational possibilities of this work. The translational research has also been a source of regulatory concern. Despite its reputation otherwise, China has, in fact, sought to regulate some of the therapies that have grown out of stem cell technologies through the passage of the 2009 Regulations on Clinical Application of Medical Technology, a set of regulations passed by the Ministry of Health (MOH). Prior to this regulatory reform, stem cell-based therapies were categorized as "biological products", with clinical trial approval provided by the Chinese State Food And Drug Administration (SFDA). However, the classification of stem cell therapies as "biological products" proved difficult for the SFDA to regulate, and jurisdiction was soon translated to the MOH. Under the supervision of the MOH, stem cell therapies were classified as "new medical technologies for clinical application" (Chen, 2009). Breaking from much of the secrecy found in Chinese policymaking, the Chinese government posted drafts of proposed regulatory guidelines on the MOH website for review, consultation, and commentary from Chinese citizens. At the same time, the Chinese government created a committee of experts to draft a series of regulations on stem cell clinical application, and this committee recommended that this clinical application be subject to strict ethical norms of research. The question remains to what degree these regulations will be implemented and enforced, especially as research brings about an increasing number of potential therapies.

The authoritarian regime, just as what is seen in China, represents a hyperbolic case of Bourdieu's bureaucratic state.⁸⁶ In looking at an issue like stem cell research policy, it is critical to look at the influence of social actors as reflected in a regime that is continually attempting to secure its power. However, China represents not only an authoritarian regime, of which there are others throughout the world, but also a nation that is seeking to make a presence for itself on the economic and scientific world stage. These two social conditions have influenced the Chinese stem cell policy to a significant degree. As a result,

⁸⁵ The majority of funding for stem cell research is found in innovation programs, like the 863 program, executed by MOST. Other sources of funding come from the National Science Foundation of China (NSFC), the Ministry of Finance (MOF), or local government and enterprises (Chen, 2009). Local governments in China have been known to implement favorable policies, financial incentives, and competitive grants to attract qualified stem cell scientists to their regions. As a result, China has attempted to build its stem cell science infrastructure using a combination of funding and regulation.

⁸⁶ According to Bourdieusian thinking, the State provides the intellectual framework that confines social thinking and teaching. Citizens of any government are bound by the thinking of the state, to the extent that possibilities outside of this structure become unimaginable. It is, according to Bourdieu, the bureaucratic agencies of the state that produced social problems, like poverty and others, despite the fact that bureaucrats become bureaucratic officials through selections made by the state. This is, according to Bourdieusian thought, the case for all governments looking to concentrate their power, and is especially the case in an authoritarian regime like China.

it would seem that no social actors would be at all relevant in an analysis of stem cell research policy in China. However, there is more to this complex case that does, in fact, draw upon the influence of social actors.

The actors included in this analysis involve the Catholic Church, which has only a very minimal presence within China but embodies a powerful social institution that challenges the symbolic capital of the Chinese government; the scientific community and the pharmaceutical industry, both of which serve as two of the very few intellectual or market elites that are, in fact, solicited by the Chinese government in its quest to build its knowledge economy; and the patient community. It would seem as though the patient community would have essentially no role whatsoever to play in the Chinese case, and this is likely true when the stem cell question is looked at purely within the national borders. However, when the focus of analysis is broadened to a global perspective, this actor does indeed play an important role. The following analysis brings into focus the dual-existence of actors operating within the national context and, within the confines of a limited political field, how they also operate in the international context.

CHINESE ACTORS

CHINA AND THE HUMAN RIGHTS DISCOURSE

When looking at a matter of national policy in China, any investigation cannot be initiated without attention given to China's rise as an international force and how this affects its human rights record. Indeed, the involvement, or lack thereof, of social actors in the creation of policy speaks directly to China's history of governmental secrecy, undemocratic practices, and human rights violations. This is most notably the case in matters pertaining to science and economic development, as these are the issues that the Chinese government pursues most aggressively in its rise to international prominence.

China is caught between the traditions of a cultural past based on isolation and a future dependent upon participation on the global stage. The tension between the reliance on a traditional value system and an international orientation has put a spotlight on how much China can claim "national sovereignty" as a rationale for its actions. This has especially been brought to light in the context of many policy measures, including stem cell research. As a result, an issue like stem cell research can also be looked at within the framework of a national versus international human rights tension.

The contest between national sovereignty and an international discourse, particularly as it pertains to human rights, is not new to China. In fact, the question of whether human rights are to be valued above Chinese sovereignty has largely dominated China's human rights discourse for many years (Wu, 2009). However, recent changes that have taken place in China to address its

human rights record have largely been in response to its growing presence as an international power, which has precipitated greater concern over its national image and responsiveness to international norms (Wu). Despite this, the historical position taken by the Chinese government in response to accusations of domestic human rights challenges has been a pro-national sovereignty, noninterventionist one. For instance, in response to accusations from the US over human rights abuses, the 1996 spokesperson for the Ministry Of Foreign Affairs had the following to say:

We consistently believe that human rights are essentially under a state's own sovereignty. States should protect and promote human rights according to their respective situations (cited in Wu, 2009).

How the Chinese government has attempted to address human rights issues was captured in its National Human Rights Action Plan Of China (2009), which was implemented to affect economic, social, and cultural rights, civil and political rights, and rights directed to minorities, women, children, elderly, and disabled. This action plan was drawn up in response to pressures by the United Nations, and incorporated the input of social scientists, legal experts, members of social groups, government officials, and academics. The primary objective of this Action Plan was to “put people first” (NHRAC, 2009) and reevaluate the priority given to the rights and protections of Chinese citizens versus the actions of the government. The statements made in the Action Plan were echoed in a propaganda speech given by President Hu in 2011, stating, “We must consult the people on policies, learn about their needs, and seek suggestions from them. We must listen to their views, truthfully reflect their wishes, help alleviate their hardships, and protect their economic, political, cultural and social rights and interest in accordance with the law” (Hu quoted in Shank & Wasserstrom, 2012, p. 5).

There is, however, a wide disparity between the human rights protections that China has purported to put into place, and what it has, in actuality, done for this effort. In many cases, the promises made by Hu Jintao have been without action, as public consultation on policy has been minimal and tactics of intimidation have remained in practice (Shank & Wasserstrom). The Chinese governments efforts at economic development and party loyalty have remained a priority over matters of public safety and human rights protections. Recent examples that have generated broad international attention and condemnation, like the tainted milk scare and high-speed railway accident cover-up, have put into place similar concerns about the government’s lack of transparency in other social matters like the advancement of biomedical research.

A totalitarian government like that found in China is characteristic of a political field with limited input from social actors. However, the limited input from Chinese citizens is not purely the result of the totalitarian regime, but also the social arrangement that the government implemented with its own citizens following the Tiananmen Square protests. Following the threat to the Chinese regime that grew out of the 1989 protests, the Chinese government put into place

the “Social Compact”. The Social Compact was a social arrangement in China that stated that the Chinese government would provide safety and order throughout China, so long as citizens refrained from protests or condemnation of government policies (Shank and Wasserstrom). It has been through the Social Compact that the Chinese government has been able to secure its sole position in Chinese policymaking, and this societal contract defines the “rules of the game” for many Chinese citizens. As a result, the degree to which there is input in the operations of the Chinese policymaking structure is embedded within the organization of the culture.

The human rights discourse bears particular relevance to the stem cell debate, as this issue has been characterized by its multidisciplinary nature that, in contexts like the US, UK, and Germany, would veritably demand input from other nongovernmental actors. China’s aggressively liberal stem cell policy, which has been crafted with little or no societal input, calls to mind not simply a diminished political field but also how economic development strategies could, contrary to Hu’s speech, put Chinese citizens in precarious positions. However, China’s movement into the worldwide arena is a buffer for some potentially abusive practices, as the importance of its international appearance comes into play. Social actors in China, then, take on a more international role in how they affect the actions of the Chinese government.

CATHOLIC CHURCH

In Field Theory, fields are the social spaces in which actors struggle for access to power. An authoritarian state like China exercises its power through all media and works to consolidate all forms of capital, including information capital, symbolic capital, economic capital, and use of force. Information capital involves many aspects of culture, like codes, language, communication, social rituals, national self-image, and national identity. The purpose of this source of capital is to establish a sense of national unity and identity. There is, perhaps, no greater threat to the cultural identity created by the State than the influence of religion.

Given the size of the Chinese population and the control of the Chinese government, it has proven particularly difficult to establish reliable estimates of religious practice in China. The contentious relationship between the Chinese government and religious sects has only complicated the matter, as the government implemented a state policy of atheism in 1949. The rejection of religion as a social practice was designed to centralize the government's power, however religion has become more widely permitted in efforts to establish a “harmonious society” in China (US Department of State, 2012). As a result of this, religious practices have shown an increased presence in Chinese census data, and the Chinese government has indicated a mildly growing acceptance of

these practices.⁸⁷

The influence of religious principles on Chinese policy is minimal to be sure, although it is to be acknowledged, nonetheless. Of the relatively few religions present in China, Buddhism is the largest, at 12% of the population or about 100 million citizens. While hardly enough to make a measurable impact on governmental actions, the position of this demographic as it pertains to stem cell research is worthy of acknowledgment. The Buddhist perspective on stem cell research, however, is not easily defined, and there are conflicting interpretations of how Buddhism ought to address this issue. According to some, embryonic stem cell research falls into alignment with the Buddhist emphasis on the virtues of knowledge, compassion, and the medical practice (Keown, 2012). From this perspective, the cures and therapies that emerge out of stem cell research ought to be welcomed. On the other hand, there are others who prefer to emphasize the Buddhist principle of “no harm”, which ought to apply to the protection of embryos. The Buddhist belief that life begins at conception makes it morally impermissible to conduct this research, lest researchers destroy a “new karmic entity” (Keown).

Other social researchers and political scientists have suggested that the Confucian and Buddhist traditions place the defining moment of life at birth rather than conception, or that this idea does not even apply in a religion that emphasizes reincarnation (Paarlberg, 2005). What complicates both of these interpretations is that Buddhism is an atheistic religion (Promta, 2004), based on general moral reasoning as opposed to the dictates of a deity. As a result, “goodness and badness in human actions are not based on God's judgment, but on the laws of nature” (Promta). Simply put, the method by which humans gain access to wisdom and the laws of nature is through experimentation.

There is, as yet, no resolute stance on the morality or permissibility of embryonic stem cell research from a Buddhist perspective, however the structure of the Buddhist religion has bearing on its role in China. While religious institutions are not embraced by the Chinese government, the fact that Buddhism is an atheistic religion, espousing a way of life rather than a deity to worship, poses less of a threat to the authority of the Chinese government. Though the

⁸⁷ In estimates that have been made in very recent years, according to polls taken in 2007, China has seen an upsurge of citizens who consider themselves “religious”. According to a 2006 survey by the Pew Global Attitudes Project, 31% of Chinese citizens consider religion to be “very or somewhat important in their lives” (Pew Research Center, 2008). As indicated by this same survey, there are essentially five main religions in China: Buddhism, Protestantism, Catholicism, Islam, and Taoism. Although the numbers provided in this survey are subject to measurement difficulties, only about 20% of Chinese adults claim to have a religious affiliation, making China “one of the least religiously affiliated countries in the world” (Pew, 2008). Of the five “major religions” presented in China, Buddhism has the greatest representation, with an estimated 12% of surveyed Chinese citizens following this religion. This translates to about 100 million followers. What is noteworthy is that, when asked about their beliefs in a spiritual presence, 60% of Chinese citizens indicated such a belief. This brings into light the disjuncture between the Chinese government's policy of atheism and how this is carried out in public life.

Buddhist faith has an unclear position on embryonic stem cell research, whatever this position might ultimately be is of little risk to the dictates of the State, as Buddhism embraces a personal way of life rather than a social code of conduct. A very different story can be told for the Catholic Church, and it is for this reason that it is of relevance in the stem cell question.

China's implementation of a state policy of atheism has led to a minimal degree of religious participation throughout the country, and it highlights how intimately the State is tied to the lives of Chinese citizens. As organized religion plays such a small role in all of Chinese social life, it plays essentially no role whatsoever in policymaking. Just as the Chinese government has control over other, more visible aspects of social life, it also has control over worship, in a way that makes most religion synonymous with the State. For this reason, religion, whether in the form of Catholicism, Taoism, Buddhism, or any other, has no role as a nongovernmental actor affecting the Chinese stem cell policy.

The role that the Catholic Church plays remains extremely limited. There are, at present, about 12 million Catholics in China, representing only about 1% of the population. Similarly, Catholic educational initiatives have essentially halted, as the Chinese government holds firm control over education curricula, even in "private" schools of a religious nature. Whereas, in many other countries, the question is to what extent does the doctrine of the Catholic Church influence policy-making, the question is the reverse in China. The control that the Chinese government has over policymaking has made external influence on policy matters all but nonexistent. When looked at purely within the confines of China, it may be the case that the Catholic Church has had minimal, if any, effect on the State's decision. However, there are other considerations to be taken into account, specifically how the powerful Catholic Church can influence the Chinese stem cell question from an external and international position.

While the nonexistent role that a religious institution like the Catholic Church plays in China's stem cell policy must be acknowledged, there is possibly a more international argument to be made. A considerable amount of China's history can be characterized as a rejection of Western ideals and practices, such as organized religion like Catholicism. Whether or not Catholicism is practiced in China, it remains a pronounced threat at the international level, especially in an age of increased communication via the Internet. While a country like the US is threatening to China through its economic, militaristic, and political advancements, or more specifically in its tangible manifestations of power, an institution like the Catholic Church is threatening to China through its promotion of ideas and ways of thought. These could be more threatening as they are both more insidious and less controllable.

Because the Catholic Church could be viewed as an external threat to the power of the Chinese government, the pervasiveness of this threat is likely dealt with in equal measure. For instance, to the extent that an institution like the Catholic Church might desire to exert influence on stem cell policy, the Chinese government might only redouble its efforts to remain true to its own social goals,

in this case the pursuit of scientific and economic advancement. This idea can be seen in China's policy that pushes the boundary of permissible research as far as any in the world.

SCIENTIFIC COMMUNITY

When looking at China's investment in science, this relationship is perhaps the greatest example of the “knowledge economy” for which World Polity Theory advocates. In fact, the relationship between the actions taken by the Chinese government and the progress of stem cell science is an extreme case of how science evolves when the goal is economic expansion. This set of circumstances has been seen time and time again throughout Chinese history, calling into question how a country like China more fully embraces the significance of the knowledge economy over other countries that put into place regulations to slow it down. However, from an important SSK perspective, the environment that China has created through other important historical policies makes it particularly fertile ground for embryonic stem cell research to expand.

In the late 20th century, China was committed to becoming a prominent world power through modernization (Luckstead, Mo Choi, Devadoss & Mittlehammer, 2011). As part of an effort to modernize the country, and in order to reach development goals, increasing numbers of Chinese students were encouraged to pursue advanced science and technology degrees in research institutions around the world. These students who returned to China with advanced scientific training were encouraged to take over jobs and positions that had been held by older, less technologically skilled laborers. In opposition to the Communist-focused ideals perpetuated by the Maoists, under Deng Xiaoping, there was a reorientation of focus toward the need for expertise in science. To this end, China began to open its borders, tap formerly unavailable resources, import technology, and flourish on an international scale.⁸⁸

⁸⁸ A central part of Deng's reform practices was an overhaul of the scientific, technological, educational institutions in China. However, information about the relative success of the Four Modernizations as an economic development plan is not widely available. As Luckstead and colleagues discuss, however, the effects of these policies were not to be underestimated (Luckstead, et al., 2011). At minimum, the Four Modernizations paved the way for over three decades of growth averaging 9%, with attention paid to human capital and the investment specific technology (IST) as primary sources of growth. While in the years prior to the Four Modernizations there was a distancing between China and the West, following the implementation of these policies, the gap between China and the West began to diminish. For instance, as Luckstead accounts, prior to 1979, labor augmented productivity (LAP) in the United States was 21 times that of China, however following the Four Modernizations reforms, this ratio dropped to 5.12 times in 2009. Both IST, which is a measure of capital technology resulting from the amount of output necessary to realize one unit of capital through a given production process, and LAP, often measured in terms of human capital or quality of workers, are critical economic predictors. Prior to the Four Modernizations, China was closed to the influence of the global economy, and as a result, its IST stagnated (Luckstead). In order to achieve this higher level of human capital, investments in education must be made, and prioritization must be given to

According to PRC data, China's GDP has grown by a factor of 17 between 1978 and 2008 as a result of economic expansion policies (Huang, Ma, & Sullivan, 2010). However, this expansion is missing a focus on the interaction between the scientific community and the creation of science policy that lies at the heart of WPT argumentation. SSK theorist, Knorr Cetina, has argued, "at the start of the 21st century, it is argued by many that we are well on the way to an era beyond modernity and the sort of industrial economy and nationstate societies that came with it; the terms suggested to revert to the transformations and the new type of system involved postindustrial society, postmodernity, information society, risk society, globalization and knowledge society. Though knowledge and information appear only in some of these terms, nearly all accounts suggest that issues of knowledge and information are central to the transformation" (Knorr Cetina, 2007). China, however, has placed a greater emphasis on the demands of economic expansion than it has on scientific strategies to achieve this expansion. It can be argued that this pursuit of expansion without a full inclusion of the scientific community is due, in part, to the cultural climate in China. China's one child policy has essentially reversed its population growth, and with a need to command expansion in other social capacities, has looked to science and technology as means to do so. This commitment would take place with or without the inclusion of the scientific community.

At present, science and technology in China is overseen by the Ministry of Science and Technology (MOST). According to the Ministry's website, MOST "takes the lead in drawing up S&T development plans and policies, drafts related laws, regulations, and department rules, and guarantees their implementation" (Ministry of Science and Technology, 2011).⁸⁹ MOST takes responsibility of securing economic growth through the investment in and coordination of basic, technology, and eventually translational research. In some ways comparable to the NSF in the United States or the DFG in Germany, MOST appraises proposals for awards for scientific research in China.

Since 2007, MOST has been led by Minister Wan Gang, who received his

domains of the educational field that drive economic growth (Lucas, 1988), of which science is primary. At the start of the modernization program, China had a grievously short supply of technologically skilled workers and personnel, with estimates of the size of the technological and scientific workforce at about 60,000 people out of 1 billion (Gereffi, Wadhwa, Rissing, Ong, 2008), or 0.006% of the population. By the 1980s, however, this number had grown to about 400,000, which still represented an exceedingly small percentage but a nearly sevenfold increase.

⁸⁹ As MOST is a ministry of the Chinese government, which operates without a democratic mandate from the Chinese citizens, the Ministry is given discretion to establish and implement its own policies in accordance with the Chinese government. As the Ministry states, "MOST is responsible for budgeting, financial accounting, and supervising of S&T funds. It also proposes, with relevant departments, major policies and measures on rational allocation of S&T resources" (MOST). In essence, MOST operates as an entity unto itself, from a policymaking point of view.

PhD in Mechanical Engineering in Germany. According to the Ministry, China, in order to leverage its position in the world, views itself as a developing nation that has limited resources and must rely on international collaborations. In particular, China has emphasized its “reform and opening” policy toward science, which was designed to increase information and resource exchange between China and the rest of the world following decades of isolationism under the Mao regime.

In order to meet the global challenges that China faced as a result of a lack of commitment to science, in 1986 Deng Xiaoping implemented a ramped up high-tech R&D program called the 863 Program (MOST, 2011). The program, which was implemented over three successive five-year plans, laid the groundwork for infrastructure and scientific investment. The objectives of the plan were to invest in strategic high-tech fields, “in order to gain a foothold in the world arena” (MOST), and “leap-frog” over other developing nations. Of the strategic areas in which China sought to make particular investments, biotechnology was one.

The Chinese government made a commitment to incorporate the voice of the scientific community, and stated “the [863] program continues practicing an expert responsibility system to engage the full role of experts and technical decision-making and judgments of the high-tech development trend while further developing the decision-making role of the government”(MOST). In addition, a central component of the 863 Program was a dedication of funds and attention to the establishment of science and technology infrastructure, which included State-funded and -run laboratories, research centers, and cooperative projects.⁹⁰ In this way, members of the scientific community have been brought into the policy making process as one of the very few social experts whose guidance is solicited. What remains questionable is how much this guidance is valued when it is dissonant with the Chinese government’s desires.

As a result of China's growing commitment to and investment in science and technology, recent reports issued by organizations like the UK's Royal Society indicate that China has made a presence for itself on the scientific world stage. In a report issued in March of 2011, the Royal Society claimed that, “China was now second only to the US in terms of its share of the world's scientific research papers written in English. The UK has been pushed into third place, with Germany, Japan, France, and Canada following behind” (Royal Society cited in Jha, 2011). The Royal Society report also indicated that, through scientific collaborations, the scientific world was beginning to change, with the growth in China and other emerging economies. Looking at publications as an indication of scientific contribution and accomplishment, the Royal Society noted

⁹⁰ On the MOST website, the Chinese government has issued a series of yearly statistics and status reports about the state of science in China. According to a recent report by MOST, issued in 2007, from 2001-2006, the government has increased its gross domestic expenditure on R&D as a percentage of GDP from 0.95% in 2001 to 1.42% in 2006. The expenditures come from a mix of government funds, business, funds from abroad, and “other”.

that, from 1993-2003, the US dominated world science by contributing 26% of research papers published in peer-reviewed, English publications. However, in the 2004-2008 timeframe, the US dropped to 21%, while China rose from 4.4% to 10.2%. While China has overtaken the UK in number of publications, should China continue this extensive expansion at this pace, it is estimated that the developing nation will surpass the United States in publications by 2013.

When committing itself to science, China has set its sights on stem cell research and regenerative medicine as particularly transformative areas. According to data presented by the Chinese Stem Cell Transplantation Department at the General Hospital of Chinese People's Armed Police Forces, China is now the fifth-largest publisher of peer reviewed papers on stem cell research, moving from 37 publications in 2000 to 1116 publications in the 2008. This estimate, according to the Stem Cell Transplantation Department, puts China on par with countries like the UK, Japan, and Germany (Stem Cell Transplantation Department, 2011). According to this same publication, China employed four major strategies in order to build up its stem cell science capacity, and these included: people; financing; permissive regulations for stem cell research; and focused research objectives. In essence, what China has done to evolve in the field of regenerative medicine and stem cell science is to put an emphasis on recruiting researchers of Chinese origin back to China and train a new generation of homegrown scientists to enter a field with highly permissive regulations. As a strategy, Chinese policymakers have emphasized research directed toward therapeutic potential, with a significant financial backing of \$293 million.

The advances that China is making in stem cell research have not gone unnoticed by the international research community. Chinese stem cell scientists have seen an increasing amount of investment in and support for their work, and numbers of highly trained stem cell researchers in China are the largest throughout Asia (Bhan, Deng, Loring, Moreno, Yin, Zhai, & Lavery, 2008). In fact, China's extensive stem cell research program houses about 300 PhD. level scientists, at least 80 of whom use embryonic stem cells (Bhan, et al.). According to interviews that McMahon and colleagues held with Chinese stem cell researchers, China has created at least 25 human embryonic stem cell lines (McMahon, Thorsteinsdottir, Singer, and Daar, 2010). China focuses on clinical implications for stem cell research and the translational and therapeutic opportunities found in this work, as this is where the greatest economic potential lies.

In China's 11th Five-Year Plan for 2006-2010, the return of Chinese researchers to China became a specific innovation-building strategy. In addition, the Chinese Ministry of Science and Technology made a commitment of \$293 million available to stem cell research, with an additional \$20 million per year from the Chinese Academy of Science. In a way that is reflective of WPT's argument that prestigious researchers are the ones to "get the prizes", most of these funds were directed toward a handful of researchers who commanded the

monies for wages, overhead, and materials, which are priced much lower in China than the US⁹¹. The international training that these researchers receive, coupled with the particularly low cost of labor in China, has created an economic and intellectual advantage in the stem cell field.

The Chinese research community has a unique and multifaceted relationship with the West, where a great deal of stem cell research has taken place over the history of the field. The Stem Cell China Network has acted as a liaison between the Chinese biotech industry and the rest of the world, presenting itself as, in essence, “a conduit for Western researchers and institutions to stay informed on the latest regenerative medicine breakthroughs around the globe” (Stem Cell China Network, 2011). What is interesting is that, in their introductory information, the Stem Cell China Network implicitly positions China as the central hub where stem cell breakthroughs are taking place at a pace exceeding the rest of the world. While this may or may not be the case, two claims can almost certainly be made about the state of stem cell science in China: that China is a relatively new player in the global stem cell field, but has built a fairly extensive research network within a short amount of time.⁹²

China’s growing presence within the international scientific community has put it on par with other world leaders like the US. In fact, some scientists have begun to acknowledge the possibility of China becoming the beneficiary of US stem cell policy challenges, in a way that was predicted for the UK ten years ago

⁹¹ The Stem Cell China Network lists three institutions that constitute the bulk of its research infrastructure: the Academy of Military Medical Sciences, The Institute of Hematology and National Research Center for Stem Cells, and the Huashan Hospital. Under each of these institutions, the Stem Cell China Network profiles researchers and their research teams as integral nodes in an expanding Chinese scientific network. For instance, the Academy of Military Medical Sciences highlights Professor Pei, chief scientist for the 863 Program, who has coordinated research exchanges with Stanford University and the University of Pittsburgh (Stem Cell China Network, 2011). According to their profile, the researchers working under Pei have produced more than 200 publications in scientific journals, have secured three patents, and have won numerous awards from the Chinese government. The work conducted by Pei has been funded by the Chinese government, and it involves both embryonic and adult stem cells. China’s Institute of Hematology and National Research Center for Stem Cells is directed by Professor Zhong Chao Han, who also heads the Chinese Stem Cell Center. Similar to Pei, Zhong has collaborated with researchers from other countries outside of China, including Dr. Scadden from Massachusetts General Hospital, and researchers from Tokyo University. Finally, China’s Huashan Hospital, founded in 1907, is directed by Professor Zhu, who focuses on neurosurgery and neurological research. The Chinese research community is attempting to make significant headway into establishing international collaborations and promoting its research in the most prestigious journals in the West.

⁹² The Chinese government has ensured that the pipeline of stem cell researchers remains active, and it continues to aggressively encourage the training of new researchers both at home and abroad. At present, about 39% of Chinese students graduate with science or engineering degrees each year (OCED,2010). As a means to measure outcomes of China’s focus on this science, the government has used measures of patent applications, patents granted, S&T papers and publications, and inventions. In the latest available data, from 2005-2006, China has seen steady growth in all of these outcome measures.

(Saar, 2012). US stem cell researcher, Hans Keirstead, stated “The stem cell field is going to see the validation of China as a stem cell center. The quality of MDs and PhDs over there is equal to that of America, in some cases exceeding it” (Keirstead quoted in Saar, 2012). However, the broad permissibility of the Chinese stem cell policy has not been without its degree of concern.

China has a stem cell policy that has gone to such a permissive degree that, within the worldwide scientific community, research in China has been looked at with skepticism. This is not an outcome that any scientist seeks to be associated with, nor is it beneficial for the scientific field, itself. As a result, there have been calls on the Chinese government from the international community to regulate questionable science. In the stem cell community, in particular, the Chinese policy on stem cell research involves a lackadaisical approach to overseeing the research, beyond a degree of permissiveness advocated by the ISSCR, with research institutions granted the permission to regulate themselves. It appears, then, that the Chinese government is not as concerned about the integrity of the science than it is about using this research to develop its economy and knowledge base. This calls to mind some of the very same challenges that plagued previous economic development strategies that took place under the Maoist regime.

Despite the achievements that China has made in stem cell science recently, the picture is not entirely rosy, even beyond the fact that China is still a developing nation with a complex history and future. As *The Economist* has reported, science in China has fallen victim to a reputation of unscrupulousness, giving it the infamous title of the “Wild East”. This unfortunate title is the result of a scientific regulatory environment that allows for potentially unproven research to take place without any governmental intervention (*The Economist*, 2010). What is more, many within the broader stem cell community fear that China and other developing nations are particularly prone to the rise of unregulated treatment clinics that provide dangerous, potentially life-threatening, “treatments” to a host of medical conditions that run the risk of maligning the entire stem cell field.

As Thorsteinsdottir, McMahon, and colleagues illustrated in their broad study of the stem cell field in China, many Chinese hospitals are making a profit from unproven therapies for conditions like heart disease, Multiple Sclerosis, and spinal cord injury. For instance, as a *The Economist* highlights, the Chinese government has essentially turned a blind eye on unauthorized and unproven stem cell therapies from companies like Beike Biotechnology in Shenzhen, Guangdong Province. This company advertises on the Internet and other media about therapies, treatments, and cures to a wide variety of diseases. These controversial treatments, which have no record of proven efficacy, can cost tens of thousands of dollars but have not been subject to peer review or scientific scrutiny. Nevertheless, companies like Belike Biotechnology continue to receive considerable funding from the Chinese government and support from the Chinese scientific community.

In recent months, largely in response to criticism from the members of the international scientific community, most notably the International Society for Stem Cell Research, China has made an attempt to crack down on unscrupulous and unproven treatments by implementing regulations and imposing fines or suspensions for violations. Despite this newfound vigilance, China has developed a reputation of lackadaisical oversight and potential for scientific abuses.

From this perspective, it is not difficult to see how the scientific community within China may not have played a particularly significant role in the formation of the Chinese policy. While Chinese researchers, themselves, have grown in international stature and credibility, the state of the stem cell field in China has lacked some of this credibility. However, the scientific community as a globalized enterprise has, indeed, had a significant effect in China's policy. To be sure, there is little, if any, acknowledgment of the details of stem cell science in China's policy, and the Chinese reliance on the "four no's" did not require any guidance from stem cell experts, Chinese or otherwise. If members of the Chinese scientific community were to have offered input on the creation of this policy, it is quite possible that they would have advocated for a less permissive policy, or would have been adherent to more of the international norms of the research. This would not have been in alignment with the Chinese government's pursuit of economic development and expansion.

The Chinese policy of "four no's", and its supplementary regulatory stipulations, echo some of the most broadly supported ethical considerations when it comes to how this research ought to be carried out. However, the policy of "four no's" indicates how the Chinese government has had to yield to the concerns of the broader scientific community. Among these considerations are the need to reject human cloning, prohibit research conducted without obtaining informed consent, prohibit the utilization of embryos farther than 14-days post fertilization, and outlaw the creation of human and nonhuman chimeras. The Chinese government, perhaps unenthusiastically, has acknowledged that some set of boundaries on human embryonic stem cell research ought to be implemented. Were it not for the influence and potential shaming by the wider research community, it is possible that the regulations put into place by the Chinese government would never have been adopted.

Despite the control that the Chinese government has over the scientific community, the relationship between these actors is, in part, a symbiotic one. First, were it not for the existence of the scientific community in China, the economic expansion goals of the Chinese government could not be realized. It is by virtue of the work that the scientific community conducts that China's economic development can take place. To this extent, the government must be mindful of the constraints put on and funds directed to these individuals. The government, then, has striven to afford the Chinese scientific community the greatest degree of latitude possible.

The funding and liberal policy that China has implemented, though, comes

with expectations from the Chinese scientists to pursue research questions of interest to the government. While there have been some efforts made to afford greater autonomy to the scientific field, through more attention to market demands and greater allowance for job mobility, the scientific field in China is still intimately connected to the State. With this in mind, the grounds on which the scientific community in China can influence or criticize the Chinese stem cell policy must be negotiated with great care. Given the Chinese scientific community's contentious history with the government, if the scientists are critical of a particular policy, they are liable to either experience cuts in funding, social alienation, or even imprisonment. To this end, it is not within the scientific community's interest to offer any input into a matter of policy other than support for it.

With this in mind, a case like China where the national nongovernmental actors have a diminished role, how these actors take on an international dimension becomes much more pressing. The Chinese scientific community must act in accordance with the Chinese stem cell policy, but it is because of their inclusion in the global scientific community that they may not fully favor the policy within which they work. To this extent, the reduction of a national Field Theory model gives way to greater international influence, like an international script predicted by WPT.

PHARMACEUTICAL INDUSTRY

No analysis of China could be considered complete without an inclusion of its market structure and how this relates to the State. China has seen a dramatic growth in its economy over the last decades, and today is responsible for no less than 10% of the world's total value of goods exports (Lunn, Lalic, Smith, & Taylor, 2006).

The relationship between the Chinese central government and its industry sector is an intimate yet complex one. In 2003, China sought to restructure its state-owned enterprises (SOEs) as a means to reform its economic system. In so doing the Chinese government established the State Assets Supervision and Administration Commission (SASAC) under the State Council (Mattlin, 2007). SOEs are entities found in a national economy that are partially or mostly state owned, as they are believed to be so critical to the economy that they must be protected from market failure. In many countries these companies involve national security and public goods, however, in China this list is considerably longer.

The People's Republic of China was previously reliant on a planned economy but in recent decades has reformed its economic structure to a more market-based economy. Nonetheless, though, the Chinese government has exerted significant control over companies in its economy that it feels are necessary to be publicly supported. Of the corporations and industries on which

China views as important enough to exert extensive state control is the pharmaceutical industry.⁹³

Similar to the United States, the pharmaceutical industry in China is one of the most powerful and lucrative. With nearly 20% of the world population, and a disproportionately small amount of the global drug market, China is in a particularly advantageous position to grow its pharmaceutical sector. However, China has had a history of inadequate intellectual property rights and governmental incentives that had undervalued the role of the pharmaceutical sector as a vehicle to translate scientific research into economic success. With China's entrance into the World Trade Organization, a stronger patent system, and greater access to medical coverage across Chinese citizens, China is poised to make great advances in this field, and in so doing, great economic advances, also. The global script of building a powerful pharmaceutical infrastructure has become even more important in China, as pharmaceutical companies around the world rely on China as a supplier for their chemical compounds. This puts China in a particularly strong position, as the development of the Chinese and even global economies are reliant on the strength of China's pharmaceutical sector.⁹⁴ Recently, China has drawn a connection between basic stem cell research and how this work can be translated into economic advantage. In so doing, the benefits of a liberal stem cell policy can become a reality that much more quickly.

Given the fact that the Chinese government has a great deal of control over the pharmaceutical industry, the demands placed on it and the role that it plays in Chinese society is very different from PhRMA, ABPI, and the VCI.⁹⁵

⁹³ This control is made manifest through the stock ownership, exceeding 50%, that the government secures in the SOEs. Expert on the Chinese political economy, Mattlin, has broken these companies into three categories based on the degree of control that the Chinese government has on them: "strategic and key industries", "basic and pillar industries", and "other industries". The considerable ownership that the Chinese government holds allows it to draft laws and regulations regarding state owned assets, hire and fire executives, ensure that corporate interests are in alignment with state interests and seize control of dividends generated from business operations (Mattlin).

⁹⁴ In a clean break from that which is seen in the US, UK, and Germany, the Chinese pharmaceutical industry is directly overseen by an entity of the State: the China Association of Pharmaceutical Commerce (CAPC). As the Association describes, the CAPC, "is a nationwide social economic organization... serving as an assistant and adviser to the government department in charge of pharmaceuticals" (CAPC, 2011). The goals of the CAPC, as itemized, are similar to other collective pharmaceutical organizations in other countries, and involve: advising governmental departments on policies and regulations for the pharmaceutical industry; researching market trends to provide guidance for the commodity trade; developing coordination between the stakeholders including industry, commerce, and medical institutions; accelerating reform in the pharmaceutical enterprise to create standards; developing international communication and exchange; undertaking relevant matters entrusted by the government department in charge of pharmaceutical issues (CAPC, 2001).

⁹⁵ According to recent statistics, about 99% of drugs produced in China are using generic or copied forms of drugs created in other countries. The pirating-nature of the Chinese pharmaceutical industry makes its demand for R&D much less pressing, as the R&D has already been done and it is a matter of reverse engineering the chemical or pharmaceutical process. In

Whereas, in the US, UK, and Germany, the pharmaceutical industry can exert influence on policymakers to promote policies that are advantageous for them, in China, the State can exert influence on SOEs like pharmaceutical companies to meet its objectives. Similarly, given the dividends that the Chinese government secures as a result of its stockholdership, what maximizes the pharmaceutical industry's profits is also a benefit to the government. Taken together, when it comes to stem cell research, the pharmaceutical industry can be put in a position to advance this work in accordance with the State policy and in the most expeditious manner. The connection between the Chinese government's economic goals, the economic potential found in advances in stem cell research, and the pharmaceutical industry's role in realizing this potential is a valuable one for China's future.

The challenge for China when it comes to pharmaceutical research, however, lies in how aggressively the country desires to pursue economic expansion, and at what potential cost. This leads to a sociological conundrum. When economic development is aggressively pursued, as is the case in many countries, and there are few opportunities for participation in the political field, the economic development strategies can take place without any social checks or balances placed on it. In the pharmaceutical industry, just as in the scientific sector, this might be the case for China as it pursues opportunities found in stem cell research. If the pharmaceutical industry, like other SOEs, is under the oversight and influence of the Chinese government, the ability that it has to express concerns over matters of policy is compromised. Without the input or reservations expressed by powerful third-party actors like the pharmaceutical industry, the bureaucratic structure of the State can proceed unfettered, sometimes putting the foundations of scientific research or economic development at risk.

This perspective sheds light on some of the challenges that the pharmaceutical industry and human embryonic stem cell research have encountered in China. The WTO has encouraged, or perhaps enforced, that China crackdown on unethical or illegal pharmaceutical practices, in order to gain entry into the worldwide organization. This mirrors the requirement that China enforce regulatory guidelines on stem cell research in order to gain worldwide legitimacy. Why these two fields have been subject to such international criticism lies in how China prioritizes the desire for economic growth conducted rigorously versus economic growth conducted responsibly.

addition, in China, hospitals are the major market for the exchange of drugs, thus avoiding many of the intermediary actors who have influenced the pharmaceutical industry in other countries. Finally, and perhaps most importantly, China is becoming increasingly enticing to many foreign companies, like GSK, Novartis, and Bristol-Myers Squibb, which have established production centers in China. The Chinese landscape has become attractive to these companies, given the cheap cost of labor and production. In fact, according to Pacific Bridge Medical, all of the top 20 pharmaceutical companies in the world have either joint ventures or facilities in China (Gross, 1998). This fact changes the interests of the Chinese pharmaceutical industry, such that it is much more focused on regulatory issues than it is on how to research drugs.

The private sector in a country like the US is “private” and has an intimate relationship with the public sector, operating very often in the political field so as to expand its profit margin. In China, the relationship between the business sector and the public sector is equally as, if not more, intimate, however for a very different reason. The business sector in China, of which the pharmaceutical industry comprises a considerable part, is heavily overseen and influenced by the government. In China, though, the responsibility of government over industry is to regulate it, and bring it into alignment with public policy objectives. These objectives can be pursued with minimal attention paid to safety or quality control, as evidence by the WTO’s concerns (Kim, 2002). This has been seen in China’s food quality, consumer protections, and even some scientific research. At least in theory, in the US, UK, and Germany, the government’s role in regulation is to protect individuals and industries from the perils of potentially risky practices. However, in China where access to the political field is quite limited, the regulations put on industry are designed to join industry goals with national goals.

The prioritization of bringing industry goals into alignment with national goals addresses the logic of the Chinese “political field”, and what knowledge or “capital” actors must have to operate in it. As the desires of the State serve as the bottom line in China, rather than any individual profit margin, it is not the maximization of profits with which pharmaceutical companies are concerned but, instead, how their initiatives might please the government. The pharmaceutical industry is not operating with a quest for *economic* capital but rather a quest for *political* capital. This is the case for the pharmaceutical and biomedical industries nearly above all other enterprises, as bioindustry is at the core of China’s current economic expansion plans. So, whether or not investing in human embryonic stem cell research is in the financial interest of the pharmaceutical sector, though there is ample reason to believe it is, it is the interest of the Chinese government that matters. This is the unique logic of the Chinese political field, and how actors position themselves within it.

There is another important point to be made. In other countries around the world, when a pharmaceutical company is not interested in investing in human embryonic stem cell research, it is for one of two reasons: first, as in Germany, that this research can bring about ethical concerns; and second, as in the US, that this research is not in alignment with the pharmaceutical industry’s established business model. In China, neither of these two concerns holds, as the ethics of stem cell research is not questioned, and, just as importantly, the Chinese business model is more conducive to this research. Specifically, the Chinese pharmaceutical and biotechnology industry, which includes such institutions as Shenzhen Beike Biotechnologies, has a great deal of overlap with the research and academic sector, providing opportunities for interdisciplinary collaboration at every level of the research. In this way, in an SSK manner, the social conditions found in the Chinese epistemic environment have a direct effect on the knowledge and science that are created there. The atheistic and Confucian moral tradition, coupled with a laboratory structure that is synonymous with pharmaceutical and national goals, provides an environment that favors both

stem cell research and the policy that regulates it.

In the UK and Germany the pharmaceutical industry is relatively removed from the policymaking apparatus, and in the US, legislators can often take commands from the pharmaceutical lobby. In China, the reverse is the case, and the pharmaceutical industry takes direction from the government. Given the repressive nature of the Chinese political regime, it is not surprising that the government would have control over various social groups. However, the fact that the Chinese government likewise maintains control over matters of industry through its SOEs, like the pharmaceutical industry is relatively more surprising. This makes for a collusion of business and government that is different from the more noteworthy challenges of business and government interactions in the US. Compared against the pharmaceutical industry in the US, in China the direction of influence is reversed, such that industry can be the vehicle of the Chinese State's strategic ends. The growth of this sector, then, is essential to the subsequent growth of the Chinese economy. This bears particular relevance to stem cell research, as potential therapies that grow out of this research could have a huge economic benefit, not simply on a national level but on an international level, as well.

The issue that has plagued the Chinese pharmaceutical industry, though, is the laxity in safety regulations that has put many Chinese citizens in physical jeopardy (Grace, 2004). Pharmaceutical companies in China have experienced unfortunate instances of providing unsafe medications to Chinese citizens, or not testing these medications at all. Not only does this have tremendous ill effects on the Chinese citizens who are negatively impacted by these drugs, but it also casts a negative light on the state of pharmacological work in China. As seen in the instance of the scientific community, the unfettered power of the State operating at the national level presents problems for social actors that subsequently must be addressed at the international level.

That the Chinese government is emphasizing the opportunities in pharmaceutical work, and how these opportunities can be maximized through advances in stem cell research, highlights the intimate relationship that these two fields could have in other social settings. Otherwise stated, the fact that the Chinese government has encouraged the support of stem cell research from the pharmaceutical industry speaks to the value that this social actor has in the stem cell debate. At the same time, China's emphasis on maximizing the pharmaceutical industry represents a social modeling of the US, in a way that is emblematic of World Polity Theory principles. Contrary to the US, though, China has made it a priority to join the formidable economic and social strengths of the pharmaceutical industry with the potential found in stem cell research, becoming a regional leader in this work (Grace). This is a marked difference from circumstances seen in other countries.

What is of note in the Chinese pharmaceutical industry example is that China provides support to corporations that serve as the framework for the Chinese economy (Zhou, 2007). In order to obtain this support, however,

corporations must play by the government's rules and policies, and for the pharmaceutical industry, this includes support for embryonic stem cell research guidelines as created by the State, irrespective of how the relatively minimal oversight might negatively affect the stem cell field. As in most entities of industry, obtaining financial and economic capital is of primary concern. However, in China, the economic capital that the pharmaceutical industry enjoys can come directly from the government in the form of State support. This creates an intimate relationship between the government and the business sector, such that the interests of the people and the research might be lost in pursuing the interests of the government. These were the circumstances that brought about international concerns over unsafe pharmaceutical products used in China. The stakes are much higher for the stem cell field.

Were the Chinese pharmaceutical industry to help create unsafe medical treatments or therapies brought about through advances in embryonic stem cell research, and were these unsafe treatments to gain international attention, the entire stem cell field could be at peril. In addition to China receiving the title of the “wild East”, the entire stem cell field could be looked at as a wild enterprise, leading to international condemnation. To the extent that this problem can be avoided, it is not only within the Chinese pharmaceutical industry's interests, but, in fact, the entire field's interest. With this in mind, the Chinese pharmaceutical industry must play both sides of this game, pleasing the Chinese government as well as appeasing international concerns. This balance has only begun to be struck. China's unusually liberal policy, though, has cast a questionable light on how much it is willing to protect research both within China and around the world.

PATIENT ADVOCACY

Without channels for advocacy, and therefore a means to enter the political field, patients rights groups in China, are little more than support groups. While support groups have an important effect on both the individuals who join them, as well as the broader society, to the extent that they can help enact social movements that change political discourse, these groups are limited. Given China's “Social Compact”, public input is only halfheartedly solicited from many social groups, even despite President Hu's proclamations otherwise. China has a lengthy and infamous history of silencing dissent or political mobilization for fear of threatening the centralized power of the State. Quite arguably, however, for every action that a federal government takes to solidify its power, it is, in actuality, an admission of the potential loss of power. In China, these ideas are front and center.

It has only been recently that China has allowed any kind of advocacy groups, and in order to exist at all, a group must gain the approval of the Chinese government. This, for obvious reasons, severely limits the kinds of advocacy statements that groups can make, as they must already be approved by the authoritarian government, itself. For all Chinese citizens, this is a daunting

prospect. However, for those citizens who already experience social hardship, rejection, and degradation, organizing can be nearly impossible. For many disabled and diseased individuals in China, the ability to achieve even basic human rights is an advocacy effort, in itself.

As the International Alliance of Patients Organizations reports, safeguarding patients' rights has been notoriously difficult in China, largely because nongovernmental patient organizations are uncommon (Tsang, 2008). While an increasing number of patients in China are becoming aware of their rights as citizens, only recently has this translated into social groups that have been able to advocate for themselves, or at least to protect themselves against abuses. To this end, lawyers and professionals have come to the aid of patient groups in navigating these new waters (Tsang). Nonetheless, there has been a growing number of advocacy groups forming in China, and they have collectively organized under the Alliance of Patient Mutual Help Organizations (APMHO).

APMHO is an umbrella organization, representing about 43 patient advocacy groups that include groups dedicated to such conditions as asthma, kidney disease, stroke, spinal cord injury, Parkinson's disease, muscular dystrophy, epilepsy, diabetes, heart disease, rheumatoid arthritis, brain damage, and cancer. Given the growing interconnectedness provided by such media as the Internet, some of these new groups have fostered long-distance relationships between people facing similar diseases and conditions. However, in opposition to similar groups in the US and UK, many of these patient advocacy groups in China give little or no attention to advocating for research, or even educating about the nature of stem cell research.⁹⁶

Many of the diseases and conditions that are represented in the APMHO umbrella group are particularly targeted by researchers conducting human embryonic stem cell research. For this reason, it is curious that few, if any, of these groups place any attention on how this research might positively affect these conditions. Why might this be the case? The Chinese political system is such that the advocacy efforts to change matters of policy are, in essence, ineffectual. What is more, China already has the most liberal and permissive stem cell policy in the world, and demands for greater attention to stem cell research surely appear unnecessary. However, there might be a more pressing

⁹⁶ China's Paraplegic and Quadriplegic Association has as its listed services such things as providing recreational activities and newsletter publications for its members, and a series of medical lectures to improve care and reduce complications. Similarly, China's Hong Kong Parkinson's Disease Association describes itself as a group for Parkinson's disease patients, their families, caregivers, and community, with the aim of connecting Parkinson's patients, promoting social awareness of Parkinson's disease, and promoting the welfare of Chinese citizens with Parkinson's disease. Finally, the Hong Kong Neuromuscular Disease Association, which provides assistance to Chinese citizens facing Motor Neuron Disease, Spinal Muscular Atrophy, Muscular Dystrophy, and ALS has as its goal to improve the quality of life and create a favorable social environment for people facing neuromuscular diseases. This goal is attained by way of support groups, educational programs, recreational activities, public education activities, and policy advocacy.

reason why these organizations have not made human embryonic stem cell research a central concern.

China has committed itself to an aggressive pursuit of science and technology, particularly human embryonic stem cell research, as a means to secure advantageous footing on the international stage. However, at the same time, China has a dubious history, as seen during the Great Leap Forward, when aggressive attempts at economic development led to widespread suffering and despair. Expressions of discontent in the repressive political regime have not changed over the years, and even today, there are restrictions placed on independent organizing throughout the country. Despite the fact that the Chinese Constitution guarantees freedom of association and assembly, there are national regulations that severely limit these activities, and the Chinese authority is given absolute discretion to deny or approve applications of public gatherings (Christus Rex, 1995). In reality, the only organizations that exist in China are those that are likewise approved by the Chinese government to exist. All other organizations not registered by the Chinese government, itself, are considered to be “illegal”.⁹⁷

China's repression of political criticism can be coupled with its ill-treatment of its disabled citizens. A 2008 Human Rights Watch (HRW) report documented a great number of these abuses in the run-up to the 2008 Paralympic games in Beijing. As HRW Asia advocacy director, Sophie Richardson, reported: “the Chinese government deserves praise for enacting laws and ratifying the Convention on the Rights of Persons with Disabilities, but so far these protections have meant little to persons with disabilities and their advocates in China who struggle to promote their rights...” (Human Rights Watch, 2008). In a similar vein, a March, 2011, LA Times report exposed treatment of China's mentally disabled citizens. The report indicated that, on a consistent basis, China's mentally disabled were exploited, abused, and even taken as slaves to do grueling manual labor (Demick, 2011). China is on a notoriously fast pace when it comes to developing its economy, and as the LA Times reports, there is a chronic shortage of manual laborers to fill the need, leading to merciless recruitment strategies that prey upon China's disabled citizens.⁹⁸

⁹⁷As a result of this repressive political regime, nearly all independent advocacy of political issues is outlawed (Christus Rex). What is more, many of the very avenues of advocacy, namely the media, are in the hands of the Chinese government. The primary mechanism of control over media is through the information that must be provided to the Chinese propaganda department from Chinese journalists (Christus Rex). According to Chinese policy, news coverage must adhere to the formula “80% positive and 20% negative”, and repressions of infringements on this regulation can range from demotion to imprisonment. A similar fate awaits those who are considered dissidents or are critical of the Chinese government.

⁹⁸ Yang Bin serves as director of China's Enable Disability Studies Institute, which is one among few of China's newly growing nongovernmental organizations, and is the only organization in China that works to investigate cases of abduction of China's mentally impaired. In a 2011 report on *Unreported World*, Enable Disability Studies Institute describes its main areas of focus as, “consulting, training, advocacy, and research” and the overall perception of, “rights of people with

Despite China's Law on the Protection of Disabled People, abuses are prevalent. To this end, organizations like China's Enable Disability Studies Institute work to help create some semblance of equal footing for Chinese citizens with disabilities, and to provide some basic protections against human rights abuses. For this reason, it is to be expected that work in disability policy groups is primarily oriented to this important goal. While even securing basic protections for people with disabilities is a monumental effort, work above and beyond this—for instance, making statements about stem cell research—is often outside of their interest or capabilities.⁹⁹

With this in mind, the types of issues that a patients rights group in China might concern itself with would, first and foremost, be those that are relevant to the members' basic civil rights. In an authoritarian regime, this activity might be less designed to influence government policy than it would be designed to influence social opinion. In fact, when it comes to advocacy initiatives in a country like China, the objective might very well be to influence social attitudes much more so than to affect any policy. It would be, then, quite understandable that an advocacy group in China would direct its attention to those issues for which it can actually generate some social difference.

In addition to this, there might be an even more insidious speculation to be made. As has been documented by the LA Times and by such organizations as Enable, some of the abuses perpetrated against China's disabled community are due to the country's aggressive attempt at economic development. As has been noted repeatedly, one of China's central areas of economic development is science and technology, particularly biomedical research. Whereas China's most vulnerable have been abused in the name of such economic development projects as construction and infrastructure building, one could conjecture that this level of abuse could conceivably be extended to the advancement of biomedical research. It is possible, then, that members of disability and patient advocacy

physical and intellectual disabilities” (Unreported World, 2011). As the organization describes, it was founded in 2009 with the mission to develop an inclusive civil society and the realization of the rights of persons with disabilities. Enable Disability Studies Institute, in its short history, has developed collaborations with Save the Children, World Vision, and Handicap International to carry out projects that promote the rights of people with disabilities in the domain of education, accessibility, and employment. The organization has also collaborated with Harvard Law School's Project on Disability to conduct disability research in China.

⁹⁹ How social groups prioritize the work they need to do is critical to the agenda setting of advocacy movements. In his book, *Agendas, Alternatives, and Public Policies*, political scientist, John Kingdon, provides an analysis about how ideas are manifested in society such that they can be acted upon by either government or social groups. When it comes to policy formation, the very first step of a multi-step process is “setting the agenda”, and by this, Kingdon implies that there, “is a list of subjects or problems to which governmental officials, and people outside of government closely associated with those officials, are in some serious attention at any given time” (Kingdon, 2003, page 3). It is not just any social group that gets paid attention to, but often those that have the ability to influence a political or economic outcome. To the extent that patient groups in China have the ability to do that, they are severely limited.

groups are hesitant to put their full weight behind human embryonic stem cell research out of fear of potential unsafe therapies that might come out of this field.

Evidence of reason for concern for the safety of patients can be seen in cases like the Chinese biotech company, Beike Biotech, which sought to treat Chinese patients with unproven and unsafe stem cell-based therapies. As Chen accounts, the translational research strategy implemented by Beike seems almost entirely to involve the coordination between scientists, clinicians, research institutes, and healthcare institutions, with little regard for the patient (Chen). The research model put into place by Beike has come under criticism for its unethical recruitment of patients on which to conduct treatments and how it has exercised its translational research efforts. This has put the rights of the patient community in China at notable risk. While biotech firms like Beike claim to be concerned that their operations might be shut down at any time due to governmental regulation, others have acknowledged that President Hu has focused on a favorable policy and regulatory system to advance this research in an expeditious way.

This is, no doubt, a bold assertion, but not one without some degree of substantiation. China has been the source of concern for the broader international stem cell community and has become one of the biggest hotbeds of a phenomenon known as, “stem cell tourism”.¹⁰⁰ Organizations like the International Society for Stem Cell Research have become increasingly aware of this phenomenon, and have expressed concern that clinics offering stem cell therapies are neither effective nor safe, posing a threat not only to the stem cell field but, more importantly, to people's lives. As the ISSCR describes on their subsidiary website, *A Closer Look at Stem Cell Treatments*, “clinics around the world are advertising treatments using stem cells for a wide range of diseases. Our organization, the ISSCR, is concerned that many of these clinics and websites are offering treatments that are not supported by our understanding of how stem cells behave and are providing treatments without the safeguards in place that test safety or expected benefit” (ISSCR, 2011).

Of all the places in the world where stem cell tourism could be a potential problem, China has been one of the most notable, due to the coupling of its permissive stem cell policy and lack of comprehensive oversight of research and therapies (Knowles, 2010). Many of these clinics offer unproven techniques and therapies based on work on unpublished data, of which China is a near leader. The BBC did a *Panorama* special on this phenomenon, wherein a British couple took their daughter to China to receive stem cell therapies, with ill effects. In fact, one of the biggest and unproven “stem cell tourism” clinics lies in Shenzhen, China, under the title Beike Biotechnology, which operates without the backing of credible scientific evidence (UK Daily Mail, 2010).

There have been attempts made by the Chinese government to enforce

¹⁰⁰ Stem cell tourism is a process by which people facing diseases and conditions travel to other parts of the world for stem cell treatments that they are unable to obtain in their home countries.

regulations and crack down on clinics notorious for stem cell quackery and tourism. For instance, vice president of the Chinese Ministry of Health Ethics co-authored a set of guidelines, wherein any stem cell clinic must obtain the approval from the health ministry before it advertises therapies. These guidelines were drafted by four Chinese and five European specialists on research and regulation (Coghlan, 2009). Nevertheless, according to Chinese officials, there are more than 50 institutions in China that engage in stem cell research, and many have offered treatments that are unsubstantiated by the scientific community, looking to benefit conditions ranging from diabetes to spinal cord injury, and all of which charge thousands of dollars per treatment, according to experts researchers in Europe and Asia.

The most likely scenario, however, for why Chinese disability rights groups have essentially nothing to say about stem cell research is that it is simply out of the realm of the their reality. In Bourdieu's terms, an oppressive political regime like that found in China defines the boundaries of social thought, becoming so pervasive that consciousness beyond these boundaries is nearly impossible. In the context of the Chinese disability rights groups, it is likely the case that "advocating" for something like scientific advancement or "cures" is well outside of the parameters of consciousness. China has managed to build its embryonic stem cell research infrastructure on the demand for scientific development, without the inclusion of additional voices. The ramped up speed with which China has made strides in this field need only have incorporated the perspective of the scientific and research communities, both of which were more than willing to provide this additional support. It is out of the social reality for members of other groups, like patients' groups, to take on this kind of advocacy work, true to Bourdieusian thought.

Citizens in China, particularly those facing some degree of physical or situational limitation, are likely in the most compromised position when it comes to affecting any governmental policy. The Chinese government makes the essentially unilateral decisions on all matters, enforcing its influence on even the most powerful social actors. It is, though, perhaps the most formidable actors that pose the greatest threat to the solidified power of the Chinese government. It is, then, likely these powerful groups that receive the greatest pressure from the government to conform. It is likewise possible that, as the most vulnerable Chinese citizens pose little direct threat to the Chinese government, they are the ones who receive the least pressure from the Chinese State, and might be in the best position to have influence.

It is from an international human rights perspective—a global social Doxa that is carried out through NGOs and a global discourse—that lies at the heart of the Chinese patient advocacy groups' ability to effectuate some influence on the Chinese stem cell policy. One of Meyer's primary issues on which he based his Theory of World Polity was on the globalization of human rights, and how a human rights discourse has been channeled not only through national legislation but also, and more importantly, through the networks created by

nongovernmental organizations worldwide.

It is at this juncture that China, once again, becomes emblematic of some of the tenets of World Polity Theory in the absence of Field Theory. Where social actors are ineffectual at participating in a national political field, they must rely on worldwide, global institutions as a means to protect their interests. To whatever extent they have been able, human rights groups around the world have collaborated with patient and disability rights advocates in China. These individuals have relied upon an international human rights discourse that may soon have a significant effect on how China conducts its policies and research.

Through the alliance of the patient organizations in China, yet more importantly through networks created with international human rights and patient's rights groups, the physically vulnerable in China have a more pronounced voice. In fact, it might not be their voice in terms of advocating for a particular position that is most influential, but more the fact that there is an international spotlight cast on the lives of these individuals. This is where the influence of international connections, as predicted by World Polity Theory, comes into full view. It is possible that potentially unsafe or unproven research might be used to create equally unsafe and unproven stem cell therapies. Should this happen, it could be at the expense of those who are already afflicted with disabling conditions, with these individuals potentially being seduced into translational trials by a government that is aggressively pursuing scientific ends, and has a history of abusive human rights practices.

For certain, this is not to argue that such a set of circumstances *will* arise, but the potentiality of this is not beyond the realm of consideration. Should this even be a conceivable concern, the international connections with worldwide human rights groups reduce the likelihood considerably. With this in mind, the pursuit of stem cell therapies that the Chinese government has focused on, or better said the result of the especially liberal and unregulated stem cell policy, cannot take place without the impact of international scrutiny and condemnation. So, while the intent of the Chinese policy is to lead the global community in advances in stem cell therapies, and the Chinese policy reflects this objective, it is curtailed by how far translational research might negatively impact the Chinese disability and patient community.

DISCUSSION

China presents a particularly fascinating case of stem cell policymaking, in the absence of a discernible political field. The Chinese system of government is precisely the type of totalitarian regime of which Bourdieu warned when describing a government's potential to command all forms of symbolic and cultural capital. The result of these circumstances is that there are no ways to understand reality outside of the reality created by the government. In the domain of stem cell research, the Chinese government has set its sights on creating a

global presence and becoming a worldwide leader, and has instituted a policy that is seemingly primed for such an outcome. Taken on face value, given the Chinese determination to pursue stem cell research therapies aggressively, it would seem that there would be no obstructions impeding this progress. However, the fact that there are any restrictions whatsoever indicate that China has indeed, had to take considerations into account.

The lack of a political field does not imply the lack of social input. While the Chinese government can use nearly any social actor to its own ends, each of these actors must also operate within a larger, international context that binds not only their individual actions but also the resulting Chinese policy. With this in mind, it is when the dynamics of Field Theory break down in the national context that the predictions of World Polity Theory and SSK take hold, with actors adhering to cultural constructs and abiding by international norms and standards rather than according to relationships with other actors.

Of all the cases analyzed in this investigation, China represents one that is as fascinating as it is unusual. Given the unusual nature of China's stem cell history, it is helpful to look at it from a Field Theory perspective first, as China is a prototypical example of Bourdieu's hyperbolic State structure. When looking at the growth of stem cell research policy in China from a Field Theory perspective, it could be understood as a veritable control case, as the political field is highly limited. Contrary to democratic countries like the US, UK, and Germany, where matters of public policy are subject to influence from a diversity of actors, in China, the Doxa is established by the hierarchy of the Chinese government, with very few opportunities for social actors to influence it. As a result, China exists as a case against which to draw comparisons about how social actors influence policy when they are afforded only a modest opportunity to do so.

In essence, at least within the confines of China, itself, social actors work to meet the approval of the Chinese government. This is the only source of capital that these actors can maximize, as social life outside of the mandates of the State is quite minimal. Actors obtain their legitimacy and credibility through the authority granted to them by the government, so it is within any actor's interest to operate in accordance with Chinese policy. Actors that are typically involved in the stem cell research question, actors like the Catholic Church, the scientific community, the pharmaceutical industry, and patient advocates have, to a large extent, fallen into line with the Chinese government's policy. The Chinese government has looked at the stem cell research issue in terms that are very reflective of World Polity Theory, as it has viewed this issue as a vehicle to advance its economy and global position. This is the policy that has been pursued at nearly any cost, and this is the policy which relevant social actors are bound to support.

With this in mind, it would seem to be the case that all of the social actors included in this investigation would, in Field Theory terms, operate as orthodoxies, supporting the policy and framework established by the Chinese government. As all actors must adhere to the dictates of the State, it would seem

that there is no position to hold other than an orthodoxy. In absolute terms, this is the case for actors in China. However, when Field Theory is implemented in conjunction with other prominent sociological theories of science, like WPT and SSK, it is evident that this interpretation is not quite so simple. The absence of a political field in which to engage in policy debates, for certain, limits the channels by which diverse social actors can have a direct impact on matters of policy. This is precisely the social configuration that an authoritative regime strives to achieve. However, the ability of social actors to have any impact on the determinations of the State would be much less possible were it not for the broader international contexts in which individual nationstates must act. This is where theories like WPT and SSK are so relevant.

In the stem cell debate, as well as any other debate, the Chinese government would like to play by its own set of rules. However, countries that are known for their authoritative practices are also under the watch of the international community. As WPT might predict, the international scripts that influence policymakers still have relevance to the actions of the Chinese government in such a way that they cannot simply behave in any manner they so choose. This fact operates through the interactions among social actors and the Chinese government, as well as among social actors and the international agenda. This is what gives actors in China much greater influence than would be expected from viewing the issue in Field Theory terms, alone.

It can be argued that, when the dynamics of the political field begin to break down, there are international checks and balances placed on a government to help prevent totalitarianism. While this is not the case across the board, as there are surely totalitarian regimes, when it comes to individual policy matters that introduce a country to the world stage, the world stage monitors itself. The manner by which the international community implements a system of checks and balances, especially in matters of science like stem cell research, is through the dynamics of WPT and SSK. With this in mind, the Chinese stem cell debate can be represented in the following way:

China



Doxa established the Totalitarian Chinese State

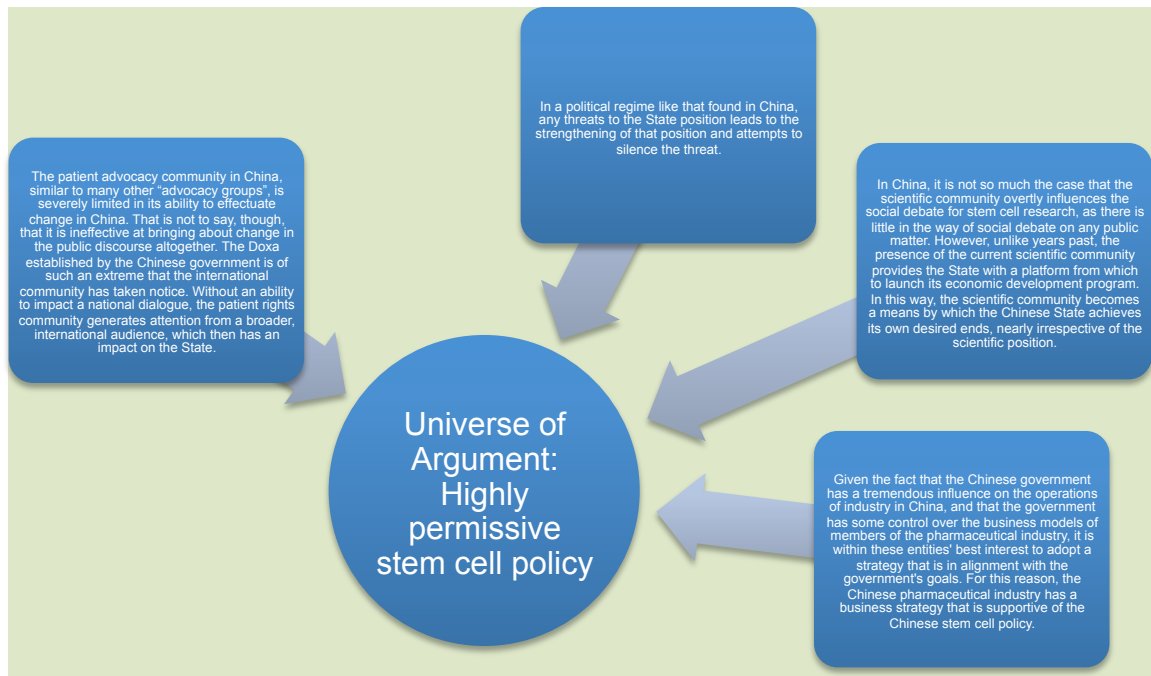


Figure 4: Field Theory Diagram of Chinese Stem Cell Policy

At least ostensibly, the Chinese scientific community has been vocally supportive of the advancement of stem cell research in China. However, it is one thing to be supportive of the research, and another to be supportive of the policy under which the research takes place. Similarly, in a country like China, a lack of opposition does not necessarily imply support, as opposition can either be silenced by the government, or might not be expressed at all, out of fear of retribution. While it would seem unusual for the scientific community in any country to be the source of criticism for a progressive stem cell policy, it is possible that this is the case in China, given the unusually permissive structure of its legislation which might call into question the ethics of their research.

The Chinese stem cell policy is so informal and unenforced that it could be looked at with skepticism. There are only general guidelines framing the work, and essentially no repercussions for failing to follow these guidelines, resulting in an “anything goes” environment. The problem arises when a lack of regulation or oversight calls into question the legitimacy of the science, itself. That is to say that, when there are no restrictions or methods of oversight placed on science, the credibility of this science can easily be called into question. For a reason like this, it is not beyond the realm of possibility that the Chinese scientific community would, in fact, desire more regulation and oversight, some framework to organize their work lest it be doubted on the international stage. To a noteworthy degree, this skepticism has already taken place, to the detriment of the Chinese scientific enterprise.

It is with this in mind that, in a case like China where the national nongovernmental actors have a diminished role, how these actors take on an international dimension becomes much more pressing. The Chinese scientific community must act in accordance with the Chinese stem cell policy, but it is because of their inclusion in the global scientific community that they may not fully embrace the policy within which they work. To this extent, the reduction of a national Field Theory model gives way to greater international influence.

A similar argument can be made for the way in which the pharmaceutical industry operates in China. In ways that are similar to how the US has paid favor to the pharmaceutical industry, China has used pharmaceutical research as a key avenue for economic development. The extremely powerful pharmaceutical industry in China has been a regular proponent of China's stem cell policy, and has trumpeted the liberal nature of its research guidelines. However, as has been evident recently, such unregulated research, whether in pharmaceuticals or in science, can become the source of international criticism or condemnation. Pursuant to the international scripts that globalization and World Polity Theory draw upon, the international research community has offered such scathing criticism to Chinese practices that the Chinese government had to crack down on

them. For this reason, with a World Polity framework in mind, the demands of an authoritative, legitimate, and international research community can temper the Orthodoxic influence of the scientific and pharmaceutical communities.

Practically speaking, there is no “patient advocacy community” in China, as the notion of “advocacy” is severely limited. There is little means by which any social group is given authority by the Chinese government to advocate for any issue, and as a result, there is little capital with which these groups can work. This is especially the case for groups of Chinese citizens who have historically been disadvantaged in China, and that is most certainly the case for those facing disease and disability. For this reason, the potential that “patient advocates” have for influencing the stem cell debate is next to nothing. For all intents and purposes, the disease and disability community in China takes on a networking, “support group” structure rather than an advocacy movement.

While it may seem that the members of the Chinese disability community are essentially without any voice or position from which to effectuate an influence on the stem cell debate, this is not so simply the case. In countries like the US and the UK, patient groups, for the most part, are found to be in support of the advancement of stem cell research. However, in China, a different position might be taken. China has a history of unethical practices perpetrated against those in positions of vulnerability, and this is noted in condemnation that China has received from the international community both in terms of biomedical experimentation and pharmaceutical research. For this reason, it is not wholly unexpected that members of the disability community might hesitate as human embryonic stem cell research moves towards marketability. As the disability community has little voice in China, interactions and networks with similarly-oriented organizations around the world provide a voice for these individuals.

The Chinese case brings to light the circumstances that arise when the political field is reduced or removed. When this takes place, there is greater room for the influence of sociological theories like WPT to affect social dynamics. Though the Chinese government is in a strong, authoritative position, and would largely like to operate according to its own discretion, it is bound by the oversight of the international community, as this community operates through WPT channels.

CHAPTER 7: DISCUSSION

TOWARD A STEM CELL STANDARDIZATION

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In the preceding analysis, stem cell policy has been investigated in four sociocultural contexts: the US, the UK, Germany, and China. There have been some theorists who have categorized stem cell policies in the binary fashion of “permissive” and “restrictive” based largely on the criterion of whether hESC research is permitted to take place or has public funding afforded to it. As the preceding chapters have brought to light, when stem cell policy is looked at from the perspectives of sociological schools of thought like World Polity Theory, Sociology of Scientific Knowledge, and Field Theory, a binary classification system neglects context and social interactions that have brought about these policies to begin with. It is sometimes asked, “Which country has the best stem cell research policy?” In some ways, the answer to this question might be “all of them”, as these policies are often the product of deeply held interests, powerful actors, and a societal logic suited just for environments in which they are created. While some in the scientific community might feel greater affinity to one particular policy outcome, other social actors like the Catholic Church or patients' rights groups might feel an affinity to another. The challenge lies in the fact that, as scientific or research expands its epistemic territory and incorporates an increasing number of epistemic authorities, each of these has a legitimate claim to some aspect of these research areas. It is from this understanding that the value of joining Field Theory with other sociological theories of science comes to light.

These cases were chosen, as they all offer an important insight into science policy seen through the lens of Field Theory. Each of these cases has approached the stem cell issue differently, but with the influence of a common, but by no means exhaustive, set of social actors that includes the Catholic Church, the scientific community, the pharmaceutical industry, and patient advocacy groups. Though these actors have multinational relevance, in the different cultural contexts, they operate differently and have variable effects on stem cell research legislation.

Bourdieu's Field Theory operates according to a social Doxa, or a commonly-accepted and taken-for-granted set of social understandings that direct thinking, influence reality, and shape actors' behaviors. Often when it comes to policy questions, a Bourdieusian social Doxa has been created already, however in the context of stem cell research, the field is so new and touches upon so many social questions that there is no Doxa in which to operate or organize thinking. As a result, some countries have relied upon heuristic Doxas based on other issues or ideals, and the effect of this has been comparable nongovernmental actors behaving in very different ways depending on context. Whereas in World Polity Theory, there is the expectation that national governments ought to adhere to a universal set of principles or guidelines, and that the input of science experts ought to direct the creation of these international guidelines, the stem cell research policy question demonstrates that this is not the case, especially in scientific questions of such a multidisciplinary nature. The

result is a political, or policy, landscape with different dynamics operating in accordance with very different values.

The history of embryonic stem cell research policy in the US has been characterized by a battle of epistemic authority between science and conservative Catholics and Christian religions. However, just as a “permissive” and “restrictive” classification structure is overly simplistic, so, too, is a “science versus religion” classification system. It is true that, beginning in President Bush's August 9, 2001 policy statement, embryonic stem cell research was decisively characterized in terms of “life” and perpetuating a “culture of life”, and that these ideas were based on conservatively Christian principles. However, this framing has made possible a series of relationships, interactions, and social considerations that have influenced how the stem cell policy has developed in a fundamentally American way.

The significance of the “life” Doxa can be brought into focus by juxtaposing the US case with that of the UK. In many respects, the US and the UK are similarly structured for scientific advancement, as both are wealthy, Western core nations with a history of commitment to science. However, within this particular scientific debate, the secular nature of British society has joined a moral tradition based on utilitarian principles, to allow the expertise of the scientific community to take authority. While an advantage was created for the Catholic Church by having a Conservative Christian in the White House during this policymaking time, an advantage was created for the scientific community in the UK by its previous resolution of questions pertaining to the moral status of the human embryo. The conditions under which these questions were resolved in the UK were significantly more favorable to the benefits of science, as they yielded the successful birth of Louise Brown: a success that could be extrapolated to this embryonic research, as well. Without the question of “life” sitting quite as prominently in the heart of this debate in the UK, a new range of relationships and interactions have been possible over those found in the US.

The German context brings into full view how the establishment of a matter of public policy can have its path structured many years before, drawing upon the arguments of path dependence. In this case, the terms and frame of the stem cell research debate were not set by an actor like the Catholic Church in the US or a secular moral tradition like that found in the UK, but rather by an idea about the need to prioritize human life over the desires of the State or the ends of science. With the Holocaust as the defining event in German history, which has given rise to the Nuremberg Code of Ethics, and the rise of the bioethical movement, stem cell research as a matter of modernizing scientific exploration has fallen behind a more broadly embraced human rights discourse.

In some ways, China is a near reverse of some of the circumstances in Germany. This is so, as China's desire for pursuing science as a means to establish a position on the world stage has given rise to concerns over inadequate research ethics or oversight, whereas in Germany, concerns over research ethics have curtailed the science. This has taken place through China's

autocratic and unilateral decision-making power that the government holds. In democratic countries like the US, UK and Germany, not only do non-governmental actors have an influence on policymaking, but these actors or social conditions can define the social Doxa. In China, it is the government that has established the Doxa, and it is the government who has sole discretion over which actors are involved in the stem cell debate. Not only does the Chinese government, then, have a monopoly on policymaking, as political scientists like Peng have suggested, but it also has jurisdiction over anyone or anything who might be in a position to challenge this monopoly.

What are left, then, are four different social and epistemic environments yielding four very different stem cell research policies. The actors that have influenced these policies, even identical actors across contexts, behave differently as a result of the logic of the political field in which they are acting. While there are international societies of research experts, like the ISSCR, the internationally drawn policy recommendations offered by these societies are understandably difficult to apply to every context. This idea exists even despite the fact that some policymakers might indeed want to adopt such an expert-based and already-created set of guidelines. How much each country's stem cell research policy is reflective of the recommended research guidelines provided by the ISSCR has less to do with the nature of the research, itself, and instead much more to do with the interaction of and relationship between this scientific question, extensively integrated social histories, and individual social actors, all of which play a role in creating a policy that is cultural in orientation.

This investigation grew out of a concern over the lack of standardization in stem cell policy, and how this lack of standardization has led to inefficiency in scientific advancement and the quest for medical treatments. As Timmermans and Epstein argue, it is through the standardization process that the world can equalize across cultures, time and geography. Standards are valuable tools for organizing social life in a modern world (Timmermans and Epstein, 2010). Are there circumstances, then, in which there can be some standardization of stem cell research policy, one adherent to the recommendations of the ISSCR? In order to answer this question, it is helpful to look at the ways in which relevant stem cell policies differ, not only from one another but also from the ISSCR guidelines, themselves.

The most recent version of the ISSCR guidelines, "Guidelines for the Conduct of Human Embryonic Stem Cell Research", issued on December 21, 2006, address in some fashion the most pressing concerns that have surrounded the stem cell research debate. The guidelines, however, focus on the ethical requirements of biomedical research pursuant to the review and approval of research projects by independent committees, and the need for voluntary and informed consent from human participants. Of the existing documents that serve as the basis of these ISSCR stem cell guidelines are the Nuremberg Code, the Declaration of Helsinki, the Belmont Report, the Council for International Organizations of Medical Sciences' International Ethical Guidelines for

Biomedical Research Involving Human Subjects, and the UNESCO Universal Declaration on Bioethics And Human Rights. Using these guidelines as a starting point, the ISSCR focused its relevant recommendations on those issues most directly related to stem cell research, including preimplantation stages of human development, research on the derivation or use of human pluripotent stem cell lines, and areas of experimentation wherein pluripotent cells could be incorporated into animal hosts (ISSCR, 2006).

According to the ISSCR, it is recommended that the research guidelines they have directed are to be used in conjunction with the applicable laws and regulations of the countries in which research might be taking place. Nevertheless, the ISSCR makes a categorical and blanket statement on reproductive cloning, stating:

Human reproductive cloning is defined as the act of seeking to establish either a pregnancy or the birth of a child by gestating or transferring into a uterus human embryos that have been derived in vitro by nuclear transfer or nuclear reprogramming. Given current scientific and medical safety concerns, attempts at human reproductive cloning should be prohibited.

That acknowledged, though, the ISSCR stipulates the importance of international collaborations in order to bring about results more quickly. The product of the ISSCR working committee is a set of recommended guidelines that are broad in their scope, deliberate in their intent, and comprehensive in their reasoning, providing acknowledgment to many of the pressing concerns expressed internationally, while similarly providing expert rationale for the group's position. Concurrently, though, despite the comprehensive nature of these guidelines, they differ from the research policies and guidelines in individual countries, in important ways.

In the US, there is particular attention given to highlighting the ethical concerns of the use of cells derived from human embryos, a concern that has been initiated by the Catholic Church and then perpetuated by the pharmaceutical industry. Differing from the guidelines established and recommended by the ISSCR, the US guidelines, starting under the Bush administration, reflect a "culture of life" that directs attention to the moral status of the human embryo. The guidelines under the Bush administration, then, are designed to prohibit the very work that the ISSCR seeks to promote when this research is on newly-derived stem cell lines. Under the Obama administration, the terms and boundaries of the stem cell debate in the US had already been put into place, making a shift from these ideas difficult to achieve. With this in mind, there has been a continuation of a social discussion that, at least in some degree, revolves around the protection of human embryos as tantamount to human life with full rights. While the ISSCR guidelines acknowledges the ethical complexity of this research, it approaches it from a concise scientific standpoint removed from many of the arguments relevant to the meaning of life, the moral status of the embryo, and what rights ought to be afforded to it. For instance, while the US guidelines expressly prohibit the derivation of stem cell lines from

embryos created through SCNT, parthenogenesis, or for research purposes, the ISSCR guidelines indicate that this research can take place following additional and comprehensive review by a specialized body of experts. The distinction here casts light on the type of broad and generalized terms of the US policy versus the nuanced approach of the ISSCR.

Of the four countries involved in this investigation, the UK policy resembles the ISSCR guidelines most closely. It is likely that this degree of similarity arises from the authority and expertise that is afforded to the scientific community as a source of guidance for a policymaking entity. The UK case reflects the guidance provided by members of the stem cell field who have contributed to the guidelines created by the ISSCR, in a way that is emblematic of the predictions of World Polity Theory. However, in the UK, the policy that has been created is not simply a result of the reliance on the scientific community as a source of authority, but also because of the societal conditions that make the influence of other actors, like the Catholic Church, pharmaceutical industry, and patient advocacy movement, either less prominent or more in alignment with that of science. The societal conditions of particular note are those that have been brought about by a valuable history of success in the fertility field, reflected in the world's first successful in vitro pregnancy, and the UK's desire to seize upon this research as a means to establish scientific prominence vis-à-vis the US. As a result, the guidelines recommended by the ISSCR are much more readily implementable in the UK.

That the UK grappled with questions surrounding the ethics of SCNT, while the ISSCR makes an allowance for this work pending additional regulatory review, speaks to this issue. While the UK policy adheres to the recommendations provided by the ISSCR guidelines, in a way that respects the need for institutional oversight, detailed informed consent, and the procurement and safety of research materials, these aspects of the British guidelines have their origins in the regulations created for the HFEA. Deviations in these guidelines exist when research goes beyond the already-negotiated areas, like SCNT and chimeric research, as these are outside of the social understandings that have already framed the debate.

The German case, conversely, offers the greatest deviation from the recommended guidelines provided by the ISSCR. To the extent that Germany does permit the use of human embryonic stem cells in research, it is somewhat in alignment with the category of research which the ISSCR deems, “experiments that are permissible under existing mandates”, or in other words, research that should not be subject to considerable debate. Both the ISSCR and Germany are in agreement that research using existing stem cell lines ought to be permitted, under the oversight of review boards, and the derivation of which ought to have adhered to the local guidelines. The notion of “existing stem cell lines” has become the hallmark of the German policy, starting with a cutoff date of January 2001, which has since been revised to a more recent date. The other German policy requirement, that these cell lines must have been derived outside of

Germany, calls into question the ethical concerns specific to the German Doxa.

It is at this point that Germany takes a decisive split from that which is recommended by the ISSCR and what it believes to be permissible. The progression of the ISSCR guidelines is crafted in such a way as to require greater oversight and more attention to aspects of human embryonic stem cell research that raise ever-increasing levels of concern. Rather than adopt the ISSCR's recommendation of added levels of scrutiny when it comes to more complex research, Germany has prohibited them altogether, thereby rejecting such avenues of research like the derivation of new stem cell lines, SCNT, chimeric research, and stem cell transplantation. In addition, while the ISSCR guidelines stipulate the requirement of informed consent for embryo and gamete donors, Germany has expanded the notion of informed consent to embryos, themselves. This is the defining feature of the German policy, and is left silent in the ISSCR guidelines.

Despite the fact that China has one of the most liberal stem cell policies in the world, it does not necessarily imply that it is in alignment with the guidelines recommended by an organization like the ISSCR. For certain, the scientific and ethical experts who comprise the ISSCR and have contributed to the recommended research guidelines are eager to see this research advance, they desire this advancement in a way that respects social concerns and have taken these concerns into account. The result has been a thoughtful document, with attention paid to the pressing bioethical questions, how these questions ought to be addressed, and what levels of oversight should be attributed to different facets of the field. In China, however, the especially liberal policy gives less priority to the nuanced bioethical questions that have surrounded embryonic stem cell research. What is more, as the ISSCR guidelines strongly recommend oversight, the Chinese policy not only limits oversight but also has no consequence for failures to abide by their research guidelines.

Among the only requirements that China makes in its regulatory policy is that any attempt at reproductive cloning must be prohibited. This is a statement made with force and clarity by the ISSCR, and it is essential to gaining any international credibility when it comes to the stem cell field. As a result, it is nearly compulsory for China to adopt some regulatory language that prohibits the exploration of reproductive cloning, yet it is unclear what the repercussions of pursuing this advance might be, other than international condemnation.

Given the diversity of positions and policies on stem cell research, the question remains whether this field can, at some point, better reflect the explanations and predictions offered by World Polity Theory or if it will remain a product of the types of social dynamics that are implicit in the Sociology of Scientific Knowledge and Field Theory. In order for the former to take place, several circumstances and changes would need to occur. First, it can be argued, as reflected in the four cases discussed, that when a country, for instance the UK, has a Doxa that is centered on the position of the scientific community, it will adopt a policy more reflective of the ISSCR. As has been equally illustrated,

countries that have a legacy of commitment to science, for instance Germany and the US, have had difficulty characterizing this field in terms of the position taken by the scientific community, and have instead relied upon the influence of historical events or other social actors. True to World Polity Theory, in order for there to be isomorphism in science policy, the scientific community must be the primary epistemic authority across contexts. In turn, in order for this to transpire, the influence of other authorities must be diminished or, as in the case of the UK, not seen as especially relevant to the question, at hand.

In order for this to take place in a country like the US, where the influence of actors like the Catholic Church and the pharmaceutical industry has been paramount, the US can take the example set by the UK, and become more discerning in terms of authority and expertise, and how much power is attributed to money in politics. There have been recent attempts to address the influence of both special interests and money in political decision-making, so the US is now at a crossroads regarding how to disentangle issues like stem cell research policy from social persuasion. Given the US' status as a global leader and core country, it is possible that changes in the US policymaking process might spearhead similar changes around the world.

In order for this to take place in a country like Germany, where the influence of historical events like the Holocaust have been the defining social feature, German scientists can take the lead in demonstrating the ways in which this research is not reflective of the concerns that the Holocaust may have brought about. To the extent that human embryonic stem cell research resembles the most atrocious aspects of the Holocaust, it is a clear disadvantage to the stem cell field. The greatest opportunity lies in members of the scientific community educating and aligning themselves with members of the patient advocacy community, so that the perpetuation of the science is viewed as synonymous with the betterment of patients' lives. As the enormity of the Holocaust might never leave the German identity, the greatest potential for science to define the terms of this research is to have it viewed as wholly separate from this event.

In order for this to take place in a country like China, where the influence of the government defines all social reality, the problem is much greater. It is through the negotiation of various social actors that any one particular social actor can emerge as central to the social debate surrounding a matter like human embryonic stem cell research. It is through the jockeying of position and quest for capital that different actors stake their claim in a complex social debate. However, in China, the field of epistemic competition does not exist, and the Chinese government has a near monopoly on the creation of policy decisions. In this case, not only does the Chinese government exert control but other actors are denied the opportunity to either offer influence or pursue a position of dominance. While initially this might appear to be in the government's best interest, the resulting policy decision is one that can lack substantiation from the actors involved. In China's case, it may be to their greater benefit to have a policy

that incorporates expert input rather than purely State interest. Without the involvement of the scientific community, the Chinese policy lacks considerable legitimacy in a broader global context.

This investigation has looked at stem cell research policies in four different contexts, under the supposition that a lack of standardization across research guidelines is inherently problematic. The challenges that a lack of standardization has created have been addressed by several bodies of research experts, including the ISSCR and the ethically-oriented Hinxtion Group. To be sure, a lack of standardization does create pronounced efficiency challenges for scientific development and questions the scientific enterprise as an authoritative institution. However, what normative claims can be made if stem cell policy guidelines are not standardized? Since stem cell research raises so many epistemic questions, like those pertaining to "life" and human rights, why should the scientific community be considered the authority on this issue? It cannot be denied that there are cultural values embedded in any social debate, and these values reflect deeply held societal interests. Yet, as a global institution, science has become an enterprise highly skilled at regulating itself, sifting out problems, and pursuing knowledge in a socially-acceptable manner. For certain, the stem cell field has had to rely on this self-policing many times in its short history. In order for science like stem cell research to implement the very types of protections and regulations that only experts in the field can anticipate, they must be given the opportunity to do so, in full public view, and through a dialogue process that addresses social concerns.

As the international community enters ever-increasing social challenges and uncertain territory, science will be called upon in greater measure to address these challenges. Unless the scientific community is looked at as an authority, it will consistently be held to the interests of any number of social actors with their own ideals and goals. The strengthening of the institution of science circumvents this. Stripping authority from science in this debate sets the precedent for how science will be respected in other, equally important debates that will affect humanity in years to come. The outcome of this epistemic debate has great consequence for the degree to which special interests will seek to influence the creation of knowledge and the policies that shape knowledge creation. A trust in science begins with its authority as an enterprise, and allows it to find global solutions without local obstacles.

The perils of these circumstances have not gone unnoticed by members of the scientific community. In 1969, faculty members at MIT created the Union of Concerned Scientists, a nonprofit organization with the goal of reducing the instances and effects of the manipulation of science. As former director of the Office of Science and Technology Policy, Neil Lane, stated of the organization, "I greatly appreciate the efforts of UCS to examine instances in which political agenda appear to be undermining the integrity of science and to report the facts". The manipulation of science in one domain is the prediction of the manipulation of science in another. The challenges before the world today are of such

enormity that the consequences of scientific manipulation are stark.

There are important implications that can be drawn from this investigation pertaining to the status of science and how it is used in the world today. The case of stem cell legislation in international contexts and how regulatory legislation can differ so considerably sets an alarming precedent for how other scientific questions might be addressed, and in some cases are already being addressed. This has a significant impact on the challenges that confront society, and how society might either tackle them or contribute to them. As this investigation has illustrated, science policy in countries around the world is subject to the dynamics of social forces and how actors within society respond to these forces. The product of scientific inquiry, then, is at the discretion of actors decidedly outside of the realm of science. In a highly politicized and globalized world, the very same degree of social influence has been directed to questions like global climate change research, nuclear technology, information technology, and others. We, as an international community confronting profound challenges, need a firmer understanding of how and why this has happened, and what the consequences are likely to be.

There are powerful actors operating throughout the world, each with its own interest and desires. In the pursuit of these ends, the production of science has many times either been misrepresented or mishandled, by lobbyists, politicians, corporations, religious groups, and social activists. The actors under investigation in this dissertation can easily be used as heuristics or models for actors looking to influence other important scientific questions. Whether looking at the oil industry's influence on the erosion of environmental protections, the agricultural lobby's influence on food quality, oppressive political regime's crackdown on social media, or conservative religions' war on reproductive health, the questions differ in form, not in type. If we are to confront important and difficult social challenges in a way that prepares for an uncertain future, we need both to value science and understand what social conditions allows it to be undermined. As this investigation demonstrates, the reasons will not always be the same, and when we assume that they are, we can run the risk of missing the dynamics altogether, and thereby failing to adequately correct them. The need to get it right and accurately diagnose the conditions that threaten the authority of science is critical as the international community moves toward bigger and more threatening environments. The quest for medical cures and treatment is but one of these. If we are to establish a safer future, science will invariably be central to this outcome. In order for this to happen, we need to view scientific advancement as societal advancement.

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APPENDIX 1

THE HUMAN EMBRYONIC RESEARCH PANEL GUIDELINES

In 1994, HERP offered a set of research areas in which the use of embryos would be permissible. These criteria included:

“The promise of human benefit from research is significant, carrying great potential benefit to infertile couples, families with genetic conditions, and individuals and families in need of effective therapies for a variety of diseases.

Although the preimplantation embryo warrants serious moral considerations as a developing form of human life, it does not have the same moral status as an infant or child. This is because of the absence of developmental individuation in the preimplantation embryo, the lack of even the possibility of sentience and most other qualities considered relevant to the moral status of persons, and the very high rate of natural mortality at this stage.”

In the continued absence of federal funding and regulation in this area, preimplantation human embryo research has been and is being conducted without federal funding and regulation would continue, without consistent ethical and scientific review. It is in the public interest that the availability of federal funding and regulation should provide consistent ethical and scientific review for this area of research. The Panel believes that because the preimplantation embryo possesses qualities requiring more respect, research involving the ex utero preimplantation human embryo must be carefully regulated and consistently monitored.”

Among the guidelines that the Human Embryo Research Panel devised and recommended were:

The research must be conducted by scientifically qualified individuals in an appropriate research setting

The research must consist of a valid research design and promise significant scientific or clinical benefit

The research goals cannot be otherwise accomplished by using animal or unfertilized gametes. In addition, where applicable, adequate prior animal studies must have been conducted.

The number of embryos required for the research must be kept to the minimum consistent with scientific criteria for validity.

Donors of gametes or embryos must have been given informed consent with regard to the nature and purpose of the specific research being undertaken.

There must be no purchase or sale of gametes or embryos used in research. Reasonable compensation in clinical studies should be permissible to defray a subject's expenses, over and above the costs of drugs and procedures required for standard treatment, provided that no compensation or financial

inducements of any sort are offered in exchange for the donation of gametes or embryos, and so long as the level of compensation is in accordance with federal regulations governing human subjects research and that it is consistent with general compensation practice for other federally funded experimental protocols.

Research protocols and consent forms must be reviewed and approved by an appropriate institutional review Board (IRB), and, for the immediate future, an ad hoc review process that extends beyond the existing review process to be established by NIH and operated for at least three years.

There must be equitable selection of donors of gametes and embryos, and efforts must be made to ensure that benefits and risks are fairly distributed among some groups of the population.

Out of respect for the special character of the preimplantation human embryo, research involving preimplantation embryos should be limited to the shortest time period consistent with the goals of each research proposal, and, for the present, research involving human embryos for should not be permitted beyond the time of the usual appearance of the primitive streak in Vivo (14 days). An exception to this is made for research protocols with the goal of reliably identifying in the laboratory the appearance of the primitive streak. (Human Embryo Research Panel, 1994).

APPENDIX 2

DEMOGRAPHIC RESULTS OF THE 2000 ELECTION

The 2000 election, which ultimately brought candidate George W. Bush to the White House, can be described as anything but ordinary. Central trends that came to bear on the outcome of the election were a campaign season dominated by three central issues: Medicare, Social Security, and tax cuts (CQ, 2000). With these issues commanding a great deal of voter attention, it is unsurprising that young voters turned out in relatively lower percentages, with voters under the age of 30 representing only 17% of the total voters. What is of interest is that, among the newly-registered young voters, the most quickly growing political demographic during the 2000 election cycle was the self-identified “independents” who, despite holding political beliefs that might ordinarily put them into one particular political party or another, declined to affiliate with either of the two major political parties. A Gallup survey uncovered that 41% of 18 to 29-year-olds identified themselves as “independent”, as opposed to numbers in the mid-30s for other age groups. These political “independents” would come to play a role in future elections, as well as in policymaking for the upcoming administration and Congress.

Another interesting feature of the 2000 election results was the apparently growing gender gap in candidate choice. As has been of note since the 1980s, the partisan and political support differential between men and women has come to play a prominent role in election outcomes, and the election of 2000 was no exception. Women supported the Democratic candidate, VP Gore, by 56%, while men supported the Republican candidate, Gov. Bush, by 56%.

Geographically speaking, the results of the 2000 election reflected many of the growing trends seen in US politics in recent decades. The once solidly Democratic South was by and large, solidly Republican territory. Conversely, the former Republican stronghold, the Northeast, has become the Democratic bastion, demonstrating solid support for Gore. In total, VP Gore received 73% of his electoral votes from the Northeast and Pacific Coast, while Gov. Bush received 83% of his electoral support from the South and Mountain West.

Perhaps more than anything, however, the election of 2000 demonstrated the stark division lines and desire for a balance of power when it comes to central personal values and visions for the American future. As has been demonstrated repeatedly, the Republican constituency is one comprised of a predominantly white, rural, and religious segment of the population, while the Democratic constituency represents a more secular, urban, and racially diverse population. In elections gone by, many of the outer-fringe of the Republican Party felt unrepresented in their presidential candidates, claiming that these candidates did not reflect their core, fundamental, and sometimes evangelical beliefs. In candidate George W. Bush, these voters believed they may have found their

political savior, and turned out to the polls in greater numbers than seen in many previous elections.

What cannot be denied is that the outcome of the 2000 election, with unprecedented legal action and a razor thin margin of victory for George W. Bush, the mandate afforded to the newly elected president ought to have influenced his leadership style and the degree to which he pursued divisive policies (CQ, 2000). As some, including, Congressional Quarterly, have suggested, George W. Bush did not enter the Oval Office with a clear and strong mandate for highly partisan policies, nor ones that defied the Congress. Following the election, political scientists claimed that Bush would need to pursue a moderate course of action in his first administration, lest he receive considerable backlash from the Congress and the public, alike.

APPENDIX 3

COMPLETE TEXT OF BUSH'S STEM CELL ADDRESS AUGUST 9, 2001

Good evening. I appreciate you giving me a few minutes of your time tonight so I can discuss with you a complex and difficult issue, an issue that is one of the most profound of our time.

The issue of research involving stem cells derived from human embryos is increasingly the subject of a national debate and dinner table discussions. The issue is confronted every day in laboratories as scientists ponder the ethical ramifications of their work. It is agonized over by parents and many couples as they try to have children or to save children already born. The issue is debated within the church, with people of different faiths - even many of the same faith - coming to different conclusions.

Many people are finding that the more they know about stem cell research, the less certain they are about the right ethical and moral conclusions.

My administration must decide whether to allow federal funds, your tax dollars, to be used for scientific research on stem cells derived from human embryos.

A large number of these embryos already exist. They are the product of a process called in vitro fertilization which helps so many couples conceive children. When doctors match sperm and egg to create life outside the womb, they usually produce more embryos than are implanted in the mother.

Once a couple successfully has children, or if they are unsuccessful, the additional embryos remain frozen in laboratories. Some will not survive during long storage; others are destroyed. A number have been donated to science and used to create privately funded stem cell lines. And a few have been implanted in an adoptive mother, and born, and are today healthy children.

Based on preliminary work that has been privately funded, scientists believe further research using stem cells offers great promise that could help improve the lives of those who suffer from many terrible diseases, from juvenile diabetes to Alzheimer's, from Parkinson's to spinal cord injuries. And while scientists admit they are not yet certain, they believe stem cells derived from embryos have unique potential.

You should also know that stem cells can be derived from sources other than embryos: from adult cells, from umbilical cords that are discarded after babies are born, from human placentas. And many scientists feel research on these types of stem cells is also promising. Many patients suffering from a range of diseases are already being helped with treatments developed from adult stem cells.

However, most scientists, at least today, believe that research on embryonic stem cells offers the most promise because these cells have the potential to develop in all of the tissues in the body.

Scientists further believe that rapid progress in this research will come only with federal funds. Federal dollars help attract the best and brightest scientists. They ensure new discoveries are widely shared at the largest number of research facilities, and that the research is directed toward the greatest public good.

The United States has a long and proud record of leading the world toward advances in science and medicine that improve human life, and the United States has a long and proud record of upholding the highest standards of ethics as we expand the limits of science and knowledge.

Research on embryonic stem cells raises profound ethical questions, because extracting the stem cell destroys the embryo and thus destroys its potential for life.

Like a snowflake, each of these embryos is unique, with the unique genetic potential of an individual human being.

As I thought through this issue I kept returning to two fundamental questions. First, are these frozen embryos human life and therefore something precious to be protected? And second, if they're going to be destroyed anyway, shouldn't they be used for a greater good, for research that has the potential to save and improve other lives?

I've asked those questions and others of scientists, scholars, bioethicists, religious leaders, doctors, researchers, members of Congress, my Cabinet and my friends. I have read heartfelt letters from many Americans. I have given this issue a great deal of thought, prayer, and considerable reflection, and I have found widespread disagreement.

On the first issue, are these embryos human life? Well, one researcher told me he believes this five-day-old cluster of cells is not an embryo, not yet an individual, but a pre-embryo. He argued that it has the potential for life, but it is not a life because it cannot develop on its own.

An ethicist dismissed that as a callous attempt at rationalization. "Make no mistake," he told me, "that cluster of cells is the same way you and I, and all the rest of us, started our lives. One goes with a heavy heart if we use these," he said, "because we are dealing with the seeds of the next generation." And to the other crucial question - If these are going to be destroyed anyway, why not use them for good purpose? - I also found different answers.

Many of these embryos are byproducts of a process that helps create life, and we should allow couples to donate them to science so they can be used for good purpose instead of wasting their potential.

Others will argue there is no such thing as excess life, and the fact that a living being is going to die does not justify experimenting on it or exploiting it as a natural resource.

At its core, this issue forces us to confront fundamental questions about the beginnings of life and the ends of science. It lives at a difficult moral intersection, juxtaposing the need to protect life in all its phases with the prospect of saving and improving life in all its stages. As the discoveries of modern science create tremendous hope, they also lay vast ethical mine fields.

As the genius of science extends the horizons of what we can do, we increasingly confront complex questions about what we should do. 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 and a warning sign that should prompt all of us to think through these issues very carefully.

Embryonic stem cell research is at the leading edge of a series of moral hazards. The initial stem cell researcher was at first reluctant to begin his research, fearing it might be used for human cloning. Scientists have already cloned a sheep. Researchers are telling us the next step could be to clone human beings to create individual designer stem cells, essentially to grow another you, to be available in case you need another heart or lung or liver.

I strongly oppose human cloning, as do most Americans. We recoil at the idea of growing human beings for spare body parts or creating life for our convenience.

And while we must devote enormous energy to conquering disease, it is equally important that we pay attention to the moral concerns raised by the new frontier of human embryo stem cell research. Even the most noble ends do not justify any means.

My position on these issues is shaped by deeply held beliefs. I'm a strong supporter of science and technology, and believe they have the potential for incredible good - to improve lives, to save life, to conquer disease. Research offers hope that millions of our loved ones may be cured of a disease and rid of their suffering. I have friends whose children suffer from juvenile diabetes. Nancy Reagan has written me about President Reagan's struggle with Alzheimer's. My own family has confronted the tragedy of childhood leukemia. And like all Americans, I have great hope for cures.

I also believe human life is a sacred gift from our creator. I worry about a culture that devalues life, and believe as your president I have an important obligation to foster and encourage respect for life in America and throughout the world.

And while we're all hopeful about the potential of this research, no one can be certain that the science will live up to the hope it has generated.

Eight years ago, scientists believed fetal tissue research offered great hope for cures and treatments, yet the progress to date has not lived up to its initial expectations. Embryonic stem cell research offers both great promise and great peril, so I have decided we must proceed with great care.

As a result of private research, more than 60 genetically diverse stem cell lines already exist. They were created from embryos that have already been destroyed, and they have the ability to regenerate themselves indefinitely, creating ongoing opportunities for research.

I have concluded that we should allow federal funds to be used for research on these existing stem cell lines, where the life-and-death decision has already been made.

Leading scientists tell me research on these 60 lines has great promise that could lead to breakthrough therapies and cures. This allows us to explore the promise and potential of stem cell research without crossing a fundamental moral line by providing taxpayer funding that would sanction or encourage further destruction of human embryos that have at least the potential for life.

I also believe 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. This year your government will spend \$250 million on this important research.

I will also name a president's council to monitor stem cell research, to recommend appropriate guidelines and regulations and to consider all of the medical and ethical ramifications of biomedical innovation.

This council will consist of leading scientists, doctors, ethicists, lawyers, theologians and others and will be chaired by Dr. Leon Kass, a leading biomedical ethicist from the University of Chicago.

This council will keep us apprised of new developments and give our nation a forum to continue to discuss and evaluate these important issues.

As we go forward, I hope we will always be guided by both intellect and heart, by both our capabilities and our conscience.

I have made this decision with great care, and I pray it is the right one.

Thank you for listening. Good night, and God bless America.

APPENDIX 4

STEM CELL RESEARCH POLLING DATA 2000-2008

In a Gallup/CNN/USA Today poll issued July of 2001, only 33% of respondents indicated being either very or somewhat concerned about the state of science in the US should President Bush decide not to allow federal funding for embryonic stem cell research. When broken down by party, 36% of Democrats were very or somewhat concerned, while 29% of Republicans were similarly concerned (Gallup/CNN/USA Today, 2001). In the same poll, respondents were asked whether the federal government should fund human embryonic stem cell research, and 54% responded favorably. Of these, Democrats responded favorably 59% of the time while Republicans responded favorably 50% of the time. (Gallup/CNN/USA Today). Finally, in this same poll, respondents were asked whether they knew enough to offer an opinion on whether the federal government should fund human embryonic stem cell research, and a full 57% said they did not know enough.

In a similar poll conducted following Bush's speech, the pollsters inquired respondents about whether or not they watched the address. 66% of respondents said they had not (Gallup/CNN/USA Today, August 2001). However, when asked, 52% of respondents believe that George W. Bush made his decision mostly because of political reasons rather than something else. In another poll taken following Bush's address, in September of 2001, respondents were asked whether they associated stem cell research with either the Democratic party, Republican Party, both, or neither. Of the respondents, only 8% responded with "both" and 8% responded with "neither", leaving a significant majority who saw the research in political, partisan terms. What is interesting is that, of these respondents, a plurality associated the researcher with the Republican Party, possibly because President Bush was of the Republican Party and was guiding the federal policy (Democracy Corps Survey, 2001).

Finally, when it came to social actors who shaped some of the public thinking about stem cell research and its benefits, Virginia Commonwealth University conducted a nationwide poll in August, 2001. This poll inquired how much the respondents trusted the information provided by different social actors. 86% of respondents answered that they trusted members of the medical and scientific community "some" or "a lot", 81% answered that they trusted medical ethicists "some" or "a lot", 49% answered that they trusted George W. Bush "some" or "a lot", 41% answered that they trusted members of Congress "some" or "a lot", and 54% answered that they trusted religious leaders "some" or "a lot" (VCU Life Sciences, 2001).

APPENDIX 5

COMPLETE TEXT OF OBAMA'S STEM CELL ADDRESS MARCH 9, 2009

Today, with the Executive Order I am about to sign, we will bring the change that so many scientists and researchers; doctors and innovators; patients and loved ones have hoped for, and fought for, these past eight years: we will lift the ban on federal funding for promising embryonic stem cell research. We will vigorously support scientists who pursue this research. And we will aim for America to lead the world in the discoveries it one day may yield.

At this moment, the full promise of stem cell research remains unknown, and it should not be overstated. But scientists believe these tiny cells may have the potential to help us understand, and possibly cure, some of our most devastating diseases and conditions. To regenerate a severed spinal cord and lift someone from a wheelchair. To spur insulin production and spare a child from a lifetime of needles. To treat Parkinson's, cancer, heart disease and others that affect millions of Americans and the people who love them.

But that potential will not reveal itself on its own. Medical miracles do not happen simply by accident. They result from painstaking and costly research – from years of lonely trial and error, much of which never bears fruit – and from a government willing to support that work. From life-saving vaccines, to pioneering cancer treatments, to the sequencing of the human genome – that is the story of scientific progress in America. When government fails to make these investments, opportunities are missed. Promising avenues go unexplored. Some of our best scientists leave for other countries that will sponsor their work. And those countries may surge ahead of ours in the advances that transform our lives.

But in recent years, when it comes to stem cell research, rather than furthering discovery, our government has forced what I believe is a false choice between sound science and moral values. In this case, I believe the two are not inconsistent. As a person of faith, I believe we are called to care for each other and work to ease human suffering. I believe we have been given the capacity and will to pursue this research – and the humanity and conscience to do so responsibly.

It is a difficult and delicate balance. Many thoughtful and decent people are conflicted about, or strongly oppose, this research. I understand their concerns, and we must respect their point of view.

But after much discussion, debate and reflection, the proper course has become clear. The majority of Americans – from across the political spectrum, and of all backgrounds and beliefs – have come to a consensus that we should pursue this research. That the potential it offers is great, and with proper guidelines and strict oversight, the perils can be avoided.

That is a conclusion with which I agree. That is why I am signing this Executive Order, and why I hope Congress will act on a bi-partisan basis to provide further support for this research. We are joined today by many leaders who have reached across the aisle to champion this cause, and I commend them for that work.

Ultimately, I cannot guarantee that we will find the treatments and cures we seek. No President can promise that. But I can promise that we will seek them – actively, responsibly, and with the urgency required to make up for lost ground. Not just by opening up this new frontier of research today, but by supporting promising research of all kinds, including groundbreaking work to convert ordinary human cells into ones that resemble embryonic stem cells.

I can also promise that we will never undertake this research lightly. We will support it only when it is both scientifically worthy and responsibly conducted. We will develop strict guidelines, which we will rigorously enforce, because we cannot ever tolerate misuse or abuse. And we will ensure that our government never opens the door to the use of cloning for human reproduction. It is dangerous, profoundly wrong, and has no place in our society, or any society.

This Order is an important step in advancing the cause of science in America. But let's be clear: promoting science isn't just about providing resources – it is also about protecting free and open inquiry. It is about letting scientists like those here today do their jobs, free from manipulation or coercion, and listening to what they tell us, even when it's inconvenient – especially when it's inconvenient. It is about ensuring that scientific data is never distorted or concealed to serve a political agenda – and that we make scientific decisions based on facts, not ideology.

By doing this, we will ensure America's continued global leadership in scientific discoveries and technological breakthroughs. That is essential not only for our economic prosperity, but for the progress of all humanity.

That is why today, I am also signing a Presidential Memorandum directing the head of the White House Office of Science and Technology Policy to develop a strategy for restoring scientific integrity to government decision making. To ensure that in this new Administration, we base our public policies on the soundest science; that we appoint scientific advisors based on their credentials and experience, not their politics or ideology; and that we are open and honest with the American people about the science behind our decisions. That is how we will harness the power of science to achieve our goals – to preserve our environment and protect our national security; to create the jobs of the future, and live longer, healthier lives.

As we restore our commitment to science, and resume funding for promising stem cell research, we owe a debt of gratitude to so many tireless advocates, some of whom are with us today, many of whom are not. Today, we honor all those whose names we don't know, who organized, and raised

awareness, and kept on fighting – even when it was too late for them, or for the people they love. And we honor those we know, who used their influence to help others and bring attention to this cause – people like Christopher and Dana Reeve, who we wish could be here to see this moment.

One of Christopher’s friends recalled that he hung a sign on the wall of the exercise room where he did his grueling regimen of physical therapy. It read: “For everyone who thought I couldn’t do it. For everyone who thought I shouldn’t do it. For everyone who said, ‘It’s impossible.’ See you at the finish line.”

Christopher once told a reporter who was interviewing him: “If you came back here in ten years, I expect that I’d walk to the door to greet you.”

Christopher did not get that chance. But if we pursue this research, maybe one day – maybe not in our lifetime, or even in our children’s lifetime – but maybe one day, others like him might.

There is no finish line in the work of science. The race is always with us – the urgent work of giving substance to hope and answering those many bedside prayers, of seeking a day when words like “terminal” and “incurable” are finally retired from our vocabulary.

Today, using every resource at our disposal, with renewed determination to lead the world in the discoveries of this new century, we rededicate ourselves to this work.

Thank you, God bless you, and may God bless America.

APPENDIX 6

USCCB'S RESPONSE TO BUSH AUGUST 9, 2001 POLICY

The Catholic bishops of the United States have strongly opposed the National Institutes of Health guidelines for embryonic stem cell research issued on August 25, 2000. The guidelines provided no federal funds for the act of destroying human embryos, or for research using embryos specially created for research; federal funds could support research on stem cells obtained by the privately funded destruction of "excess" embryos from fertility clinics. On August 9, 2001, after suspending the guidelines for several months' review, President Bush announced that he will implement them, with one change: funding will extend only to cell lines already in existence as of August 9, in an effort to prevent such funding from encouraging the destruction of human embryos in the future.

Key points in the critique of this policy by the Catholic bishops' conference:

Research on cell lines already established by destroying human embryos does not avoid moral complicity in such destruction.

These human embryos did not die of natural causes, or for reasons unrelated to researchers' goals. They were destroyed *for the sake* of this research, in ways tailored to provide the most usable cells for the research. Federal funds will be awarded directly to those researchers who destroyed the embryos for this purpose, or to those who pay those researchers for the right to use the cell lines.

The fact that the embryos were destroyed with private funds does not solve the moral problem.

The embryos were destroyed in anticipation of receiving federal grants for the resulting research. The researchers created the cell lines following the NIH's standards for obtaining consent from the embryos' parents, etc., so they would qualify for federal grants.

The new policy abandons important ethical limits found in current law on fetal tissue research.

Fetal tissue research is ineligible for federal funding if: an abortion was performed specifically to obtain the tissue; the researcher influenced the timing, manner or method of the abortion; or the tissue was harvested before fetal death (42 USC §§289g-1, 289g-2). These limits are violated when federal funds support research that depends for its existence on destructive cell harvesting from live embryos.

Past Catholic statements on individuals' use of vaccines developed from fetal tissue are not relevant to this issue.

Catholic moralists have concluded that individuals, when they have no practical alternative, may use vaccines to protect their health and the health of their loved ones without serious sin, even if the vaccines were cultured in fetal cells that ultimately came from an elective abortion. However, Catholic teaching rejects all complicity in abortion, and the Church has opposed any collaboration with abortionists (including government collaboration) to obtain tissue for vaccines or other research. The embryonic stem cell issue poses an even more serious problem because live human embryos were directly destroyed precisely to obtain the cells.

Some doctrinal sources to explain the problem of funding this research.

Donum Vitae (Instruction on Respect for Human Life In its Origin and on the Dignity of Procreation: Replies to Certain Questions of the Day, Sacred Congregation for the Doctrine of the Faith, 1987):

"To use human embryos or fetuses as the object or instrument of experimentation constitutes a crime against their dignity as human beings having a right to the same respect that is due to the child already born and to every human person...

The corpses of human embryos and fetuses, whether they have been deliberately aborted or not, must be respected just as the remains of other human beings.Furthermore, the moral requirements must be safeguarded, that there be no complicity in deliberate abortion and that the risk of scandal be avoided" (I.4).

"It is a duty to condemn the particular gravity of the voluntary destruction of human embryos obtained 'in vitro' for the sole purpose of research..." (I.5).

Declaration on the Production and the Scientific and Therapeutic Use of Human Embryonic Stem Cells (Pontifical Academy for Life, 2000):

"Is it morally licit to use ES [embryonic stem] cells, and the differentiated cells obtained from them, which are supplied by other researchers or are commercially obtainable?"

"The answer is negative, since: Prescinding from the participation – formal or otherwise – in the morally illicit intention of the principal agent, the case in question entails a proximate material cooperation in the production and manipulation of human embryos on the part of those producing or supplying them" (Libreria Editrice Vaticana, p. 17).

A policy limitation to "already existing cell lines" is an arbitrary line which may not hold in practice.

When this proposal was first discussed, there were said to be only 12 existing cell lines; now there are said to be 60, many of them perhaps created in recent weeks in anticipation of such a policy. Scientists will undoubtedly continue to kill additional embryos with private funds, and if the first set of 60 proves inadequate they will recommend these new cell lines for use in federally funded research. On what principled basis will such funding be refused, since these embryos as well will now be "dead already"?

The problem of scandal is also relevant, as even limited government funding encourages for-profit companies to engage in this destructive research.

The value of stock in for-profit stem cell companies increased the day of the President's speech. Federal funding tends to encourage more privately funded destructive embryo research, by (a) removing some of its ethical stigma and (b) providing the "seed money" for the early, non-profitable stages of the research. If this research leads to possible treatments, private investment in such efforts will increase greatly and the demand for many thousands of cell lines with different genetic profiles will be difficult to resist.

APPENDIX 7

USCCB'S RESPONSE TO OBAMA'S MARCH 9, 2009 POLICY

Though tempered by sober realism, President Obama's inaugural address in January delivered a message of hope – including a hope that science will help our nation solve its serious problems. "We will restore science to its rightful place," he said, "and wield technology's wonders to raise health care's quality and lower its costs."

But now the President has decided to force U.S. taxpayers to subsidize research that requires destroying live human embryos. That decision actually ignores his pledge to take science seriously -- because science is moving on, and embryonic stem cells are becoming "obsolete."

That's the considered judgment of the first female director of the National Institutes of Health, Dr. Bernadine Healy, writing in the March 4 issue of *U.S. News and World Report*. Dr. Healy cites a recent study in Israel, showing the formation of multiple tumors in a boy's nervous system after he was treated with derivatives from early fetal stem cells.

In January, a study in *Nature Biotechnology* confirmed that embryonic stem cell cultures generally contain abnormal cells that can cause cancer – and there is no simple way to tell which cells are abnormal, as they have a normal genome and may seem to be the healthiest and most viable cells. Dr. Martin Pera, stem cell expert at the University of Southern California in Los Angeles, comments: "Ultimately it may be difficult or impossible to rule out with certainty that a given culture is totally free of abnormal cells." How reassuring for those needing therapies!

Producing genetically tailored embryonic stem cells that cannot be rejected as "foreign" by a patient's body also remains a challenge. To solve this problem, teams around the world have tried to obtain usable stem cells from cloned human embryos, but failed. Cloning also requires a huge supply of women's eggs – and according to the February 1 issue of the *American Journal of Epidemiology*, the drugs needed to stimulate women's ovaries to produce these eggs boosts the women's risk of, yes, cancer. The bizarre approach of using eggs from animals instead was approved last year in Great Britain, but scientists now find that animal eggs (big surprise) do not program a human genome properly.

That's the sobering reality. Here's the hope. Adult stem cells, obtained without harming the donor, are benefiting more and more real patients, reversing the symptoms of multiple sclerosis and Parkinson's disease in the latest published trials.

An advance hailed by the journal *Science* as the top scientific breakthrough of last year – a technique for reprogramming ordinary adult cells into "induced pluripotent stem cells" – looks better with each passing month. These "induced" cells can be an exact genetic match to any patient, and the journal *Nature* just published two studies showing that initial concerns about the safety of the procedure are being resolved. If there is any research purpose for which embryonic stem cells have an advantage, these reprogrammed cells seem able to perform that task as well or better, without ethical problems. Science and ethics are pointing the way forward together. The only thing standing in the way now is an ideology favoring embryo destruction – an ideology that is reflected in the President's new executive order, but that the American people do not support.

APPENDIX 8

UNITED STATES CONFERENCE OF CATHOLIC BISHOPS PRO-LIFE MOBILIZATION INFORMATION

The USCCB has a page dedicated specifically to “political responsibility”, which forwards to a subsidiary website entitled, “Faithful Citizenship”, which includes suggested voting behaviors for devoted Catholics. Included on this webpage are prayers to be said before and after elections, including the following:

This statement highlights the role of the Church in the formation of conscience, and the corresponding moral responsibility of each Catholic to hear, receive, and act upon the Church’s teaching in the lifelong task of forming his or her own conscience. With this foundation, Catholics are better able to evaluate policy positions, party platforms, and candidates’ promises and actions in light of the Gospel and the moral and social teaching of the Church in order to help build a better world.

—United States Conference of Catholic Bishops, Forming Conscience for Faithful Citizenship, No. 5

USCCB also includes what they refer to as, “The Prayer for the Protection of Embryonic Children. The prayer is as follows:

Lord God, you lovingly knit us in our mothers’ womb. Grant that each human embryo will be respected as a human being, and not dismissed as a product to be manipulated or destroyed.

Grant us the courage and conviction to be your voice for our sisters and brothers at the very earliest stages of their development, and for all defenseless unborn children.

Jesus, Divine Healer, foster in those conducting medical research a commitment to finding cures in ways that respect these little ones and all your vulnerable children.

Holy Spirit, grant us the wisdom to develop morally sound treatments for conditions now thought to be incurable. Help us persevere in defending human life while alleviating suffering.

Show mercy to all who have cooperated in killing our tiniest brothers and sisters. Bring them and all who support destructive embryo research to true conversion. Grant them the ability to see the immeasurable dignity of all human beings even in the first days of life.

Father, we ask this in Jesus’ name, through the Holy Spirit. Amen.

APPENDIX 9

DATA ON US COMMITMENT TO THE SCIENTIFIC FIELD

In order to gauge the US' present commitment to science as a discipline, and subsequently the legitimacy it affords to it, it is helpful to look at some data provided by the National Science Foundation on science resources statistics, which the foundation issues on a biennial basis. In terms of research space allotted to research-performing colleges and universities, space has expanded 4% between 2007 and 2009, from 188,000,000 ft.² to 196,000,000 ft.², a percentage that was almost 3 times the growth rate of the previous two years (Christrovich, 2011). In terms of biomedical sciences, in particular, research space has increased 12% between 2007 and 2009, which was the biggest gain of any scientific or engineering fields.

An interest in science and engineering fields in the United States among students, however, has seen a bit of a decline since the mid-1960s, as seen by the numbers of bachelors, Masters, and doctoral degrees awarded to students over this time. While the absolute numbers of the degree recipients has increased, the percentage of students pursuing these degrees with respect to all degrees in all disciplines awarded, has been variable but on an overall decline. For instance, in 1966, there were 504,008 bachelor's degrees awarded in the United States, and of these, 184,313, or 35.2%, were in the science and engineering fields. In 2008, though, there were 1,580,036 bachelors degrees awarded, and 494,627, or 31.3%, were in the science and engineering fields (National Science Foundation, 2008). Similarly, over this same time frame, there were 140,772 master's degrees awarded, and of these, 41,049, or 29.2%, were in the sciences and engineering fields. In 2008, though, there were 631,608 master's degrees awarded, and of these, 124,754, or 19.8%, were in science and engineering. A difference can be seen, though, in doctoral degrees awarded, as in 1966, there were 17,949 doctoral degrees awarded, with 11,570, or 64.5%, awarded in science and engineering. In 2008, there were 48,802 doctoral degrees awarded, and of these, 32,827, or 67.3%, were in science and engineering (NSF, 2008).¹⁰¹

¹⁰¹ These numbers present an interesting picture. While a clear minority of undergraduate students pursues science and engineering as their fields of study, of students who continue on to pursuing doctoral degrees, a strong majority it is these fields. Perhaps it is that, in order to make further headway in either of these fields, one must have a PhD to do it, thereby reducing the overall number of students who pursue these fields yet favoring the number of students who ultimately obtain a PhD. Alternately, it is possible that students who pursue science and engineering take their work especially seriously, such that they are encouraged to complete their graduate educations. What can be said for certain, though, is that students excelling in science and engineering are much more likely than students than any other discipline to become experts in their field.

APPENDIX 10

RECOMMENDATIONS OF THE DONALDSON REPORT

The Donaldson Report was the product of a team of experts assembled by the British government. A great deal of authority and credibility was placed in this team of experts, and subsequently in the recommendations they are issued. The Donaldson Report issued the following recommendations:

1. Research using human embryos, whether created by in vitro fertilization or cell nuclear replacement, to increase understanding about human disease and disorders and their cell-based treatments should be permanent, subject to the controls on the Human Fertilization and Embryology Act Of 1990.
2. In licensing any research using embryos created by cell nuclear replacement, the HFEA should satisfy itself that there are no other means of meeting the objectives of the research.
3. Individuals whose eggs or sperm are used to create the embryos to be used in research should give specific consent indicating whether the resulting embryos could be used in a research project to derive stem cells.
4. Research to increase understanding of and develop treatments for mitochondrial diseases using cell nuclear replacement technique in the human eggs, which are to be fertilized subsequently by human sperm, should be permitted, subject to the controls in the Human Fertilization and Embryology Act of 1990
5. The progress of research involving stem cells which have been derived from embryonic sources should be monitored by an appropriate body to establish whether the research is delivering the anticipated benefits and to identify any concerns which may arise.
6. The mixing of adult (somatic) cells with the live eggs of any animal species should not be permitted.
7. The transfer of an embryo created by cell nuclear replacement into the uterus of a woman (so-called “reproductive cloning”) should remain a criminal offense.
8. The need for legislation to permit the use of embryo-derived cells in treatments developed from this new research should be kept under review.
9. The Research Councils should be encouraged to establish a program for stem cell research and to consider the feasibility of establishing collections of stem cells for research use.

APPENDIX 11

BISHOPS CONFERENCE OF ENGLAND AND WALES STEM CELL PRESS RELEASE, MAY 2008

Scientists, ethicists, heads of medical charities and religious leaders met tonight (16 May) at the Wellcome Collection in London to discuss the Human Embryology and Fertilisation Bill currently before parliament.

Archbishop Peter Smith and Professor Colin Blakemore co-sponsored the meeting. BBC Radio 4 will broadcast an edited version of the conversation on Saturday 17 May at 10.15pm. The full conversation will also be available for viewing on: www.wellcome.ac.uk following the broadcast.

The focus of the conversation was the ethics and science surrounding the use of human embryos in research and the creation of embryos that contain both human and animal material. Some of the questions discussed included:

- Drawing out the clear distinction between cybrid embryos and true 50/50 hybrid embryos, with specific reference to how useful scientists believe each could be in research and also how human they are.
- Whether there are ways of producing of stem cells for therapeutic use as versatile as embryonic stem cells without the creation and destruction of human embryos.
- Whether and how views about the moral status of embryos should respond to rapidly evolving scientific evidence.
- Whether scientific research requires ethical boundaries, and if so how these should be set.
- Whether there are any risks associated with commercial exploitation in this area.
- Whether the UK should have a national bioethics commission to consider similar questions in the future.

The conversation sought to move beyond sound bites and to encourage the exchange of opinions and information in a framework of mutual respect. Both sponsors were keen that the conversation was not a stylised debate about science versus religion but rather a chance to discuss both the science and the ethics: Scientists, both those in favour of the HFE Bill and those who pursue stem cell research without using embryos, explained what they planned to do and what it might achieve. Experts in bioethics with a range of views on the moral status of the embryo then presented their arguments for and against the proposal in the Bill. These brief formal presentations were followed by all discussing the pros and cons of these plans in a wide-ranging discussion.

While there was no expectation that this initial conversation would lead to total agreement between all the participants, especially about the moral status of the human embryo, the sponsors said it had helped remove misunderstanding, offered new perspectives, and was of considerable help in seeking to clarify and address the central scientific and ethical questions underlying this debate.

Archbishop Peter Smith said: “This was a very useful exchange and provides a model for a national bio-ethics committee. While we all seek to relieve suffering and pain, the science and ethics of what we are now capable of is both challenging and complex. While there may not be complete agreement on the ethical parameters, discussing the issues in this way is both useful and constructive. These issues will not go away and it is our sincere hope that we will be able to meet again to continue the dialogue on these vital issues that go to the heart of what it means to be human.”

Professor Colin Blakemore, of the University of Oxford said: “This conversation was not about scientists challenging the spiritual leadership of Clergy, it was about creating a fuller dialogue between researchers and faith leaders which could help each group to understand the intentions and aspirations of the others. A polarisation of the debate on stem cells serves no-one, especially the patients who hope to benefit from such research.”

APPENDIX 12

DFG'S "RECOMMENDATIONS FROM THE GERMAN RESEARCH FOUNDATION CONCERNING RESEARCH WITH HUMAN EMBRYONIC STEM CELLS"(ROUGH TRANSLATION)

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DFG's opinion on the problem area "Human embryonic stem cells"

I. Scientific Background

First Research objectives and purposes of the work on and with human stem cells

The term of each stem cell is not yet differentiated cell of an embryo, fetus or born people referred to the subdivision and development capability has. Takes on the path of specialization the differentiation potential of cells gradually decreases. While from the totipotent fertilized egg and may still arise from the totipotent embryonic cells later than the 8-cell stage, a whole person, develop from the pluripotent stem cells in the embryonic development of the following different tissue types in the body. Finally, in the fetus and in adult humans encountered organ-specific stem cells such as bone marrow, digestive tract, skin or Central nervous system are severely restricted in their differentiation potency, because they already Determination have reached a certain cell type. They fulfill essential functions in the continuous Regeneration of tissues and organs. The present opinion refers only to the research and with pluripotent embryonic stem cells. The ability to keep pluripotent human stem cells in culture, opens up a whole new dimension medical research. It is possible for the first time in humans that are largely misunderstood, complex processes of tissue differentiation and organ formation in vitro study.

The objectives of this research include:

- Understanding the mechanisms of cell differentiation as a basis for development. Specifically, the Identification of a marker for the differentiation of differentiated and undifferentiated cells Investigation of the differences between ES and EG cells (s.2.) And the development of methods for controlled, artificial induction of cell differentiation.
- The identification of previously non-detectable, the regeneration of specific tissues determining stem cells in adult humans. This could be analogous to those already used blood stem cells are used therapeutically.
- The understanding of principles and factors that limited the genetic program of differentiated body cells back to the broad differentiation potential of stem cells. In the long term aims this research is to replace the work with embryonic stem cells and pluripotent stem cells to gain from specialized cells.

- The study of external factors such as drugs and environmental influences on the
- Embryonic development, so that the causes of developmental disorders.
- The development of novel drugs based on the knowledge of the mechanisms of action of the substances involved in the cell differentiation are involved.
- The development of cell transplantation therapies for diseases for which currently no therapies are available, such as Alzheimer's disease, and for diseases for which a improved treatment is urgently needed, such as cardiovascular disease,
- Cancer, diabetes and diseases of the nervous system, such as Parkinson's disease. A long-term goal consists in the generation of complex tissues or whole organs associations, the current shortages and immunologically related problems and the risks of disease transmission in the organ transplantation could bypass.
- Detailed tests of new drugs and toxicological studies in vitro. Those on human Cell cultures are far more reliable data obtained be transferable to humans than previously in animal testing results obtained.

Second Extraction of stem cells in human

Currently, three approaches can be differentiated to pluripotent stem cells.

a) The extraction of embryonic stem cells (ES cells) obtained by in vitro fertilization Blastocysts After the union of the pronuclei of the fertilized egg undergoes a series of cell divisions until after about 4 Days, the blastocyst stage is reached. From the inner cell mass (embryoblast) of the blastocyst embryonic stem cells can be isolated. The removal of these cells may, within a period of about 3 days further growth in vitro and has performed with great probability the destruction of Blastocyst result. During the first embryonic division processes are still totipotent, occurs later than the 8 - Cell stage (Day 3) to differentiate one that the development potential of individual embryonic cell (Blastomere) is limited. The manner in which the 4 - to 8-cell stage in this transition from a totipotent a pluripotent differentiation stage takes place, is not yet known in humans and in vitro conditions not clearly ascertainable. According to information currently isolated ES cells are not totipotent.

b) Primordial germ cells from aborted fetuses or early dialed

Primordial germ cells, the precursors of the egg or sperm cells, induced or spontaneous abortion after isolated from fetuses and stem cells under culture conditions (EG cells, embryonic germ cells) further developed. The working group led by J. Gearhart has evidence that from the generated by it created pluripotent stem cell lines such as neuronal cell assemblies can.

c) Individual-specific embryonic stem cells by nuclear transfer into enucleated oocytes Nature realizes the one hand, asexual, on the other hand, for the mammals and humans characteristic of sexual reproduction. In addition to the

latter development of a male and a female germ cell has recently been experimentally realized the possibility of asexual reproduction by cell nuclear transfer into an enucleated oocyte entered. This first cloned sheep Dolly in made experience was confirmed in other species. Obviously, the highly differentiated genetic program of a somatic cell nucleus after transfer into the Eizellplasma an extensive reprogramming

. learn This creates a new totipotent cell that is analogous to a fertilized egg to the blastocyst

can develop. This method could open up the possibility of a body cell of a patient and a

enucleated oocyte to obtain embryonic stem cells with the genotype of the patient. From this

individual-specific stem cells could be preserved healthy cells and tissues, which, when transmitted to the

Patients do not cause immunological problems.

Modifications of this procedure are conceivable, such as the transfer of a nucleus from a differentiated

Somatic cell into an enucleated embryonic stem cell or primordial germ cell.

The recovery of viable primordial germ cells from aborted tissue is due to the death

the fetus associated autolytic processes and the highly variable time course of abortion technically

more problematic than the isolation of ES cells from a blastocyst. The path of primordial germ cells

avoids the ethically and legally permissible use of totipotent cells. For the extraction

individual-specific ES cells, nuclear transfer into enucleated oocytes offers advantages. It is not currently

predict which of the three strategies for the respective issues is particularly suitable. The quality of

each generated or existing stem cell lines is not currently estimated.

In animal models has so far neither of ES cells from primordial germ cells or EG cells alone after

Transfer into the uterus of a complete living being developed. That human pluripotent stem cells, all stages

pass through to the development of a viable human beings can be, based on present knowledge most

unlikely.

Third Reasons for the particular research on human stem cells

The comparative analysis of the structure and function of genes from different species has many

Similarities but also significant differences in humans and animals arise. Thus, the past 15 years

accumulated knowledge concerning the differentiation of ES and EG cells of the mouse valuable information for the

The studies provide direction on human cells, they can be in a specific case but not necessarily on the

Transfer situation in humans.

You want the potential of stem cells cultured in vitro with application-oriented validity for humans

, we study these complex research will therefore have to make to human cells. The

molecular basis of early embryonic development in humans is virtually unknown. This is true

particularly for the differentiation potentials of different embryonic cell clusters. Also, the principles

fixed after reprogramming the differentiation gene programs after nuclear transfer into enucleated

Oocytes are not understood. To decrypt the control programs of stem cells, it will be important

their functional states in the early stages of embryonic development - such as during the first two weeks after

fertilization - to study. Knowledge of these control programs could also be targeted in future modification

of genetic programs further enable differentiated somatic cells without the path of embryonic

Stem cells or cell nuclear transfer into enucleated oocytes is followed.

II Ethical and legal assessment

First Introduction

The freedom of science and research is guaranteed in the Basic Law. This freedom is, even though the

Limitations of the Basic Law does not expressly provide, not unlimited, but they can be by other

Constitution of goods to be restricted. Constitution of goods that are here to give specific consideration are the

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Protection of human dignity and the protection of human life and human health. The

Concretization of such constitutional barriers is primarily in the legislature, the one

Must restore balance between the competing constitutional goods. The Embryo Protection Act were

constitutional barriers to the freedom of research with regard to working on and with embryos

concretized. The prohibitions of the Embryo Protection Act to protect human life and dignity of life

beginning to save. As an individual human life, beginning in Germany, the completion of the

Fertilization of an egg, ie the union of the chromosomes of an egg and a sperm cell to a

new individual genome views. This also applies in the case of in vitro fertilization. As embryos

All documents will also be an embryo taken from totipotent cells defined at the presence of this

to share and further necessary conditions to develop into an individual asset. In the

Development of a human embryo must by law only for the benefit of the embryo to intervene.

The ethical and legal assessment of the scientific research on stem cells and has three

Different areas, namely:

- The way the derivation of human stem cells
- In the context of research with human stem cells and methods
- Pursued by the scientific research goals.

It is obvious, even to ask the legitimacy of the objectives for which the above

Possibilities for action can be taken advantage of, and the justifiability of the means

to consider in terms of their intended and unintended effects. Assessment criteria are as it

to use the ethical principles set out in the Constitution, especially its legal precipitation

have found.

Second Goals of scientific research on and with human stem cells

Described in I. The goals of scientific research as such, are not only ethical and constitutional

legally justifiable, but imperative, because the improvement of medical care of people is a

Task of the medical research is required.

Research on human stem cells and their targets is not intended to - and may in the opinion of the

DFG also not meant to - to develop reproductive techniques or to apply, were contrary to the basic

Act guaranteed human dignity and the protection of life notices. The DFG is therefore fully

behind in the Embryo Protection Act worded ban on human cloning, regardless of the

method used, and the prohibition of the production of human beings with artificially altered genetic material,

For example, by germline or chimeric or hybrid formation. The DFG maintains the

Production of human beings, but by the - possibly artificially supported - fertilization of an egg by

a sperm cell to be ethically unacceptable.

Third Derivation of human ES cells and human EG cells

The roads to the derivation of human stem cells differ from an ethical and legal perspective. The

Embryo Protection Law contains, the relevant legal principles.

It is essential that the Embryo Protection Act and the jurisprudence of the Constitutional Court which

, assume that the human being from its beginning in cell fusion of the nuclei under the protection of

of human dignity. This results in the prohibition of the use of human benefit of others

Embryos and the prohibition of cloning of human life. Of crucial importance in relation to the

latter prohibition is the fact that even the creation of an embryo with genetic material of the same

People is prohibited. These provisions are derived from other prohibitions of certain methods and results

working with pluripotent cells and tissues from.

The extraction of embryonic stem (ES) cells from blastocysts made for purposes other than for

Preservation of the embryo. It is therefore not compatible with the Embryo Protection Act. This is true even for the

Case in which the embryo is not harmed by the removal of some cells in its development.

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The removal of primordial germ cells from dead fetuses for scientific, therapeutic and

diagnostic purposes in the guidelines for use of fetal cells and fetal tissues of

Federal Chamber of Physicians regulated. The Embryo Protection Act does not cover the withdrawal, since it only covers the period up

for embryo implantation in the uterus regulates. The Transplantation Act does not apply to embryonic and fetal

Organs and tissues. This means that the removal of primordial germ cells from dead fetuses after the applicable

Law is allowed. This makes sense, since a similar situation, an embryo is not the extent,

as totipotent cells are not affected.

For research with human EG cells should be noted that the - not scientifically feasible at present

- Reprogramming of pluripotent cells to totipotent cells under the provisions of

Embryo Protection Act is defined as cloning, since a totipotent cell is considered as an embryo and therefore

"Is produced artificially, that a human embryo is created with the same genetic information as a fetus." The

means that both the implementation of such reprogramming and the test are prohibited.

In addition, any further development is the resulting totipotent cell, whether extracorporeal

or in vivo, is prohibited. The same applies, according to the DFG for the implementation and experimental

a reprogramming of genetically modified pluripotent cells.

The generation of germ cells (egg and sperm cells) from pluripotent cells, according to the

Embryo Protection Act prohibited, regardless of whether the genetic information of the cell before artificially modified

was or not. Furthermore, nor shall such human pluripotent cells with altered genetic information on

an embryo, fetus or human transfer.

The cell nuclear transfer into enucleated oocytes fulfilled human cloning a criminal offense, as a totipotent cell

arises under the provisions of the regulations of the Embryo Protection Act as an embryo. The further development

of the totipotent cell to blastocyst and the derivation of embryonic stem cells would be prohibited from

and punishable. The same applies for the try.

III. Consequences of the current legislation for working with human stem cells and Suggestions

the DFG

The DFG provides that with research on human stem cells and essential diagnostic and

therapeutic purposes may be prosecuted, their great potential for medicine in all its range

still can not be estimated accurately. The DFG is also that against certain methods of

Production of pluripotent stem cells from different points of legal and ethical concerns

. there The research is faced with a dilemma. It is unclear to what extent, for the purpose

Methods derived pluripotent stem cells are truly identical, or an identical potential for the

Tissue engineering have. This can not be determined under the applicable law in Germany.

In substance, the limitation takes on only one of the possible forms for the derivation of human stem cells

research on stem cells in view of the stated medical goals boundaries.

In Germany, as shown, allows the derivation of human stem cells from fetal tissue only. Again, this

is not free of ethical concerns, given that the rights of the parents and the necessary

Piety obligations not yet eliminates the danger that the medical use of tissue from aborted

Fetuses as subsequent ethical justification of abortion could be considered. Since the extraction

may be limited to a small number of stem cells from taking cases and achieving the

mentioned high-level scientific, preventive, diagnostic and therapeutic purposes in other

Question would be, the DFG is of the opinion that the removal of fetal tissue for these purposes by

careful consideration and therefore regarded as acceptable by the applicable law are given the option of

Sampling may be used.

By international comparison, there is broad consensus that practices of human dignity

that contradict such germ-line interventions and replicating human cloning should be banned,

provided that, as in Germany, is not already the case. This is reflected in the UNESCO Declaration on the

Human Genome and Human Rights as well as in the Council of Europe Convention on Human Rights and

Biomedicine. Significant differences exist between nations, however, in determining the

Protection of human life in its different development phases and in attitudes towards

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Research on and with human embryos. It is agreed that no embryos

Research purposes may be generated. In Great Britain there are efforts, the possibility of licensing

obtain for certain research projects on embryos, extending it to cell nuclear transfer methods.

This technique for obtaining embryonic stem cells is terminologically as "therapeutic cloning" clear of

"Reproductive cloning", ie the deferred cloning of a human being.

This represented in some other countries score approach raises the question about whether she's in Germany

Future might seem ethically justifiable, and with regard to research on human

Stem cells than previously given to that if the applicable methods and techniques legitimate

therapeutic goals.

For a limited facilitate research on and on and on embryonic stem cells or totipotent with

Cells, caused by cell nuclear transfer into an enucleated oocyte, could the research in this

lying diagnostic and therapeutic potential, and the fact that in other countries the opportunity for

such research is opened or will speak. It would be ethically difficult to argue later take over the therapeutic methods developed from this research to try if the first Permissibility of research has been denied.

Against the opening of research with embryonic stem cells from blastocysts, and which by in vitro

Were obtained by fertilization or nuclear transfer into an enucleated oocyte speaks, however, that these

Routes via totipotent cells, which carry the Entwicklungspotential zu one man to himself.

The DFG provides a variety of reasons in terms of research using human pluripotent stem cells

currently no action for a change in German law.

The DFG can imagine that given the rapid and surprising developments in this area

In the past two years, known by technical modifications or improvements to date

Process will be ensured that the production of pluripotent cells, totipotent cells on the way

avoidable. Furthermore, according to the DFG is the opinion-forming process on the ethical and

embryological questions in connection with research on stem cells in Germany and abroad have

at the beginning. The DFG suggests that this opinion-forming process is performed on a broad basis, and will

participate in it. At the same time, the DFG will seek, in this issue on the development of uniform

to work of European standards, which also provided the risk estimates towards fundamental and

constitutionally guaranteed life values such as human dignity and health include. The DFG

will stimulate targeted research projects that aim to use pluripotent cells without the path

to go on totipotent cells. This research funding is in conjunction with a discussion of the

be made deputy ethical questions.

According to the DFG, however, must be excluded in any case, that of ES or EG cell embryos

regardless of their genetic development. It must also be ruled out that egg or sperm cells from human

Stem cells created and used in the impregnation of an ovum and its development will be.

In addition, through effective measures to ensure that human cloning or the production of

People with artificially altered genetic material remain excluded. The establishment of a Commission headquarters,

research projects with EC and ES cells on ethical, legal and scientific [knowledge] assesses and monitors their implementation and supported, would be a logical way.

APPENDIX 13

NUREMBERG CODE OF ETHICS

1. The voluntary consent of the human subject is absolutely essential. This means that the person involved should have legal capacity to give consent; should be so situated as to be able to exercise free power of choice, without the intervention of any element of force, fraud, deceit, duress, over-reaching, or other ulterior form of constraint or coercion; and should have sufficient knowledge and comprehension of the elements of the subject matter involved as to enable him to make an understanding and enlightened decision. This latter element requires that before the acceptance of an affirmative decision by the experimental subject there should be made known to him the nature, duration, and purpose of the experiment; the method and means by which it is to be conducted; all inconveniences and hazards reasonable to be expected; and the effects upon his health or person which may possibly come from his participation in the experiment. The duty and responsibility for ascertaining the quality of the consent rests upon each individual who initiates, directs or engages in the experiment. It is a personal duty and responsibility which may not be delegated to another with impunity.
2. The experiment should be such as to yield fruitful results for the good of society, unprocurable by other methods or means of study, and not random and unnecessary in nature.
3. The experiment should be so designed and based on the results of animal experimentation and a knowledge of the natural history of the disease or other problem under study that the anticipated results will justify the performance of the experiment.
4. The experiment should be so conducted as to avoid all unnecessary physical and mental suffering and injury.
5. No experiment should be conducted where there is an a priori reason to believe that death or disabling injury will occur; except, perhaps, in those experiments where the experimental physicians also serve as subjects.
6. The degree of risk to be taken should never exceed that determined by the humanitarian importance of the problem to be solved by the experiment.
7. Proper preparations should be made and adequate facilities provided to protect the experimental subject against even remote possibilities of injury, disability, or death.
8. The experiment should be conducted only by scientifically qualified persons. The highest degree of skill and care should be required through all stages of the experiment of those who conduct or engage in the experiment.
9. During the course of the experiment the human subject should be at liberty to bring the experiment to an end if he has reached the physical or mental state where continuation of the experiment seems to him to be impossible.

10. During the course of the experiment the scientist in charge must be prepared to terminate the experiment at any stage, if he has probable cause to believe, in the exercise of the good faith, superior skill and careful judgment required of him that a continuation of the experiment is likely to result in injury, disability, or death to the experimental subject.

Reprinted from Trials of War Criminals before the Nuremberg Military Tribunals under Control Council Law No. 10, Vol. 2, pp. 181-182.. Washington, D.C.: U.S. Government Printing Office, 1949.
