CONTROLLING CONTROVERSIAL SCIENCE: BIOTECHNOLOGY POLICY IN BRITAIN AND THE UNITED STATES (1984-2004)

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ABSTRACT

This thesis addresses the puzzle of variation in first-generation regulatory policies for controversial science and technology, as demonstrated in the cases of agricultural genetically modified organisms (GMOs) and human embryonic stem cell research in the United Kingdom and the United States. Why did policy outcomes vary in each technology case? This study answers this question by placing greater emphasis on institutional factors.

Although works within institutional analysis, bureaucracy and regulation literatures make significant progress in revealing how existing institutions can shape outcomes, how far one can characterize bureaucratic behavior and whether interest groups capture regulation, they nevertheless create an opening for research that: describes a mechanism for path dependence to explain variation in policies; shows the degree to which bureaucratic behaviors can influence outcomes; and, highlights instances in which regulatory officials hold power. This thesis makes an original contribution by providing new historical details relating to these cases, and by providing an extensive elaboration of Pierson's criteria for increasing returns and a so-called secondary test of path dependence to explain outcomes.

The study recounts the biography of key policy documents in each case by tracing the process of decision-making through government and archival sources, secondary literature and more than 40 elite interviews. In doing so, it details the activities of key governmental bodies within the European Union, UK and US. Moreover, it shows how the Coordinated Framework (1986) and *Human Fertilisation and Embryology Act 1990* framework represented decision-making structures which triggered changes in actors and interests and shaped permissive outcomes for GMOs and stem cell research in the US and UK, respectively.[1] Furthermore, lack of comparable structures may help account for restrictive policies for GMOs in Europe and the UK, and for stem cell research in the US.

[1] US Executive Office of the President, Office of Science and Technology Policy, "Coordinated Framework for Regulation of Biotechnology," *Federal Register* 51 (June 26, 1986), 23302; UK Parliament, *Human Fertilisation and Embryology Act 1990*.

FOR MY PARENTS

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Any errors in this work of course remain my own.

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CHAPTER 1: INTRODUCTION

The period from August 1998 to the following summer was a calamitous year for the biotechnology industry in Europe. During that time, producers seeking to commercialize agricultural genetically modified organisms (GMOs) across the European Union (EU) saw a slow-burning opposition movement of environmentalists and consumers quickly explode in a succession of negative media coverage and a successful commercial boycott. The conflagration culminated in decisions by officials in Brussels and member states such as the United Kingdom to halt the already sporadic regulatory approvals pending further safety studies of engineered crops and food, and reforms to the oversight system.

In the United States the picture looked very different. Although "green biotechnology" had so far failed to deliver a wide range of viable new crops, modified corn and soybeans were well on their way to replacing their traditionally bred counterparts both in farmers' fields, and in the potentially endless number of processed and packaged foods containing their derivatives. Moreover, although the US possessed an extensive oversight system with the power to block various products from advancing, officials ultimately approved most modified crops and products, and without further conditions such as mandatory labeling.

This variation in first-generation policy approach is the underlying puzzle of this thesis. Why did the United States embrace a permissive regulatory policy while the European Union implemented a much more restrictive one? Although explanations in journalism and scholarship varied considerably, many commentators described policy

variation in terms of culture, such as national differences in public opinion.[1] Other works emphasized differences in interest group activity as critical to the outcome in both cases.[2]

Although these explanations undoubtedly pointed to important factors, they do not tell the whole story. Moreover, they often underplay the influence of another critical variable: institutions. Indeed, in 1998, less than two years after engineered foods had entered the European food supply via shipments of corn and soybeans from America, the EU's complex and decentralized oversight system based on legislation remained unfinished and incomplete. Furthermore, consumers across the continent were still reeling from the devastating spread of bovine spongiform encephalopathy (BSE), which despite government safety warnings had led to numerous human deaths and cost the British beef industry several billion pounds. Under these circumstances, the EU regulatory system was highly susceptible to shocks.

In the United States, by contrast, the arrival of the first modified crops and food products from the mid-1990s had also prompted protests, threats of a boycott and demands for mandatory labeling. However, the opposition encountered a very different landscape: Unlike the EU, the US had previously implemented a far-reaching and flexible oversight system under the "Coordinated Framework," and it seemed to function reasonably well via the executive branch agencies administering the regime.[3] Moreover, efforts to block engineered food subsequently failed to get off the ground.

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[1] Jasanoff, Sheila, *Designs on Nature: Science and Democracy in Europe and the United States*, (Princeton, N.J.: Princeton University Press, 2005); Han, Lianchao, Thesis: "The New Food Pyramid: Culture, Policy and Technology in the Transatlantic GMO Controversy," (George Mason University, 2005).

[2] Meins, Erika, *Politics and Public Outrage: Explaining Transatlantic and Intra-European Diversity of Regulations on Food Irradiation and Genetically Modified Food*, (London: Lit Verlag, 2003); Bernauer, Thomas, *Genes, Trade and Regulation*, (Princeton, N.J.: Princeton University Press, 2003).

[3] US Executive Office of the President, Office of Science and Technology Policy, "Coordinated Framework for Regulation of Biotechnology," *Federal Register* 51 (June 26, 1986), 23302.

This thesis proposes that these contextual differences in existing regulatory institutions played a critical role in shaping the contrasting permissive and restrictive first-generation policies in the United States and the EU, respectively, possibly as much as—or even more than—other factors. Specifically, it shows how early policymaking decisions impacted later ones in each case, and highlights the Coordinated Framework as a critical decision-making structure shaping the permissive policy in the United States. To support this claim, the following account aims to provide a more complete recounting of each first-generation policy, based on new information from documentary sources, elite interviews and secondary literature.

In addition to generating novel descriptive insights on the basis of these sources, this study also informs theoretical debates within political science on the nature of institutional agency, bureaucratic behavior and regulatory capture. In doing so, the thesis builds on the works of other scholars who emphasized institutional influences to explain policy outcomes for GMOs.[4]

These descriptive and theoretical insights speak to a broader 21st-Century paradox in which controversial science and technology practices repeatedly resulted in mixed permissive and restrictive policy outcomes among countries. Indeed, variation in policies for GMOs is not an isolated case. Within the domain of loosely related policy issues, countries have embraced contrasting approaches to applications such as irradiated food, rBST growth hormones in dairy production and the sale and consumption of cloned livestock. More broadly, developments in a range of sectors, from energy (nuclear power) to assisted reproduction (*in vitro* fertilization), have also resulted in varying policies internationally.

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[4] Pollack, Mark, and Shaffer, Gregory, *When Cooperation Fails: The International Law and Politics of Genetically Modified Foods*, (Oxford: Oxford University Press, 2009).

However, because a study of policymaking for GMOs is limited to a single technology field, critics could reasonably challenge attempts to apply findings to other policy sectors. Therefore, in order to provide a broader basis for the research, this study looks to a contemporaneous science practice discovered in 1998, the same year policies for GMOs became so polarized across the Atlantic: human embryonic stem cell research. Like GMOs, this promising "red biotechnology" also led to contrasting policy approaches between the UK and US.

Indeed, soon after US President George W. Bush took office in 2001, he delivered a devastating blow to bio-medical researchers hoping to use embryonic stem cells in a range of disease treatments, by imposing a ban on federal funding for any work which created new stem cells or utilized cells created after an August 2001 deadline. The Bush decision, which pre-empted the National Institutes of Health staff from issuing the first grants for the work, followed extensive lobbying from pro-life opponents of the research and from scientists and patient advocates who supported it. Within weeks of the decision, the scientific community in the US would protest that Bush had imperiled the nation's progress in the field.

Across the Atlantic, however, the government of Prime Minister Tony Blair extended legal status and public funds to embryonic stem cell research in the same year, with legislation following the deliberations of two expert advisory committees, including one led by the country's chief medical officer. Although the issue had divided British partisans along similar lines, the successful vote cleared the way for the UK to become a world leader in the field and a mecca for researchers from more restrictive policy regimes.

What explains the variation in policies for stem cell research? As with the case of GMOs, many journalistic and scholarly accounts of stem cell policies focused on

cultural factors shaping policy outcomes, including national differences in public opinion.[5] Other sources attributed a critical role to interest groups.[6] Like the example of GMOs, this study acknowledges the potential importance of these factors, but notes that these explanations often overlook critically important dynamics.

Without discounting the agency of opinion and interest groups, this study will show that in the United States, the Bush decision of 2001 represented an extension of an earlier and sweeping restriction on embryo research funding known as the Dickey Amendment.[7] Indeed, the years preceding the country's first stem cell policy were dominated by a lengthy effort by the prior administration to bypass this constraint, with the effect of leaving power centralized under the president and creating the context for Bush to act in the manner in which he did.

Conversely, the United Kingdom's stem cell policy built on earlier legislation for embryo research, the *Human Fertilisation and Embryology (HFE) Act 1990*, and utilized the existing statutory regulator, the Human Fertilisation and Embryology Authority (HFEA).[8] Far from representing an issue universally accepted by the public or free of political risks for the government, the stem cell measure progressed slowly and with considerable caution and strategy by ministers concerned that it might actually fail. However, it eventually passed, due in large part to a second decision-making structure that this thesis describes as the HFE Act 1990 framework.

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[5] Fink, Simon, "Politics as Usual or Bringing Religion Back In?" *Comparative Political Studies* 41, no. 12 (December 2008), 1631–1656.
[6] Sheingate, Adam, "Promotion Versus Precaution: The Evolution of Biotechnology Policy in the United States," *British Journal of Political Science* 36 (2006), 243–268; Smith, Alexander, "Faith, Science and the Political Imagination: Moderate Republicans and the Politics of Embryonic Stem Cell Research," *The Sociological Review* 58, no. 4 (2010), 624–638.
[7] US House of Representatives, "Report of the Committee on Appropriations: Departments of Labor, Health and Human Services, and Education, and Related Agencies Appropriations Bill, 1996," (Government Printing Office, 1995), 213-214.
[8] UK Parliament, *Human Fertilisation and Embryology Act 1990*, (London: HMSO).

In the case of both GMOs and stem cell research, institutional dimensions provide a critical link missing from other narratives. Therefore, rather than reject explanations based on public opinion or interest groups, this study aims to augment them by providing an account of first-generation policies that describes how factors fit together in shaping the outcome, during both the policy design and execution phases.

The analytical framework which follows this section describes the theoretical aims of this study in greater detail. Operationalizing the puzzle of policy variation, the research looks primarily to the political science literature on institutional analysis to address the question of how institutions shaped policy outcomes. The analysis proposes that path dependence, Pierson's criteria for increasing returns, and a distinct method of extending the analysis in a so-called secondary test of path dependence provide a superior answer. The chapter also draws from the literatures on bureaucracy and regulation, offering two propositions in response to the question of how far one can characterize bureaucratic behavior and whether interest groups capture regulation. Furthermore, the framework briefly explains how theoretical insights will apply in empirical chapters.

Chapter Two engages the question of case selection and seeks to justify the choice of GMOs and stem cell research based on the varying policies in approximately 23 countries worldwide. The chapter defines "permissive" and "restrictive" policies, and proposes research methods to explain variation, including the use of Small-N case studies and process tracing, to recount the biography of key policy documents in the context of at least two technologies and two countries. Chapter Two also explains why the methods selected represent a relevant approach for making the theoretical propositions listed in the previous chapter. Lastly, the chapter explains why the United Kingdom and the United States represent suitable jurisdictions for detailed study.

In Chapter Three, the study describes policymaking activities in the first of four case studies: genetically modified organisms in the United States. Beginning with the early response to rDNA technology, the discussion outlines the development of the Coordinated Framework inside the Reagan White House, and the policies crafted subsequently by the US Department of Agriculture (USDA), Food and Drug Administration (FDA) and Environmental Protection Agency (EPA). The chapter concludes with a lengthy theoretical analysis of institutional influences vis-à-vis other factors.

Chapter Four, on GMOs in the European Union and the United Kingdom, traces the development of the policy that took shape in Britain, i.e. with oversight shared between Brussels and Whitehall. The chapter describes early regulatory activity by the United Kingdom, and then the European-led system which superseded it. Following the passage of Directives 90/219 and 90/220 and their implementation by the European Commission and UK Health and Safety Executive (HSE), Department of the Environment (DOE), and Ministry of Agriculture, Fisheries and Food (MAFF), officials would make numerous revisions to the system in the years ahead.[9] The chapter concludes with a lengthy theoretical analysis of institutional influences vis-à-vis other factors.

In Chapter Five, the study recounts Britain's first-generation policy for human embryonic stem cell research, beginning with policymaking efforts for embryo research, which pre-dated stem cell research but nevertheless shaped the policy path for the technology. After describing the effort to pass the *Human Fertilisation and Embryology Act 1990*, the chapter recounts the government's successful bid to extend the act—and

[9] EU Council, *Council Directive 90/219/EEC of 23 April 1990 on the contained use of genetically modified micro-organisms*; EU Council, *Council Directive 90/220/EEC of 23 April 1990 on the deliberate release into the environment of genetically modified organisms*.

HFEA oversight—to cover stem cell research in 2001. The chapter concludes with a lengthy theoretical analysis of institutional influences vis-à-vis other factors.

Chapter Six, on stem cell research in the United States, illustrates the early activities relating to the federal funding of embryo research and the successful passage of the Dickey Amendment to the budget in 1996. The discussion then outlines efforts by Clinton Administration officials to navigate around this legislative impediment later in the decade; and finally, it describes the subsequent effort by Bush and aides to craft the nation's first-generation policy according to the President's preferences. The chapter concludes with a lengthy theoretical analysis of institutional influences vis-à-vis other factors.

Chapter Seven, the Conclusion and Epilogue, highlights the study's key empirical findings, and outlines strategies for verifying them through systematic falsification. The chapter also reviews theoretical propositions offered in Chapter One, and critically discusses their relevance in light of Chapters Three through Six. Finally, the chapter outlines policymaking activities for each case in the years after the first-generation policies, engaging the question of how well the empirical and theoretical findings presented in this study stand up in light of later events.

ANALYTICAL FRAMEWORK

The Introduction highlighted the underlying puzzle of this study and asked why first-generation policies for biotechnology in the United Kingdom and the United States varied. However, embedded in this question is another: How did individual policies unfold? Indeed, before explaining policy differences one must understand policy development. This study aims to address both questions, and the following analytical framework describes the points of theory applied and proposed in the process.

In the thesis that follows, a country's "policy" refers to the practical application of its regulatory standards, or the goals and targets established to govern the processes and products of biotechnology.[10] Chapters Three through Six recount the biography of key policy documents containing these standards. However, since this study is concerned not only with what was enshrined in legal or other agreements but with what occurred in practice, the research describes policies in terms of the general pattern of regulatory outcomes. Chapter Two provides coding details for "permissive" and "restrictive" policy outcomes and defines the term "first-generation policy."

The "institutions" described earlier as the potentially critical factors shaping outcomes are the regulatory standard-setting institutions for biotechnology, and they refer generally to the agencies, laws and other instruments of government specifically applied to design and execute policies. Within the context of this study, the following

[10] Hood, Christopher, Rothstein, Henry, and Baldwin, Robert, *The Government of Risk: Understanding Risk Regulation Regimes* (Oxford University Press, 2001), 21; for further discussion of regulatory standard-setting, see Scott, Colin, "Standard-Setting in Regulatory Regimes," in *The Oxford Handbook of Regulation* (Oxford: Oxford University Press, 2010), 104-119.

discussion describes these institutions as "decision-making structures" and delineates their comparative context in the UK and US.[11]

Given this study's concern with understanding the effect of institutions on policy outcomes, the following framework will look to theoretical literatures which provide the "inside" view of government through rigorous examination of the policymaking process. It will draw mostly from institutional analysis, but also from bureaucracy and regulation. Together, these literatures highlight important institutional dimensions whilst addressing the central questions of biotechnology policy development and variation.

However, other fields address issues in biotechnology governance as well. One of the most prominent is the literature expressly concerned with the political dimensions of science: science policy studies and related disciplines. The following paragraphs discuss science policy in greater detail and explain why this study will not explore it further.

1.1 Science Policy Studies

Drawing on research from diverse fields and yielding both normative and positivist works, scholarship in science policy shares a topical consistency in its concern for scientifically themed political phenomena. Indeed, science policy and related fields often take the point further by implying that the politics of science differs so

[11] To the extent that this study addresses regulatory-standard setting, one could technically apply the term "regulatory regime" to the institutions and outcomes of biotechnology policymaking. However, the research does not explore in detail the other two functions associated with the regime approach: monitoring and enforcement. See Hood, Christopher, Rothstein, Henry, and Baldwin, Robert, *The Government of Risk: Understanding Risk Regulation Regimes*. Section 1.4 below addresses regulation issues in greater detail.

significantly from other areas of politics that it requires a separate field of study. However, it is not clear that this distinction is justified.

In its original sense, science policy refers to a government's strategy for addressing scientific and technological enterprise. Until the mid-20th Century scholars generally produced normative analyses of the situational dilemmas of contemporaneous policymaking, including questions of the distribution of resources and the social implications of scientific outputs. However, beginning in the 1960s, many theorists began to challenge the consensus view of scientists as benevolent producers of social and economic goods, and questioned the system which gave practitioners funding and relative autonomy but yielded morally questionable outputs such as the atom bomb.[12]

In one key text from this period, political scientist Don Price questioned whether scientists were democratically accountable, and questioned how the worlds of science and politics should coexist.[13] However, although Price successfully pinpointed the tension between science and politics—writing in his seminal work *The Scientific Estate* that "Science has turned loose technological forces in society which we have not yet learned to control in a responsible manner"—Price provided minimal direction for expanding on the interplay and urged readers to adapt to life within the scientific estate.[14]

Tensions identified in *The Scientific Estate* became more acute in later decades, particularly in response to growing environmental awareness, concerns about industrial pollution and a range of controversial innovations, from nuclear power to genetic

[12] Kleinman, Daniel, *Politics on the Endless Frontier: Postwar Research Policy in the United States* (Durham, N.C.: Duke University Press, 1995).
[13] Price, Don K., *The Scientific Estate* (Cambridge, Mass.: Belknap Press of the Harvard University Press, 1965).
[14] Ibid, 278.

engineering.[15] Moving into the 21st Century, the problematic relationship between science and the state would drive the further development of new theory, including analyses from the interdisciplinary field of science and technology studies (STS), which traced the effect of cultural, political and economic forces on science and technology, and *vice versa*.[16] Along these lines, STS viewed science policy outputs as the result of culturally embedded activities.

This emphasis on culture permeates the comprehensive treatise on biotechnology by STS scholar Sheila Jasanoff, *Designs on Nature*.[17] Performing a "multi-sighted ethnography" of green and red biotechnology policies, Jasanoff attempts to show that biotechnology policymaking underscores a wider global shift toward the creation of "knowledge societies;" that questions of nationhood critically shaped outcomes; and lastly, that policy outcomes reflected distinct "civic epistemologies" or "culturally specific ways of knowing."[18]

Although Jasanoff mostly avoided discussions of direct causality, the book arguably pointed to culture as the dominant variable driving policy outcomes. While one could operationalize cultural variables in multiple ways, perhaps the most straight-forward treats public opinion as a reflection of culture, impacting decisions made by government officials and other political actors. Other scholars have embraced this approach, including political scientist Lianchao Han, who argues that decisions on

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[15] Carson, Rachel, *Silent Spring* (Boston, Mass.: Houghton Mifflin, 1962); Fukuyama, Francis, *Our Posthuman Future: Consequences of the Biotechnology Revolution*, London: Profile Books Ltd, 2002

[16] Sarewitz, Daniel, *Frontiers of Illusion: Science, Technology and the Politics of Progress*, (Philadelphia, Penn.: Temple University Press, 1996); Guston, David, *Between Politics and Science: Assuring the Integrity and Productivity of Research*, (Cambridge: Cambridge University Press, 2000); Sarewitz, Daniel, and Pielke, Roger, "The Neglected Heart of Science Policy: Reconciling Supply of and Demand for Science," *Environmental Science and Policy*, vol. 10, no. 1, Feb. 2007, 5-16; for an overview of key issues, including use of scientific knowledge in decision-making, see Jasanoff, Sheila, Markle, Gerald, Petersen, James and Pinch, Trevor, *Handbook of Science and Technology Studies* (Thousand Oaks, Calif.: Sage, 1995).

[17] Jasanoff, Sheila, *Designs on Nature: Science and Democracy in Europe and the United States*, (Princeton, N.J.: Princeton University Press, 2005).

[18] Ibid, 6-9, 39.

GMOs in the US and EU reflected public opinion as operationalized in officials' decision-making.[19] The emphasis on cultural influences, such as public opinion, informs this study of biotechnology policy variation by prompting a discussion of comparative factors, which Chapters Three through Six feature in detail.

Beyond the discussion of causal factors, however, this study gleans few insights from the field of science policy studies. Returning to the opening question in this section, whether the politics of science differs enough from other political phenomena to justify a separate field, numerous problems emerge. Given that "science and technology" in the abstract includes a range of activities, from laboratory practices to commercial products to large-scale weapons systems, one could fairly challenge science policy as an effective category for analysis, and dispute claims that the politics of science is *a priori* different from other types of politics.

Moreover, even if one acknowledges the field's distinctiveness, this study will turn away from science policy studies for a further reason: Works in this field do not focus expressly on activities inside political institutions but rather on the relationship between science and politics, or between science and society more generally. While scholars specifically concerned with this interrelationship can justify work within the science policy subfield, those focused on gaining an inside view of government institutions must look to literatures specifically targeting these elements.

1.2 Institutional Analysis

Whereas science policy focused on the nexus between science and politics, institutional analysis seeks to understand the role that institutions play in political phenomena.

[19] Han, Lianchao, Thesis: "The New Food Pyramid: Culture, Policy and Technology in the Transatlantic GMO Controversy," (George Mason University, 2005).

Because this study aims to explain variation in biotechnology policies in a way that highlights the influence of existing oversight institutions, institutional analysis holds important implications, including the potential to describe causal mechanisms leading to permissive or restrictive policies in the UK and US. To bring these into clearer view, the following section will review key dimensions of the institutional literature seeking to answer the question of how institutions shape policy outcomes.

Institutionalism and Behavioralism

Theorists have debated the role of institutions in political life for over a century, and consequently, institutional analyses reflect a variety of approaches. Theorists James March and Johan Olsen famously dated the discourse from the so-called "old institutionalists," including political scientists Woodrow Wilson, John Burgess and Westel Willoughby, who from the late 19th Century addressed the formal features of government and politics in order to explain resulting social and political phenomena.[20] These scholars generally attributed significant—and in some cases, overarching—agency to institutions, and as a result many works in this category held prescriptive implications. However, by the mid-20th Century, the belief that institutional design linked directly with outcomes had diminished considerably, perhaps as a result of the institutional failures associated with the causes of World War II, as political scientist Sven Steinmo suggested in the example of the Weimar Republic.[21]

Many social scientists in this period began to turn away from institutions and infused their research with ambitious new methodologies that looked to quantitative data to understand political behavior. Indeed, works by political scientists Charles

[20] March, James, and Olsen, Johan, "The New Institutionalism: Organizational Factors in Political Life," *American Political Science Review*, vol. 78, no. 3, Sept. 1984, 734-749.
[21] Steinmo, Sven, "What Is Historical Institutionalism?" in *Approaches in the Social Sciences*, (Cambridge: Cambridge University Press, 2008), 119.

Merriam, David Easton and others sought to explain politics and government in terms of general propositions about human motivation.[22] These so-called behavioralists utilized a wide range of analytical strategies to explain outcomes, including placing a critical emphasis on factors such as income, class, geography, culture and ethnicity. In this way, institutions seemed to matter much less.

New Institutionalism

Whereas "old institutionalists" placed primary emphasis on institutions, behavioralists strongly de-emphasized them, and in doing so arguably led a subsequent generation of scholars to return the state and its institutions to prominence. From the 1970s these early practitioners of "new institutionalism" included political scientists such as Eric Nordlinger and Stephen Krasner, who asserted that state structures in fact possessed a degree of autonomy in shaping decisions, and could have an agenda apart from the will of powerful interests.[23] Whereas Nordlinger described state autonomy as following from the actions of self-interested individuals within government, Krasner characterized state power as reflecting a coherent national interest in foreign policy.

Other theorists, such as political scientist Theda Skocpol, emphatically sought to "bring the state back in" to the discussion, but these early descriptions carefully balanced institutional factors with other ones.[24] In one cogent example, political scientists James March and Johan Olsen sought to accommodate both "reductionist" theories about the aggregated conduct of rational actors, and "contextualist" approaches

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[22] Ibid, 119-122.
[23] Krasner, Stephen, *Defending the National Interest: Raw Materials Investments and U.S. Foreign Policy* (Princeton, N.J.: Princeton University Press, 1978); Nordlinger, Eric, *On the Autonomy of the Democratic State* (Cambridge, Mass.: Harvard University Press, 1981).
[24] Evans, Peter, Rueschemeyer, Dietrich, Skocpol, Theda, Editors, *Bringing the State Back in* (Cambridge: Cambridge University Press, 1985).

that viewed political events as products of wider historical circumstances.[25] The final result is an approach that emphasizes institutions as well as the actors all around them.

Three Institutionalisms

After so-called new institutionalists had refocused attention on state institutions, many unanswered questions still remained, particularly regarding how institutions shaped outcomes, how much and when. As theorists addressed these areas in subsequent years, three distinct schools of institutionalism emerged: historical, rational choice and sociological.[26] Whereas historical institutionalism looked to temporal issues, such as the timing of key events, to explain political phenomena, rational choice institutionalism generally addressed the decision-making of rational actors maximizing their utility within set institutional constraints. Lastly, sociological institutionalism described how organizational culture and rules impacted political behavior. These distinctions provided useful markers for future scholarship, although political scientist Sven Steinmo described the categories as fluid, placing historical institutionalism between the two others because it not only emphasized contexts but allowed for self-interested individuals and rule-abiding behavior.[27]

Historical Institutionalism

Although rational choice and sociological institutionalism undoubtedly provide insights into biotechnology policymaking, historical institutionalism offers the superior analytical frame because the biotechnology cases in this study developed over time—

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[25] March and Olsen, "The New Institutionalism: Organizational Factors in Political Life," 738.
[26] Hall, Peter A., and Taylor, Rosemary C.R., "Political Science and the Three New Institutionalisms," *Political Studies*, vol. 44, no. 5, Dec. 1996, 936-57.
[27] Steinmo, Sven, "What Is Historical Institutionalism?" in *Approaches in the Social Sciences*, (Cambridge: Cambridge University Press, 2008).

rather than in response to a distinct actor or organizational arrangement—and because of the importance of historical events. Moreover, historical institutionalism's broad definition of institutions is particularly relevant to the diverse regulatory standard setting institutions involved in designing and executing biotechnology policies. Indeed, historical institutionalists defined institutions as formal organizations as well as informal rules, believing that both contained the implications of temporal processes embedded within them.[28]

Created through historical processes, institutions can structure subsequent political activity by constraining or enabling the behavior of various actors and interests. According to Peter Hall, "organizational factors affect both the degree of pressure an actor can bring to bear on policy and the likely direction of that pressure."[29] However, even as institutionalists made a strong case for organizational factors, they were careful not to overstate their impact: "Institutions constrain and refract politics but they are never the sole 'cause' of outcomes."[30] In other words, institutional agency was not limitless. Institutions did not act alone.

Path Dependence

As the historical institutionalist school took shape, scholars sought to develop the mechanisms by which temporal factors impacted social phenomena. The concept of path dependence was one popular example. Although applied in various fields,

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[28] Thelen, Kathleen, and Steinmo, Sven, "Historical Institutionalism in Comparative Politics," from Steinmo S., Thelen, K. and Longstreth, F., editors, *Structuring Politics: Historical Institutionalism in Comparative Analysis* (Cambridge: Cambridge University Press, 1992), 1-2; Paul Pierson, "Increasing Returns, Path Dependence, and the Study of Politics," *American Political Science Review* 94, no. 2 (June 2000), 265.

[29] Hall, Peter, *Governing the Economy: The Politics of State Intervention in Britain and France* (Oxford: Oxford University Press, 1986), 19.

[30] Thelen, Kathleen, and Steinmo, Sven, "Historical Institutionalism in Comparative Politics," in *Structuring Politics: Historical Institutionalism in Comparative Analysis* (Cambridge: Cambridge University Press, 1992), 3.

including economics and sociology, political scientists from the 1990s increasingly cited the concept as a means of explaining how earlier events shape later ones. According to theorists, such as Paul Pierson, path dependent analyses have the potential to move beyond explanations based solely on current circumstances, and instead reveal prior developments and circumstances as potential factors.[31] Path dependence also counters so-called functionalist arguments which view outcomes simply in terms of the function they serve rather than as arising from other—and potentially unintended—consequences, wrote Pierson.[32]

However, few works provided systematic discussions of the concept. In one notable exception, Ruth and David Collier described "critical junctures" in time, with their associated mechanisms of production and reproduction, to explain variation in the politics of labor movements in Latin America.[33] These placed great significance on large events occurring early in a process.

Given the importance of historical developments in biotechnology policymaking as described in the Introduction, the constraining nature of early decisions and the importance of temporal ordering, this study proposes path dependence as a conceptual strategy that can describe how policies developed and began to diverge. Indeed, if applied coherently in each of the four cases—GMOs and stem cell research in the UK and US—path dependence holds the potential to show how early institutional contexts shaped outcomes. Moreover, such a finding would give considerable weight to explanations of policy variation that point to institutional variables.

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[31] Paul Pierson, "Increasing Returns, Path Dependence, and the Study of Politics," 263.
[32] Ibid.
[33] Collier, Ruth Berins, and Collier, David, *Shaping the Political Arena: Critical Junctures, The Labor Movement, and Regime Dynamics in Latin America* (Princeton, N.J.: Princeton University Press, 1991), 29-30.

But how can one apply path dependence to our cases? While Collier and Collier provide a relevant conceptual strategy for understanding institutional influences, their approach creates some difficulties. For example, although large events, such as the BSE crisis, significantly impacted the UK-EU policy for genetically modified food, it was incidental to the main policymaking story. Moreover, unlike Collier and Collier's approach, small developments often mattered too, such as when an obscure rider to the 1996 budget known as the Dickey Amendment played a critical role in shaping the subsequent US policy for stem cell research.[34]

Pierson's Criteria

In seeking a conceptualization of path dependence that accounts for large, small and seemingly unrelated events, this study looks to Pierson. In contrast with Collier and Collier, Pierson noted that a range of events can have a major impact on historical processes.[35] In one of the most systematic and replicable accounts of the concept, Pierson described path dependence as a process of "increasing returns," in which preceding steps in a particular direction have a self-reinforcing effect or positive feedback.[36] He described four features likely to exist in settings marked by increasing returns processes:

[34] For more information relating to the Dickey Amendment, see Chapter Six.
[35] Paul Pierson, "Increasing Returns, Path Dependence, and the Study of Politics," *American Political Science Review* 94, no. 2 (June 2000), 263.
[36] Ibid, 252.

Multiple equilibria –Under a set of initial conditions conducive to increasing returns, a number of outcomes—perhaps a wide range—are generally possible.

Contingency—Relatively small events, if they occur at the right moment, can have large and enduring consequences.

A critical role for timing and sequencing—In increasing returns processes, *when* an event occurs may be crucial. Because earlier parts of a sequence matter much more than later parts, an event that happens "too late" may have no effect, although it might have been of great consequence if the timing had been different.

Inertia—Once an increasing returns process is established, positive feedback may lead to a single equilibrium. This equilibrium will in turn be resistant to change.[37]

According to Pierson these features —multiple equilibria, contingency, timing and sequencing and inertia—signal increasing returns because, taken together they describe the self-reinforcing effect of early decisions and subsequent events and choices. Moreover, if identified successfully in historical cases, these features can reveal the early institutional arrangements that drive policy development later, and in doing so reveal the influence of institutions themselves. Furthermore, when compared with other cases that utilize this analytic approach, results can potentially identify where policies diverged.

Pierson's features present an opportunity for understanding path dependence in biotechnology policymaking for multiple reasons. First, they provide a clear and replicable approach that can be applied to historical cases. Second, because the features account for large, small and seemingly unrelated events, they arguably could apply to cases of biotechnology policymaking with similar trajectories. Indeed, as the Introduction made clear, cases for GMOs and stem cell research in the UK and US reflect the influence of a wide range of events and developments, from the widely felt repercussions of the BSE crisis to the nearly unpublicized passage of the Dickey Amendment.

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[37] Ibid, 263.

Using these four features as criteria, this study proposes to apply Pierson's concepts to biotechnology cases in order to reveal whether and how institutions shaped policy development, and where policies diverged. But how should one apply Pierson's criteria? Attempting to compose empirical chapters as an explicit search for the criteria could overlook other important variables and create systemic biases in favor of Pierson's approach. Therefore, the study proposes to trace the process of decision-making for first-generation policies in a historical review of design and execution phases, and then to apply Pierson's criteria subsequently.[38] In this way, coherent examples would signal increasing returns.

What do the findings in this study show with regard to Pierson's criteria? The detailed process tracing and theoretical discussion in empirical Chapters Three through Six seek to answer this question. Indeed, based on the evidence and analysis presented, the study proposes that in each case multiple equilibria existed; that contingent events critically impacted later developments; that timing and sequencing were essential; and that once policies started along a certain path the cost of reversal increased significantly. In other words, these biotechnology policymaking cases contained Pierson's features and therefore reflect increasing returns.

Criticism of Path Dependence

Analyses of path dependence have faced considerable criticism over the years from political scientists, including Giovanni Capoccia and Daniel Kelemen, who argued that theorists often pay too little attention to the critical junctures at the origin of the policy path.[39] Others, such as James Mahoney and Kathleen Thelen described path dependence

[38] Chapter Two discusses process tracing and other methodological concerns in greater detail.
[39] Capoccia, Giovanni, and Kelemen, R. Daniel, "The Study of Critical Junctures: Theory, Narrative, and Counterfactuals in Historical Institutionalism," *World Politics* 59, April (2007): 341–69.

as only applicable in rare examples of institutional change.[40] Still other critics describe path dependence as overly broad, and advancing the unsurprising notion that history matters.[41]

While this study does not claim to defend path dependence from all criticism, it nevertheless upholds the concept as a reasonable mechanism for expanding social science knowledge. Regarding path origins, the fact that cases in this study possessed short time frames of 10 to 20 years means that in each case policymaking occurred in discrete periods, with starting points marked by an identifiable critical mass of activity. On the question of the applicability, this study embraces the expansive view of Pierson, who said path dependence applies to situations in which time itself helps to explain political phenomena.[42] Moreover, other institutional works have emphasized the importance of asking "big questions," in order to test existing theories and explore new theoretical ground.[43] Although first generation policies in each case represent a shorter time frame than other historical developments, e.g., the evolution of the UK House of Lords, variation in biotechnology policies is arguably a big question that warrants detailed analysis of historical processes shaping outcomes. This study embraces the conceptual mechanism of path dependence in this light.

Path Dependence and Biotechnology Policy Outcomes

Despite criticisms of path dependence, a number of works have already weighed in on the debate, and applied the concept to cases on genetically modified organisms and

[40] Mahoney, James, and Thelen, Kathleen, *Explaining Institutional Change: Ambiguity, Agency and Power*, (Cambridge: Cambridge University Press, 2010), 3.
[41] Page, Scott, "Path Dependence," *Quarterly Journal of Political Science* 1 (2006), 87–115.
[42] Pierson, Paul, *Politics in Time: History, Institutions and Social Analysis*, (Princeton and Oxford: Princeton University Press, 2004).
[43] Steinmo, Sven, "What Is Historical Institutionalism?" In Della Porta, Donatella, and Keating, Michael, *Approaches in the Social Sciences*, (Cambridge: Cambridge University Press, 2008), 134; Pierson, Paul, and Skocpol, Theda, "Historical Institutionalism in Contemporary Political Science," in *Political Science: State of the Discipline*, (New York: Norton, 2002), 696.

embryonic stem cell research. Political scientist Thomas Banchoff utilized path dependence to explain Britain and Germany's diverging policies for human embryonic stem cell research.[44] In articulating the path dependent processes in these cases, Banchoff described three causal pathways in which institutional legacies affected outcomes: the constellation of actors, balance of interests and the terms of legislative debate.[45] In the UK, centralized institutions empowered Prime Minister Tony Blair, mobilized pro-research factions against comparatively weaker pro-life advocates and guided debates in Parliament toward the incremental step of extending the HFE Act 1990, leading to a permissive outcome.[46] In contrast, in Germany, decentralized political institutions empowered the Bundestag and a key parliamentary committee, undermined the development of pro-research interest groups and bolstered the validity of arguments about human dignity, leading to a restrictive outcome.[47]

These causal pathways represent a critical step forward for analyses of path dependence in stem cell policies. However, the analysis does not include genetically modified food, and Banchoff notes that the framework would not extend to the US. Furthermore, although Banchoff describes how institutions shaped permissive and restrictive policies, the approach accounts for variation only by providing respective historical narratives, rather than categories that scholars can explicitly compare.

Whereas Banchoff looked to path dependence to explain policies for stem cell research, political scientist Mark Pollack and legal scholar Gregory Shaffer utilized the concept—and some of Pierson's features—to account for varying policies for

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[44] Banchoff, Thomas, "Path Dependence and Value-Driven Issues: The Comparative Politics of Stem Cell Research," *World Politics* 57, no.2 (January 2005), 200-230.
[45] Ibid, 207.
[46] Ibid, 211-219.
[47] Ibid, 219-226.

genetically-modified food in the EU and US.[48] Rather than describe institutions as the single determinant of policy outcomes, they argued for a more subtle interplay between variables, explaining the cause of polarized policies as a combination of interest groups, institutions, ideas and contingent events.

While the United States possessed biotechnology-supporting producers and product-based regulation of risk, the EU case included skeptical farmers and retailers, a decentralized regulatory structure and contingent events, such as the BSE crisis, the authors said. After reviewing key historical episodes, Pollack and Shaffer evoked path dependence to explain the resilience of each policy regime, utilizing numerous concepts cited by Paul Pierson, including contingent events, inertia and timing and sequencing.[49]

Describing events in this way, Pollack and Shaffer provide a convincing account of policymaking for GMOs. However, their coherent discussion of path dependence is relatively limited, and they do not provide a full application and elaboration of Pierson's criteria. Also, like Banchoff, their use of path dependence to explain both permissive and restrictive policies leaves us with an account of variation made solely in terms of the narrative history of each case. The authors can show where policies diverged, but not specifically why or how they differed, or by how much.

Works by Banchoff and Pollack and Shaffer create a distinct opening for this study, which seeks to apply path dependence to both technologies in both countries—and to do so within a single framework. Indeed, this research will provide a comprehensive application and elaboration of Pierson's criteria, which arguably do not currently exist for either technology.

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[48]Mark A. Pollack and Shaffer, Gregory C., *When Cooperation Fails: The International Law and Politics of Genetically Modified Foods* (Oxford: Oxford University Press, 2009).
[49] Ibid, 75-77.

Furthermore, since both Banchoff and Pollack and Shaffer explain permissive and restrictive outcomes in terms of narrative histories, the result in each case is an account of path dependence that is difficult to verify, and therefore open to the criticism of the approach as overly broad. On this basis, further scholarship could seek to extend the analysis to provide specific details of institutional differences that scholars can assess comparatively.

Extending Path Dependence

Although the comprehensive application and elaboration of Pierson's criteria proposed earlier can provide new details of institutional influences in biotechnology policymaking, such an approach arguably leaves some questions about variation unanswered. The criteria successfully reveal the contours of policy development in each case; and in comparative analysis they can show where policies diverged. However, like the discussion of Banchoff and Pollack and Shaffer suggests, scholars must explain any differences in cases in terms of their narrative histories, rather than in specific terms that can be assessed comparatively. Pierson's criteria can show us where policies varied, but they do not tell us exactly how or why.

In order to complete the explanation of variation we arguably need more information about policy differences. To obtain this, the study will look to the implications of diverging policies by analyzing the institutional paths taken in each case to establish whether a more precise explanation for variation exists. In doing so, the study can provide a more complete answer to the question of variation in biotechnology policies, and in the process address the aforementioned characterization of path dependence as overly broad.

To achieve these goals, the study proposes a "secondary test of path dependence," which will analyze aspects of the policy path in each case for the purpose of comparative assessment. This concept, which is intended to complement findings relating to Pierson's criteria, will be described in greater detail in the following pages. Note that the study does not propose this as a formal test, but rather as a strategy for identifying the institutional variable in each case. Under these circumstances, further empirical verification could occur later.

Decision-Making Structures

To delineate the secondary test of path dependence the study looks to Pierson's criteria, the first of which, multiple equilibria, states that in path dependent processes, numerous potential pathways exist from a single starting point. Because the early decision of an institutional framework set the subsequent process in motion, this study proposes to pursue this initial path—as the chosen equilibrium—for further assessment. To do so, it will analyze the regulatory standard-setting institutions, or the agencies, laws and other instruments of government used to design and execute policies for GMOs and stem cell research, in order to determine if measurable differences between them existed.

This study proposes to describe these institutions as "decision-making structures," defined generally as government regulatory mandates enshrined in a formal or informal institutional agreement. Although the political venue differed in each case, decision-making structures each had primary responsibility for designing and executing policies. The decision-making structures included, for GMOs, the Coordinated Framework in the US and the EU-UK legislative framework, and for stem cell research, the HFE Act 1990 framework in the UK and the US Bush framework.

If a study aims to create a secondary test of path dependence on this basis, one could fairly ask why Pierson's criteria were applied earlier. However, as stated above, the criteria describe the contours of policy development, and in doing so tell us where policies diverged. Moreover, attempts to bypass the criteria and proceed directly to analysis of institutions could lead to a skewed or improper selection based either on current circumstances or the perceived "function" of various institutions. In this way, the study views the secondary test as complementary to Pierson.

Given the importance placed on decision-making structures as the analytical bases for the proposed secondary test of path dependence, this study turns to the inherent qualities which may allow for the detailed analysis proposed earlier. Principally, in each of the four cases in this study, decision-making structures directly or indirectly involved bureaucratic officials. Some decision-making structures were staffed (in whole or part) by bureaucratic officials, whereas others liaised with them. In this way, bureaucratic behavior or activity may have played an important role in their emergence and functioning. To learn more about this dimension of decision-making structures, we turn to the political science literature on bureaucracy and public administration.

1.3 Bureaucracy

The literature on institutional analysis yielded this study's strategy for addressing the puzzle of policy variation—and proposed to apply Pierson's criteria and a secondary test of path dependence to assess the influence of institutions. However, because decision-making structures often contained bureaucratic dimensions directly or indirectly, writings on bureaucracy provide insights that can help inform the secondary test of path dependence. In order to grasp the role that bureaucratic politics played in

policymaking for biotechnology, the following section will briefly review the field of bureaucracy and public administration seeking to answer whether we can effectively characterize bureaucratic behavior.

Characterizing Bureaucratic Behavior

The nature of bureaucracies—both bureaucrats and the offices they hold—has perplexed theorists since political scientist Woodrow Wilson, in some of the earliest scholarly writings on the subject in the late 19th Century, described public administration as a rational and efficient instrument of government power. Although theorists in other fields would extend and modify this conventional view of bureaucracy in the following decades—including sociologist Max Weber in his landmark writings—political scientists developed theories of bureaucracy more slowly, embracing the field from the middle decades of the 20th Century.

One prominent contribution came from political scientist Anthony Downs, who produced a detailed typology of bureaucratic archetypes in his book *Inside Bureaucracy*.[50] Published in 1966, the book upended conventional wisdom by describing a new series of behavior patterns that defied previous accounts. According to the typology, Downs classified behaviors in two general categories: purely self-interested, and those with a mixture of motives. Among the self-interested, Downs described two basic types: "climbers," or officials seeking to maximize personal income, power or prestige; and "conservers," who seek security and convenience. So-called "mixed-motive" officials have variously defined loyalties to the public interest that differ considerably in practice. "Zealots" focus intensely on single policy goals within the organization often to the exclusion of other policies, duties and concerns;

[50] Downs, Anthony, *Inside Bureaucracy* (Boston, Mass.: Little, Brown & Company, Ltd., 1967).

"statesmen" pursue broad-minded public interest goals which undercut their own loyalties to their particular bureau and potentially threaten their advancement; finally, the most common type, "advocates," seek to promote the range of policies and interests of the office that they hold, including those of officials under their supervision.

Downs' colorful and wide-ranging view of bureaucratic behavior provides a useful starting point for studies seeking to describe activities within organizations. His work informs the study of policy variation by encouraging scholars to assess the dynamics at play among both regulators crafting government policies and those who seek to have the privilege. Applying Downs, we see the potential for bureaucratic players in both the US and UK to engage in the range of behaviors at multiple levels in search of relative power and budgetary windfalls for themselves and their home agencies.

However, whereas Downs focused on understanding the behavior of individual bureaucrats, other scholars emphasized the need to explain the collective effect of individuals within bureaucracies. Where did it lead? Subsequent theorists would describe these aggregated activities as having an enormous impact on political behavior. In 1971, economist William Niskanen provided a dynamic illustration of the bureau, and the incentive structure for those who worked within it, in *Bureaucracy and Representative Government*.[51] According to Niskanen, bureaucrats seek to maximize the budgets of their respective administrative divisions in order to increase their overall power.

Niskanen's "budget-maximizing" model significantly influenced discussions of bureaucratic behavior, and in the years that followed other scholars attempted to extend

[51] Niskanen, William, *Bureaucracy and Representative Government* (Chicago: Aldine Publishing Company, 1974).

and modify it. This included political scientist Patrick Dunleavy, whose book *Democracy, Bureaucracy and Public Choice* responded to Niskanen by describing a "bureau-shaping" model in which bureaucrats modified their own divisions to provide the most advantageous working conditions, not simply the largest budgets.[52]

Like Downs' typology, Niskanen and Dunleavy offer useful insights to the study of biotechnology policy variation to the extent that they articulated direct budget-maximizing and bureau-shaping behaviors. One possible implication for biotechnology policies is that these behaviors significantly shaped outcomes in Britain and the US.

A Limited Bureaucratic Theory

Alongside these numerous insights into bureaucratic behavior, the literature contains many works by scholars who warned against making overly broad generalizations about bureaucrats and the offices that they hold. Indeed, rather than describe the ways in which bureaucrats achieved their goals, political scientist Christopher Hood addressed why they often failed to attain them, showing that increases in resources did not translate automatically to commensurate gains in political outputs.[53] In *The Limits of Administration*, Hood described a model of "perfect administration" and then revealed the range of problems which prevented it from being realized, including challenges of coordination, categorization and control.[54] In keeping with this less sweeping depiction of bureaucratic behavior, Hood subsequently described the affirmative activities of

[52] Dunleavy, Patrick, *Democracy, Bureaucracy and Public Choice: Economic Explanations in Political Science* (Harlow: Prentice Hall, 1991).
[53] Hood, Christopher, *The Limits of Administration* (London: Wiley, 1976).
[54] Wilson, H.T., "Review of Andrew Dunsire 'The Executive Process,' Vol. 1," *Canadian Journal of Political Science* 12, no. 3 (September 1979), 654–657.

government as "tools," rather than the more wide-ranging categories of policymaking efforts or issue-areas.[55]

Along these lines, political scientist James Q. Wilson also doubted the value of grand theories of bureaucracy, explaining in a book of the same name that many generalizations failed to hold in particular cases. Instead, Wilson emphasized the varieties of bureaucracies and bureaucratic behaviors that existed.[56] Rejecting the notion that all bureaucrats sought to maximize their authority or wealth, Wilson noted that some bureaucrats actually resisted certain gains for strategic reasons.[57]

Given the limits of our knowledge of bureaucracy and public administration, this study proposes to characterize bureaucratic behavior only to a degree. Therefore, rather than looking for evidence of a sweeping paradigm in the activities of decision-making structures for biotechnology, it instead highlights two relevant features that potentially influenced outcomes: the appearance of civil servants with a range of unique preferences, and the shifts in policymaking focus away from direct partisan politics that can occur as a result of their emergence. In addition to explaining variation in position issues, such an approach could weigh in on more recent claims about bureaucratic behavior by theorists, such as political scientist Moshe Maor, who has asserted that regulatory institutions claim jurisdiction over emerging technologies when their reputations are at stake, looking to the case of the US Food and Drug Administration.[58]

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[55] Hood, Christopher, *The Tools of Government* (London and Basingstoke: The Macmillan Press Ltd., 1983).
[56] Wilson, James Q., *Bureaucracy: What Governments Do And Why They Do It* (New York: Basic Books, Inc., 1989).
[57] Rourke, Francis, and Doig, Jameson, "James Q. Wilson's 'Bureaucracy:' Two Reviews," *Journal of Public Administration Research and Theory* 1, no. 1 (January 1991), 90–99.
[58] Maor, Moshe, "Organizational Reputation and Jurisdictional Claims: The Case of the U.S. Food and Drug Administration," *Governance* 23, no. 1 (2010), 133–159.

Secondary Test of Path Dependence

Having articulated the basis for a limited application of bureaucratic theory, the study applies these insights to decision-making structures to perform the proposed secondary test of path dependence. The research asks whether aspects of decision-making structures aligned systematically with permissive or restrictive policy outcomes. Specifically, the study will look for changes both in the composition of actors within decision-making structures, and shifts in the interests that those actors held. To realize this approach, the study reinterprets two terms from Banchoff's study of stem cell research policymaking: the constellation of actors and the balance of interests. The constellation of actors will refer to the individuals involved in the design and execution stages of policymaking; the balance of interests refers generally to the preferences held by these actors.

The secondary test of path dependence will closely review actor constellations and balances of interest in decision-making structures during the design and execution stages of policymaking to determine whether changes occurred. In each of the four empirical chapters, this analysis will follow the historical section and the discussion of Pierson's criteria.

On this basis the study proposes that a causal relationship exists between expansions in the constellations of actors and shifts in the balances of interests and permissive policies for GMOs in the US and stem cell research in the UK. Indeed, such changes arguably allowed empowered civil servants to showcase preferences other than partisan politics and to make permissive oversight decisions on those bases.

Similarly, the study also proposes that a similar relationship may exist between the lack of changes in actors and interests and the restrictive outcomes for GMOs in the EU and UK and for stem cell research in the US. In such cases, a failure to remove

decision-making from direct political bargaining during the design and execution phases of policymaking arguably limited actor constellations and prevented shifts in interests, ensuring that outcomes reflected partisan rather than administrative concerns.

This study cannot numerically prove that these relationships existed. However, the empirical chapters can nevertheless demonstrate their basis through systematic elaboration, rigorous analytical evaluation and counterfactual discussion. Furthermore, any claims made here about actors and interests apply only to decision-making structures within the context of policymaking for GMOs and stem cell research. The study makes no claim for their application to bureaucratic institutions, agencies or organizations specifically or in general.

The secondary test of path dependence completes this study's discussion of institutional influences. Whereas Pierson's criteria revealed the early decisions, events and choices that showed us where policies diverged, this secondary test of path dependence analyzes decision-making structures in specific terms that can describe how, exactly, policies varied, and in doing so, why they varied. In this way, the two complementary strategies fulfill the main theoretical aim of the study, explaining how institutions shaped diverging biotechnology outcomes.

Although the central puzzle of this study relating to policy variation pointed mainly to institutional analysis, it also touched on issues discussed in other literatures, such as the nature of bureaucratic behavior. A further theme in this study concerns the question of how officials in biotechnology decision-making structures operated within the political system as a whole, i.e. whether they served clients' interests, or by contrast, wielded power in their own right. To gain a better understanding of civil servant influence, this study turns to a literature which specifically addresses questions of bureaucratic power: regulation.

1.4 Regulation

In the preceding section, decision-making structures helped to establish the implications of respective policy paths for biotechnology in a way that touched on questions of bureaucratic behavior, and to a much more significant degree, of institutional agency. However, the dynamics of decision-making structures for biotechnology can also weigh in on long-running debates within political science about the ability of external interest groups to influence government. Along these lines, this section attempts to answer the question of whether interest groups capture regulation.

Defining Regulation

While scholars have explored the concept of "regulation" for at least a century, the topic has gained force in recent decades after some theorists pointed to the rise of the "regulatory state."[59] In his influential 1997 essay, political scientist Giandomenico Majone described the governmental trend toward maintaining oversight through privatization and decentralization instead of more expensive and cumbersome centralized methods. Spurring scholarship on a range of regulation-themed topics, particularly those relating to the future of European welfare states, Majone and others arguably expanded the notion of what regulation is. Indeed, a subsequent essay by theorists Robert Baldwin, Colin Scott and Christopher Hood observed that regulation in its various manifestations could describe: a set of rules monitored or enforced by public agencies; the sum of all national efforts to direct the economy, including expenditures and taxation; and lastly, anything that controls social behavior, including non-state

[59] Majone, Giandomenico, "From the Positive to the Regulatory State: Causes and Consequences of Changes in the Mode of Governance," *Journal of Public Policy* 17, no. 2 (May 1997), 139–167.

actors.[60] As regulation studies grew in popularity within political science, some theorists warned against making overly broad generalizations about regulatory behavior.

In one early admonition, political scientist James Q. Wilson described any general theory of regulation as "about as helpful as a single explanation of politics generally, or of disease."[61] Although specific examples of regulation abounded in political life, the topic defied simple categorization. In this light, many scholarly contributions emerged incrementally, and with insights focused on particular areas.[62] Some theorists refrained from discussing general features of regulation and instead addressed questions of regulatory reform or failure.[63]

The cases explored in this study embrace a broad definition of regulation, with one pair addressing the commercial planting and sale of biotechnology products, and the other focused on the legal and publicly-funded derivation and utilization of embryonic stem cells.[64] For this reason, the thesis does not seek to make a major contribution to the regulation literature, but rather to contribute to a single issue area within it, the body of works on the subject of regulatory capture.

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[60] Baldwin, Robert, Scott, Colin, and Hood, Christopher, *A Reader on Regulation* (Oxford: Oxford University Press, 1998), 2-4.
[61] Wilson, James Q., *The Politics of Regulation* (New York, N.Y.: Basic Books, 1980), 393.
[62] For further discussion of issues in regulation see Majone, Giandomenico, *Risk Regulation in the European Union: Between Enlargement and Internationalization*, (Florence, Italy: European University Institute, 2003); Ansell, Christopher, and Vogel, David, *What's the Beef?: The Contested Governance of European Food Safety* (Cambridge, Mass.: MIT Press, 2006); and, Baldwin, Robert, Cave, Martin and Lodge, Martin, *The Oxford Handbook of Regulation* (Oxford: Oxford University Press, 2010); For further discussion of interest groups more generally, see Grant, Wyn, *Pressure Groups and British Politics* (London: MacMillan, 2000), and Olson, Mancur, *The Logic of Collective Action: Public Goods and the Theory of Groups* (Cambridge, Mass.: Harvard University Press, 1971).
[63] Lodge, Martin, "The Wrong Type of Regulation? Regulatory Failure and the Railways in Britain and Germany," *Journal of Public Policy* 22, no. 3 (2002), 271–297.
[64] Chapter Two operationalizes these variables in greater detail.

Theories of Regulatory Capture

Like other political science sub-fields, the study of regulation developed in cycles. From the late 1880s to the 1950s, public opinion and academic scholarship in the United States had grown relatively comfortable with regulatory bodies as a reasonable check on corporate power.[65] But in the decades after World War II, cracks formed in the consensus view of regulation as a trusted government management tool. In a closer examination of the institutions governing economic policy, political scientist Marver Bernstein noted the consistent ability of regulated interests to have a disproportionate influence over regulators. Focusing on the activities of independent regulatory commissions, such as the Federal Communications Commission, Securities and Exchange Commission and National Labor Relations Board, Bernstein described the direct and indirect efforts of external interest groups to influence policy-making in their favor. Many scholars would come to share this view in the decades after the 1950s, with economists George Stigler, Richard Posner and Sam Peltzman describing regulation and regulatory bodies as "captured" by industry or other interest groups.[66]

While theories of capture certainly revolutionized thinking on regulation, the ideas generated criticism over the years for failing to provide consistent explanations for how capture occurred and when one could predict it. In the later decades of the 20th Century, a number of theorists took up the challenge of producing a more stable explanation for how regulatory processes functioned. James Q. Wilson explored flaws in the capture thesis by drawing on the robust regulatory activity of the 1970s. Arguing

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[65] Bernstein, Marver, *Regulating Business by Independent Commission* (Princeton, N.J.: Princeton University Press, 1955), 3.

[66] Stigler, George, "The Theory of Economic Regulation," *Bell Journal of Economics and Management* 2, no. 1 (Spring 1971), 3-21; Posner, Richard A., "Theories of Economic Regulation," *Bell Journal of Economics and Management Science* 5, no. 2 (Autumn 1974), 335-358; Peltzman, Sam, "Toward a More General Theory of Regulation," *The Journal of Law and Economics* 19, no. 2 (August 1976), 211-240.

for a more complex model of how agencies worked, Wilson refuted common generalizations by showing that capture explained some policy outcomes but not others; for example, public interest regulatory policies relating to the environment and consumer safety. Expanding the analytical categories of the capture thesis, Wilson described four distinct forms of regulatory politics:

> "Majoritarian politics," with costs and benefits widely distributed;
> "Interest group politics," with costs and benefits narrowly concentrated;
> "Client politics," a wide distribution of costs and a narrow distribution of benefits; and,
> "Entrepreneurial politics," with concentrated costs and widely distributed benefits[67]

Deepening the analysis of regulatory capture, Wilson's typologies allowed for outcomes which could benefit or imperil a range of private and public interests. Moreover, applying Wilson's approach to the study of biotechnology policies arguably expands the spectrum of interest group activity beyond a monolithic depiction of "capture."

However, discerning what constitutes each typology of regulatory politics presents a challenge. For example, biotechnology advocates might view efforts by environmental and religious interests to block regulatory approvals as a kind of client politics whereas opponents might see it as entrepreneurial politics. Therefore, although Wilson's categories clearly expand the analysis, at best his typologies provide an ambiguous interpretation of policy outcomes.

Capturing Biotechnology Policies?

While works on regulation touch on a range of industries, few theorists deal expressly with biotechnology. However, political scientists Thomas Bernauer and Erika Meins provided a compelling example in research that revisited the capture hypothesis and

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[67] Wilson, James Q., *The Politics of Regulation* (New York: Basic Books, Inc., 1980), 364-372.

explained variation in policies for GMOs in Europe and the United States largely in terms of interest group activity.[68] Building on previous models which stated that industry generally captures economic policy outcomes, Bernauer and Meins argued that sustained "public outrage" increased the collective action capacity of consumer and environmental interests. In Europe, empowered interest groups, along with decentralized regulation and weak producer coalitions explained the restrictive position, whereas in the United States, muted interest coalitions, along with centralized regulation and strong producers explained the permissive policy.

This study embraces many findings of Bernauer and Meins, particularly discussions of institutional dimensions, and subsequent chapters highlight the comparative causal effects of regulatory institutions vis-à-vis public opinion and interest groups. However, the thesis extends the institutional discussion in new directions. While Bernauer and Meins effectively conveyed interest group activity in Europe, this study emphasizes the institutional context that allowed it to occur, first in terms of Pierson's criteria for increasing returns, and then through a secondary analysis of decision-making structures. Moreover, although Bernauer and Meins implied that the biotechnology industry captured policymaking in the US, producer opposition to the policy suggests that something besides capture explains the permissive policy. In such cases, this study gives more weight to the role of expertise in shaping policy outcomes.

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[68] Bernauer, Thomas, and Meins, Erika, "Technological Revolution Meets Policy and the Market: Explaining Cross-National Differences in Agricultural Biotechnology Regulation," *European Journal of Political Research* 42 (2003), 643–683; Bernauer, Thomas, *Genes, Trade and Regulation* (Princeton, N.J.: Princeton University Press, 2003); Meins, Erika, *Politics and Public Outrage: Explaining Transatlantic and Intra-European Diversity of Regulations on Food Irradiation and Genetically Modified Food* (London: Lit Verlag, 2003).

Measuring Power

To address questions of bureaucratic influences in regulatory decision-making, this study draws from a theorist who provided one of the strongest retorts to the capture thesis: Daniel Carpenter. Whereas earlier works had described capture as inevitable, Carpenter deftly challenged that scenario by asserting that civil servants could gain autonomy in the political system. Looking to the histories of several US executive branch agencies, Carpenter argued that the specialized skills of certain bureaucrats allowed them to form alliances with a range of interest group players, and subsequently influence if not guide the policy-making process.[69]

A subsequent work by Carpenter extended the scope of bureaucratic power further and turned the capture thesis on its head by asserting that in some cases industry was beholden to expert civil servant regulators. In *Reputation and Power*, Carpenter described how the FDA possessed a reputation for consumer protection and scientific expertise that gave it immense and often informal power over the pharmaceutical industry, both domestically and internationally.[70] Agency decisions critically impacted stock prices, but more importantly, gave civil servants the power to determine standards of scientific evidence.

Carpenter's insights have significant implications for this study of biotechnology policymaking, considering that it examines the activities of the FDA and other agencies known for their expertise. Indeed, policy cases on GMOs in particular have the potential to address not only the question of capture but that of civil servant influence. Returning to the question posed at the beginning of this section—whether interest groups capture

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[69] Daniel P. Carpenter, *The Forging of Bureaucratic Autonomy: Reputations, Networks, and Policy Innovation in Executive Agencies, 1862-1928* (Princeton, N.J.: Princeton University Press, 2001).
[70] Carpenter, Daniel, *Reputation and Power: Organizational Image and Pharmaceutical Regulation at the FDA*, (Princeton and Oxford: Princeton University Press, 2010).

regulation—this study proposes that in some cases agency expertise drove outcomes along the lines described by Carpenter. Such a proposition rejects the uniform capture of biotechnology policy by industry and leaves room for other political dynamics.

Summary of Propositions

The literatures on new institutionalism, bureaucracy and regulation provide a useful framework within political science for addressing questions arising from variation in policies for biotechnology. Looking to the literature on new institutionalism, this study asks how institutions shaped policy outcomes, and proposes path dependent processes as a conceptual mechanism. However, due to on-going controversy about path dependence, the research asks whether there is a conceptualization that accounted for large, small and seemingly unrelated events, and proposes to utilize Pierson's criteria for identifying increasing returns, or the self-reinforcing effect of early decisions and subsequent events and choices. Upon successful application, the criteria will show in each case that multiple equilibria existed; that contingent events critically impacted later developments; that timing and sequencing were essential; and that once policies started along a certain path the cost of reversal increased significantly. In this way, Pierson's criteria can describe institutional influences by revealing the early arrangements that drove policy developments later.

When comparing cases, Pierson's criteria can show how policies developed and diverged, but they do so strictly in terms of narrative history. This study asks whether one can explain variation in specific terms that scholars can assess comparatively, and proposes a secondary test of path dependence to look to the implications of the policy path in each case. This will involve reviewing the regulatory standard setting institutions, or what this study proposes to call decision-making structures, including,

for GMOs the Coordinated Framework in the US and the EU-UK legislative framework, and for stem cell research the HFE Act 1990 framework in the UK and the US Bush framework.

To develop the secondary test of path dependence, the study turned to the literature which describes the bureaucratic officials often associated directly or indirectly with decision-making structures: bureaucracy and public administration. The study asked whether we can characterize the behavior of bureaucratic officials, and following a review of numerous works, this study proposes that to a limited degree we can.

Following a detailed analysis, the secondary test of path dependence will describe a causal relationship between the changes in actors and interests and permissive policies for GMOs in the US and stem cell research in the UK. The test will also describe a relationship between the lack of changes in actors and interests and the restrictive outcomes for GMOs in the EU and UK and for stem cell research in the US.

Finally, given the significance attributed to decision-making structures in shaping biotechnology policies, the study turned to the literature on regulation to highlight the role of these structures in the regulatory process. The study asked whether interest groups captured regulation and proposed that in some cases agency expertise drove outcomes.

Limitations of the Approach

Scholars could legitimately wonder how this study will verify these propositions for the research that follows. How can we know that early events shaped later ones; that cases reflected increasing returns; that a relationship exists between changes in decision-making structures and permissive or restrictive outcomes; and, that empowered civil

servants in many cases influenced regulatory politics? Because this study is not intended as a formal test it does not provide numeric measures or narrowly focused studies of event chains. Nor can it guarantee that in all cases the causal relationships described are not examples of correlation. However, the systematic historical and theoretical analyses provided here do aim to establish causal relationships as far as possible within the evidence provided. Collectively, they form the basis of an important thematic argument that applies to biotechnology and possibly other contested applications of science and technology.

CHAPTER 2: CASE SELECTION: BIOTECHNOLOGY IN 23 COUNTRIES

Chapter One identified the puzzle of varying policies for two controversial applications of science and technology—GMOs and stem cell research—and outlined a research strategy that offered numerous theoretical propositions for analysis. This chapter reviews this strategy to ensure that it comports with basic social science principles, including what King, Keohane and Verba describe as the "logic of inference."[1] Examining both research content and methods, this process begins and ends with case selection.

Any attempt to understand why policies for controversial science and technology varied between countries encounters the immediate dilemma of how to conduct the necessary research, and indeed what kind of inquiry to begin. If a researcher wishes to understand how a particular country approached a technology, then a single-country policy-history would suffice. However, if scholars seek to make generalizations with broader applicability, then they must select research subjects using consistent criteria. The following discussion engages the issue of case selection by identifying valid subjects for research, and justifying their contribution to the explanation of policy variation. The following discussion therefore seeks to answer two questions:

- What activity or artifact of science and technology should one study?
- In which countries should one study them?

[1] King, Gary, Keohane, Robert, and Verba, Sidney, *Designing Social Inquiry: Scientific Inference in Qualitative Research*, (Princeton, N.J.: Princeton University Press, 1994).

"Controversial Science and Technology"

Before answering these two questions, one must first address another: What is meant by "controversial science and technology?" There are many ways to answer this question, since pinpointing an unpopular or contested application of science or technology is not difficult, particularly at the turn of the 21st Century.[2] Looking to history, the record inevitably provides many examples of novel processes and products which polarized public opinion and prompted varying governmental responses. Many such examples would undoubtedly make suitable subjects for research. However, this study does not pretend to offer a comprehensive account of all disputed activities. It is not concerned with selecting a "best" possible subject, but merely one which could foster an apposite discussion of policy variation in recent decades. The criteria for selecting are as follows.

First, with regard to choosing an appropriate application, "science and technology" could refer to two separate things, or to a more general singular meaning. This study embraces the latter option, justifying the generalization as sufficient to yield new social science insights. In this way, "science and technology" could describe activities or processes utilized by trained professionals in a laboratory, or it could represent the artifacts and products used or created in such a setting. However, given the above stated commitment to embracing a streamlined approach, this project stipulates that the "science and technology" under examination here could include any product or activity which encompassed traditional laboratory-style research in a central way.

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[2] Grady, Denise, "Girl or Boy? As Fertility Technology Advances, So Does an Ethical Debate," *The New York Times*, February 6, 2007; Naik, Gautam, "A Baby, Please. Blond, Freckles - Hold the Colic," *The Wall Street Journal*, February 12, 2009; Joy, Bill, "Why the Future Doesn't Need Us," *Wired*, April 2000; Fukuyama, Francis, *Our Posthuman Future: Consequences of the Biotechnology Revolution*, (London: Profile Books Ltd, 2002); Kurzweil, Ray, *The Age of Spiritual Machines: When Computers Exceed Human Intelligence*, (New York: Penguin Books, 1999); Rees, Martin, *Our Final Century: Will the Human Race Survive the 21st Century?*(London: William Heinemann Ltd., 2003).

Similarly, scholars could expend considerable effort debating the term "controversial" or "contested." This study defines the word as engendering both support and opposition in a general public, and prompting varying policies among countries. However, a more systematic characterization of controversial science employs the coding used by political scientist Donald Stokes to distinguish between two types of issues that emerge in the mind of the voter: "valence" issues and "position" issues.[3] Stokes described "valence" issues as those which typically enjoy universal support among voters—public safety, education and clean air, for example—and on which parties may compete on competence. "Position" issues refer to those which lead voters and parties to embrace varying stances. Consistent with this typology, controversial science and technology by definition represents a position issue in this discussion.

Based on these selection constraints, the global policymaking legacy of agricultural genetically modified organisms (GMOs) in food and human embryonic stem cell research represent potentially compelling examples of controversial science and technology, since both became clear position issues in the domestic political systems of numerous countries. The following pages introduce both technologies, describe their reception throughout the world and critically discuss their suitability for research.

[3] Stokes, Donald, "Valence Politics," in *Electoral Politics,* edited by Kavanagh, Dennis, (Oxford: Clarendon Press, 1992).

2.1 Agricultural Genetically Modified Organisms in Food[4]

The term "genetically modified organisms" refers to agricultural food products created using an array of novel breeding techniques known collectively as genetic modification, biotechnology, genetic engineering, transgenesis and other names. The techniques, which allowed researchers to insert genes directly into a target organism, built upon the 1973 discovery of recombinant deoxyribonucleic acid (rDNA), or DNA crafted from non-naturally-occurring components.[5] Often described as "green" biotechnology in contrast to "white" (industrial) and "red" (medical) variants, agricultural applications, such as modified crops and food products were developed in the 1980s, and first entered the marketplace in the mid-1990s.[6]

Emergence

Despite its novelty, genetic engineering represented only the latest innovation in industrial agriculture techniques which had transformed global agriculture starting in the preceding century. Although agriculture had existed for thousands of years, most 20th-Century crops bore little resemblance to antecedent varieties. The rediscovery of Mendelian principles in the early part of the century brought many new applications to plant breeding. However, arguably the most dramatic shift occurred in the decades after World War II, when the innovations of agronomist Norman Borlaug and the "Green

[4] The following discussion draws generally from two comprehensive reports: Working Party on Genetically Modified Crops, Nuffield Council on Bioethics, *Genetically Modified Crops: Ethical and Social Issues* (London: Nuffield Council on Bioethics, 1999); and, US Congress, Office of Technology Assessment: *Commercial Biotechnology: An International Analysis*, (U.S. Government Printing Office, January 1984).

[5] Cohen, Stanley; Chang, Annie; Boyer, Herbert; Helling, Robert, "Construction of Biologically Functional Bacterial Plasmid in vitro," *Proceedings of the National Academy of Sciences* 70, no. 11 (November 1973), 3240-3244.

[6] For a further discussion of the politics of agriculture, including GMOs, see: Coleman, William, Grant, Wyn, Josling, Tim, *Agriculture in the New Global Economy* (Cheltenham, UK: Edward Elgar 2004).

Revolution" helped double world food production between 1960 and 2000 through the use of chemical fertilizers, herbicides and pesticides.[7] Global in scale, the research, development and technology transfers associated with the Green Revolution helped transform yields for cereal staples, such as corn, rice and wheat, and earned Borlaug the Nobel Peace Prize in 1970.

The Science of Genetic Engineering

Any successful product of biotechnology began with the gene of interest or "transgene," which scientists isolated and removed from a donor organism's DNA, and inserted into the target plant through a variety of methods. One of the most common involved merging the transgene with the DNA of a vector—such as a bacterium or virus—and then transferring the vector's resulting "recombinant" DNA into the target organism, where replication would occur. Researchers described successful introductions of the donor gene into host cells as "transformations." Other methods of introducing foreign genes included the use of a "gene gun," which injected the transgene directly into the target organism.[8]

In order for researchers to identify successful transformations, they often inserted a so-called marker gene into target organisms alongside the transgene. One marker gene designed to resist antibiotics would spur controversy in the mid-1990s, following the BSE crisis in Europe, when some scientists worried that a crop's resistance to antibiotics could pass to humans, cattle and other animals.

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[7] Working Party on Genetically Modified Crops, *Genetically Modified Crops: Ethical and Social Issues*, 20.
[8] US Congress, Office of Technology Assessment, *Commercial Biotechnology: An International Analysis*, 36-37.

Viable Varieties

When the first modified crops entered the marketplace in the mid-1990s, most genetic engineering in agriculture aimed for three things: improving crop quality, increasing yields or reducing inputs.[9] Although researchers applied genetic engineering techniques in many different ways, and to most major crops, only a few practices yielded commercially viable varieties. One of the more simple applications was an accelerated form of basic plant breeding, in which researchers inserted native genes into the same target species in a procedure that would normally require more time using traditional techniques.

More complex changes included so-called antisense technology, in which researchers inserted a gene to interfere with normal plant functions.[10] In 1994, this process yielded the first commercially approved whole food, CalGene's "Flavr Savr" tomato, engineered to delay ripening by inhibiting the enzyme for cell wall breakdown.

The most commercially successful modified crops achieved transformation by using genes from bacteria and viruses. These included a variety of corn popular in the United States which contained a gene from the naturally-occurring bacterium *Bacillus thuringiensis* (Bt), repellent to insects.[11] Other varieties included a range of herbicide-tolerant plants, such as Monsanto's "Roundup Ready" soybeans, which possessed a gene that allowed farmers to apply the company's signature weed killer, "Roundup." This saved farmers considerable time and effort, as they could plant seeds without ploughing by applying the herbicide directly to untilled soil. It also potentially allowed growers to use less toxic herbicides.

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[9] Ibid, 172-174.
[10] Working Party on Genetically Modified Crops, *Genetically Modified Crops: Ethical and Social Issues*, 24.
[11] Kolata, Gina, "How Safe Are Engineered Organisms?" *Science* 229 (July 5, 1985), 34-35.

Producers

Much of the early work on genetic engineering, including the discovery of rDNA in 1973, occurred in university and publicly funded research settings. Because basic research played such a large role in developing genetic engineering, the technology first emerged in nations with strong science infrastructures, including the United States, Germany and the United Kingdom.

Following the early work done in these government-sponsored settings, by the mid-1980s private sector entrepreneurs had entered the field and soon came to dominate it. In the 1980s and 1990s, the biotechnology industry consisted mostly of small start-up companies and chemical and seed firms on both sides of the Atlantic seeking to maximize their advantage by patenting products as intellectual property. As products moved closer to the field and marketplace, larger corporations consolidated their holdings by purchasing smaller firms.

Table 2.1 Top Ten Corporate Patent Holders in Agricultural Biotechnology (as of 2004)

Rank	U.S. and Non-U.S. Companies (including subsidiaries)	Number of Utility Patents Held
1	Monsanto Co., Inc.	674
2	DuPont, E.I. De Nemours and Co.	565
3	Pioneer Hi-Bred International, Inc.	449
4	Syngenta	284
5	Novartis AG	230
6	BASF AG	217
7	Dow Chemical Co.	214
8	Hoechst Japan Co.	207
9	Mycogen Plant Science, Inc.	196
10	Bayer AG	184

SOURCE: USDA[12]

[12] US Department of Agriculture, Economic Research Service, "Agricultural Biotechnology Intellectual Property: Standard Tables" (2004).

Table 2.1 shows the top ten corporate patent holders in agricultural biotechnology by 2004, when most leading scientific powers had established first-generation policies. The larger players in the United States included the chemical and seed conglomerates Monsanto, DuPont and Pioneer, Dow and Mycogen. In Europe, the Swiss-based Syngenta and Novartis, and the German companies BASF AG and Bayer AG led the way, along with the Japanese division of the German conglomerate Hoechst Japan. Each firm typically held numerous subsidiaries within its market area. For example, Monsanto obtained CalGene in 1996 following that firm's invention of the "Flavr Savr" tomato, while the bioscience division of Britain's long-standing Imperial Chemical Industries (ICI) merged with Zeneca in 1993 before becoming part of Syngenta in 2000. In most cases, corporations retained the rights to all new seed varieties, and required growers to obtain a license for their use.

Table 2.2 Number of Transgenic Field Trials by Continent 1986-1995

The contents of this table cannot be made freely available via ORA due to copyright concerns.

SOURCE: ISAAA[13]

Although Europe had many centers of innovation, the US had the greatest concentration of GMO planting activity by the mid-1990s, due in part to the suitability of the few successful engineered crops to that country's soils and the government's early steps to create a regulatory pathway for modified crops. Table 2.2 shows the concentration of planting activity in various continents measured in cumulative field trials conducted.

[13] James, Clive, and Krattiger, A.F., *Global Review of the Field Testing and Commercialization of Transgenic Plants, 1986 to 1995: The First Decade of Crop Biotechnology*, ISAAA Briefs (Ithaca, NY: ISAAA, 1996), 10-11.

Obstacles

Despite the gains they afforded in some types of agriculture, modified crops also presented problems that producers and activists watched closely. One was their potential to cause unintended, or pleiotropic, effects, for example, when a new engineered variety produced a toxin or caused an allergic reaction. However, the same possibility existed for any traditionally-bred varieties; and, in theory, researchers could eliminate such problems over multiple generations.

Modified varieties also faced the problem of resistance. In the case of Bt crops, mutant insect strains had the potential to develop a resistance to the pest-repelling gene in the plant and render the engineered variety ineffective. Herbicide-tolerant plants presented a similar difficulty, if a wild strand of weed unaffected by the herbicide developed, and thereby canceled out the crop's usefulness. However, like the possibility for unintended effects, resistance also occurred in traditional breeding, for example, when a pesticide or herbicide used with a traditionally-bred crop no longer eliminated its target.

Supporters

Despite gains in crop yields fostered by Green Revolution techniques in the middle and later decades of the 20th Century, experts anticipated production levels to plateau, due to problems such as groundwater exhaustion, micronutrient depletion and low-level pest build-up.[14] At the same time, demographers expected world population to exceed eight billion in 2020, and the number of acres devoted to food production per person to fall

[14] Working Party on Genetically Modified Crops, *Genetically Modified Crops: Ethical and Social Issues*, 59-61.

from 0.64 to 0.37 between 1999 and 2050.[15] From the 1970s onwards, scientists and agronomists believed that biotechnology could help make up the difference with increased yields. In developed nations, in Europe and North America, they argued, genetic engineering could stabilize food prices, by reducing inputs, increasing yields and improving the flavor and nutritional content of food.

But according to advocates, arguably the greatest benefit of genetic engineering was its potential to help the developing world, where agricultural production also began to level off following the Green Revolution of the 1960s and 1970s. While Asia and Latin America had experienced dramatic increases in food production, future population increases would require similar growth in yields.[16] Moreover, Africa presented an even greater concern. Mostly overlooked by the Green Revolution, governments across the continent had frequently failed to prioritize agriculture spending or to create the scientific infrastructure needed to embrace intensive farming techniques.[17] Thus, while experts predicted that the number of "food insecure" people in developing countries was falling overall, they expected it to increase in sub-Saharan Africa.[18]

Opposition

As a "position" issue, GMOs fostered both support and opposition in countries around the world. Given the technology's relatively long gestation period, public opinion shifted considerably from the first laboratory experiments on rDNA in the mid-1970s through the first decade of commercial product sales ending in 2004. For this reason the

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[15] Ibid.
[16] Borlaug, Norman, "Ending World Hunger: The Promise of Biotechnology and the Threat of Antiscience Zealotry," *Plant Physiology* 124 (October 2000), 487-490.
[17] Ngongi, Namanga, "An African Green Revolution Leading to Development," in *World Food Security: Can Private Sector R&D Feed the Poor?* (presented at the Crawford Fund 2009 Annual International Conference, Canberra, Australia, 2009).
[18] Working Party on Genetically Modified Crops, *Genetically Modified Crops: Ethical and Social Issues*, 59.

limited global poll data available is both unsystematic and inconclusive, and we must beware of simplistic claims about public opinion on the issue. For example, Europe without question possessed a higher concentration of anti-GMO interest group activity in the late 1990s, but this fails to account for significant interest group opposition in the United States which, although less concentrated, played an active role over a longer time span.

Criticism of GMOs generally followed a consistent pattern. The objection receiving the most attention from critics, producers and governments concerned the potential harm to human health from consuming foods containing GMOs. Despite a handful of high-profile media stories, including one featuring a UK researcher who alleged in 1998 that engineered potatoes had caused rats to have weaker immune systems and stunted growth (the Royal Society later discredited this claim), little evidence has supported the assertion that eating modified whole foods or products caused health problems.[19]

Scientists generally agreed that GMOs had the potential to create allergic qualities or pleiotropic effects that could harm consumers. However, the same risk arguably existed in equal measure with traditionally bred varieties. Although advocates of the technology pointed to the many years since the mid-1990s in which US residents have consumed GMOs without incident, critics have said that without mandatory labeling one cannot successfully track the effect of GMO consumption in a population.

[19] The Royal Society, "Review of Data on Possible Toxicity of GM Potatoes" (The Royal Society, June 1999).

Environmental Concerns

The second most prominent concern about GMOs related to the potential effect of "releasing" an engineered crop into the environment. Just as the most serious food safety concerns largely dissipated in the years after producers introduced GMOs into the food supply, alarm in the 1980s about the immediate and potentially devastating effect of releasing GMOs also disappeared. However, a number of other environmental criticisms would emerge and gain credibility, especially those pertaining to the effect of modified crops on nature and wildlife.

Critics argued that modified crops had a greater impact on the environment than other crops, pointing to studies showing that herbicides used with herbicide-tolerant crops in fact killed all weeds and insect life, unlike more targeted (and more toxic) products which farmers sprayed directly on to selected weeds.[20] This had the potential effect of reducing the insect population in the vicinity, they said, and the number of birds. (However, the same studies showed that some herbicide tolerant plants had the potential to improve the environment by allowing farmers to use a less toxic herbicide as well as less herbicide on the whole.)[21] Environmental critics also faulted insect-repelling varieties of GMOs, saying that they could kill benign insects, and thereby reduce bird populations.[22]

A further environmental concern regarded the potential spread of transgenic varieties to non-engineered crops growing nearby, with studies showing that such "gene flow" could occur at varying rates depending on the variety. Although supporters and

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[20] Burke, Maria, Farmscale Evaluations Research Consortium and Scientific Steering Committee, *Managing GM Crops with Herbicides*, (Department for Environment, Food and Rural Affairs, March 21, 2005).
[21] Ibid.
[22] Working Party on Genetically Modified Crops, *Genetically Modified Crops: Ethical and Social Issues*, 102.

opponents generally agreed that "buffer" areas between engineered and non-engineered varieties could mitigate this problem, parties have clashed over specific measures.

Other Concerns

In addition to the specific concerns above, other critics challenged the need for biotechnology vis-à-vis other modes of land use and food production, such as organic farming. Indeed, for those who opposed the industrialization of agriculture in general, GMOs became a popular target. Some environmentalists and consumers focused their opposition on the competitive practices of specific players, such as the US-based conglomerate Monsanto, which critics challenged for its efforts to patent plant varieties, lease growing rights and block attempts to label modified products.

Biotechnology advocates have challenged these criticisms as first world concerns that could block assistance to indigent populations. However, in response, critics noted that most research infrastructures were housed in wealthy developed countries, and not producing crops that could create jobs and lower food prices in poorer areas. According to the Nuffield Council on Bioethics, alleviating world hunger with the help of modified crops would require "radical changes in the current focus and structure" of research and development.[23] To help sub-Saharan Africa, an area with famously dry soils, scientists would need to create food staples more essential to the African market and engineer them in a more relevant way, for example to require less water.

Some critics have described the problem facing hungry nations in the developing world as not one of production but distribution, with world food supplies providing

[23] Ibid, 59.

more than enough to feed everyone. Others have insisted that organic farming practices could make up for projected drops in future yield growth.

Policy Variation

By the mid-2000s most nations around the world had policies for the use of GMOs within their borders, including laws and rules pertaining to laboratory experiments, field testing of crops, commercial planting and product sales. Of course, not all of these activities spurred controversy. While officials in various governments had once considered the contained use of GMOs a potential safety threat in the late 1970s and early 1980s, it no longer generated serious concern thereafter. Similarly, although field trials had sparked intense opposition among activists around the world, including those who destroyed countless crop experiments, most governments typically allowed them under certain conditions.

But the commercial planting of engineered varieties and the sale of modified products generated considerably diverse and conflicting policy approaches from the 1980s onward, based mostly on potential concerns about food safety and the environment. These policies developed in different ways, and therefore no single explanation holds in all cases. Nations with strong concentrations of industry, such as the United States, embraced the technology, but so did developing nations like Argentina with less scientific infrastructure. Similarly, while some nations rejecting the technology had strong Green movements, such as Germany, others such as Japan did not.

Table 2.3 First-Generation Policies for Agricultural Genetically Modified Food Crops and Products (1990-2005)

	Laws	Commercial Planting Allowed	Acres in 1997 (millions)	% of Global Total	Acres in 2004 (millions)	% of Global Total	Permissive or Restrictive
Europe							
EU	Directive 90/220; Regulation 259/1997	--	--	--	--	--	--
France		No					Restrictive
Germany	Gene Technology Act (1990)	Yes			<0.25	< 1	Restrictive
Italy		No					Restrictive
Spain		Yes			0.25	< 1	Hybrid
UK	Environmental Protection Act (1990)	No					Restrictive
Africa							
Kenya		No					N/A
S. Africa	GMO Act (1990)	Yes			1.2	1	Permissive
Zambia		No					N/A
Asia							
China	Order No. 7 (1996)	Yes	4.5	14	9.1	5	Permissive
India		Yes			1.2	1	Hybrid
Japan	Guidelines (1989, 1992, 1995)	No					Restrictive
Aust./ Oceania							
Australia	Gene Technology Act 2000	Yes	0.1	1	0.5	< 1	Permissive
N. Zealand		No					Restrictive
N. America							
Canada		Yes	3.3	10	13.3	6	Permissive
Mexico	Biosafety Law (2005)	Yes	< 0.1	< 1	0.25	< 1	Hybrid
United States	Coordinated Framework (existing statutes) (1986)	Yes	20.1	64	117.6	59	Permissive
S. America							
Argentina	Regulatory Framework (1991)	Yes	3.5	11	40	20	Permissive
Brazil	Biosafety Law (2005)	Yes			12.3	6	Hybrid
Chile		No					Restrictive

Table 2.3 (Continued)

	Mandatory Product Labeling	Cartagena Protocol (Signed, In Force)	Permissive or Restrictive
Europe			
EU	Yes	(2000, 2003)	Restrictive
France	Yes	(2000, 2003)	Restrictive
Germany	Yes	(2000, 2004)	Restrictive
Italy	Yes	(2000, 2004)	Restrictive
Spain	Yes	(2000, 2003)	Hybrid
UK	Yes	(2000, 2004)	Restrictive
Africa			
Kenya	No	(2000, 2003)	Restrictive
S. Africa	No	(in force 2003)	Hybrid
Zambia	No	(2004)	Hybrid
Asia			
China	Yes	(2000, 2005)	Hybrid
India	No	(2001, 2003)	Hybrid
Japan	Yes	(in force 2004)	Hybrid
Australia/ Oceania			
Australia	Yes	No	Hybrid
New Zealand	Yes	(2000, 2005)	Restrictive
N. America			
Canada	No	No	Permissive
Mexico	No	(2000, 2003)	Hybrid
United States	No	No	Permissive
S. America			
Argentina	No	No	Permissive
Brazil	No	(in force 2004)	Hybrid
Chile	No	(Signed 2000)	Hybrid

SOURCE: See Appendix One

The policies themselves also developed in a heterogeneous fashion. Some countries passed laws directly, while others utilized frameworks which delegated regulatory decision-making to civil servants. In either case, the resulting policy approaches often gave civil servants a degree of flexibility in implementing laws, especially at the crucial stage of approving or denying applications. Table 2.3 provides a sample of the initial laws, rules and regulations for the commercial planting and sale of GMOs on each continent. In many cases, nations had a lengthy collection of provisions. The table does not attempt to provide an exhaustive list. Countries with no entry either lacked a formal policy document or possessed too many to list in a meaningful way.

Commercial Planting

Policies for commercial planting began to take shape in the late 1980s when producers of early modified varieties sought to take their inventions beyond small scale field trials. China in 1992 became the first country to approve a modified crop for commercial planting, a virus-resistant tobacco, and the United States followed in 1994 with the "Flavr Savr" tomato.[24] By 1997, several other governments had made approvals, including Argentina, Australia, Canada, Mexico and the European Union in conjunction with several of its member states.[25]

In these and other nations where producers first sought to apply GMOs, governments generally laid out a clear regulatory path to approvals. But the path did not always lead to successful applications, and global policies began to diverge. Table 2.3 shows governments' first-generation policies for planting as a function of approvals and acreage totals, including the percentages of engineered crops grown globally. Nations marked "Yes" consistently approved modified varieties, while those marked "No" either banned GM crops outright or made very few approvals. In the mid-1990s, following the BSE crisis in Europe, environmental and consumer groups in nations around the world began to pressure governments to stop regulatory approvals in many countries, most notably in the European Union but also in other developed nations, such as Japan. Thereafter, a largely transatlantic divide opened up, with the US and its trade allies supporting GMOs, while the EU and its partners opposed them.

Acreage totals denote not only nations which approved modified crops but those which could actually make use of the few viable varieties in existence. By 1997, only

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[24] James, Clive and Krattiger, A.F., *Global Review of the Field Testing and Commercialization of Transgenic Plants, 1986 to 1995: The First Decade of Crop Biotechnology*, 23.
[25] James, Clive, *Global Status of Transgenic Crops in 1997*, ISAAA Briefs (Ithaca, NY: ISAAA, 1997), 9.

certain varieties of modified soybeans, maize, tobacco, cotton and canola had emerged as successful competitors to traditionally bred crops, with new additions to follow only gradually. For this reason, many countries, including developing nations, had no need for GMOs, which potentially impacted decision-making. Having no viable crops to plant and possibly lacking the resources to develop new ones, many opposed GMOs from the outset. Other nations, such as China and India began to adopt only select varieties, such as cotton, allowing them to benefit from biotechnology while maintaining their export markets in countries such as the EU and Japan.

GM Products

After governments approved the first transgenic varieties, they had to determine their safety for human consumption. Engineered products appeared in stores as wholefoods and in many processed food items. They also became a key export commodity for nations such as the United States, which starting in the mid-1990s markedly refused to label its Europe-bound shipments of corn and soybeans. The European Union and many of its member states and trade allies opposed these unmarked commodities and pushed for mandatory labeling laws domestically and internationally, while the US-led trade bloc fought against labels, calling them unnecessary and potentially damaging to sales. The group even filed a formal complaint with the World Trade Organization in 2003.[26]

By the late 1990s, a clear divide on labeling had opened up among countries. Table 2.3 shows countries with mandatory labeling laws and those which did not require labels on GMOs sold as food products. Although many pro-labeling nations acted in response to consumer attitudes, some, such as China, supported labeling so that they could export products to pro-labeling nations, such as Japan. Many developing countries

[26] Denny, Charlotte, "America Challenges GM Crops Ban," *The Guardian*, May 14, 2003.

endorsed labeling officially but failed to implement it in practice, often due to deficiencies in bureaucratic capacity.[27] In such cases, I describe these countries as not possessing a mandatory labeling policy.

Labeling also factored heavily into what became the Cartagena Protocol on Biosafety (2000), an international agreement aiming to ensure the safe handling, transport and use of GMOs.[28] The 162 parties to the treaty, many of which are displayed in Table 2.3, agreed to detailed identification, assessment and monitoring requirements governing the movement of GMOs between nations. Countries that had opposed labeling typically also declined to sign and ratify the protocol, including the US, Canada and Argentina.

"Permissive" vs. "Restrictive"

Policies for the commercial planting and sale of modified food products existed on a normative spectrum between full acceptance and complete rejection, with most countries falling somewhere in the middle. For this reason, any attempt to impose broad categories upon policymaking efforts could seem imprecise. However, making simple distinctions about core differences in policy is not difficult. More importantly, doing so can help advance scholarly knowledge of how and why differences emerged.

One could evaluate policies for the planting and sales of GMOs by many different metrics. However, this study focuses on planting approvals for crops and the mandatory labeling of products, respectively, as the preferred measures of a nation's approach to the technology. To distinguish between policies the thesis utilizes the terms "permissive" and "restrictive." For planting, permissive policies describe those which

[27] Gruere, Guillaume, and Rao, S.R., "A Review of International Labeling Policies of Genetically Modified Food to Evaluate India's Proposed Rule," *AgBioForum* 10, no. 1 (2007).
[28] Conference of Parties, United Nations Convention on Biological Diversity, Cartagena Protocol on Biosafety, 2000, http://bch.cbd.int/protocol/, accessed January 31, 2012.

yielded consistent and regular approvals of crops for commercial scale cultivation. For product sales, permissive policies describe jurisdictions which did not require labels on foods and which declined to sign and ratify the Cartagena Protocol.

In this way, one could say that Argentina, Canada, the United States and other nations embraced permissive policies. In contrast, restrictive policies failed to provide consistent approvals, and generally required mandatory labeling of all GMOs, and the signing and ratification of the Cartagena treaty. Examples of restrictive policies include Japan, the European Union, their trading partners, but also developing nations such as Zambia.

Regulatory Status

Measures of permissive and restrictive policies do not refer to differences in the respective regulatory status as measured in bureaucratic capacity, but to the consistency of commercial planting approvals, requirements for product labeling and willingness to join international biosafety agreements. While policy positions and regulatory status sometimes aligned, this was not always the case. Indeed, permissive policies could emerge in states with considerable bureaucratic oversight, such as the United States, and restrictive ones in nations with little regulatory capacity at all, such as Zambia.

Although regulatory status in some cases had the potential to influence a country's policy approach, it more often reflected its degree of relative affluence. Wealthy, science-supporting countries typically could afford full-scale regulatory oversight and implemented it regardless of the overall policy positions taken on GMOs.

Hybrid Policies

In addition to permissive and restrictive policies, this study identifies a further "hybrid" category for those nations somewhere in the middle. For planting, it includes countries which planted engineered varieties but not food crops, such as China and India. For product sales, it describes countries which joined the Cartagena Protocol but failed to implement mandatory labeling, such as Mexico and Kenya.

Until nations around the world created labeling policies, both planting and sales rules served as roughly equal measures of a nation's approach to GMOs. However, after labeling policies became widespread and countries joined the Cartagena Protocol, commercial planting arguably provided the better indication of a nation's normative view of GMOs. While scholars may reasonably disagree about the degree of a single policy's permissiveness or restrictiveness, the varying nature of national approaches to GMOs is indisputable. With nations around the world embracing such dramatically different positions, the technology represents an excellent case for exploring the causes of policy variation.

2.2 Human Embryonic Stem Cell Research

Global first-generation policies for GMOs provided a compelling example of how an emerging technology could translate into vastly different approaches among nations. Such variation therefore constitutes an important potential test of causal explanations for what shapes policy outcomes. However, an even more robust test would include more than one policy domain.

In order to generate comparative findings with broader applicability, this study proposed to review policymaking in a second scientific context. Specifically, it aimed to select a scientific application similar enough to justify comparison but sufficiently

distinct so that conclusions could describe science and technology governance more broadly.

The emergent science practice of human embryonic stem cell (HESC) research meets both of these criteria. Building on discoveries in cell biology, stem cell research was a "biotechnology" like genetic engineering. However, it involved a very different scientific procedure and its outputs remained much less developed at the start of this research.

Stem cell research refers to a laboratory practice aimed at increasing scientific understanding of certain types of cells known as stem cells, for the potential treatment of ailments, including diabetes, cancer, Alzheimer's and Parkinson's diseases and others.[29] Because of stem cells' unique properties, many believed that they could potentially restore a wide range of damaged and diseased tissues. Although researchers had identified stem cells in a variety of human tissues, most believed that the ones obtained from human embryos would yield the greatest results in terms of scientific knowledge and potential treatments.

The Science of Human Embryonic Stem Cell Research

Cells—the basic units which make up all organic material—come in 200 different varieties in adult mammals.[30] The stem cell is one which has not yet specialized, and possesses the ability both to self-replicate and, when given the appropriate chemical signal, to change or "differentiate" into other kinds of cells.[31] Although researchers

[29] Although it existed in many different varieties, "stem cell research" hereafter will refer specifically to human embryonic stem cell research unless otherwise stated.
[30] US Department of Health and Human Services, National Institutes of Health (NIH), Office of Science Policy, *Stem Cells: Scientific Progress and Future Research Directions* (National Institutes of Health, June 2001), 1.
[31] Ibid.

knew about stem cells for decades, most clinical knowledge of them began to emerge only in the 1980s and 1990s, from animal studies.

By the turn of the millennium, scientists had found stem cells in two main sources: developed or "adult" tissues; and, in embryos.[32] In humans, adult stem cells came from the bone marrow, skin, brain, liver and pancreas. Scientists called these stem cells "unipotent" because they possessed the ability to develop into the more specialized cell types of only the originating tissue.[33] Researchers had historically experienced difficulty identifying and isolating adult stem cells, which also lacked the ability to replicate indefinitely in culture.[34]

The second type of stem cells scientists called embryonic stem cells, because of their origin within the five-day-old embryo, a 250-cell entity called the blastocyst.[35] American scientist James Thomson and colleagues first obtained or "derived" stem cells from a human embryo in 1998, building on the successful derivation of primate stem cells three years earlier.[36] Unlike adult stem cells, embryonic stem cells were "pluripotent," meaning they could differentiate into most cell types, and therefore had much broader applicability. And because they could also replicate indefinitely in culture, in theory researchers needed only a small number to generate an unlimited amount of stem cells. Furthermore, stem cells containing the patient's own DNA offered potentially unlimited opportunities to produce new replacement tissues, especially one that patients would not reject. For these reasons, researchers generally viewed embryonic stem cells as scientifically superior.

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[32] While researchers technically created a third category for fetal stem cells, such as those produced from the umbilical cord, these cells closely related to adult stem cells in quality.
[33] US Department of Health and Human Services, *Stem Cells: Scientific Progress and Future Research Directions*, 1.
[34] Ibid, Executive Summary, page 3.
[35] Ibid, 13.
[36] Thomson, James A. et al, "Embryonic Stem Cell Lines Derived from Human Blastocysts," *Science 282*, no. 5391 (November 6, 1998), 1145-1147; Thomson, James A. et al, "Isolation of a Primate Embryonic Stem Cell Line," *Proceedings of the National Academy of Science 92* (August 1995), 7844-7848.

Before researchers could begin work on embryonic stem cells they first needed early-stage embryos less than five days old. Because abortions typically occurred well after the fifth day from conception, aborted fetal material was not useful. Thus, all embryos for stem cell research came from those created by *in vitro* fertilization (IVF) or in the laboratory. These embryos fell into three main categories: "supernumerary" embryos leftover from infertility treatments, embryos created expressly for stem cell research; and, most controversially, embryos generated via cell nuclear transfer or cloning so that they would possess the matching DNA of a patient.

Derivation and Utilization

To derive embryonic stem cells researchers removed the outer portion of the blastocyst in order to isolate the 30-cell interior known as the inner cell mass.[37] Placed in a culture dish containing growth medium and fetal bovine serum, the clump of cells began to separate and divide. After nine days researchers removed and re-plated cells to create separate stem cell lines.[38]

When the first derivation occurred in 1998, scientists still knew very little about how they would actually utilize or apply stem cells in treatments and therapies. Some practitioners believed they could repair the functionality of diseased and damaged tissues and organs by simply populating them with stem cells.[39] Such claims created the greatest urgency for the research because they implied that therapies could be imminent. More long-term scenarios involved even bolder uses of stem cells, such as growing completely new organs and tissues in the laboratory for transplantation. Patient

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[37] US Department of Health and Human Services, *Stem Cells: Scientific Progress and Future Research Directions*, 13.
[38] Ibid, Appendix C, page 1.
[39] UK Chief Medical Officer's Expert Group, *Stem Cell Research: Medical Progress with Responsibility* (Department of Health, June 2000), 18.

advocates enthusiastically encouraged these potential therapies. However, until scientists completed more basic research into stem cell science, all applications remained strictly hypothetical.

Practitioners

Stem cell research entered the lexicon slowly, typically following discoveries in the spectrum of biomedical research conducted throughout the 1980s and 1990s. By the mid-1990s, only a vanguard group of biologists were experimenting with them on both sides of the Atlantic. However, the landmark discovery of human embryonic stem cells in 1998 pushed a stream of practitioners into the field, and generated a torrent of media coverage which raised awareness of developments among the general public.[40]

Most early stem cell scientists worked in government-funded laboratories, such as those at hospitals, universities and other research centers. Despite the promise of the research, however, by the late 1990s, few private-sector firms engaged in stem cell research because of the remote nature of potential products.

Challenges

The 1998 breakthrough represented only a first step in stem cell science. Indeed, further progress in the field would require significant knowledge gains, both in terms of the basic functionality of stem cells in the laboratory, and of potential therapeutic applications. A detailed report released by the US in June 2001 outlined key problem areas pertaining to the successful derivation and differentiation of stem cells by

[40] Wade, Nicholas, "Scientists Cultivate Cells at Root of Human Life," *The New York Times*, November 6, 1998.

researchers.[41] For derivations, researchers needed to know more about how stem cells replicated without differentiating and how they could change in quality. In order to master the process of differentiating stem cells into more specialized cell types, scientists needed to understand their internal switches, how stem cells changed during differentiation and which stages would provide the most useful cells in treatment.[42]

Regarding the more distant future of utilizing stem cells in therapy, researchers anticipated a range of potential difficulties, including the potential for patients' cells to reject stem cells with foreign DNA.[43] For such an outcome, researchers identified a possible solution in the use of cell nuclear transfer, the cloning process first used by UK scientists to make Dolly the sheep in 1996, whereby they would create an embryo (and later, stem cells) with the approximate DNA of patients. But this solution carried risks, including the potential for stem cells from a cloned embryo to age more quickly, or to cause other problems due to the fact that the embryos contained traces of mitochondrial DNA from the donated egg and were not exact copies.

Other problems included the potential for mutations and tumors to develop in the patient as a result of laboratory manipulations.[44] Researchers also questioned the number and quality of stem cells produced, and the purity of tissues derived from the cells. Furthermore, practitioners needed to address the challenge of producing stem cells and tissues on a large scale, rather than for mere study in the laboratory.

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[41] US Department of Health and Human Services, *Stem Cells: Scientific Progress and Future Research Directions*, 19.
[42] Ibid.
[43] UK Chief Medical Officer's Expert Group, *Stem Cell Research: Medical Progress with Responsibility*, 26.
[44] Ibid, 26-27.

Support

Perhaps the most obvious group to come forward and endorse embryonic stem cell research was that which sought to engage in it: scientists, doctors and other medical researchers. This included not only those working in basic research, such as molecular biologists and biochemists, but investigators from across the full range of applied health fields, such as cancer, brain, heart specialists and more. In addition to organized science and medicine, patient advocates in various countries added their voices to the political debate, seeking to influence legislatures and executives in their favor.

While allied science and health sectors lobbied for the development of this research, one faction remained largely absent from political discussions: the business community. Although entrepreneurs clearly wanted to benefit from these expansions, and early patenting activity reflected this, the remoteness of measureable progress meant that firms had few viable products in which to invest. Therefore, stem cell research did not yet factor heavily in their lists of priorities.

Opposition

Embryonic stem cell research received substantial criticism from sizeable coalitions which believed that it would compromise the moral status of the human embryo. Many if not most active opponents came from religious communities, especially evangelical Christians and Catholics, groups which traditionally opposed abortion and viewed the fertilized embryo as the equivalent of a human life. Therefore, any research resulting in an embryo's destruction amounted to the killing of a life. However, not all opponents based their arguments on religious grounds. For example, Germany's prohibitions on the use of embryos in research likely reflected that country's experiences under the Nazi regime. Similarly, a minority of politicians and commentators on both sides of the

Atlantic framed their opposition in secular terms, and attempted to draw a moral line against embryonic stem cell research for reasons other than religion.

Just as the ideological motivation of opponents varied, opposition to research also existed in subtle shades, depending on the exact method in question. Some critics took up the most restrictive or prohibitive position by opposing any research that caused harm to an embryo, including any form of embryonic stem cell research. They opposed the derivation of stems cells created from any embryo source, including embryos produced for infertility treatments but not used for that purpose. And because they rejected on principle the notion of harming any embryo they also opposed the utilization of embryonic stem cells in therapy.

Some opponents endorsed what many derided as a hypocritical view by disallowing stem cell derivations but allowing research that utilized stem cells already derived. Other opponents supported a less restrictive position that would support research on those embryos leftover from infertility treatments. Other opponents endorsed a still less restrictive approach that would create IVF embryos expressly for stem cell research. This contingent supported most kinds of stem cell derivations and utilizations, except those that required the use of cloned embryos. The least restrictive position, which basically equated to the most permissive or liberal position, would allow researchers to clone embryos for stem cell research using cell nuclear transfer.

Policy Variation

Following the first derivation of human embryonic stem cells in 1998, governments were slow to enact policies, with many delaying action for several years due to the complexity and sensitivity of the issue, or a lack of relevant scientific activity in their countries. Nations that moved quickly to create research policies included Australia,

Germany, Japan, the United Kingdom and the United States. Others, such as Argentina, France, India, Italy, Mexico, and South Korea, were slower to take action, relying on existing statutes governing the use of embryos and in some cases declining to create new laws at all.

Table 2.4 shows the diverse collection of first-generation policies between nations for the legal derivation and utilization of stem cells. Although the act of deriving stem cells required the destruction of an embryo, utilizing them from existing stem cell lines for therapeutic applications did not. Therefore, countries that forbad derivations, such as Italy, could simultaneously endorse the utilization of stem cells in research. For both derivations and utilizations, countries often made distinctions between the sources of embryos used to create stem cells. The heading "Supernumerary" describes those embryos produced *in vitro* for infertility treatment but not used; "Created" refers to embryos fertilized *in vitro* expressly for stem cell research; and, "*Cloned*" describes embryos produced for stem cell work produced through cell nuclear transfer or "therapeutic cloning."

Table 2.4 First-Generation Policies for Human Embryonic Stem Cell Research (1999-2005)

	Law	Derivation of HESCs (by Embryo Source) Supernumerary	Created	CNT (Cloned)	Permissive or Restrictive
Europe					
France	Bioethics Laws (1994, 2004)	Yes	No	No	Hybrid
Germany	Embryo Protection Act (1990); Stem Cell Act (2002)	No	No	No	Restrictive
Italy	Law 40 (2004)	No	No	No	Restrictive
Spain	Biomedical Research Law (2003)	Yes	No	No	Hybrid
UK	HFEA Act (1990); HFEA (Research Purposes) Regulations (2002)	Yes	Yes	Yes	Permissive
Africa					
South Africa	National Health Bill (2003)	Yes	Yes	Yes	Permissive
Tunisia	Law 01-93 (2001)	No	No	No	Restrictive
Asia					
China	Ethical Guidelines for Research on HESCs (2003)	Yes	Yes	Yes	Permissive
India[45]	(No national policy)	Yes	Yes	Yes	Permissive
Japan	Law No. 146 (2000)	Yes	Yes	Yes	Permissive
South Korea	Bioethics and Biosafety Act (2005)	Yes	No	Yes	Hybrid
Saudi Arabia	Fatwa (2003)	Yes	No	No	Hybrid
Australia					
Australia	Research Involving Human Embryos Act (2002)	Yes	No	No	Hybrid
N. Zealand	Human Assisted Reproductive Technology Act (2004)	Yes	Yes	Yes	Permissive
N. America					
Canada	Assisted Human Reproduction Act (2004)	Yes	No	No	Hybrid
Mexico	(No national policy)	Yes	Yes	Yes	Permissive
USA[46]	Funding restricted only	Yes	Yes	Yes	Restrictive
S. America					
Argentina	Decree (1997)	Yes	Yes	No	Hybrid
Brazil	Biosafety Law (2005)	Yes	No	No	Hybrid
Peru	General Health Law No. 26842 (1997)	No	No	No	Restrictive

[45] In 2007, the Indian government implemented compulsory Guidelines for SCR and Therapy, affirming the legality of ongoing ESC derivation and utilization activities.

[46] Although President Bush's August 9, 2001, decision outlined specific restrictions on federal funding, it had no effect on the legal status of research.

Table 2.4 (continued)

Utilization of HESCs by Embryo Source

	Supernumerary	Created	CNT (Cloned)	Permissive or Restrictive
Europe				
France	Yes	Yes	No	Hybrid
Germany	Yes	No	No	Hybrid
Italy	Yes	Yes	Yes	Permissive
Spain	Yes	Yes	Yes	Permissive
UK	Yes	Yes	Yes	Permissive
Africa				
South Africa	Yes	Yes	Yes	
Tunisia	No	No	No	Restrictive
Asia				
China	Yes	Yes	Yes	Permissive
India	Yes	Yes	Yes	Permissive
Japan	Yes	Yes	Yes	Permissive
South Korea	Yes	Yes	Yes	Permissive
Saudi Arabia	Yes	No	No	Hybrid
Australia				
Australia	Yes	Yes	Yes	Permissive
N. Zealand	Yes	Yes	Yes	Permissive
N. America				
Canada	Yes	Yes	Yes	Permissive
Mexico	Yes	Yes	Yes	Permissive
USA	Yes	Yes	Yes	Restrictive
S. America				
Argentina	Yes	Yes	Yes	Permissive
Brazil	Yes	Yes	Yes	Permissive
Peru	Yes	Yes	Yes	Permissive

SOURCE: See Appendix One

While most nations made no distinction between the legal status of research and the government's willingness to fund it, exceptions existed, such the United States, one of the leading centers for stem cell work. Without banning the research itself, President George W. Bush in August 2001 blocked federal government funding for all future derivations, and for utilizations of stem cells derived after that date.

Table 2.5 First-Generation Policy (Federal Funding) for the Derivation and Utilization of Human Embryonic Stem Cells in the United States

	Embryo Source			
	Leftover	Created	CNT (Cloned)	Policy
Derivation	No	No	No	Restrictive
Utilization[47]	No	No	No	Restrictive

Because most work on stem cells in the US received funding from the federal government, the decision severely restricted practitioners' ability to conduct research (see Table 2.5). While other nations, such as Canada, also distinguished between the legal status and the funding status of research, they generally aligned the two eventually by implementing new laws or passing new statutes. This did not occur in the United States for the duration of George W. Bush's presidency.

"Permissive" vs. "Restrictive"

Similar to the discussion of GMOs earlier in this chapter, the study describes policies for stem cell research as either "permissive" or "restrictive." So-called permissive approaches to stem cell derivations extended legal status and government funding to research on supernumerary embryos, on embryos created expressly for stem cell research and on those produced through cell nuclear transfer. Similarly, permissive policies for the utilization of stem cells extended legal status and public funds to research on lines created from the same embryo sources.

Restrictive policies disallowed stem cell derivations and utilizations, or else blocked government funding for the work. However, adopting a restrictive policy did not necessarily mean that a country possessed a significant research capacity in the first

[47] The Bush policy provided funding for the utilization of stem cells derived before Aug. 9, 2001. While administration officials asserted that this would provide numerous stem cell lines for research, scientists have challenged the number and quality of these.

place. In fact, some nations, such as Tunisia, embraced one of the most restrictive policies in the world but actually had very limited biomedical activity.

Regulatory Status

Although the terms permissive and restrictive refer to what governments legally allowed and supported financially, they do not necessarily describe the nature of a country's regulatory apparatus. Indeed, a country with permissive policies for stem cell derivations and utilizations, such as the United Kingdom, could simultaneously possess a significant bureaucracy for monitoring activities and enforcing legal guidelines. Similarly, nations with minimal regulatory capacity, such as Tunisia, could forge a restrictive position. Therefore, for clarity this study will focus on what governments actually implemented, not to the size of respective bureaucracies.

Hybrid Policies

Many policies for both derivations and utilizations combined permissive and restrictive elements, and are described as policy "hybrids." Some nations allowed derivations on supernumerary embryos but banned them for embryos created expressly for research. Others made similar distinctions for scientists wishing to utilize stem cell lines. However, in general, the bulk of the restrictions concerned derivations, not utilizations, because the former required the destruction of embryos.

Technology Selection

Although policies for embryonic stem cell research did not conform to simple binary variation, they nevertheless reflected a general cleavage between those nations supporting the research and those opposed. Like GMOs, these examples of policy

variation around the world prompt important questions about why and how such variations occurred.

A comparative study of policies for both technologies in multiple countries could therefore go beyond the limitations of a single-country case study by providing a more general account of why policies vary when technologies are contested. Because each technology built upon earlier developments in biology, they arguably came from the same family of discovery, a fact which could justify their comparison. However, their clear differences, both in terms of their physical applications and the varying constituencies they affected, mean that a comparison could generate conclusions that extend beyond a single field.

2.3 Method

The data on first-generation policies for GMOs and stem cell research shown earlier in Table 2.3 and Table 2.4 create many openings for further research. Scholars attempting to understand why policies varied within these two "Large-N" (or perhaps "Medium-N") samples, could measure the effect of specific variables on policy outcomes. One might do this by charting the statistical correlation between specific independent and dependent variables, such as religious affiliation and a restrictive policy outcome, respectively. For clearly-expressed and well-measured variables, including those documented in census data and other records, this numerical approach could yield great dividends.

"Large N" vs. "Small N"

However, more complex independent variables, such as institutions, pose numerous difficulties for researchers because they are not always easily identified; they can wield

their causal agency in less precise ways; and, they often defy simple measurement. Moreover, while the extensive data available from sources, such as World Bank Governance Indicators and OECD "Government at a Glance" reports, offer to tell the "outside" story, this project aims to tell the "inside" story of how policies developed, by generating unique indicators through focused qualitative study. Therefore, in order to identify and describe the mechanisms of institutional agency within government, this study embraces a Small-N approach.

Of course, further research options exist between Large- and Small-N studies. For example, one could conduct a "Medium-N" study employing the Qualitative Comparative Analysis (QCA) approach described by Charles Ragin. This would seek to boost the validity of case study findings by increasing the number of comparisons between individual cases.[48] However, such an approach relies on a hypothesis based on a clearly expressed variable. Because this study of biotechnology cases must first describe how institutions shaped outcomes, Small-N case study research is arguably required to articulate the variable in full.

Document Biography through Process Tracing

While Small-N research allows investigators to probe more deeply into contextual data, the task of pinpointing causal mechanisms within a small number of case studies requires careful methodological strategy and analysis. How exactly does one identify the necessary information and disclose it? This project addresses this question by recounting the biography of key policy documents in the policymaking process, telling

[48] Rihoux, Benoit, and Ragin, Charles, Eds., *Configurational Comparative Methods* (Thousand Oaks, Calif.: SAGE Publications, 2009).

the story of these government instruments from drafting stages or "design" to implementation or "execution."

To provide these biographical details, the study turns to a popular approach within case study research: process tracing. As theorists Alexander George and Andrew Bennett describe, process tracing can test hypotheses by identifying the "links between possible causes and observed outcomes."[49] For cases involving the possible effect of institutions on biotechnology outcomes, process tracing can show how, exactly, permissive or restrictive policies developed and emerged within government. Did they come from politicians or civil servants? How did public opinion factor in? Process tracing answers these questions by producing an account reflective of what anthropologist Clifford Geertz described as "thick description," or a highly-detailed factual analysis that utilizes existing contextual sources. [50] From such an analysis scholars can understand a complex variable by reviewing its constituent parts.

Process tracing provides an ideal approach for addressing the theoretical points raised in Chapter One. Rather than organizing the cases as an explicit search for Pierson's criteria or other institutional features—an approach which could bias the study against other variables—the thesis provides an extended document biography followed by analysis of Pierson and the so-called secondary test of path dependence described in Chapter One. The result is a strong presentation of evidence followed by rigorous analytical discussion.

The four document biographies reflect the "first-generation policy," or the first stable and consistent policy approach enacted for each technology in the UK and US. Although the policymaking timescale varied in each case, policies for GMOs took

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[49] George, Alexander, and Bennett, Andrew, *Case Studies and Theory Development in the Social Sciences*, (Cambridge, Mass.: MIT Press, 2005), 6.
[50] Geertz, Clifford, *Thick Description: Toward an Interpretive Theory of Culture* (London: Fontana Press, 1993).

longer to complete than those for stem cell research. However, all first-generation policies arguably featured distinct periods of design and execution, or the phases in which officials crafted polices and when they implemented them. Moreover, each empirical chapter is organized explicitly to describe these periods.

Because the policy documents reflect varying political arrangements in each case, the empirical chapters similarly review different decision-making venues, or decision-making structures as described in Chapter One. For example, the UK Parliament represented a significant portion of the decision-making structure for stem cell research, whereas in the US the White House played a large role. The structures included, for GMOs, the Coordinated Framework in the US and the EU-UK legislative framework, and for stem cell research, the HFE Act 1990 framework in the UK and the US Bush framework.

Data Sources

In order to achieve a thick description account of document biographies through process tracing, this study utilized documentary evidence, journalistic and secondary accounts and approximately 40 elite interviews. The bibliography lists sources in the following categories: secondary sources and government documents, with separate headings for European Union, United Kingdom, United States and other national and international government documents. In most cases, this study obtained documents from source governments, either in person, via e-mail communication or downloaded directly from government or other websites. In a few exceptions, this study obtained documents through other means, such as from personal archives, and in each case details are provided in the bibliography. Journalism sources, including newspaper articles, were

obtained mostly through search services such as Nexis UK and via the Internet search engine "Google."[51]

All interviews conducted for this study occurred in Oxford, Washington, DC, London, Brussels or via telephone. In exceptional cases, interviewees submitted answers to questions via e-mail. Moreover, all sessions followed the ethical guidelines stipulated by the Central University Research Ethics Committee (CUREC).[52] For further information relating to interviews, including a complete list of interviewees and details on protocols and data coding, see Appendix Two.

Reliability and Validity

To ensure that data and analysis conforms to established social science norms, this study aims to follow the "logic of inference" proposed by theorists Gary King, Robert Keohane and Sidney Verba."[53] This includes conducting research that aims to make descriptive and explanatory observations of phenomena; follow public and transparent procedures; address the question of uncertainty; and, uphold a defensible method from beginning to end. These desiderata, which call for maximizing levels of achievable scientific objectivity, broadly overlap with two scientific principles emphasized by theorists Jerome Kirk and Marc Miller: reliability and validity.[54] In essence, reliability is the extent to which one can replicate the process of research to produce equivalent findings; validity is the extent to which a measure captures what it is intended or purported to represent.

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[51] Although scholars have gleaned important analytical clues from differences in media content between countries, this study utilizes journalism outputs primarily as a historical resource. See: Lodge, Martin, "Risk, Regulation and Crisis: Comparing National Responses in Food Safety Regulation," *Journal of Public Policy*, vol. 31, no. 2 (2011), 25-50.
[52] For further information, see: http://www.admin.ox.ac.uk/curec/.
[53] King, Gary, Keohane, Robert, and Verba, Sidney, *Designing Social Inquiry: Scientific Inference in Qualitative Research*.
[54] Kirk, Jerome, and Miller, Marc, *Reliability and Validity in Qualitative Research*, (Newbury Park, Calif.: SAGE, 1986).

This study systematically incorporates these concepts in its attempts to produce not only new causal insights but new knowledge about biotechnology policymaking. To achieve these aims, cited documentary evidence and secondary accounts conform to transparent and replicable research methods; and, to verify the validity of sources, this study systematically triangulated all claims made therein as far as possible.

However, elite interviews, the novel sources of data produced exclusively for this study, presented an inherent challenge due to their origin. How can researchers verify the accuracy, intent and meaning of interviewee contributions? To answer this question this study pursued a replicable approach that involved creating digital and transcribed records of all interviews; questioning along consistent lines of inquiry; providing attributed quotes from interviewees in the text where possible; and, rigorously triangulating findings with other data sources, including other interviewees. For a more detailed discussion of interview protocols and coding, see Appendix Two.

Although this study is not intended to serve as a formal test, and therefore cannot guarantee that causal relationships are not examples of correlation, Chapter Seven systematically attempts to verify findings by stating how scholars could falsify the reported results with counterfactual evidence. While this does not provide conclusive "proof" of any claims in the study, it nevertheless describes the kind of findings that could disprove the hypothesis. Therefore, this study's claims to reliability and validity are defensible.

Number of Cases

Arguably the first challenge for any Small-N researcher is to identify how many cases to explore in a detailed study. For works that aim to generate inference which extends beyond a single historical episode, comparison is critical. While some single country

case studies allow for temporal or jurisdictional comparisons, the nature of GMOs and stem cell research as national policies requires examination of multiple countries. Therefore, in order to show that the influences shaping policy outcomes applied more broadly than in a single context, this project chose at least two countries for study.

Moreover, because the study sought to understand variation in national approaches, for each technology I have selected countries with varying policy positions. While the addition of two similar policy cases could arguably bring important knowledge to bear on the effect of institutions on policy outcomes, it remains unclear whether the additional policy cases should be permissive or restrictive ones, potentially expanding the number of cases to eight, or larger than many Small-N research projects.

Country Selections

After choosing the technologies of focus and the minimum number of country case studies, researchers must select which national policies to compare. How does one make such a choice—what criteria should researchers employ? If one simply aims to capture the most permissive or the most restrictive policies then a social scientist might choose the most extreme examples available. However, this approach does not necessarily provide the most meaningful selections. For example, although Zambia and Tunisia established two of the most restrictive policies for GMOs and stem cell research, respectively, they did not possess major centers for research. In fact, their investment in research and development represented only a small fraction of other nations. Similarly, countries which created no restrictions on technology did not necessarily have strong scientific infrastructures.

Because the size of a nation's research capacity determined not only its engagement with biotechnology but its ability to influence other countries' policy

directions, this study took governments with the largest science budgets to be the most potentially important. Table 2.6 lists the ten countries with the largest Gross Domestic Expenditure on Research and Development (GERD) in years 1996, 2000 and 2004.

Table 2.6 Top Ten Gross Domestic Expenditures on Research and Development

GERD in '000 PPP$ (in constant prices – 2005)

	1996	2000	2004
1. United States	239,087,842	302,490,695	310,306,750
2. Japan	99,574,433	110,452,891	120,330,935
3. Germany	50,380,736	61,625,135	63,825,065
4. France	34,467,978	36,945,913	39,395,432
5. United Kingdom	27,766,625	31,615,680	32,474,424
6. Korea	18,440,601	20,213,193	28,305,232
7. Italy	14,312,000	16,510,911	17,962,196
8. China	13,927,081	30,405,283	59,276,271
9. Canada	13,679,503	19,062,878	22,797,809
10. India	9,414,052	13,849,164	17,128,647

SOURCE: UNESCO[55]

Among this small circle, nations with permissive policies included Canada and the United States, for GMOs, and Japan and the United Kingdom for stem cell research. Countries with restrictive policies included Germany and the UK, for GMOs, and Germany, Italy and the United States, for stem cell research. Table 2.7 details these countries and their policy approaches.

[55] Data obtained from the United Nations Educational, Scientific and Cultural Organization (UNESCO), Institute for Statistics: www.unesco.org, accessed January 20, 2012.

Table 2.7 First-generation policies for GMOs and HESCR among GERD leaders

	Permissive	Restrictive
GMOs	Canada United States	Germany Japan United Kingdom
HESCR	Japan United Kingdom	Germany United States

While selecting all nine cases for in-depth study would provide a definitive account of policy variation in top GERD countries, the limited resources of a D.Phil. study require the use of the minimal number necessary to achieve an accurate measure. Therefore, the ideal candidates would be two countries, each adopting a permissive policy for one technology and a restrictive policy for the other. From the countries listed in Table 2.7, only three did this: Japan, the United Kingdom and the United States. While the United States embraced GMOs and blocked embryonic stem cell research funding, Japan and the United Kingdom impeded modified crops and foods and sanctioned stem cell research.

2.4 The United Kingdom and the United States

Based on these options, one could compare the United States with either Japan or the United Kingdom. Both scenarios have built-in advantages and disadvantages. Comparing the United States and Japan would provide a considerable contrast of cultures. However, according to Mill's method of difference, when the variable in question is heterogeneous, e.g. permissive and restrictive policies, researchers should aim to select cases that resemble each other in other respects. In this way, the United Kingdom undoubtedly possessed a stronger cultural affiliation with the United States,

given the two countries' historical ties. Moreover, Japan's highly subsidized agricultural sector, described recently by political scientist Sven Steinmo, creates a clear separation from the other two.[56] Furthermore, Britain and the United States' shared language offers a clear efficiency for English-speaking researchers.

Perhaps the biggest problem with selecting the United Kingdom is its role as a nation-state within the supra-national European Union. As such, policymaking for GMO-containing crops and foods within UK territory occurred in two capitals, Brussels and London. While this split-level governance structure presented a challenge in data collection, it does not disqualify the case. Since both the EU and UK adopted restrictive positions, there is a basic consistency between them which could equate to a single policy.

For the reasons given above, the policies for GMOs and stem cell research in the United Kingdom and the United States were chosen as test cases for understanding why—and how—governments vary in their approaches to controversial science and technology. The following chapters explore these positions in detail, recounting the biography of key policy documents and pinpointing the main influences that shaped decisions.

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[56] Steinmo, Sven. *The Evolution of Modern States: Sweden, Japan and the United States* (Cambridge: Cambridge University Press, 2010).

CHAPTER 3: AGRICULTURAL GENETICALLY MODIFIED ORGANISMS IN THE UNITED STATES

Table 3.1 Timeline: Genetically Modified Organisms in the United States

1983	NIH Approved "Ice Minus" Release
1984	White House Launched Working Group
1986	Coordinated Framework Announced
1987	APHIS Finalized Rules for Plant Releases
1992	FDA Issued Policy Statement
1994	First Engineered Whole Food Approved
2001	EPA Completed Rules for PIPs

From the time global investors and producers first sought to commercialize the products of rDNA in the early 1980s, biotechnology would remain a significant preoccupation of the United States government. In a report highlighting the importance of the sector to the nation's economic competitiveness, officials proposed that the US take steps to nurture the innovations of genetic engineering.[1] Two decades later, the country had become the global leader in agricultural biotechnology, with a policy approach that reflected this early push to develop rDNA products, and accept them politically. Table 3.2 provides an overview of the first-generation policy, a regulatory approach that has changed little since its inception. The policy reflected three major uses: experiments in laboratory containment; planting engineered crops; and commercial sales of foods containing GMOs.

[1] US Congress, Office of Technology Assessment, *Commercial Biotechnology: An International Analysis* (U.S. Government Printing Office, January 1984).

Table 3.2 First-Generation Policy for GMOs in the United States

Activity	Document	Policy Outcome
Contained Use (1976-1982)	National Institutes of Health (NIH): "Guidelines for Research Involving Recombinant DNA Molecules"	While officials never regulated private-sector research on rDNA conducted in containment, federally-funded work from the mid-1970s required a strict safety protocol, which the NIH had mostly relaxed by 1982.
Planting (1987)	US Department of Agriculture (USDA): "Introduction of Organisms and Products Altered or Produced Through Genetic Engineering Which Are Plant Pests or Which There Is Reason to Believe Are Plant Pests" US Environmental Protection Agency (EPA), "Plant-Incorporated Protectants; Final Rules"	Producers seeking to release potential "plant pests" required a permit from USDA. Plant pests became "regulated articles," requiring detailed product information and a 120-day (maximum) waiting period. USDA relaxed some categories in 1993. Over the years, most applications were accepted. EPA rules required producers of many crops containing pesticidal qualities to register with the agency and obtain permits.
Commercial Sales (1992)	US Food and Drug Administration (FDA) "Statement of Policy: Foods Derived From New Plant Varieties; Notice" US Environmental Protection Agency (EPA), "Plant-Incorporated Protectants; Final Rules"	Treating genetic engineering as a more precise form of breeding and not inherently dangerous, FDA regulated GMOs as food additives only if inserted material was not "Generally Recognized As Safe" (GRAS). However, FDA urged producers to consult with the agency. EPA rules allowed the agency to regulate products derived from plant pesticides which posed new dietary risks.

SOURCE: See Below[2]

[2] Johnson, Judith A., *The NIH Recombinant DNA Guidelines: Brief History and Current Status* (U.S. Library of Congress, Congressional Research Service, July 7, 1982); US Department of Health and Human Services, NIH, "Guidelines for Research Involving Recombinant DNA Molecules," *Federal Register* 47 (April 21, 1982), 17180-17198; US Animal and Plant Health Inspection Service, Department of Agriculture, "Introduction of Organisms and Products Altered or Produced Through Genetic Engineering Which Are Plant Pests or Which There Is Reason to Believe Are Plant Pests; Final Rule," *Federal Register* 52 (June 16, 1987), 22892-22915; US Environmental Protection Agency, "Plant-Incorporated Protectants; Final Rules," *Federal Register* 66 (July 19, 2001), 37772-37817; US Food and Drug Administration (FDA), "Statement of Policy: Foods Derived From New Plant Varieties," *Federal Register* 57, no. 104 (May 29, 1992), 22984-23005.

Over the years, the permissive policy embraced by the US served as a model for other countries seeking to bring engineered varieties into their agriculture, and modified products into stores. However, for those who opposed GMOs, both inside and outside the US, America's policy approach signaled a range of maladies: Domestically, critics have accused officials of colluding with corporate interests seeking to maximize profits at a potential cost to human health and the environment; and internationally, opponents have said the US position imposed the new technology on other, and often less affluent, nations.[3]

A more subtle but equally controversial debate has engaged scholars: How did the United States arrive at its permissive policy? Many scholars have attempted to explain the origin of the policy that would contrast so sharply with the more restrictive one embraced by the European Union. Of course, given the complexity of the policymaking case, overly-simplistic or mono-causal explanations almost certainly fail to provide a sufficient answer, and threaten to obscure the rich constellation of political actors and interests, and their mutual interactions.

Some scholarly accounts emphasized differences in national culture as a key determinant.[4] Although many variations of this thesis existed, most implied that the US accepted GMOs because the general public had a favorable opinion of them, or at least minimal opposition. Other works stressed the agency of interest groups, observing the advantage of industry and the relative weakness of public interest organizations in

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[3] These and other criticisms are reflected in countless books, articles and blogs, including: Smith, Jeffrey, *Seeds of Deception: Exposing Industry and Government Lies About the Safety of the Genetically Engineered Foods You're Eating*, (Fairfield, Iowa: Yes! Books, 2003); Eichenwald, Kurt, Kolata, Gina, and Petersen, Melody, "Biotechnology Food: From the Lab to a Debacle," *The New York Times*, June 25, 2001; Cauvin, Henry, "Zambian Leader Defends Ban On Genetically Altered Foods," *The New York Times*, September 4, 2002; http://www.combat-monsanto.co.uk/.

[4] Jasanoff, Sheila, *Designs on Nature: Science and Democracy in Europe and the United States*, (Princeton, N.J.: Princeton University Press, 2005); Han, Lianchao, Thesis, "The New Food Pyramid: Culture, Policy and Technology in the Transatlantic GMO Controversy," (George Mason University, 2005).

lobbying for a preferred outcome.[5] A third group has begun to review structural causes in the policy case and provide accounts based on institutional factors inside government.[6]

While accounts based on public opinion or interest groups clearly provide relevant causal data, institutional arguments have the advantage of offering a view from inside government. Such accounts have the potential to explain not only the effect that institutions can have on policy outcomes, but the links between other factors and the policymaking process. Therefore, to expand scholarly knowledge of the US case, this chapter extends previous institutional accounts by providing a biographical analysis of the key policy documents, tracing the process used by officials in crafting the US approach.

The first period addresses the early stages in the regulatory process, when officials debated whether and how to take action. The second and third periods detail the development of a decision-making structure created by the White House, known as the Coordinated Framework. In the fourth, fifth and sixth periods, I describe how respective agencies crafted specific policy documents under the framework's aegis. Like Chapters Four through Six, the conclusion summarizes the principal findings from earlier in the chapter, engages in a discussion of likely causal mechanisms and analyses theoretical strategies—including Pierson's criteria and a secondary test of path dependence—for describing institutional influences.

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[5] Meins, Erika, *Politics and Public Outrage: Explaining Transatlantic and Intra-European Diversity of Regulations on Food Irradiation and Genetically Modified Food* (London: Lit Verlag, 2003).
[6] Pollack, Mark, and Shaffer, Gregory, *When Cooperation Fails: The International Law and Politics of Genetically Modified Foods* (Oxford: Oxford University Press, 2009).

3.1 Early Stages (1974-1984)

The breakthrough discovery of rDNA in 1973 by researchers Stanley Cohen of Stanford, Herbert Boyer of UC San Francisco and others represented something so fundamentally new that even the scientists involved wanted to move slowly.[7] Therefore, when biochemist Paul Berg of Stanford convened the landmark "Asilomar" conference on the safety of genetic engineering in 1975, scientists proposed a strict regulation of rDNA experiments that the National Institutes of Health established in the mid-1970s and later relaxed.[8]

Ten years after the initial rDNA discoveries, new developments in the 1980s spurred fresh calls for government action. Whereas the NIH-administered guidelines applied only to federally-funded rDNA experiments in containment, plans to release genetically engineered organisms into the environment through various means created a portfolio of new issues for elected officials, agency civil servants and the general public.

State of the Industry

Fuelled by the promise of advancements in pharmacology, agriculture and industrial applications, the pace of biotechnology innovation grew steadily from the mid-1970s. However, the speculative floodgates spilled open in 1980 when the US Supreme Court, in its *Diamond v. Chakrabarty* decision, allowed for the patenting of living organisms modified through the use of rDNA techniques.[9] Although most basic research occurred in universities, biotechnology "startups" quickly entered the scene. Genentech, Inc., the

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[7] Cohen, Boyer and others produced several groundbreaking papers, including: "Construction of Biologically Functional Bacterial Plasmid *in vitro*," *Proceedings of the National Academy of Sciences USA* 70, no. 11 (November 1973), 32040-3244; Johnson, Judith A., *The NIH Recombinant DNA Guidelines: Brief History and Current Status* (US Library of Congress, Congressional Research Service, July 7, 1982).
[8] Ibid, 3.
[9] *Diamond v. Chakrabarty*, 447 U.S. 303 (1980).

nascent South San Francisco research firm first to capitalize on the technology, set a record with its initial public offering (IPO) in 1980 for the fastest increase in individual stock share ($35 to $89 in 20 minutes).[10] Firms around the world rushed into the marketplace, including one across the bay, Cetus Corp. of Berkeley, which set a record in 1981 for the largest IPO in Wall Street history: $115 million.[11]

While industry experienced some early success with medical products, such as "Humulin," Genentech's engineered version of human insulin produced by Eli Lilly and Co., which the FDA approved in 1982, agricultural products emerged more slowly. After proposals by various researchers failed to succeed, researchers Steven Lindow and Nickolas Panopoulos of UC Berkeley sought permission from NIH in 1983 to release two genetically-modified bacteria, *Pseudomonas* and *Erwinia*, on to field crops, to reduce frost damage. The micro-organisms became known as "Ice Minus" because scientists had removed a gene known to promote ice-crystal formation.[12]

Congress Inquires

The Ice Minus proposal soon triggered a sequence of events that would lead to government action. Indeed, when NIH officials approved the experiments in June 1983, they had had to modify existing guidelines to allow for rDNA releases into the environment.[13] However, because scientists had created the guidelines expressly for

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[10] Source: US Congress, Office of Technology Assessment, *Commercial Biotechnology: An International Analysis* (US Government Printing Office, January 1984), 4.
[11] Ibid.
[12] "NIAID Director Withholds Approval of Two Open-Air Agricultural Experiments with Recombinant Organisms," *Biotechnology Law Report* 2 (February 1983), 23.
[13] The NIH approved release proposals by teams at Stanford and Cornell in August 1981 and April 1983, respectively. However, the releases did not occur because investigators stopped work at an earlier stage. See Jones, Mary Ellen, Thesis, "Politically Corrected Science: The Early Negotiation of US Agricultural Biotechnology Policy" (Blacksburg, Va.: Virginia Polytechnic Institute and State University, 1999), 127.

contained experiments, and because the rules applied only to federally funded research, environmental groups began to raise alarm about the apparent regulatory vacuum.[14]

In response, two Democratic congressmen, Al Gore and Doug Walgren, chaired a joint hearing of their subcommittees later that month, entitled "The Environmental Implications of Genetic Engineering."[15] Warning that genetic engineering presented "great potential benefits" and "tremendous risks," the hearing aimed to review the issue, the appropriate role for government and the need for any additional legislation.[16] Although the two Democrats led the charge, the issue concerned lawmakers from both parties. Indeed, Walgren's Republican counterpart on the subcommittee, Judd Gregg, concurred about protecting against environmental risks, as would other Republican members of Congress.[17]

Gore opened the hearing with remarks on the potential dangers of GMOs: "I am concerned that we have a proper understanding of all potential environmental ramifications *before* a genetically novel organism is released, rather than having to learn about them after the damage has occurred."[18] Testifying witnesses included geneticists experimenting with GMOs, ecologists concerned about environmental impacts and agency officials versed in existing regulatory law. Gore concluded that GMO releases produced a "low probability of high consequence risks."[19] The subsequently issued

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[14] Milewski, Elizabeth, "Congressional Hearing on the Environmental Implications of Genetic Engineering," *Recombinant DNA Technical Bulletin* 6, no. 3, National Institutes of Health (September 1983), 105-106.
[15] US Congress, House of Representatives, *The Environmental Implications of Genetic Engineering* (Washington, D.C.: US Government Printing Office, June 22, 1983).
[16] Ibid, 103.
[17] Ibid.
[18] Ibid, 103.
[19] Milewski, Elizabeth, "Activities Pertinent to NIH's Role in Overseeing Recombinant DNA Activities," *Recombinant DNA Technical Bulletin* 7, no. 2, Public Health Service National Institutes of Health (June 1984), 61.

"Gore Report" would also highlight the weakness of the current regulatory framework, and the difficulty of predicting the type, magnitude and probability of effects.[20]

Although far from conclusive, the hearing provided the first public airing of issues surrounding GMO releases, and would play a key role in shaping the government's initial response. Indeed, it launched a dialogue about regulation predicated on the clear need for government action.

EPA Moves Forward

ENVIRONMENTAL PROTECTION AGENCY
Established: 1970 Mission: To protect human health and the environment Employees: 11,420 (1984), 17,106 (1994), 17,611 (2004) Budget: $4.6 billion (1984), $6.4 billion (1994), $8.3 billion (2004) Reputation: Often considered a stringent regulator and a trusted environmental steward, the agency has employed a range of scientists, attorneys and other specialists to set national standards, write regulations and implement and enforce those regulations

SOURCE: See below[21]

Sitting behind the witness table at the June 1983 hearing, Don Clay, Acting Assistant Administrator of the Environmental Protection Agency (EPA) reacted swiftly to concerns about a vacuum in the regulatory landscape. He explained to members of Congress how EPA could fill it.[22] Repeating what officials within the agency had already been discussing for months internally, Clay said they would utilize the existing statutes the agency uses to regulate pesticides and toxic substances: the Federal

[20] Ibid.
[21] US Office of Management and Budget, Table 5.2--Budget Authority by Agency: 1976-2010, *The Budget for Fiscal Year 2006, Historical Tables*, (Government Printing Office, 2005): EPA employment data is available on the agency's website: http://www.epa.gov/planandbudget/budget.html.
[22] Milewski, Elizabeth, "Congressional Hearing on the Environmental Implications of Genetic Engineering," 109-110.

Insecticide, Fungicide and Rodenticide Act (FIFRA) and Toxic Substances Control Act (TSCA).[23]

But Clay's solution created potential problems. While oversight for bioengineered pesticides seemed straight-forward, regulating GMOs using TSCA did not. Because the law required producers of new "chemical substances" to submit product information to EPA prior to environmental releases, applying TSCA would require defining the products of genetic engineering as "chemical substances."[24] While such an approach could give EPA leave to regulate all products containing rDNA, the definition could also invite a potential legal challenge. "There was a lot of discussion about whether TSCA should cover plants, animals and microbes, a broader scope," said Jane Rissler, a plant pathologist and assistant to EPA Assistant Administrator John A. "Jack" Moore.[25] An internal memorandum from Associate General Counsel Stan Abramson to Assistant Administrator John Todhunter confirmed that the agency believed TSCA could apply to rDNA and "new life forms."[26]

TSCA presented a further problem: It had numerous weaknesses as a statute, since the law only required producers to notify EPA, leaving it to the agency to follow-up and ensure safety and compliance. As a regulatory statute, it was arguably weak and required additional legislation if officials wanted to strengthen it. To strengthen it, officials would need new legislation.

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[23] Ibid; Abramson, Stanley, "Memorandum to John A. Todhunter, Ph.D., Assistant Administrator for Pesticides and Toxic Substances," March 14, 1983. Passed in 1947, FIFRA has undergone numerous modifications subsequently; Congress passed TSCA in 1976.

[24] Milewski, Elizabeth, "Congressional Hearing on the Environmental Implications of Genetic Engineering," 105.

[25] Rissler, Jane, Interview, September 21, 2009. For further information about interviews conducted for this study, including a complete list of interviewees, see Appendix Two.

[26] Abramson, Stanley, "Memorandum to John A. Todhunter, Ph.D., Assistant Administrator for Pesticides and Toxic Substances."

Ice Minus

Despite these challenges, America's environmental watchdog spent the next year planning an oversight system for rDNA products. In September 1983, the agency's efforts gained momentum when a political activist named Jeremy Rifkin filed suit against the NIH, alleging that its officials had violated the law in approving the Ice Minus release proposal. The [Rifkin] suit, which called for further environmental assessment, generated considerable media attention, and drew the attention of other government branches, including Congress and the White House.[27] It also pushed EPA ahead, with the agency rushing in to fill the perceived regulatory gap. By November, agency lawyers had claimed jurisdiction over Ice-Minus bacteria under FIFRA, arguing that the micro-organisms constituted a pesticide, because they displaced the non-modified bacteria that facilitated frost formation.[28] At the same time, EPA officials announced that they intended to regulate rDNA products using TSCA, and that EPA would issue a new rule on the subject in the coming months.[29]

With backing from Democrats in Congress, EPA received a boost in February 1984 when the Gore Report recommended a broad and permanent leadership role for the agency. Among other things, the report directed the EPA "to extend its authority to include all deliberately released organisms not specifically identified as part of the legal obligation of another agency."[30] It upheld the EPA's broad scope for TSCA authority, and recommended that the agency lead an interagency task force until EPA could complete the new regulations. In fact, the agency had formed such a panel in September

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[27] Cohrssen, John, Interview, September 1, 2010.
[28] Jones, Mary Ellen, "Politically Corrected Science: The Early Negotiation of US Agricultural Biotechnology Policy," 164.
[29] "US Task Force Plans Regulation of Gene-Spliced Products," *McGraw-Hill's Biotechnology Newswatch* 3, no. 21 (November 7, 1983), 3.
[30] Milewski, Elizabeth, "Activities Pertinent to NIH's Role in Overseeing Recombinant DNA Activities," 61.

1983: the Interagency Risk Management Council (IRMC).[31] Thus, with the IRMC and a working proposal to extend the TSCA statute, EPA began 1984 aiming to play the dominant role in regulating genetic engineering.

Restraining EPA

But detractors throughout the Reagan Administration would halt EPA's steady advance. Various research-promoting agencies within the large, $46 billion-budgeted Department of Agriculture (USDA), opposed EPA's moves, with most preferring the status quo under NIH.[32] And discontent with EPA soon flowed from the highest echelons of power. In March 1984, the White House itself, which had already proclaimed its general opposition to regulatory obstruction, would pre-empt the EPA's efforts by asserting its prerogative and launching a regulatory effort under the President's control.[33]

3.2 Policy Design: Proposal for a Coordinated Framework for Regulation of Biotechnology (1984)

PRESIDENT RONALD REAGAN
Party: Republican In office: 1981-1989 Reputation: Known as "the great communicator," the former actor and California Governor launched a far-reaching economic program to cut taxes, reduce government spending and eliminate unnecessary regulations. Although the White House policy for biotechnology in some ways belied Reagan's deregulatory philosophy, it arguably comported with his underlying support for science, innovation and industry.

[31] "OMB Challenges EPA Plan to Regulate Biotechnology in Cabinet-level Draft," *Inside EPA*, March 30, 1984, 10-12.
[32] US Department of Agriculture, "Office of Budget and Program Analysis (OBPA)," website; Jones, Mary Ellen, "Politically Corrected Science: The Early Negotiation of US Agricultural Biotechnology Policy," 166-177.
[33] Anonymous, "OMB Challenges EPA Plan to Regulate Biotechnology in Cabinet-level Draft," *Inside EPA*, March 30, 1984.

Ronald Reagan was swept into office on famously pro-growth, anti-government winds.[34] From his 1980 election, opposition to government interference in the private sector would permeate the administration, from a landmark 1981 tax cut to specific policy proposals, such as an executive order the same year which required that all proposed regulations be assessed for their impact on the economy.[35] In another bid to oppose red tape, the White House created the Presidential Task Force on Regulatory Relief under "deregulation czar" Christopher DeMuth, a political appointee in the Office of Management and Budget (OMB), the executive division which oversees agencies via the purse.

White House officials expressed concern over EPA's regulatory designs on biotechnology, especially given the agency's long history of stringent regulation and battles with industry. "We thought [EPA regulation] could kill the technology," said John Cohrssen, a White House attorney in a statement broadly reflective of the administration position.[36] Moves to regulate too quickly, officials reasoned, could stifle the progress of a nascent industry the United States hoped to dominate.[37]

And, despite the power of individual players, such as Monsanto, industry was relatively weak and disorganized. Indeed, for much of the 1980s and into the 1990s, the producer coalition was fragmented between large and small companies, and between firms with expressly different concerns, e.g. seed engineering, agriculture, food products. Carl Feldbaum, who in 1993 became the first President of the Biotechnology Industry Organization (BIO)—which itself was formed by the merger of two competing

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[34] Cannon, Lou, *President Reagan: The Role of a Lifetime* (New York and London: Simon & Schuster, 1991).
[35] US Executive Office of the President, "Executive Order 12291," *Federal Register* 46 (February 17, 1981), 13193.
[36] "Interview with John Cohrssen, former legal counsel, Cabinet Council Working Group on Biotechnology, by Mary Ellen Jones," December 19, 1997, see Jones, Mary Ellen, Thesis, "Politically Corrected Science: The Early Negotiation of U.S. Agricultural Biotechnology Policy," 168.
[37] "OMB Challenges EPA Plan to Regulate Biotechnology in Cabinet-level Draft," *Inside EPA*, March 30, 1984.

trade groups—described industry's early relations as antagonistic. "I was actually hired in 1993 to bring the two organizations together because in the five or ten previous years they had done nothing but fight with each other and it was already a very tiny industry that was split."[38]

Citing concern about international competitiveness and the negative effect that over-regulation could have on Wall Street, DeMuth proposed to take the regulatory reins away from EPA by forming a working group under one of the President's domestic policy committees or cabinet councils.[39] Referred by DeMuth to the Cabinet Council on Economic Affairs, by April the proposal had shifted to the Cabinet Council on Natural Resources and the Environment, which then created a panel known as the Domestic Policy Council Working Group on Biotechnology.[40]

The working group met for the first time on May 9, 1984, and voiced its general concern about over-regulation and the need to support, not inhibit, industry.[41] With a membership that included high-level civil servants from nearly two dozen agencies, the working group met at least once a month at the White House.[42] The size of the group depended on whom the White House invited: sometimes principles only; or, principles with staff.[43] The agencies invited ranged from those more directly concerned with biotechnology, such as EPA and USDA, to more peripheral units, such as the Departments of Labor, Justice and Energy. "It was a large, complex group," said David Kingsbury, the National Science Foundation (NSF) representative to the panel.[44] Their goal, he described, was "to come up with a rational set of regulatory policies" that

[38] Feldbaum, Carl, Interview, September 2, 2010.
[39] Ibid; Easterbrook, Gregg, "Ideas Move Nations," *The Atlantic Monthly*, January 1986.
[40] US Office of Science and Technology Policy, "Proposal for a Coordinated Framework for Regulation of Biotechnology," *Federal Register* 49, no. 252 (December 31, 1984), 50856-50857.
[41] Jones, Mary Ellen, Thesis, "Politically Corrected Science: The Early Negotiation of U.S. Agricultural Biotechnology Policy," 242.
[42] Cohrssen, John, Interview, September 1, 2010.
[43] Ibid.
[44] Kingsbury, David, Interview, January 21, 2010.

would clarify the path for producers and assure the public about the safety of the technology.[45] Most critically, they would aim to avoid creating new legislation and base the US policy on existing statutes.

With Democrats in Congress scrutinizing the process from outside, the working group directed lead agencies EPA, USDA and FDA to craft policy statements interpreting the statutes they administered.[46] Although officially led by George Keyworth, the President's science advisor and director of the Office of Science and Technology Policy, acting chairman duties were filled by Keyworth's deputy director, Bernadine Healy Bulkley, who oversaw day-to-day activities, and the running of working group meetings.[47] Healy, an accomplished cardiologist, who would go on to head the NIH and the American Red Cross and make an unsuccessful run for the US Senate in Ohio, led the panel with a close attention to detail.[48] As the agencies crafted their policy statements, Healy and her White House staff wrote and edited the introduction to the document that became the official first draft of the US policy: the Proposal for a Coordinated Framework for Regulation of Biotechnology (hereafter "the 1984 proposal").[49]

Early Missteps

The 1984 proposal represented a preliminary document that delayed many key decisions into the future. Most critically, it stopped short of explaining how agencies would distribute regulatory responsibilities and coordinate effectively to review biotechnology

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[45] Ibid.
[46] Dingell, John; Waxman, Henry; Brown, George; and, Gore Jr., Albert, "Letter to Hon. George A. Keyworth, II, Science Advisor to the President, Office of Science and Technology Policy, Executive Office Building, Washington, DC," May 24, 1984.
[47] Hereafter referred to as Bernadine Healy.
[48] Kingsbury, David, Interview, January 21, 2010.
[49] US Office of Science and Technology Policy, "Proposal for a Coordinated Framework for Regulation of Biotechnology," *Federal Register* 49, no. 252 (December 31, 1984), 50856-50857.

products. In some cases, such as with USDA, agencies wanted no role, opposing regulation on philosophical grounds and preferring to maintain the advisory committee structure provided by NIH. However, as former NIH molecular biologist Elizabeth Milewski described, "[NIH] was not a regulatory agency and it really did not want regulatory authority or powers."[50] So Bernadine Healy aimed to fill the gap, drafting a larger, White House-led version of NIH's Recombinant DNA Activities Committee (RAC). "The 1984 policy was looking at trying to design some overall Super RAC," said Terry Medley, a USDA staff member who attended council meetings.[51] Healy's vision included a committee of committees to review all biotechnology proposals seeking approval.

Another problem stemmed from the scope of the regulation, which officials failed to define. What exactly would agencies regulate, the things made from rDNA or the rDNA being used? The NIH rules clearly viewed rDNA as the regulated substance, and EPA initially employed a similar scope to interpret TSCA. However, some working group attendees, including biologist and physician Henry Miller of the FDA, objected to unscientifically prejudicing everything that contained rDNA as substantively different.[52] Officials opted to remain temporarily silent on the scope issue, delaying into the future the question of regulating the *process* versus the *products* of genetic engineering.

The 1984 Draft

Published in December 1984, the proposal opened with a call to protect US pre-eminence in the nascent biotechnology sector, while acknowledging the legitimacy of safety concerns. Framing regulation as a way to assure the public and industry, the

[50] Elizabeth Milewski, Interview, September 9, 2009.
[51] Medley, Terry, Interview, September 16, 2009.
[52] Cohrssen, John, Interview, September 1, 2010.

government clearly wanted biotechnology to succeed. Any regulation must therefore "adequately" address health and environmental safety, it stated, but in a coherent and consistent manner reflecting "the best available science."[53]

Following the preamble, EPA provided the most detailed of the agencies' policy statements, but also one that reflected its newly diminished role. After being pushed back by the White House earlier in the year, the agency reached for considerably less regulatory authority. Whereas officials had previously sought to extend the TSCA statute to cover rDNA and "new life forms," the agency's 1984 statement had a much narrower reach, specifically limiting TSCA to non-food, non-drug products.[54] The EPA's bid to oversee new engineered pesticides under FIFRA statute was not controversial.[55] Despite signs that the EPA had accepted its minimized role, the agency's document maintained a definition of engineered products as those containing rDNA, setting the stage for a confrontation with other agencies.

PROPOSAL FOR A COORDINATED FRAMEWORK FOR REGULATION OF BIOTECHNOLOGY (1984)

The Editor:

Bernadine Healy, MD: Deputy Director, White House Office of Science and Technology Policy

The FDA took a very different approach in its statement, proposing to treat new biotechnology products in the same manner as other products with similar uses. Looking to the agency's signature law, the Food, Drug and Cosmetic Act, officials would review products on a case-by-case basis and utilize its existing rules where

[53] US Office of Science and Technology Policy, "Proposal for a Coordinated Framework for Regulation of Biotechnology," *Federal Register* 49, no. 252 (December 31, 1984), 50856-50857.
[54] Abramson, Stanley, "Memorandum to John A. Todhunter, Ph.D., Assistant Administrator for Pesticides and Toxic Substances."
[55] US Office of Science and Technology Policy, "Proposal for a Coordinated Framework for Regulation of Biotechnology," 50882.

applicable.[56] FDA also formally introduced a dichotomy that would reverberate into the future: process versus product regulation. "Regulation by FDA must be based on the rational and scientific evaluation of products, and not on *a priori* assumptions about certain processes," the statement said, reflecting Henry Miller's insistence that the policy not judge engineered products as *a priori* different.[57]

USDA's approach resembled FDA in that it described the existing regulatory framework as adequate. The department, which itself possessed constituent agencies that had helped develop biotechnology products, viewed genetic engineering as essentially safe. New products, according to the agency's statement, "will not differ fundamentally from conventional products."[58] USDA sought to maintain the status quo, with NIH overseeing GMO releases for federally-funded research, and said the Plant Pest Act could address any potential threats to plant health.

Although the 1984 proposal represented a tentative document, it nevertheless achieved something profound: It located decision-making firmly within White House control, rather than leaving the design of regulation to congressional Democrats and their agency of choice, the EPA. This would set the stage for a reshuffling of responsibilities at the President's discretion.

3.3 Policy Design: The Coordinated Framework for Regulation of Biotechnology (1985-1986)

Because the December 1984 draft delayed decisions into the future, working group members started Reagan's second term with a full agenda. In one of its first moves, the

[56] Passed in 1938, the Food, Drug and Cosmetic Act is the principal legislation ensuring the safety of food and pharmaceutical products in the United States.
[57] US Office of Science and Technology Policy, "Proposal for a Coordinated Framework for Regulation of Biotechnology," *Federal Register* 49, no. 252 (December 31, 1984), 50880.
[58] Ibid, 50904.

working group discarded Healy's proposal to create a number of interrelated committees overseen by the White House.[59] Finding the idea unduly complicated, officials opted to allow agencies to develop regulatory policies which they would also administer.[60] To address scientific questions, they created a new interagency panel called the Biotechnology Science Coordinating Committee.[61]

In addition to jettisoning the Super RAC concept, the working group also lost its leader. In 1985, Healy left to take a leadership position at the Cleveland Clinic. David Kingsbury, a UC Berkeley microbiologist who represented NSF at working group meetings, took on the role.

But eliminating the Super RAC would also mean that agencies needed to step up their own efforts to craft a viable regulatory approach. Kingsbury credits working group members for achieving this on the second try. "The [1986 policy] was where we had worked everything out," he said. However, achieving accord would take considerable work.[62]

Recruiting USDA

With EPA oversight limited to pesticides and non-plant products under the 1984 draft, and with the NIH opting out of regulation of rDNA releases entirely, White House officials needed to identify a viable mechanism for reviewing engineered crops. USDA, which administered a series of plant quarantine laws, including the Plant Pest Act, had previously opposed playing a greater role, with many of its research-oriented divisions calling additional oversight unnecessary. However, after numerous conversations between USDA attorney Terry Medley and the White House, the agency began to

[59] Cohrssen, John, Interview, September 1, 2010; Medley, Terry, September 16, 2009.
[60] Ibid.
[61] Kingsbury, David, Interview, January 21, 2010.
[62] Ibid.

rethink its resistance. "There was interest in [USDA] coming forward," Cohrssen said. "They were encouraged to come up with an approach based on sound science."[63]

Over time, Medley joined with other working group members informally known as the "pragmatists," and began to view some form of oversight as essential to assuring both industry and the public. "Good regulations should accomplish both," Medley said. USDA's expanded role developed slowly. In the 1984 proposal, the department barely mentioned its subsidiary agency, the Animal and Plant Health Inspection Service (APHIS). However, in the final document, APHIS had a significant and clearly delineated role in regulating engineered crops.

After the White House identified broad roles for APHIS (plants), FDA (food) and EPA (pesticides and non-agricultural bio-chemicals), officials still needed to establish how regulation would work. What would agencies regulate and how? The answers to these questions would emerge in an unfolding debate about scope.

Process vs. Product

At the working group's weekly meetings, held next to the White House in an Old Executive Office Building conference room, members debated whether engineered products created with rDNA posed a risk simply because of the process used to produce them.[64] "We were trying to get people to stop focusing on the fact that recombinant DNA was the mechanism that was being used to produce these things, and to focus on what the nature of the plant or product was," said Kingsbury.[65] Even attendees from the typically-vigilant EPA had difficulty arguing that rDNA presented inherent risks. "It's not *a priori* just because it's genetically engineered that it's risky," said Elizabeth

[63] Cohrssen, John, Interview, September 1, 2010.
[64] Kingsbury, David, Interview, January 21, 2010.
[65] Ibid.

Milewski, a molecular biologist at the NIH who was recruited to join the EPA in 1986.[66] Between the three agencies, Milewski explained, officials could track the genes introduced, monitor their behavior and test any food products. These aims framed the working group's discussion of scope principles, that is, how the US would design and justify regulation. Would agencies regulate the process of genetic engineering or the products resulting from it?

Despite members' general belief in the basic safety of rDNA techniques, some argued that a process-based scope made the most sense. "That's the whole purpose, that's what got the scientists thinking about oversight, having something novel, unpredictable... You might wind up with problems you hadn't anticipated," said Elizabeth Milewski.[67] Without rDNA as the scope, what exactly would agencies regulate? They would certainly need to specify which products required oversight. "If you can't describe transgenic plants as what it is you're going to focus on, you're pulling in all plants."[68] Furthermore, Milewski felt that a process-based scope would still allow agencies to review individual products for potential problems.[69]

But attendees from FDA and USDA felt that using rDNA as the scope would create problems. Terry Medley, an attorney for the USDA, said such a process-based approach could have prevented his agency from extending the laws it administers to cover GMOs. Citing the Plant Pest Act, which protected agriculture against harmful organisms, he said: "It would have been difficult because these statutes are all based on a type of risk," Medley said. "So unless you can *a priori* say that genetic engineering equates to increased plant pest risk, what would be the basis for taking authority? You

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[66] Milewski, Elizabeth, Interview, September 9, 2009.
[67] Ibid.
[68] Ibid.
[69] Ibid.

would need a new statute."[70] Medley and others argued for a regulatory scope that made no inherent assumptions about rDNA, but rather based the regulatory review on the nature of the product, i.e. its intended use and potential risk. To utilize the Plant Pest Act and other existing laws, Medley argued that officials would need to look for more proximate risk indicators than simply use of rDNA. These could include any specific changes to a plant that might create a measurable risk. "But that's the bottom line: [Potential risk existed] not because it's engineered, but because it has the ability to do these things," Medley said.[71]

FDA would also raise concerns about a process-based scope, saying it could make it difficult to interpret the authority of the Food Drug and Cosmetic Act. Using rDNA as the scope, for example, could force the agency to treat all biotechnology products as food additives, or food adulterants, a potentially awkward fit that could prompt a legal challenge.[72] "The likely implication of a process-based approach would have been we need new laws to do it," said FDA civil servant Eric Flamm.[73]

The case for creating a scope based on a risk spectrum broader than rDNA ultimately won out. Each agency agreed to identify criteria that would allow for a review of some rDNA products, but not all. While FDA and USDA certainly favored the product-based approach, some officials at EPA had trouble with the concept. "We spent a lot of time and twisted ourselves into knots," said Jane Rissler, who worked as a top aide to Assistant Administrator Jack Moore. Rissler said officials who preferred a product-based approach often did so because they believed it would help industry. "Trying to regulate in a product rather than a process way would lessen that burden because fewer things would be regulated," Rissler said. Although observers would

[70] Medley, Terry, Interview, September 16, 2009.
[71] Ibid.
[72] Kahl, Linda, Interview, September 11, 2009.
[73] Flamm, Eric, Interview, September 11, 2009.

continue to disagree on the appropriateness of a product-based scope, and indeed whether such an approach was truly achievable in practice, most agreed that focusing on products signaled less regulation.

Decision-making

In general, the working group made decisions through consensus, deliberating on major issues collectively.[74] When disagreements occurred, the group leaders, and members based at the White House, typically weighed in. These included Kingsbury, staff members from OMB and John Cohrssen, an attorney in the Council on Environmental Quality (CEQ), whom Healy hired specifically to assist the working group.[75] Numerous attendees described the meetings as acrimonious at times. But Cohrssen said disagreements were no different than in any other Washington policy context. "Turf is a big issue in Washington," said Cohrssen, who noted that clashes over portfolios did at times become personal. "Some people didn't like each other."[76]

But members ultimately accepted the group's decisions, Cohrssen said. "There's always the concern that if this goes to a higher political level you're going to have a worse result."[77] Looking back on the sessions, attendees from EPA, the agency with the most to lose, did not fault the decision-making process employed. Before leaving EPA to work for the Union of Concerned Scientists, Jane Rissler attended some Coordinated Framework sessions with Assistant Administrator Jack Moore. Recalling the period, she said: "I didn't see anything that was corrupt."[78]

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[74] Ibid.
[75] Cohrssen, John, Interview, September 1, 2010.
[76] Ibid.
[77] Ibid.
[78] Rissler, Jane, Interview, September 21, 2009.

The Final Document

COORDINATED FRAMEWORK FOR REGULATION OF BIOTECHNOLOGY (1986)
Authors: David Kingsbury, PhD: UC Berkeley microbiologist and Assistant Director for Biological, Behavioral and Social Sciences, National Science Foundation, acting chair, Domestic Policy Council Working Group on Biotechnology. John Cohrssen: White House attorney and special assistant to Kingsbury

Presented to the Reagan Cabinet at a meeting in the White House's Roosevelt Room weeks before its public release in June 1986, the Coordinated Framework for Regulation of Biotechnology detailed the approach agencies would take in reviewing the products, not the processes, of genetic engineering.[79] The FDA stated that officials would apply the agency's stringent food additive rules if new foods contained any added substances not "generally-recognized as safe (GRAS);" EPA settled on a scope for regulating engineered pesticides and any non-plant and non-food products containing "inter-generic" species, i.e. modified organisms containing material from dissimilar source organisms; lastly, USDA's APHIS, as the primary regulator of crops, would oversee potential plant pests.[80]

Critics have pointed out subsequently that despite the framework's insistence, agencies in practice took a process-based approach, i.e. regulating based on the presence of rDNA. "I think the process versus product debate has always been a farce, because FDA [and] USDA regulate according to process, and basically EPA does too," said Jane Rissler, a former EPA plant pathologist who later advocated for a range of

[79] Kingsbury, David, Interview, January 21, 2010
[80] US Executive Office of the President, Office of Science and Technology Policy, "Coordinated Framework for Regulation of Biotechnology," *Federal Register* 51 (June 26, 1986), 23302.

environmental issues as a senior scientist at the Union of Concerned Scientists. Challenging the claim that agencies regulated based on the product alone, Rissler suggested that the approach embraced by the US was not a meaningful one. "I'm not sure what was accomplished other than something cosmetic."[81] In other words, although the White House had sought an official line emphasizing a less burdensome focus on products, necessity often required that they regulated based on process.

Regardless of what happened in practice, however, the product-based scope represented a critical compromise. "There were people who didn't want any regulation," said Elizabeth Milewski of the EPA, who considered herself one of the "pragmatists" who supported regulation of GMOs. Other members, such as the FDA's Henry Miller, opposed creating special oversight for rDNA-derived products. "That agreement made it possible for the US to do regulation," Milewski said.[82]

Some Reagan officials expressed concern when Kingsbury presented the finished policy to cabinet members gathered in the Roosevelt Room of the White House.[83] After the presentation, Commerce Secretary Howard Malcolm "Mac" Baldrige questioned whether it would constrain industry and violate the President's commitment to deregulation. But the framework's purpose became clear after a lengthy discussion. Indeed, lack of regulation, Kingsbury told attendees, would hurt public confidence in the nascent technology. "This was a case where new regulations were really important to give a sense of confidence to the public that this was an industry that was responsible and was being watched," Kingsbury said.[84]

Others were skeptical of the White House approach. "In my view they were trying to put together something that would at least look like regulation but would not

[81] Rissler, Jane, Interview, September 21, 2009.
[82] Milewski, Elizabeth, Interview, September 9, 2009.
[83] Kingsbury, David, Interview, January 21, 2010.
[84] Ibid.

be a burden to the industry," said Rissler.[85] In fact, many environmentalists over the years would come to believe that the administration wanted to please industry. However, Rissler stops short of suggesting anything untoward. "What was done was well within what administrations do to get their policies made according to their views," Rissler said.[86] In other words, the push and pull of agency deliberations had produced a legitimate result, even if the framework displeased some.

Because the basic approach taken by Reagan officials would withstand subsequent attempts to change it, some observers have argued that it achieved the correct balance, even for an administration committed to helping business. Noting that the approach would remain in place despite unsuccessful attempts to amend it, David Kingsbury argued that the policy had stood the test of time: "There's no doubt about it. It was an anomaly. The Reagan administration was a deregulatory administration. This was the major exception."[87] Even some environmentalists, such as molecular biologist Margaret Mellon, Rissler's colleague at the Union of Concerned Scientists, acknowledged that the administration had shown foresight and diligence in launching the framework in the 1980s. "You have to be fair to them," said Mellon, who had at the time lobbied for a more restrictive policy. "They did it on their own and it was quite remarkable."[88]

3.4 Policy Execution: APHIS (1986-1987)

With the contentious debates about regulatory turf behind them, agencies could proceed with the task of producing policies for biotechnology under existing laws. Some had

[85] Rissler, Jane, Interview, September 21, 2009.
[86] Ibid.
[87] Kingsbury, David, Interview, January 21, 2010.
[88] Mellon, Margaret, Interview, September 18, 2009.

already started. In fact, the June 26, 1986, issue of the *Federal Register* contained both the final Coordinated Framework and a proposed rule from USDA's Animal and Plant Health Inspection Service (APHIS).[89] With research scientists eager to begin testing transgenic plants in the field, the government needed to create a system for reviewing proposals. APHIS, which officials enlisted after overcoming USDA's initial doubts about regulation, became the first agency to implement the framework.

US DEPARTMENT OF AGRICULTURE
Established: 1862 Mission: To protect and promote US agriculture Employees: 101,792 (2006) Budget: $46.7 billion (1984), $65.4 billion (1994), $93 billion (2004) Reputation: Approximately five percent of the US federal budget, the department contained numerous constituent agencies, playing a multitude of roles including advocacy and regulation.

SOURCE: See below[90]

When officials began work, multiple releases of rDNA products had already occurred on US soil.[91] Therefore, regulators could take comfort in the fact that no known damage had occurred as a result. But Medley said officials wanted to take no chances, and sought to create robust oversight that they could later adjust with new information about safety.[92]

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[89] Animal and Plant Health Inspection Service, US Department of Agriculture, "Introduction of Organisms and Products Altered or Produced Through Genetic Engineering Which Are Plant Pests or Which There is Reason to Believe Are Plant Pests" (Proposed Rule), *Federal Register* 51, no. 123 (June 26, 1986), 23352-23366.

[90] US Office of Management and Budget, Table 5.2--Budget Authority by Agency: 1976-2010, *The Budget for Fiscal Year 2006, Historical Tables*, (Government Printing Office, 2005). USDA employment data is available on the agency's website: http://www.ascr.usda.gov/reports_esummary_06.html.

[91] AGS Inc. of Oakland released Ice Minus in February 1985 without a license. The first NIH-approved experimental release, of Agracetus Corporation's engineered tobacco, occurred in May 1986. See: US Animal and Plant Health Inspection Service (APHIS), "Biotechnology Regulatory History."

[92] Medley, Terry, Interview, September 16, 2009.

From a Proposal to a Final Draft

As an attorney in the General Counsel's office at USDA, Terry Medley led APHIS' attempt to build a regulatory structure. "I was the primary counsel to APHIS in the development of those regulations," said Medley, who helped write the proposal along with a dedicated core of biotechnology staff.[93] In later years, Medley would rise to the highest rank in the agency, APHIS Administrator, before accepting a position at leading chemical and engineered seed producer DuPont.[94]

As they contemplated a direction for the regulation, Medley said officials sought to include specific changes to plant genetics that raised questions, such as the use of so-called promoters to help inject a transgene into a plant. "When you start asking those questions you say, what we really need is a process where we can say if you do certain things you have to come in and have those things reviewed," Medley said.[95] Acting under the legal authority of the Plant Quarantine and Plant Pest Acts, the draft policy proposed a mandatory permitting process for some but not all genetically modified plants. Regulated species would include those derived from known and suspected "plant pests," i.e. living organisms which can directly or indirectly harm plant species. To receive a permit for a species dubbed a "regulated article," producers must submit detailed product information, including details on processes utilized in production.

After publishing the proposed rules, APHIS launched an accelerated effort to complete and implement them by hiring Medley to lead a new division called the Biotechnology Biologics and Environmental Protection Group (BBEP). The division aimed to sort out problems with the proposal and, more importantly, serve as the

[93] Ibid.
[94] Medley, Terry, Interview, September 10, 2010.
[95] Ibid.

backbone for the APHIS regulatory effort. Medley hired staff from across USDA with diverse backgrounds, including molecular biologists and ecologists.[96]

To finish the effort, BBEP had up to a dozen dedicated staff working on the various sections. The policy had many hurdles to jump. "It had to meet all the requirements of the Administrative Procedure Act in terms of looking at the cost of compliance, impact on small business, compliance with environmental statutes," Medley said. "There's a whole gamut of things that you go through." The final version required review by other USDA divisions and then by outside agencies, such as EPA.

APHIS published the final rules on 16 June 1987.[97] Medley said the policy aimed to assure safety but also maintain flexibility. For example, officials would aim to add or eliminate requirements after collecting more data. "That was the commitment that was made in 1987 … that these regulations will be evergreen because the science is growing, is changing," Medley said.[98] As such, in 1993 APHIS shifted its policy from a permitting system to one based on notification.

APHIS Rules in Practice

Despite USDA efforts to build a regulatory program that could assess risks while guiding industry, critics would brand the attempts as inadequate. "USDA, no matter what it regulates, regulates weakly, and it operates under industry's tutelage whatever it's regulating," said Jane Rissler.[99] Much of the criticism centered on the fact that the agency approved the vast majority of applications. "USDA has never seen a risk that it

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[96] Ibid.
[97] U.S. Animal and Plant Health Inspection Service, Department of Agriculture, "Introduction of Organisms and Products Altered or Produced Through Genetic Engineering Which Are Plant Pests or Which There is Reason to Believe Are Plant Pests" (Final Rule), *Federal Register* 52, no.115 (June 16, 1987), 22892.
[98] Medley, Terry, Interview, September 16, 2009.
[99] Rissler, Jane, Interview, September 21, 2009.

couldn't minimize," Rissler said. "They take the data, which by the way are all generated by the companies, and they always are able to put a safety spin on those data."[100]

In defense of the APHIS program, Terry Medley said the approvals proved that the system had worked. He described attending public forums, at which members of the public would insist that the agency's denial of only a handful of applications demonstrated the weakness of the regulations. Medley disagreed. "No, what it means is we've developed a guidance document which says if you want approval here's what you have to do," Medley said, explaining that the regulations served as a guide. "Good regulations provide that type of clarity and guidance. People know in advance if they have what they need to apply for something."[101]

[100] Rissler, Jane, Interview, March 11, 2010.
[101] Medley, Terry, Interview, September 16, 2009.

3.5 Policy Execution: FDA (1992)

FOOD AND DRUG ADMINISTRATION
Established: 1927 Mission: To ensure the safety and efficacy of pharmaceuticals, food and other products Employees: 11,516 (2009) Budget: $1.7 billion (2004) Reputation: Although a relatively small division of the US Health and Human Services Department, FDA was known for its influential pre-market approval process for new drugs. To ensure food safety, the agency relied on its post-market authority to remove unsafe products from stores.

SOURCE: See below[102]

During the Coordinated Framework discussions, FDA Commissioner Frank Young and his assistant Henry Miller, both scientists, staunchly supported biotechnology and opposed regulation. They considered engineered products no different from conventionally bred ones, and believed FDA's existing food laws would provide adequate oversight. Together, they helped secure the agency's place as the lead regulator for bioengineered food.

But throughout the 1980s FDA's involvement was merely academic, since no company had created a viable food product. That changed when CalGene of Davis, CA, approached FDA in 1989 with its "Flavr Savr" tomato, a whole food crop engineered to delay ripening.[103] The company sought regulatory approval, but of course FDA had no system for ensuring food safety. So Young's successor as commissioner, David Kessler, created a team in the agency's Center for Food Safety and Applied Nutrition (CFSAN) to craft what would become the agency's 1992 policy statement. As a first step, Kessler asked for a scientific paper on evaluating the safety of engineered food, telling members

[102] US Department of Health and Human Services, "FY 2004 Budget in Brief," 2003. Employment data is available from the agency's website. See: US FDA, "About FDA."
[103] Maryanski, James, Interview, August 30, 2010; US Food and Drug Administration, Center for Food Safety and Applied Nutrition, "First Biotech Tomato Marketed," September 1994.

of what became known as the Task Group on Food Biotechnology to keep an open mind. "He told us we didn't need to worry about the law," said James Maryanski, the microbiologist and civil servant tapped to lead the Task Group. "He just wanted to know what the science would tell us and suggest in terms of protecting public health."[104]

The Task Group would use the Flavr Savr tomato as their model. Maryanski called it a "big advantage" for FDA to have the CalGene application and data to review when writing the policy.[105] Although the FDA employed many scientists, they generally relied on the scientific testing data provided by industry applicants. Since no one had attempted to demonstrate the safety of engineered foods before, Maryanski described the process as an evolutionary one.[106]

FDA regulators had several regulatory options at their disposal to address potential hazards, including additive rules and labeling requirements. But the most critical tool was FDA's post-market safety provisions, which placed the burden of product safety on producers. Failure to sell a safe product could result in swift enforcement action by the agency, including the removal of products from store shelves. The challenge facing officials in the late 1980s was to create a system that utilized these existing tools. "We still had a lot of thinking to do about how to approach our interpretation of the statutes in order to get to where we were in 1992," said FDA staff scientist Linda Kahl, one of Maryanski's collaborators.[107]

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[104] Ibid.
[105] Maryanski, James, Interview, August 30, 2010.
[106] Ibid.
[107] Kahl, Linda, Interview, September 11, 2009.

FDA STATEMENT OF POLICY (1992)

Authors:

James Maryanski, PhD: Microbiologist and Biotechnology Coordinator, Center for Food Safety and Applied Nutrition; FDA employee from 1977 to 2005; private sector consultant from 2005
Eric Flamm, PhD: Microbiologist, Center for Food Safety and Applied Nutrition; PhD; FDA employee from 1988
Linda Kahl, PhD: Biochemist and Compliance Officer, Center for Food Safety and Applied Nutrition; FDA employee from 1992
Catherine Copp: Office of the General Counsel, FDA

Although Maryanski technically led the group, he served in a coordinating role and had no subordinate staff.[108] He worked closely with Kahl and Eric Flamm, both scientists and career civil servants; and Catherine Copp, an FDA attorney. Together the group oversaw the production of "many, many, many drafts" over the nine-month period leading up to publication of the policy in May 1992.[109]

The group produced a preliminary draft in August 1991 outlining types of new foods, potential concerns and regulatory options. It also contained the rudiments of a policy that would rely on the agency's food additive law; utilize a regulatory "umbrella" to exempt certain additives considered safe; place a significant portion of the safety burden on industry; and promote strictly science-based labeling.[110] From there, the team began circulating the draft for review within FDA and beyond. Specifically, Maryanski asked agency scientists to develop criteria for the "umbrella" regulation. The Task Group worked on the policy document itself, and on a guidance for industry. Finally,

[108] Maryanski, James, Interview, August 30, 2010.
[109] Flamm, Eric, Interview, September 11, 2009
[110] FDA Collection, Maryanski, James, "FDA Task Group on Food Biotechnology: Progress Report 2," August 15, 1991.

the team would enlist National Research Council scientists to study the agency's scientific criteria and consensus.[111]

Product vs. Process

While the Coordinated Framework mandated a product-based regulation, FDA officials struggled to put this into practice. If officials aimed to treat engineered products without prejudice, how could they justify a policy designed for those products alone? The apparent contradiction revived the debate about process versus product, and it would recur throughout the drafting of the FDA policy. It inspired Kahl in January 1992 to describe a recent draft as "very schizophrenic" for appearing to pertain to all products, not just those produced from biotechnology.[112] In a memorandum to Maryanski, Kahl described efforts to enforce a strict product-based approach as "trying to fit a square peg into a round hole."[113] Kahl argued that genetic engineering and traditional breeding were different processes and had different risks. Potential differences did not preclude a product-based approach, but they should be factored into the final document, she said. Looking back, Kahl said the draft "didn't make sense" and noted that it changed considerably in later versions.[114] Nevertheless, the episode represented a significant, early challenge to the product-based approach. Others would follow. And while they would not reverse FDA's general commitment to a product-based approach they arguably tempered it in ensuing discussions.

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[111] Ibid.
[112] FDA Collection, Kahl, Linda, "Comments," January 8, 1992, 1.
[113] Ibid.
[114] Kahl, Linda, Interview, September 11, 2009.

Drafting the Statement

Debates about process versus product would arise intermittently, such as when officials sought to apply the agency's food additive laws. Officials had to determine whether an engineered food contained an "added substance," which triggered regulation under the Act. Although the question may strike some as obvious, Flamm explained that one could challenge the notion that GMOs contain added substances on scientific grounds. While a gene is inserted into a plant cell, it is the plant that copies the gene and regenerates it throughout the other cells. Successive breeding gradually removes any evidence of human manipulation, Flamm said.[115] Officials writing the 1992 policy took a more cautious route, assuming that the process of genetic engineering would in fact create products with added substances not normally found in food.

After resolving the issue of added substances, officials had to decide what actually constituted the added substance. Was it the gene inserted into a tomato or the entire tomato after the insertion? Taking the whole food itself as the added substance represented a conservative approach, and one that could catch internal disruptions and unintended changes caused by an inserted gene. On the other hand, officials noted that the science did not justify the broader definition. "The risk of unintended changes through biotechnology is arguably no greater, [and] conceivably less, than with other methods of breeding," said Flamm. "So it didn't make sense from a scientific perspective if you weren't worried about the sort of magical properties that we didn't believe in."[116] Moreover, defining an entire tomato as an added substance presented potential legal difficulties. "We don't really know that such a thing could have been

[115] Flamm, Eric, Interview, September 11, 2009.
[116] Ibid.

sustainable under legal challenge," said Kahl.[117] In the end, officials chose the narrower definition, agreeing to regulate only the genes inserted into plants.

Food Additives

FDA then set out to apply the agency's strict food additive rules, which stipulated that added substances not generally recognized as safe required pre-market review and approval by the agency, and possibly labeling. While consumer advocates and critics of GMOs favored using the additive law, industry opposed it because of the stigma it created for products.

Grappling with the quandary, officials noted that no evidence suggested that inserted genes created unique risks.[118] Like any other food, engineered products could have allergic or toxic qualities, or they could also have so-called pleiotropic (unintended) effects, such as the production of an unknown toxin due to activation of a previously cryptic gene.[119]

Moreover, regulating all GMOs as food additives would place the burden on the agency to demonstrate that a safety risk existed, something FDA was not prepared to do. Rather than devote staff and resources to an area with no known risks, FDA opted to use the additive rule only for situations that demanded it scientifically.[120] "We would presume that substances were GRAS as long as they were proteins that were similar to other proteins in food," Maryanski said.[121] FDA would reserve the right to regulate any inserted gene as a food additive.

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[117] Kahl, Linda, Interview, September 11, 2009.
[118] Maryanski, James, Interview, August 30, 2010.
[119] FDA Collection, Johnson, Carl, "Comments from Dr. Carl B. Johnson on the "draft statement of policy 12/12/91," January 8, 1992.
[120] Maryanski, James, Interview, August 30, 2010.
[121] Ibid.

Ensuring Safety

In their deliberations, FDA staff members debated how exactly they could verify the safety of eating engineered foods. While they found no evidence of new risks, some scientists had expressed concern about unintended effects. [122] In addressing safety questions, the FDA approach shifted to a discussion of risk. As Kahl explained, FDA could not ensure "absolute certainty of no harm" but it could demonstrate "reasonable certainty of no harm," the standard established by Congress in passing the food additive laws in 1958.[123] "It's a question of what are the data we need in any given circumstance and you learn to know it when you see it," Kahl said.[124] Looking at detailed product information, the agency could make determinations about potential allergic and toxic effects, as well as major changes in nutritional or biological content.

But because the FDA did not perform safety studies, officials needed a method of generating product data. They identified one in industry. Because any food marketed in the US must ensure safety or risk its forced removal from store shelves, producers generated considerable product safety information of their own. Indeed, industry generally could not risk the financial losses associated with having an unsafe product removed from stores, a prospect that could tarnish a producer's entire portfolio. "We would never want that," said Monsanto spokesman Dan Jenkins. "That would be a very bad day for Monsanto."[125] Thus, industry had a significant interest in verifying safety, and FDA sought to take advantage of this.

Agency officials thereafter created a voluntary consultation process, whereby companies could take their data to FDA. The step later became a standard practice for

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[122] FDA Collection, Pribyl, Louis, "Comments on Biotechnology Draft Document 2/27/92," March 6, 1992.
[123] Kahl, Linda, Interview, September 11, 2009.
[124] Ibid.
[125] Jenkins, Dan, Interview, August 31, 2010.

most companies and most products, fostering a form of *de facto* regulation. Moreover, FDA required producers to make safety information available to the public, adding a further check to the process.[126]

Labeling

Officials also confronted the question of requiring labels for all GMOs, and decided they could not do so under the law. Writing in the 1992 statement, they noted that the statute mandated labeling only if "the common or usual name no longer applies to the new food, or if a safety or usage issue exists."[127] However, because officials found nothing essentially different about GMOs, the agency had no basis for requiring labels. "To mandate labeling when there isn't an objective need, a reason for it, we don't have that authority," said Eric Flamm, explaining that the Act did not allow for "right-to-know labeling." "That's up to Congress to mandate, to change the law that would require labeling, and Congress hasn't done it."[128] Although members of Congress would subsequently introduce labeling measures, these attempts would not succeed.

US law would also stop producers of non-engineered foods from labeling their products as such. "Companies can voluntarily label if it's truthful and not misleading," Flamm said. But that does not give them the right to assert or imply things that were not true statements. "If you're trying to imply that the non-biotech stuff is safer or better than the biotech stuff and there's no reason to believe that's true, then that's misleading," Flamm said.[129]

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[126] Maryanski, James, Interview, August 30, 2010.
[127] U.S. Food and Drug Administration (FDA), "Statement of Policy: Foods Derived From New Plant Varieties," 57 *Federal Register* 57 (May 29, 1992), 22984.
[128] Flamm, Eric, Interview, September 11, 2009.
[129] Ibid.

Table 3.3 US Public Support for Mandatory Labeling of GMOs[130]

The contents of this table cannot be made freely available via ORA due to copyright concerns.

Although officials did not conduct authoritative opinion polls at the time, data from subsequent years showed overwhelming support for mandatory labeling of engineered products. Table 3.3 provides the percentages of support for labeling in years 1995 to 2001. The results seemed to place the FDA position in contravention with the public will.

Completion

When producing the document, Task Group members sought broad input within the FDA, and worked toward achieving consensus.[131] Maryanski and other members provided regular updates to Michael Taylor, Kessler's deputy and an attorney who had done legal work for Monsanto prior to joining FDA. While he does not remember

[130] This table appeared in Meins, Erika, *Politics and Public Outrage: Explaining Transatlantic and Intra-European Diversity of Regulations on Food Irradiation and Genetically Modified Food*, (London: Lit Verlag, 2003), 204. The data were compiled by the Center for Food Safety: www.centerforfoodsafety.org.
[131] Maryanski, James, Interview, August 30, 2010.

Taylor or Kessler providing specific directions, Maryanski noted that it probably occurred.[132]

The finished policy required the approval of Fred Shanks, Director of the Center for Food Safety and Applied Nutrition (CFSAN). But, most of all, the policy needed Kessler's approval. "He had to be fully on board," said Maryanski, who remembered one group meeting in which Kessler asked officials if they had any reservations about moving forward with engineered whole foods. No one did. "We worked very hard to get to a point where everyone was in agreement," Maryanski said.[133]

After completing the policy, officials sought approval from its parent division, the Department of Health and Human Services (HHS), and the White House. In addition to other tweaks, the White House suggested a title for the policy that sufficiently obscured any implied differences between traditionally bred foods and genetically altered ones: "Statement of Policy: Foods Derived from New Plant Varieties." Officials embraced it.

Announced in May 1992 by Vice President Dan Quayle, the policy statement represented a gradual development from the basic parameters established in the previous year.[134] In addition to stating the agency's policy, the document provided a detailed guidance for industry on investigating potential allergic and toxic effects, as well as major changes in nutritional or biological content.[135]

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[132] Ibid.
[133] Maryanski, James, Interview, August 30, 2010.
[134] Eichenwald, Kurt, Kolata, Gina, and Petersen, Melody, "Biotechnology Food: From the Lab to a Debacle," *The New York Times*, June 25, 2001.
[135] U.S. Food and Drug Administration (FDA), "Statement of Policy: Foods Derived From New Plant Varieties," 22984.

Table 3.4 FDA Policy Decisions (in Capital Letters) Leading up to the agency's 1992 Statement of Policy: Foods Derived From New Plant Varieties

	Process	Product
Coordinated Framework	New Law	EXISTING STATUTES
Statement of Policy	ADDED SUBSTANCE	No Added Substance
	Entire Plant	GENE ONLY
	Additive Regulation	EXEMPT IF "GRAS"
	CONSULTATIONS	No Requirement
	Labeling Required	NOT REQUIRED

The document set the tone for future FDA decision-making on biotechnology. Two years later, FDA completed the consultation with CalGene for the "Flavr Savr" tomato, the first engineered whole food approved by the FDA. While some critics have sought to draw simplistic connections between the product-based approach taken in the Coordinated Framework and FDA's later policy, the relationship was not a linear one. As Table 3.4 shows, officials mostly adhered to a product-based approach, apart from two findings: that a genetically-modified food did in fact contain an "added substance" under existing law, and the provision of consultations as a *de facto* requirement for producers. Moreover, the pattern revealed that even an agency which had favored product regulation experienced difficulty achieving it.

3.6 Policy Execution: EPA (1994-2001)

Following approvals at USDA and FDA, CalGene's Flavr Savr tomato in 1994 became the first commercially grown GMO sold as a whole food in stores. In addition to the historic precedent it set, the product is noteworthy for another reason: Its approval occurred without the direct oversight of EPA, the country's environmental watchdog that had sought to play a leading regulatory role in the early 1980s, before Reagan officials blocked its advances.

Plant Pesticides

Although the EPA succeeded in claiming oversight for Ice Minus and other micro-organisms, these genetically-engineered microbes never took off commercially. Nevertheless, the agency would still play a participating role in regulating some GMOs, including pesticides and non-food toxicants. The most significant EPA rule was its policy for GMOs containing pesticidal qualities.[136] These "plant pesticides" included Bt corn, and other crops in which scientists had inserted a gene from a bacterium repellant to pests but safe for human consumption.

To craft its policy for plant pesticides, the EPA followed its standard rulemaking procedure, proposing a rule in November 1994 that created a broad exemption for certain varieties but required producers to register other plant pesticides under the agency's FIFRA statute.[137] Most critically, the policy required producers of some engineered Bt crops—such as corn and cotton—to register.[138] Officials crafted a methodology for issuing experimental use permits (EUPs) for planting non-exempt varieties, and outlined the agency's obligations under the Food, Drug and Cosmetic Act, which included regulating plant pesticides with the greatest potential for new dietary exposures.

In subsequent deliberations, the agency acknowledged the unique nature of the pesticide, in which the agent is produced and used in the living plant, and following complaints that EPA terminology had a negative connotation, changed the name of the

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[136] US Environmental Protection Agency, "Plant-Incorporated Protectants; Final Rules," *Federal Register* 66 (July 19, 2001), 37772-37817.

[137] Schneider, William, Interview (email), September 11, 2009; US Environmental Protection Agency, "Plant-Pesticides Subject to the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the Federal Food, Drug, and Cosmetic Act (FFDCA); Proposed Policy; Notice," *Federal Register* 59 (November 23, 1994), 60496-60547.

[138] US Environmental Protection Agency (EPA), "EPA's Regulation of Bacillus Thuringiensis(Bt) Crops, website.

product class to "plant-incorporated protectants" (PIPs) before issuing the final rule in 2001.[139]

Overall, the EPA's diminished role in overseeing GMOs meant that the USDA and FDA became the focus of attention and controversy regarding genetic engineering policy matters. Furthermore, EPA's reputation as a strong regulator further reduced potential opposition and concern to the activities attached to its portfolio.

3.7 Conclusion

The United States policy toward agricultural biotechnology is not a singular doctrine, but a collection of rules spread over time. While use of rDNA in containment did not become a lasting position issue that resulted in significant oversight, the legal right to plant engineered crops, and to sell the end products commercially, however, did. Policymaking activities occurred in roughly two stages. First, the Coordinated Framework laid the groundwork for creating new policies by organizing the government's approach: oversight based not on the *a priori* process of genetic engineering, but on the risk potential of individual products. It said the US would rely on existing statutes, and look to the regulatory agencies that administered those statutes, to create and execute policies.

Second, after the Coordinated Framework established regulatory roles for USDA, FDA and EPA, civil servants with scientific and legal backgrounds could proceed with rulemaking to advance the technology while assuring human health and environmental safety. Based on officials' ability to facilitate consistent planting and commercial approvals, this study described the US policy as permissive.

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[139] US Environmental Protection Agency, "Plant-Pesticides, Supplemental Notice of Availability of Information," *Federal Register* 64 (April 23, 1999), 19960.

Given the lengthy timeframe of policymaking efforts, and the numerous entities involved, theorists seeking to explain how and why the US policy unfolded as it did have ample material. Among the various works on the subject, two explanations hold special prominence. The first suggests that the United States public ultimately supported biotechnology, or at least did not strongly oppose it. The second suggests that government officials colluded with industry and acceded to interest group pressure. Both explanations have strengths and limitations.

Public Opinion

Although polling data from the 1980s and 1990s was not extensive, the notion that the American public supported GMOs is problematic. According to one survey by an industry-funded non-profit in the late 1990s, the public knew very little about GMOs. When asked whether engineered foods were available in stores, most respondents said "No" or indicated that they did not know.[140] Since many engineered products had already migrated to store shelves, the result suggests limited public awareness, a finding that apparently contradicts the claim that Americans "supported" GMOs.[141] Furthermore, according to poll data mentioned earlier in this chapter, people that knew about GMOs strongly backed mandatory labeling (see Table 3.3).

Rather than suggesting that Americans supported GMOs, more precise arguments could state that opposition was simply weak. However, these also present problems. Lack of awareness is not the same thing as lack of opposition. From the early 1980s, a degree of public opposition always existed. Indeed, the fact that Reagan officials proposed regulation at all demonstrated a baseline of public concern which a

[140] International Food Information Council, "US Consumer Attitudes Toward Food Biotechnology," 2001.
[141] Bates, Stephen, "Why Americans Are Happy to Swallow the GM Food Experiment," *The Guardian*, February 1999.

business-friendly White House aimed to mollify. As David Kingsbury, the leader of the working group, explained, Congress would have taken action if the President had failed to.[142] Similarly, FDA would experience strong opposition to its 1992 policy in the years thereafter, with the agency receiving thousands of letters demanding stricter oversight, and the labeling of all engineered food.

Cumulatively, the evidence shows that opposition existed for specific practices, such as releasing GMOs in the 1980s, and selling and labeling engineered food in the 1990s and beyond. Moreover, polling in subsequent years would point to sustained majority support for mandatory labeling.[143] But opposition movements never worked in concert: They failed to emerge at the same time or for the same issue at once. And, as I discuss later in this study, these voices would have a limited effect because of structural decisions made earlier.

Therefore, public opinion is a useful starting point in evaluating the policy outcome, but it fails to explain various details, such as the persistent opposition to GMOs over time and the precise mechanism through which officials reacted to it. While this study does not discount public opinion, it nevertheless turns to other dimensions of the explanation.

Interest Groups

In some ways, interest group activity provides a more compelling explanation for the US policy because it offers a clear mechanism for government influence: industry lobbying. From the early 1980s, the US government had wanted GMOs to succeed. Moreover, the nascent industry had a friend in the Reagan White House.

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[142] Kingsbury, David, Interview, January 21, 2010.
[143] Moskin, Julia, "Modified Crops Tap a Wellspring of Protest," *The New York Times*, February 7, 2012.

But interest group explanations also have shortcomings. As earlier sections described, White House concern for industry surrounded the long-term viability of biotechnology, not the fortunes of individual companies. "It was really at a higher level," said working group chairman David Kingsbury. "The biotech industry as a whole was going to be retarded by the lack of regulatory paradigm that they needed to work under."[144] Kingsbury and Cohrssen said they had no direct engagement with industry when drafting the framework, even if some members were personally aware of the producer perspective.[145]

Furthermore, the White House's deregulatory philosophy did not always comport with the goals of individual companies. In fact, large companies like Monsanto actually favored an EPA-led approach because it would advantage producers that could afford to comply.[146] "That gave them an upper hand," Kingsbury said.[147] Moreover, Monsanto, as a leading pesticide producer, already had a close relationship with EPA regulators, and knew the agency would protect its regulatory data, its secrets, in which it had invested countless millions.[148]

But the administration could not countenance EPA-led regulation. "This was not an EPA-friendly White House," working group attorney John Cohrssen said.[149] Thus, when it came to choosing a regulator, the White House and large companies found themselves at odds. Similarly, agencies crafted policies with a diverse group of clients in mind, too diverse to bias them in favor of only one company. While agency staff had

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[144] Kingsbury, Interview, January 21, 2010.
[145] Ibid; Cohrssen, John, Interview, September 1, 2010.
[146] Kingsbury, David, Interview, January 21, 2010.
[147] Ibid.
[148] Cohrssen, John, Interview, September 1, 2010; Jenkins, Dan, Interview, August 31, 2010.
[149] Cohrssen, John, Interview, September 1, 2010.

more regular exchanges with industry, communication did not necessarily translate to capture.[150]

Like public opinion, interest groups were clearly an important part of the equation. Indeed, industry was the driver of biotechnology innovation, and as a result sought to protect its investment. In this regard, one could attempt to say that producers played a collective role in pushing the government. However, given that companies within the industry had disparate goals, for example, with large companies favoring more restrictive oversight to gain competitive advantage over smaller firms, this explanation becomes more problematic.

Institutions

Despite their clear importance, public opinion and interest groups alone leave the question of the US policy incomplete. With public opinion, one saw not unilateral acceptance for biotechnology but an under-informed public which began to engage the subject years after products became a reality, with policies already comfortably in place. Similarly, industry's concerns helped drive the issue of regulation on to the Reagan Administration's agenda, but the respective preferences of individual companies were too various for White House officials and agency regulators to bias policies strictly in one direction or another. Thus, if public opinion and interest groups enhance the discussion of policy variance, they do not complete it. Moreover, they focus on external factors and treat government institutions as arenas instead of agents.

This study hypothesized that a significant portion of the explanation followed from what occurred inside government with countries' respective approaches to policymaking. But what did the chapter uncover? As earlier sections described, officials

[150] Ibid.

in the early 1980s faced a major decision in how to oversee GMOs: new legislation or existing statutes under either the EPA or a White House-determined regulator.

The choice would have serious consequences, since legislation signaled a potentially more restrictive result, as did any EPA-led regulation. As a first step, the EPA came forward to take the regulatory lead. In doing so, the agency helped convince Congress that an approach based on existing statutes would suffice. This subsequently allowed the White House, as the executive branch decision-maker, to claim authority over policymaking, and to redistribute duties in a way that both minimized EPA involvement and maximized the permissiveness of the US approach.

With the White House as a guide, agency officials debated questions of safety and scope mostly away from the din of partisan politics, and discussions reflected members' administrative expertise, and at times, self-interested bureaucratic behavior. Although participants produced a consensus document broadly sympathetic with the President's pro-industry goals, the policy result emphasized scientifically informed decision-making over narrow special interests. Announced in 1986, the Coordinated Framework represented an efficient, if anomalous step toward regulation by the Reagan White House.

The chapter then described policymaking efforts devolved to agencies from the White House, including those of the various policymaking teams. Although civil servants had occasional communications with external bodies, such as the White House, industry and interest groups, their work generally reflected the narrow enterprise of answering highly technical questions, for which their expertise was required. The arrangement yielded policies which ensured that the technology would advance but under clear guidance.

In addition to active policymaking efforts, the ordering of the work, and the fact that it took place in sequence, also impacted the outcome. Indeed, because officials crafted the Coordinated Framework in the mid-1980s, well before any commercial variety had emerged, the awareness and interest of the general public remained minimal. However, by the time engineered foods actually entered the marketplace, policymakers had already taken most major decisions. Furthermore, having a completed policy already in place created enormous obstacles for those who sought to change course later.

Pierson's Criteria

These distinctly institutional features of the policymaking process suggest a significant explanatory role for structural factors, in concert with other influences, such as opinion and interest groups. However, as a work of social science, the chapter must address a further dimension: How exactly did institutions impact outcomes? To answer this question, Chapter One proposed to describe policy development as an increasing returns process that can reveal the early institutional arrangements that drove policymaking later. The following paragraphs apply Pierson's criteria for increasing returns to GMOs in the US.

Multiple Equilibria

One could say that multiple equilibria existed when the environmental release of modified microorganisms first became an issue in the early 1980s, and officials in Congress and the White House debated how to address it. Congress could have passed a new statute, or the government could have relied on existing laws. White House officials opted for the latter. This decision would become important later on, when it

helped quell subsequent efforts by GMO opponents to pursue an alternate course from the one previously taken.

Contingency

Early in the policymaking process one could say that the EPA's support for using its existing statute, TSCA, to regulate rDNA and new life forms, had a critical impact on policymaking because it helped convince congressional Democrats that new legislation was not needed. But it also allowed the Reagan White House to assume control of the policy-making process, and ultimately diminish EPA's oversight role. In the end, TSCA was not used in the sweeping way some officials had envisioned. Furthermore, the embrace of an approach based on existing statutes would help stop later attempts by congressional Democrats to pass legislation.

Timing and Sequencing

The fact that the United States launched a regulatory system for biotechnology *before* most planting had occurred and well before engineered food products reached the market arguably eased public acceptance of the technology. When officials first began discussing regulation in the wake of the proposal to release Ice Minus bacteria in 1983, most opposition came from ecologists and environmental activists, but not the general public. Environmentalist Margaret Mellon, who had campaigned for stricter oversight from the early 1980s, described the initial regulatory debate as "a snoozer," meaning too remote and technical to engage a large audience[151] That changed in the early 1990s, when FDA prepared its policy for the first engineered food. The agency received a strong response from interest groups and consumers, who submitted several thousand

[151] Mellon, Margaret, Interview, September 18, 2009.

comment letters, many of them hostile toward GMOs. However, the fact that the government had already established a clear approach in the Coordinated Framework helped blunt opposition and assure the public.

Inertia

A kind of inertia developed after officials embarked on a regulatory path defined by the Coordinated Framework. Indeed, subsequent attempts by Congress to pass legislation ultimately foundered because agencies already had a workable approach in place and were following it. Critics of engineered food who had pushed the FDA to regulate GMOs as food additives also described the framework as having closed the window on an alternative approach. "We felt that it was probably not possible to make big changes at that level," said Jane Rissler of the Union of Concerned Scientists, who described the experience as "very sobering."[152] Subsequent changes to the framework, Rissler estimated, would have required a serious GMO-related health scare, such as a human death.

Extending Path Dependence

These applications of Pierson's criteria suggest that an increasing returns process existed in the development of the US policy for GMOs. On this basis, one should conclude that the permissive policy emerged not simply from tepid interest group activity or limited public awareness but from the early commitment to the Coordinated Framework, elaboration of policy documents before food products emerged and the difficulty of pursuing a legislative alternative.

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[152] Rissler, Jane, Interview, September 21, 2009.

Although Chapter One described Pierson's criteria as sufficient to reveal the institutional influences in policy development, this study proposed a secondary test of path dependence in order to describe variation in specific terms that scholars can assess comparatively. The following paragraphs apply this to the US decision-making structure, the Coordinated Framework, during the policy design and execution phases of the case.

Genetically Modified Organisms: The Policy Design

Actor Constellation. When the White House convened meetings of the Cabinet Council Working Group on Biotechnology, a new constellation of actors entered the policy-making process. While the previous domain featured activist Jeremy Rifkin confronting a regulation-shy NIH, and EPA civil officials eager to regulate environmental releases, the new field consisted of politically-sheltered negotiations between civil servants with conflicting views. Some attendees, like FDA's Frank Young and Henry Miller, believed genetic engineering posed no unique risks and generally opposed creating new food safety laws. Others, including officials from the EPA, expressed strong concerns about releasing GMOs into the environment, with some displaying noticeable alarm, according to one observer.[153] Attendees from USDA included supporters of GMOs, but also "pragmatists," like Terry Medley, who believed regulation was necessary to generate public confidence in the technology. Some of the most important actors were the White House officials overseeing the discussions, for they arguably injected the deregulatory philosophy of the Reagan Administration, which supported industry but did not necessarily align with specific companies.

[153] Cohrssen, John, Interview, September 1, 2010.

Balance of Interests. Deliberations over the Coordinated Framework also showed a marked shift in the balance of interests. While partisans in earlier and highly polarized public debates aimed to block GMOs by generating headlines and filing lawsuits, the White House sessions steered discussion away from the public sphere. In the closed-door sessions, Working Group members engaged in measured discussions of statutory authority and scientific risk analysis. As described in Chapter Three, the group's chair David Kingsbury described the group as working toward a consensus result based on what the science told them. And they had a clear motivation to work toward the common goal of risk-based oversight: Their own interests were at stake.

While the motivations of attendees depended on varying factors, including personal values, rank and career ambitions, the unifying factor was the rise or fall of their home agency. Indeed, any gain or loss in agency regulatory power also represented a gain or loss for individuals. "There was a lot of career-building," observed White House attorney John Cohrssen.[154] Therefore, the Working Group sessions focused the discussion on identifying adequate statutory authority. No one questioned that FDA had authority over food, and that EPA would oversee GMOs with pesticidal qualities. The major quandary surrounded regulation of plants. While EPA had made a play for broad authority under its TSCA statute, the claim was tenuous and the White House already had a strong anti-EPA bias. Officials encouraged USDA's APHIS to propose regulation of plants under its plant pest laws.

In the end, all agencies would play a role. "This was a compromise where everybody got something but nobody got everything," said White House attorney John Cohrssen.[155] Certainly, Working Group members had their particular interests. But the

[154] Ibid.
[155] Ibid.

number of members and the structure of the settings meant that no single party's interest would prevail, including those of the White House.

GMOs: The Policy Execution

Actor Constellation. Since the regulatory structure imposed by the Coordinated Framework assigned specific policymaking roles to agencies, a new slate of political actors emerged at each division crafting rules for GMOs: APHIS, EPA and USDA. These typically included the policy-making teams which coordinated and conducted work on major policy documents. Other agency actors involved included higher-level officials, such as bureau chiefs, and in some cases, the agency executive appointed by the President. Each of these offices and sometimes others needed to sign off on a policy document. As with most agency activities, the administration was not deeply involved in policy-making for GMOs. "The White House was much more into coordination than directing at that point in time," said White House attorney John Cohrssen.[156]

Like the Coordinated Framework sessions, agency policy-making limited the involvement of the general public and interest groups to specific intervals when it was solicited, as required by the Administrative Procedures Act. However, one exception existed: Since agencies already worked closely with industry, informal communication between regulators and industry was considered common.[157]

Balance of Interests. Policymaking at the agency level in turn shifted interests to the concerns of the civil servants conducting their highly specialized and often technical work. Like the Coordinated Framework sessions, agency policy teams aimed for consensus on issues such as risk assessment and policy approach. And since staff

[156] Ibid.
[157] Ibid; Maryanski, James, Interview, August 30, 2010.

members represented a more homogeneous group of actors than the inter-agency representatives at White House sessions, consensus decisions came more easily or at least had less at stake. This meant that civil servants at APHIS, EPA and FDA could conduct their work more directly within the contours of their job descriptions, approaching the task of creating a regulatory path for products as a technical question which they would evaluate in the usual manner.

Jim Maryanski of FDA described the policy-making process as an evolution, during which Task Group members sought to carry out the mission of applying science to create a safety evaluation system for GMOs. At a final meeting, FDA Commissioner David Kessler questioned staff members, and encouraged them to raise any outstanding concerns. None did. This suggests that staff members, after applying scientific methods to the question of regulation, were basically satisfied with the answer and confident enough to put their reputations on the line.

Secondary Test of Path Dependence

Based on this analysis one can say that the early path adopted in the US policymaking process, the embrace of the Coordinated Framework, provided the context and the incentive for policymakers at the White House and agencies to work toward a consensus-based result: producing a policy that would give industry a clear path to the market while at the same time ensuring human health and environmental safety.

On this basis, the Coordinated Framework approach arguably led to significant expansions in the constellation of actors and shifts in the balance of interests during both the design and execution phases of policymaking. Although this development does not singularly explain the US policy, the study suggests that a plausible relationship exists between changes in actors and interests and the permissive outcome. In this way,

the secondary test of path dependence provides a specific mechanism for assessing institutional influence along the policy path.

Without the framework, the government arguably would have required new legislation, which would have added considerable delays to the calendar and very likely a more restrictive policy result. Chapter Seven, the conclusion, will review this finding more closely in a comparative analysis that addresses the broader question of variation in biotechnology policies.

CHAPTER 4: AGRICULTURAL GENETICALLY MODIFIED ORGANISMS IN EUROPE AND THE UNITED KINGDOM

Table 4.1 Timeline: Genetically Modified Organisms in Europe and the United Kingdom

1988	Commission proposed directives drafted by DG Environment
1990	Council adopted Directives 90/219 and 90/220
1996	At the height of the BSE crisis, officials launched a multi-year cattle eradication plan.
1996	The first engineered food product, Zeneca's tomato paste, appeared in Sainsbury's supermarkets
1997	Commission approved controversial maize variety which deadlocked other EU institutions
1998	*De facto* moratoria began in Brussels and London
2001	Directive 2001/18 enacted
2003	US filed legal challenge at WTO; EU passed Regulations 1829 and 1830
2004	Moratoria lifted in Europe and Britain

Whereas the United States earned a reputation as an early incubator for genetic engineering by means of its permissive policy approach, the European Union and many of its member states famously opposed the technology.[1] Indeed, among the leading scientific powers, Europe's restrictive approach provided one of the sharpest contrasts with America. During the first five years of the European policy, from 1993 to 1998, officials made only sporadic approvals for commercial planting and sales. And between 1998 and 2004, when the EU revised its regulatory system, no applications moved forward at all.

This chapter aims to shed new light on the European policy, but before doing so, it must address one major methodological challenge: delineating the decision-maker of focus, since day-to-day oversight for GMOs took place both in Brussels and member

[1] Unless otherwise stated, the terms "European Union" and its predecessor organizations, the "European Community" and the "European Economic Community" will refer to the same political entity, as will any descriptions of "Europe" or "Europeans," depending on the context.

state capitals. Should research focus on the institutions of the EU, those of the member states, or a combination of the two? While arguably the most exhaustive account would detail policymaking activities in the EU and every member state, such an undertaking exceeds the ambition and resources of this study, which aims to explain the policy that took effect in the United Kingdom. Therefore, the following narrative provides a complete account of policy activities relevant to Britain, including those which occurred at both the EU and UK levels.[2] And except where otherwise mentioned, it concerns only those activities relevant to bioengineered food crops and food products grown, sold or produced in Britain.

Although the UK had made strides toward creating its own regulatory system by the late 1980s, the nation's first fully-fledged policy originated in Europe, when the European Economic Community (EEC) in 1990 passed the first of several laws for GMOs: Directives 90/219 and 90/220.[3] Directive 90/220, the principal document in Europe's new framework, stipulated that while member states would oversee crop trials

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[2] Although "Britain" may technically exclude Northern Ireland, this study treats it as synonymous with the United Kingdom unless otherwise noted.

[3] EU Council, *Council Directive 90/219/EEC of 23 April 1990 on the contained use of genetically modified micro-organisms*; EU Council, *Council Directive 90/220/EEC of 23 April 1990 on the deliberate release into the environment of genetically modified organisms*; other key policy documents in the framework included EU Parliament and Council, *Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001*, which replaced 90/220 and gave member states more autonomy over commercial planting; and three product safety laws: EU Parliament and Council, *Regulation (EC) No. 258/97 of the European Parliament and of the Council of 27 January 1997 Concerning Novel Foods and Novel Food Ingredients*; *Regulation (EC) No. 1829/2003 of the European Parliament and of the Council of 22 September 2003 on Genetically Modified Food and Feed*; and, *Regulation (EC) No. 1830/2003 of the European Parliament and of the Council of 22 September 2003 Concerning the Traceability and Labelling of Genetically Modified Organisms and the Traceability of Food and Feed Products Produced from Genetically Modified Organisms and Amending Directive 2001/18*.

within their own borders commercial planting and sales would require European approval. Thus, although Europe gave birth to the policy, it shared oversight duties with member states.

Table 4.2 Europe's Restrictive First-Generation Policy for GMOs under Directives 90/219/EEC and 90/220/EEC, in force from 1993

Activity	Jurisdiction	Policy Document	Policy Outcome
Contained Use	UK	EU Directive 90/219/EEC; UK Health and Safety at Work Act of 1974	Health and Safety Executive approval required; most applications granted
Experimental Trials	UK	EU Directive 90/220/EEC (later 2001/18/EEC); UK *Environmental Protection Act 1990*[4]	Permission required from the Dept. of the Environment; most applications approved
Commercial Planting	UK	Directive 90/220 (replaced by 2001/18)	Review by Department of the Environment; several approvals granted initially, but few after 1998
	Europe		Review by European Commission and committees under Directive 90/220 and 2001/18; several approvals granted initially, but none between 1998 and 2004
	UK		Ministers issue final consents for approvals made in Brussels; none issued before 2004
Commercial Sales	UK	Directive 90/220 (replaced by 2001/18); EU Regulation 258/1997 (replaced by 1829/2003 and 1830/2003)	Voluntary (mandatory after 1997) review by the Advisory Committee on Novel Foods and Processes (ACNFP), of the Ministry of Agriculture, Fisheries and Food (MAFF) and the Department of Health; several products cleared
	Europe		Review by Commission and committees until European Food Safety Authority established in 2002; several approvals granted initially, but none between 1998 and 2004

[4] UK Parliament, *Environmental Protection Act 1990*, (London: HMSO).

Under the 90/220-led policy frame, the UK's Department of the Environment (DOE) oversaw experimental trials from the early 1990s, and gave most applications the green light. In Brussels, where officials had jurisdiction over commercial planting and sales applications, a handful of applications succeeded in making it through Europe's complex "comitology" procedure. However, when a chain of events later in the decade galvanized public opposition to GMOs across the member states and created untenable political pressure within European institutions, the EU policy morphed into a *de facto* moratorium in 1998. After making numerous reforms to the system, officials lifted the ban in 2004 and approvals commenced on a limited basis. Similarly, during the six-year moratorium, the UK imposed its own ban on issuing commercial planting consents already approved by Brussels until the government could conduct further studies of environmental impacts.

These early changes in Europe's first decade of policymaking prompt a further methodological challenge: describing as a single policy an approach which actually changed over time. Since officials altered the policies for crop trials and commercialization significantly from the early to late 1990s, one could argue that the first-generation policy should refer only to the restrictive period between 1993 and 1999, when the handful of early applications gained approval. Indeed, the highly-restrictive moratoria imposed by Brussels and Whitehall came later, between 1998 and 2004.

However, arguments in favor of viewing these periods together outweigh those which would treat them as distinct. Although the regulatory climate would grow considerably more restrictive later, the policy from 1993 to 1998 still presented a clear contrast with the United States. Furthermore, one could not fairly describe the policy of 1993-1998 as stable, or at equilibrium, given the short life of the nascent policy regime.

Therefore, this study takes the first-generation policy to mean the policies in force in Britain from 1993 until the lifting of both moratoria in 2004.

To its supporters, the European policy represented a paragon of consumer- and environment-friendly policymaking, and a model for other regimes inclined to take a skeptical view of GMOs. However, critics derided the policy as one based on politics rather than scientifically demonstrated risk, and pointed to the loss of jobs and profits domestically, and the breech of established trade laws on the international front.

Many scholars have explored the causal mechanisms of the European policy, especially in contrast with the United States. While there are too many works to summarize here, most theorists have highlighted one or two common story lines. The first, emphasizing differences in national culture, described how public opposition to GMOs among general publics drove political leaders to restrict approvals.[5] The second, regarding interest groups, stated that strong environmental and consumer interest group lobbying combined with a politically weak industry effectively soured officials on the technology.[6]

However, a growing body of work has advocated greater consideration of institutional factors to explain the European policy outcome. Looking from "within" government, these accounts emphasized the policymaking context of key early decisions and the effect that it had on later decisions. While public opinion and interest groups certainly added critical details to the policy case, they do not tell the entire story. Indeed, the complexity of EU governance and its interaction with industry, activists and

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[5] Jasanoff, Sheila, *Designs on Nature: Science and Democracy in Europe and the United States*, (Princeton, N.J.: Princeton University Press, 2005); Han, Lianchao, "The New Food Pyramid: Culture, Policy and Technology in the Transatlantic GMO Controversy," Dissertation, George Mason University, 2005.

[6] Meins, Erika, *Politics and Public Outrage: Explaining Transatlantic and Intra-European Diversity of Regulations on Food Irradiation and Genetically Modified Food* (London: Lit Verlag, 2003); Bernauer, Thomas, *Genes, Trade and Regulation*, (Princeton, N.J.: Princeton University Press, 2003).

the public suggests that institutional dynamics may have also shaped the outcome in a conclusive way. Moreover, in addition to providing new information on causal mechanisms, institutional analyses have the potential to enhance knowledge of other factors by showing how they linked with decision-makers inside government.

Chapter Four explores how institutional factors influenced the restrictive outcome by recounting the biography of key policy documents as it unfolded chronologically. During the first period, from the mid-1970s to the late 1980s, the UK worked toward creating its own policy for GMOs, alongside other European member states. Meanwhile, in Brussels, officials took up the issue of biotechnology and deliberated over whether to create a community policy; what kind of policy to advance; and, who would lead policy-making efforts.

The second period, from 1988 to 1993, witnessed efforts to propose, approve and implement a workable policy led by Brussels. Laying the groundwork for a new decision-making structure, officials crafted and passed Directives 219 and 220, and the UK Parliament implemented them with the *Environmental Protection Act 1990* and other transposing measures. The third period, from 1993 to 1999, describes the first approvals in the UK and EU and the ensuing response, culminating in moratoriums in both jurisdictions. In the fourth period, from 1999 to 2004, European officials sought to address problems within the regulatory system, while in Britain ministers conducted further review of the environmental impacts of engineered crops.

Despite the promise of a scholarly focus on institutions, this approach presents a further methodological issue: At the time of policymaking for GMOs, EU governance structures were still developing. While the most significant entities existed prior to the 1980s and 1990s, others arrived later. This chapter addresses this challenge by

describing European institutions as they existed at the time, and conveying historical events as they occurred, while taking into account the changing nature of Europe.

4.1 Early Period: United Kingdom (1974-1990)

Between the discovery of recombinant DNA in the early 1970s and Europe's entry into the policy domain in the late 1980s, the United Kingdom created a sophisticated policy infrastructure for regulating GMOs, involving numerous divisions and hundreds of employees, before the European framework legally superseded it in 1993.

British Industry

From the 1970s, the British case resembled its American counterpart in several ways. The UK possessed a cutting edge research base, with its own laboratories having provided the setting for James Watson and Francis Crick's landmark discovery of DNA's structure in 1953. Britain had also nurtured a nascent biotechnology sector well-poised to compete in the global marketplace.[7] And, like the US, the British public remained largely unaware of the technology in the 1980s and early 1990s, according to the periodical press and observers of the period.

Containment

Even before US scientists convened the international conference at Asilomar in 1975, British researchers played an active role in the emerging global discussion on the safe use of rDNA in the lab. Indeed, successive working parties led by botanist Lord (Eric) Ashby and bacteriologist Sir Robert Williams prompted the UK to establish regulations

[7] A 1984 report by the US government cited the United Kingdom as its leading competitor, after Japan and Germany: US Congress, Office of Technology Assessment, *Commercial Biotechnology: An International Analysis* (U.S. Government Printing Office, January 1984).

under the *Health and Safety at Work Act* of 1974 and the first advisory panel on the subject: the Genetic Manipulation Advisory Group (GMAG) in 1976.[8] Going forward, rDNA researchers would need approval from both GMAG and a local biological safety committee to conduct experiments.[9]

However, when the potential dangers of rDNA failed to materialize, officials relaxed the restrictions in the early 1980s, and in 1984 replaced GMAG with a new panel that had broader advisory powers: the Advisory Committee on Genetic Modification (ACGM), operating under the auspices of the Health and Safety Executive (HSE).[10] The controls for rDNA work in containment would come to resemble those produced by America's NIH save in one key respect: Rather than applying only to government-funded research, the UK rules extended to all work done in Britain.

[8] Report of the Working Party on the Experimental Manipulation of the Genetic Composition of Micro-organisms, (London, 1975), Command 5880; Report of the Working Party on the Practice of Genetic Manipulation (London: HMSO, 1976); GMAG, created by the Department of Education and Science, reported to DES and the Health and Safety Executive; the Health and Safety (Genetic Manipulation) Regulations 1978 took effect on 1 Aug. 1978;.

[9] UK Health and Safety Executive, "Review of the Health and Safety (Genetic Manipulations) Regulations 1978," September 1987.

[10] Before 2008, the HSE consisted of two separate but related divisions: the Health and Safety Commission, with jurisdiction to create policy; and, the HSE, charged with policy implementation. Unless noted otherwise I will refer to both institutions as the HSE.

DEPARTMENT OF THE ENVIRONMENT (DOE)
Established: 1970 Employees: 6,404 (1987) Budget: £686 million (1999) Reputation: Although like other government ministries DOE's character and composition has varied depending on the government in power, departmental activities in recent decades have generally reflected society's increasing awareness of environmental threats such as industrial pollution. Created in 1970 by the merger of the Ministry of Housing and Local Government and the Ministry of Public Building and Works, DOE also included the Department of Transportation until the 2001 creation of the Department for Environment, Food and Rural Affairs, following the dissolution of the Ministry of Agriculture Fisheries and Food in the wake of the BSE crisis.

SOURCE: See below[11]

As industry began to move forward with experimental releases in the mid-1980s, British officials faced a quandary over how to regulate these so-called releases to the environment. HSE, based on its experience overseeing rDNA experiments in containment, asserted its regulatory authority by creating a voluntary notification system in 1986 that it would make statutory three years later.[12] However, officials at Department of the Environment (DOE) subsequently argued that health and safety legislation provided no direct safeguards for potential damage to the environment, and began to build a competence in the area, creating an *ad hoc* advisory committee in 1987, and proposing new legislation in 1989.

As HSE and DOE struggled over the authority for regulating releases, publication of the long awaited report of the Royal Commission on Environmental

[11] Hennessy, Peter, *Whitehall*, (London: Pimlico, 2001), 436-442; UK Treasury, "Budget 1999, Section B The Public Finances," March 1999, http://webarchive.nationalarchives.gov.uk/20100407010852/http://www.hm-treasury.gov.uk/b_the_public_finances.htm, accessed July 3, 2012.

[12] U.K. Health and Safety Executive, "Genetic Manipulation Regulations (1989)" (Her Majesty's Stationery Office, November 1, 1989).

Pollution (RCEP) strengthened the case for the latter.[13] Founded in 1970 and a respected authority on issues such as air and water quality, emissions, waste and nuclear power, the commission produced an exhaustive review of more than 100 pages. Most critically, the RCEP's scientists, lawyers and other professionals placed a greater emphasis on potential uncertainties and environmental impacts than a contemporaneous effort by the US National Research Council.[14] Among other things the RCEP report recommended new legislation, case-by-case evaluation and publication of all releases.

Environment officials paid close attention to the RCEP report, and included the above recommendations and others in provisions for GMO releases which became part of broader legislation already in the works: the *Environmental Protection Act 1990*. While the bill failed to incorporate all of the protections proposed in the RCEP report, the measure did incorporate the commission's recommendation to create an advisory panel dedicated to the environmental impact of GMO releases: the Advisory Committee on Releases to the Environment (ACRE).[15]

UK Capacity

Just as the UK began to address GMO releases in the late 1980s, European policy-making activities began to accelerate, and within a few years, a Brussels-led effort would supersede Whitehall operating alone. Both before and after the shift to Brussels, Britain maintained a strong infrastructure for regulating GMOs in terms of staff and

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[13] UK Royal Commission on Environmental Pollution, "Thirteenth Report: The Release of Genetically Engineered Organisms to the Environment" (Her Majesty's Stationery Office, July 1989).
[14] Jasanoff, Sheila, *Designs on Nature: Science and Democracy in Europe and the United States*, (Princeton, N.J.: Princeton University Press, 2005), 57; US National Research Council, Committee on Scientific Evaluation of the Introduction of Genetically Modified Microorganisms and Plants into the Environment, *Field Testing Genetically Modified Organisms: Framework for Decisions*, (National Academy of Sciences, 1989).
[15] Hartley, Sarah, Thesis, "The Risk Society and Policy Responses to Environmental Risk: A Comparison of Risk Decision-Making for GM Crops in Canada and the UK, 1973-2004," (University of Toronto, 2005), 42.

resources, and often lent expertise to activities on the continent. Like America, the government clearly wanted to advance biotechnology under appropriate safeguards.

Europe (1974-1986)

Table 4.3 European Membership from 1957-2004

1957	Belgium Italy France Luxembourg Germany Netherlands
1973	Britain Denmark Ireland
1981	Greece
1986	Portugal Spain
1995	Austria Finland Sweden
2004	Czech Rep. Lithuania Cyprus Malta Estonia Poland Hungary Slovakia Latvia Slovenia

When researchers discovered rDNA in the early-1970s, Europe was contemplating its first enlargement beyond its original six continental members making up the European Economic Community (EEC). The succeeding two decades leading up to the *Maastricht Treaty* of 1992 creating the European Union would see further enlargement and increased policymaking activity. Therefore, the emergent field of biotechnology would serve as an important case in Europe's policy-making development, and reveal some of the inherent challenges of addressing public concerns in legislation but also maintaining flexibility to adjust regulations to changing risks.

Industry Landscape

When US government researchers evaluated the competitive position of biotechnology in the early 1980s, they acknowledged Europe's strengths in research and development but also that large pharmaceutical and chemical companies were slow to invest on the

scale of US firms, such as Monsanto.[16] However, Europe never fell far behind. Indeed, by the late 1990s, out of the six conglomerates controlling 100 percent of the market for engineered seeds, four were headquartered in Europe.[17]

Early Policymaking

In the years after Asilomar, Europe mostly left the question of biotechnology to member state governments. The Commission of the European Communities (the Commission), Europe's quasi-executive, proposed mandatory containment measures in 1980, but later withdrew the plan in light of the emerging global consensus on rDNA's safety. However, when a 1984 report by the US Office of Technology Assessment showed Europe trailing America and Japan in the emerging biotechnology sector, the Commission took aggressive action, with Commissioner for Research Etienne Davignon leading the charge.[18] In communications to the Council, officials highlighted Europe's strategic weaknesses and proposed various solutions, including new research and development funds, and a plan to promote "concertation" (or coordination) of member state regulations.[19]

[16] US Congress, Office of Technology Assessment., *Commercial Biotechnology: An International Analysis*, (US Government Printing Office, January 1984), 8.
[17] Bernauer, Thomas, *Genes, Trade and Regulation* (Princeton, N.J.: Princeton University Press, 2003), 32.
[18] US Congress, Office of Technology Assessment, *Commercial Biotechnology: An International Analysis*, (US Government Printing Office, January 1984).
[19] EU Commission, "Biotechnology in the Community" COM (83) 672 final/2, October 3, 1983.

DIRECTORATE GENERAL FOR RESEARCH

Commissioner for Research: Filippo Maria Pandolfi
Director General: Paolo Fasella

Concertation Unit for Biotechnology in Europe (CUBE)
Established: 1984
Head of Unit: Mark Cantley

Reputation: Although the DG Research leadership did not aggressively pursue the biotechnology file, its CUBE division strongly opposed legislative efforts and unsuccessfully sought to limit regulation plans.

SOURCE: See note[20]

The Commission proposed a multi-year funding scheme under the aegis of the Directorate General for Research early the next year, and the Council approved it two years later.[21] The division created a bureau which specifically aimed to coordinate regulations, the Concertation Unit for Biotechnology in Europe (CUBE). Although these early efforts by the Commission focused on preventing Europe's research engine from falling behind, they also acknowledged the potential for public concern, and highlighted the importance of tracking "the social dimensions of biotechnology."[22]

Growing Concerns

Contrasting DG Research's support for the nascent field, later policy-making activities would reflect growing doubts about the technology within the European Parliament, member state governments and the commission itself. Following the push for greater funding and concertation, members of parliament launched a two-year investigation in 1985 led by Dutch Socialist Phili Viehoff. The inquiry on rDNA work led to a report which recommended "horizontal" legislation, reaching across the Commission's

[20] Cantley, Mark, Interview, August 11, 2010.
[21] EU Council, *Council Decision of 12 March 1985 Adopting a Multiannual Research Action Programme for the European Economic Community in the Field of Biotechnology*.
[22] EU Commission, "Biotechnology in the Community" COM(83) 672 final/2, October 3, 1983, 69.

"vertical" directorates general, and a moratorium on releases until Brussels enacted legislation.[23] While the Parliament at that time did not possess the power to veto legislative proposals from the Commission, it often influenced European institutions. Commission officials have said at various points in the process that Parliament's actions affected their decision to pursue legislation.[24]

Meanwhile, biotechnology began to spur controversy in some member state governments.[25] While the UK and France generally supported the technology, Denmark and Germany by the mid-1980s started down the path to restrictive policy regimes. In 1986, Denmark passed a measure banning GMO releases except those approved by a minister on a case-by-case basis. A similar trajectory emerged in Germany, where a history of Nazi experimentation combined with a strong environmental tradition already prompted suspicion of and opposition to rDNA work. The elevation of the Greens to the Bundestag and a subsequent parliamentary inquiry led by Social Democrat Wolf-Michael Catenhusen resulted in strict controls on GMOs under the Gene Law of 1990.

Concerns about biotechnology in Parliament and member states spurred the Commission in July 1985 to create a panel called the Biotechnology Regulatory Inter-service Committee (BRIC) to look at existing laws on the subject and determine the need for new legislation.[26] Although directorates with GMO-relevant competencies (e.g. Agriculture and Research) could attend BRIC sessions, Commissioners gave the leadership to the two competencies they considered most relevant to GMOs in contained

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[23] Patterson, Lee Ann, Dissertation, "Regulating Competitiveness: The Development and Elaboration of Biotechnology Regulatory Policy in the European Union" (Pittsburgh, Penn.: University of Pittsburgh, 1998), 85.
[24] Ibid, 86.
[25] Numerous sources discuss biotechnology policies at the member state level, including Cantley, Mark, "The Regulation of Modern Biotechnology: A Historical and European Perspective," from Brauer, Dieter, editor, *Biotechnology, vol. 12: Legal, Economic and Ethical Dimensions* (Weinheim, Germany: VCH, 1995); and, Patterson, Lee Ann, Dissertation, "Regulating Competitiveness: The Development and Elaboration of Biotechnology Regulatory Policy in the European Union."
[26] Cantley, Mark, "The Regulation of Modern Biotechnology: A Historical and European Perspective," 543.

use and in the environment: DGs Industry and Environment. For the next few years, BRIC served as the main battleground for charting Europe's approach to biotechnology.

Debating Legislation

BIOTECHNOLOGY REGULATORY INTER-SERVICE COMMITTEE (BRIC)
Created: 1985
Co-Chairs: Goffredo Del Bino, DG Environment, and Paul Gray, DG Industry
Secretariat: DG Research
Mission: To review existing regulations on biotechnology; to identify other laws that might apply; to clarify the regulatory path for biotechnology products; to determine whether the current regulations adequately address potential risks; and, to review the scientific data necessary for assessing risk.

SOURCE: See note[27]

With policy options ranging from concertation of existing national approaches to pursuing more binding European legislation, sharp differences would emerge on the BRIC panel. Officials from DG Research sought the former, while those from DG Environment preferred the latter approach. A 1986 report from the Organization for Economic Cooperation and Development (OECD) highlighted the dilemma, and attempted to create a consensus on safety in order to advance the technology.[28] The report encouraged nations to share information, create harmonized guidelines and avoid legislation. At the same time, it pointed to a lack of data on environmental risks and encouraged case-by-case evaluation of releases.

The OECD report called for a flexible regulatory approach that would allow the technology to move forward while adjusting periodically to new information about risks. But the recommendation required a level of coordination that presented a

[27] Ibid, 544; Cantley, Mark, Interview, August 11, 2010.
[28] Organization for Economic Co-operation and Development, *Recombinant DNA Safety Considerations*, 1986.

challenge for competing DGs organized by sectoral competence.[29] "That absolutely disagreed with the fundamental structure of the Commission," said Mark Cantley, a civil servant from DG Research who served on BRIC's staff.[30] Multi-sectoral and horizontal in nature, biotechnology challenged the vertical focus of the Commission's separate DGs. "Biotechnology didn't fit," Cantley said.

BRIC convened separate meetings with industry and member state representatives before advising the Commission, which announced its decision in November 1986: Europe would pursue legislation.[31] In a brief communication to the Council, officials wrote of the "urgent" need for regulation to provide certainty for business, and to address public concerns with "adequate protection of human health and the environment."[32] Although the brief statement resembled the approach embraced by the US in its Coordinated Framework, the decision to pursue horizontal legislation would have dramatically different implications later, locking in a rigid policy structure discussed in detail below.

Opponents of legislation, such as Cantley, suggested that the positioning of DG Environment's Goffredo Del Bino as BRIC Co-chair, and Del Bino's prior success in securing horizontal chemicals legislation in the wake of a chemical accident near Seveso, Italy, in the 1970s, helped shape the Commission's decision to pursue

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[29] For the period before 1996, Lee Ann Patterson explores the coordination issue in the following Dissertation: "Regulating Competitiveness: The Development and Elaboration of Biotechnology Regulatory Policy in the European Union."
[30] Cantley, Mark, Interview, August 11, 2010.
[31] Cantley, Mark, "The Regulation of Modern Biotechnology: A Historical and European Perspective," 552.
[32] EU Commission, "Communication from the Commission to the Council: A Community framework for the regulation of biotechnology," COM (86) 573 final (Brussels, November 4, 1986).

legislation.[33] "This was a sort of second-round after the triumph of legislation on chemicals," Cantley said.[34] "They could gain additional power, resources, authority."

Brian Ager, an HSE civil servant who was detailed to the Commission in the late 1980s and worked with Cantley in DG Research, questioned the use of a legislative model designed to combat toxic chemicals. "They automatically were passing the message that this GMO thing is intrinsically dangerous and needs to be dealt with as such—as they did with the Seveso chemicals [legislation]," Ager said.[35]

However, Ager and Cantley both acknowledged that the leadership of other key directorates, including Research, Agriculture and Industry, preferred to focus on other matters and leave biotechnology to Environment.[36] Moreover, as officials from DG environment observed, no viable alternatives to legislation existed at the time. "When you're talking about an area of environment and health and consumer policy where there is something new and you want to make sure that certain parameters are respected...you have to legislate," said former civil servant Joanna Tachmintzis, who began working on biotechnology within DG Environment in 1988.[37]

Chef de File

While DG Environment's influence over the Commission's decision to pursue legislation remains in dispute, the division's authority over the drafting of rules is clear. As *Chef de File* on the issue of direct releases of GMOs into the environment, DG Environment would have broad control over the content of any directive proposed,

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[33] EU Commission, DG Environment, "Chemical Accidents (Seveso II) - Prevention, Preparedness and Response - Environment - European Commission," website.
[34] Cantley, Mark, Interview, August 11, 2010.
[35] Ager, Brian, Interview, November 12, 2010.
[36] Ibid.
[37] Tachmintzis, Joanna, Interview, December 14, 2010.

including the power to draft proposals and veto changes. The final legislation would bear the entire Commission's imprimatur.

4.2 The Policy Design: Europe (1986-1993)

Charged with drafting legislation on the contained use and direct release of GMOs, BRIC met ten times before the Commission released proposals for the two council directives in May 1988.[38] During this time, civil servant panelists from across the services met to debate the contents of the legislation, often clashing over specific policy differences. However, since DG Environment served as *Chef de File* for both draft directives (DG Industry shared the responsibility for the contained use measure), any suggestions needed the ultimate approval of the DG Environment's Biotechnology Unit Chief and BRIC Co-Chair Goffredo Del Bino.

One early battle occurred over the question of regulatory scope. While proponents of legislation argued that all modified organisms should be regulated based on the process used to create them, opponents pushed for a scope based on specific risk factors—a product-based scope—insisting that no scientific evidence identified them as substantively different or more harmful. "There was disquiet at the essentially political reasoning for focusing on rDNA organisms," Cantley later wrote in a detailed history of the period.[39] Although officials included language in the proposal stating that they would explore ways to alter the scope in the future by focusing on risk, these failed to make it into the final directive passed by the Council.[40]

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[38] Cantley, Mark, "The Regulation of Modern Biotechnology: A Historical and European Perspective," 555.
[39] Ibid.
[40] EU Commission, "Proposal for a Council Directive on the contained use of genetically modified microorganisms," COM (88) 160 final (Brussels, May 4, 1988), 4; EU Commission, "Proposal for a

DIRECTORATE GENERAL FOR THE ENVIRONMENT

Established: 1973
Employees: approximately 300 (1990)

Commissioner for the Environment: Carlo Ripa Di Meana
Director General: General Laurens Brinkhorst
Director: Tad Bennett
Head of Unit, Biotechnology and Chemicals: Goffredo Del Bino
Head of Sub-Unit, Biotechnology: Joanna Tachmintzis
Reputation: As one of the major departments of the European Commission, DG Environment had taken the lead in crafting sweeping "horizontal" legislation pertaining to chemical use in following the 1976 chemical accident at Seveso, Italy. Despite criticism from other Commission services, the division also served as *Chef de File* for biotechnology.

SOURCE: See note[41]

Officials from DG Environment defended the rDNA- or process-based regulatory scope as germane. "You had to define what your product is," said Joanna Tachmintzis, a former civil servant in the DG's biotechnology sub-unit who worked under Goffredo Del Bino.[42] "It wasn't just a seed. It wasn't just a microbe." Officials argued that rDNA techniques created uncertainties that did not exist in traditional breeding. Supporters of legislation, like opponents, marshaled science to make their case, describing regulation as necessary until research could eliminate uncertainty. This view would frame a lengthy debate in the years to come over Europe's precautionary approach.

During the drafting, civil servants from DG Research made numerous suggestions that the BRIC leadership vetoed. These included the creation of an advisory committee of scientific experts that could establish general principles on safety and risk,

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Council Directive on the deliberate release to the environment of genetically modified organisms," COM (88) 160 final, (Brussels, May 4, 1988), 5.

[41] Cantley, Mark, August 11, 2010; Trippier, Sir David, July 29, 2009; Tachmintzis, Joanna, Interview, December 14, 2010; Ager, Brian, Interview, November 12, 2010; EU Commission, DG Environment, "Chemical Accidents (Seveso II) - Prevention, Preparedness and Response - Environment - European Commission," website.

[42] Tachmintzis, Joanna, Interview, December 14, 2010.

similar to the US Biotechnology Science Coordinating Committee.[43] Although the Commission had asked DG Research to draft a plan for such a panel, the idea met with "indifference or outright opposition," according to Cantley.[44]

Arguably the most contentious exchange followed after DG Research submitted a draft directive calling for regulation based on registration and monitoring.[45] Like DG Research's other contributions, the draft failed to advance. "All our suggestions and amendments and so on got sidelined," Cantley said. "We learned the meaning of the phrase *Chef de File*."[46]

Besides taking the lead role in crafting the draft directive on releases, DG Environment also crafted the greater part of the measure on contained use. While DG Industry also served as *Chef de File* for the latter, it mostly deferred to DG Environment.[47] After BRIC completed its work, DG Environment reviewed the draft measures internally, first among civil servants, then among cabinet members of the Commissioner for the Environment, Carlo Ripa di Meana. Like all other legislative proposals, the directives came before the College of Commissioners for official approval, although officials typically made up their minds at a previous step, when commissioners' heads of cabinet meet. According to Tachmintzis, a veteran of two cabinets, biotechnology prompted considerable discussion at both the cabinet and commissioner level.[48]

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[43] Cantley, Mark, "The Regulation of Modern Biotechnology: A Historical and European Perspective," 555.
[44] Ibid, 556.
[45] Patterson, Lee Ann, Dissertation, "Regulating Competitiveness: The Development and Elaboration of Biotechnology Regulatory Policy in the European Union," 126.
[46] Cantley, Mark, Interview, August 11, 2010.
[47] Patterson, Lee Ann, Dissertation: "Regulating Competitiveness: The Development and Elaboration of Biotechnology Regulatory Policy in the European Union," 128.
[48] Tachmintzis, Joanna, Interview, December 14, 2010.

Draft Directives

The first directive outlined a notification system for the use of engineered micro-organisms in containment, distinguishing between pathogenic and non-pathogenic varieties, and between small- and large-scale quantities. The second and more controversial of the two directives, regulating releases into the environment, described a system of requiring consents obtained at the member state level for experimental releases and then in Brussels for commercial planting and sales.

After the Commission released its proposed directives the measures headed to the European Parliament. At the time, the so-called Co-operation Procedure gave Parliament the power to offer amendments and vote against legislative proposals, but the Council could overturn these with a unanimous vote.[49]

Meanwhile, supporters of the technology began to make their voices heard. In October 1988, the life scientists comprising the European Molecular Biology Organization (EMBO) issued a statement, praising rDNA as a breakthrough, and disputing the need for legislation, saying that no scientific justification for it existed.[50] The scientists also criticized the scope of the proposal: "Any rules or legislation should only apply to the safety of products according to their properties, rather than according to the methods used to generate them."[51] Days before the Parliament began its debate on the subject in May 1989, sixteen European Nobel Laureates sent a similar letter questioning the need for legislation and defending rDNA work as safe. US officials, such as FDA Commissioner Frank Young and his assistant Henry Miller, also

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[49] Eurofound, "Cooperation Procedure."
[50] Cantley, Mark, "The Regulation of Modern Biotechnology: A Historical and European Perspective," 560.
[51] European Molecular Biology Organization, "Statement to European Parliament" (May 16, 1989), reproduced in Cantley, Mark, "The Regulation of Modern Biotechnology: A Historical and European Perspective," from Brauer, Dieter, editor, *Biotechnology, vol. 12: Legal, Economic and Ethical Dimensions* (Weinheim, Germany: VCH, 1995), 560.

communicated their concern to Brussels, challenging not only the scope of the directives, but their potential to inhibit research and create trade barriers with other nations.

One notably absent voice was industry. Although producer representatives recognized the need to organize as early as 1984, several factors prevented them from joining forces.[52] Most of all, with firms ranging considerably in size, producers had different strategic preferences, fostering mutual mistrust and suspicion. Some had not yet developed engineered plants that would succeed in European soil.[53] Others looked to regulation as a way to vanquish smaller competitors that lacked the resources to compete.[54] Although the US possessed a similar landscape for industry, producers in that country benefitted from the Reagan White House's strong opposition to burdensome regulation whereas European industry arguably lacked a similar support in the policymaking process. More basically, because biotechnology possessed a diverse and decentralized producer coalition—from seed engineers, farmers and food producers and retailers—a vacuum emerged inside government where strong support was needed. "No one [trade] association had lead responsibility for it," said Brian Ager, a former civil servant in DG Research who went on to lead the first industry lobby group in Europe, the Senior Advisory Group for Biotechnology (SAGB), which later became EuropaBio.[55]

However, that lobby group, formed in mid-1989 in response to legislative proposals it considered alarming, arguably arrived too late. Although the biotechnology

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[52] Cantley, Mark, "The Regulation of Modern Biotechnology: A Historical and European Perspective," 536; The following also contains a useful summary: Patterson, Lee Ann, Dissertation, "Regulating Competitiveness: The Development and Elaboration of Biotechnology Regulatory Policy in the European Union."
[53] Poole, Nigel, Interview, July 28, 2010.
[54] Cohrssen, John, Interview, September 1, 2010.
[55] Ager, Brian, Interview, November 12, 2010

industry would later become a viable lobbying force, its efforts to issue position papers and urge officials to regulate products based on their characteristics rather than the processes that created them failed to stop legislative activities already set in motion.[56] "In spite of rapid efforts, it was too late to play a decisive role in the months leading up to adoption of the two Directives."[57]

The final directives contained numerous restrictions added during a parliamentary amendment process led by the German rapporteur Gerhard Schmidt.[58] These included changes which prevented the future alteration of the legislation's scope, even if new scientific information emerged. More significantly, officials dramatically altered the deliberate release directive from serving as a stop-gap measure that applied only to bioengineered products not already captured under existing legislation to one that required a safety assessment for all engineered crops and food.[59] Under the change, any genetically modified product required an environmental review, even if it qualified for assessments under other legislation. Such a stipulation would have sweeping implications. Most of all it created the legal requirement for a unique regulatory system overseen by DG Environment.

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[56] Ager, Brian, Interview, November 12, 2010; Senior Advisory Group for Biotechnology, reproduced in, "Community Policy for Biotechnology: Priorities and Actions" (January 1990), in, Cantley, Mark, "The Regulation of Modern Biotechnology: A Historical and European Perspective," 634-635.
[57] Cantley, Mark, "The Regulation of Modern Biotechnology: A Historical and European Perspective," 561.
[58] Ibid, 557.
[59] Ibid, 562.

Passage

DIRECTIVE 90/220
Lead Author: DG Environment Amended by: Commissioners, the European Parliament and Council Passed: April 23, 1990 Description: The more significant and controversial of the two GMO directives, 90/220 authorized regulation of all commercial products (crops and foods) based on the process used to create them, with DG Environment as *Chef de File*. Horizontal in reach, the law required environmental safety assessments in all cases and allowed member states to opt out of approvals through the use of a safeguard clause.

After lengthy deliberations between the Commission, Parliament and Council, the draft directives passed unanimously in the Council on April 23, 1990. While the agreement required extensive negotiating among parties, most interests had already coalesced around the idea of taking action. Indeed, even scientists who had opposed using an rDNA- or process-based regulatory scope acknowledged the need for a Europe-wide policy. And, since few viable strategies for coordinating biotechnology policy existed beyond passing legislation, parties came to agree that the directives presented the most expedient way of advancing biotechnology while protecting human health and the environment.

Since council members came to support the idea of passing legislation, the key sticking points surrounded the degree of its restrictions. Former DG Environment staff member Joanna Tachmintzis said the detailed terms of the legislation reflected efforts to placate various member state interests prior to passage. For example, Directive 90/220 contained a safeguard clause allowing individual member states to opt out of marketing a specific product within its territory if evidence of potential risk existed. "If [the

clause] wasn't there, there wouldn't have been the possibility to allow marketing of products at all," Tachmintzis said.[60]

Despite the tussling over the contents of the legislation among officials, existing sources, including journalism accounts, suggested that the public had a limited awareness of the issue. And, although DG Environment maintained formal links with a coalition of interest groups, these organizations had not yet launched a major campaign against the technology.[61]

Implementation

After the Council approved the directives, the Commission's DG Environment began the lengthy process of implementing them. This included both establishing the protocols and committees needed to commence work in Brussels, but also working with member state governments to develop the necessary capacity throughout the community. With less than 20,000 employees for all of its divisions, the Commission frequently utilized resources from nations with more developed regulatory structures, such as the UK, observed former Minister of State for the Environment Sir David Trippier, who regularly represented his country at Council meetings in Brussels.[62] Moreover, British and other civil servants were routinely detailed to the Commission to help oversee GMOs.[63]

Under the directives, the member states would play a critical role in regulation. Directive 90/219 on contained use required countries to name a competent authority to set guidelines and oversee experiments in the laboratory. Britain looked to the HSE to

[60] Tachmintzis, Joanna, Interview, December 14, 2010.
[61] Ibid.
[62] Trippier, Sir David, Interview, July 29, 2009; Peterson, John, and Shackleton, Michael, *The Institutions of the European Union* (Oxford: Oxford University Press, 2002) 148.
[63] Ager, Brian, Interview, November 12, 2010; Bosworth, David, Interview, December 17, 2010.

serve this function. Since work on rDNA in the laboratory posed few existing or perceived risks by the 1990s, the contained use directive had a modest impact on industry and created little opposition.

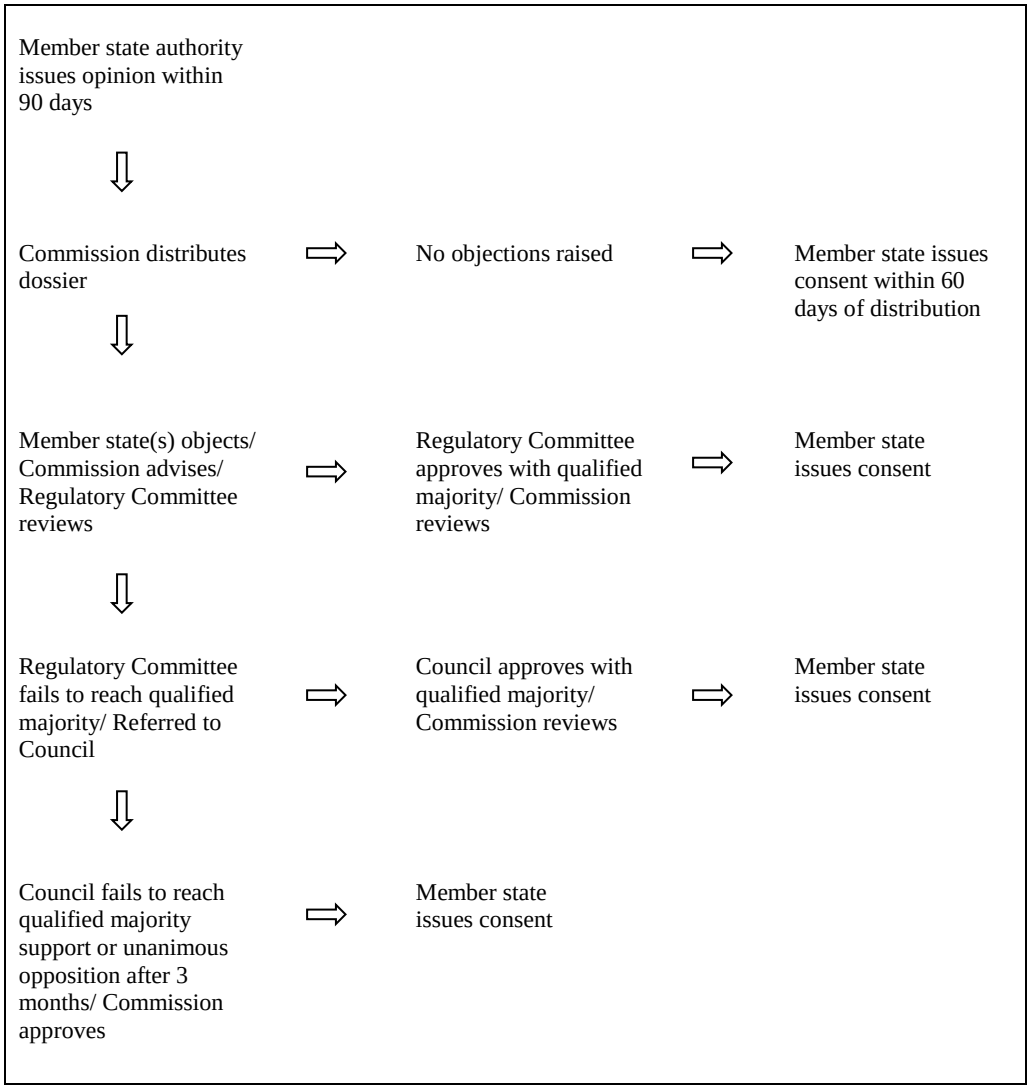
Directive 90/220 on releases to the environment, required member states to designate a body to review experimental release applications under Part B. In the UK, the DOE filled this role, receiving advice from its Advisory Committee on Releases to the Environment (ACRE). Part C of the directive required applicants seeking to grow GMOs commercially or sell engineered products on the European market to submit an application to the relevant member state authority, which would then assess applications and forward successful ones to the EU within 90 days. Once a file landed in Brussels, the Commission distributed it to other member states for review. In theory, approvals could move quickly if member states failed to challenge the risk assessments conducted by other member states. However, when a member state objected, the application was required to follow Europe's standard "comitology" procedure to gain approval.

Originally conceived in the 1960s as a way for the European Commission to implement policy measures, the procedure utilized specifically designated comitology committees made up of member state representatives who deliberated over issues as directed by legislation.[64] Officials employed three types of comitology committee—advisory, management and regulatory—each operating according to different rules. Although potentially lengthy and subject to delays, the comitology procedure was considered common. "Hundreds of things are done through comitology," said Paul

[64] Eurofound, "Comitology," website.

Speight, a European civil servant in DG Environment.[65] "That, in itself was not unusual."

Table 4.4 Comitology Procedure for Commercial Planting and Sales Applications Under Directive 90/220 Part C



SOURCE: EU Commission, Directive 90/220/EEC; and, Bradley, Kieran, "The GMO-Committee on Transgenic Maize: Alien Corn, or the Transgenic Procedural Maze," *EU Committees as Influential Policymakers* (1998), 207-221.

Under the comitology procedure stipulated by Directive 90/220 (see Table 4.4), the Commission would issue a tentative decision, and then forward the dossier to the designated Regulatory Committee of member state representatives. The committee

[65] Speight, Paul, Interview, December 1, 2010.

could approve the application with a qualified majority, and then send the application to the commission, for approval, and later, a consent from the member state authority. But if the Regulatory Committee failed to reach a qualified majority, the dossier came before the Council. And if the Council failed to approve the file with a qualified majority or else a unanimous rejection, it returned to the Commission, which would automatically approve it, leaving member states to issue the final consent. Approvals to grow or sell products in one country applied throughout Europe.

Although commercial planting and product applications triggered an elaborate system for reviewing potential environmental impacts, the product safety dimension remained incomplete. Although DG Industry had attempted to carve out a competence for itself within product safety, officials in Brussels would not have a formal system until 1997, when the so-called novel food regulation came into force.[66]

United Kingdom (1986-1993)

In the years leading up to 1990, when it became increasingly clear that Europe would act, UK officials began to pivot from its independent regulatory structure to one that would work within a European framework. During this time Britain significantly enhanced its oversight of releases to the environment, culminating in passage of the *Environmental Protection Act 1990*, which established Britain's oversight for releases through the DOE. The UK formally transposed the European directives into legislation with separate statutory instruments in 1992 and 1993.

[66] *EU Parliament and Council, Regulation (EC) No. 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients*.

First GMOs

Before Brussels took the policy lead, Britain had approved its first experimental plant releases, and even some engineered products, including, in 1990, a modified yeast, and chymosin, an engineered enzyme used in making vegetarian cheeses.[67] Approved quietly and under the regulatory structure in place before the European policy came into force, officials imposed no mandatory labeling requirements, and the products stirred little public reaction. With modified crops still in development stages, British customers would not see bioengineered wholefood products for several years.

4.3 Policy Execution: Europe (1993 - 1996)

At the start of the 1990s, biotechnology enthusiasts within European industry had a reason to feel optimistic about GMOs. Despite the United States' predominance in the market, Europe possessed strong research infrastructures capable of competing at the international level. Moreover, the new European regulatory framework offered a modicum of the assurances industry needed to move from research and development to product deployment.

As the 1990s progressed, officials in Brussels and London made numerous commercial approvals, albeit at a slower pace than their US counterparts. "The system was starting to work," observed Terry Medley, a former US Department of Agriculture official.[68] However, in the coming years, a chain of events would galvanize public opinion against the technology, and cause consumers to turn away.

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[67] Advisory Committee on Novel Foods and Processes, *Annual Report 1990*, (London: Department of Health; Ministry of Agriculture, Fisheries and Food, 1991).
[68] Medley, Terry, Interview, September 16, 2009.

Emerging Opposition

According to observers such as former Greenpeace UK Executive Director Peter Melchett, NGOs and the general public in Britain and other EU member states started the 1990s with limited awareness of GMOs.[69] However, interest groups began to address biotechnology in the early 1990s, and markedly stepped up their involvement after American anti-GMO activist Jeremy Rifkin came to London during this time to share his experiences and brief staff about this new threat. Indeed, Rifkin is credited with stoking opposition among activists around the world, by explaining that the FDA's policy required no special government safety testing for GMOs and no mandatory labeling.[70] "That was a key moment," Melchett said.[71] In the mid-1990s, the groups attempted to engage the public in anti-GMO campaigns, with mixed results.[72] But their successes would increase with time.

[69] Melchett, Peter, Interview, December 13, 2010.
[70] Eichenwald, Kurt, Kolata, Gina, and Petersen, Melody, "Biotechnology Food: From the Lab to a Debacle," *The New York Times*, June 25, 2001.
[71] Ibid.
[72] Ibid.

Table 4.5 National Changes in Support for Engineered Food 1996-1999 (percentage of supporters and "risk-tolerant supporters" in the decided public)[73]

	1996	1999
Belgium	72	47
Denmark	43	35
Germany	56	49
Greece	49	19
Italy	61	49
Spain	80	70
France	54	35
Ireland	73	56
Luxembourg	56	30
Netherlands	78	75
Portugal	72	55
UK	67	47
Finland	77	69
Sweden	42	41
Austria	31	30

As Table 4.5 reveals, widespread public concerns about GMOs would harden by the end of the decade, when polls showed a majority of people opposing engineered food in all EU nations except Ireland, the Netherlands, Portugal and Spain.[74] While critics faulted GMOs on a number of fronts, most opposition coalesced around the issue of food safety, culminating in successful supermarket boycotts across Europe, including in the UK. "Food is what won it," said Melchett.[75] With the boycotts serving as an effective block on the technology for years to come, many in industry would decide to go elsewhere. In addition to food safety, many environmental critics warned that GMO releases could adversely impact crops and wildlife. Other criticisms hinged on questions of consumer choice, the intensification of agriculture, the third world and American imperialism.

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[73] Gaskell, George, Allum, Nick, and Stares, Sally, "Europeans and Biotechnology in 2002: Eurobarometer 58.0, a Report to the EC Directorate General for Research from the Project 'Life Sciences in European Society'," March 21, 2003, 18.
[74] Ibid.
[75] Melchett, Peter, Interview, December 13, 2010.

United Kingdom (1993-1996)

First Approvals

ADVISORY COMMITTEE ON RELEASES TO THE ENVIRONMENT

Established: 1990
Chairman: Professor John Beringer (1990-1998)
Secretary: Helen Marquard, PhD, Deputy Director, Department of the Environment
Reputation: Composed mostly of academic biologists with a representative from industry and environmental groups, the panel reviewed applications for engineered crop trials and commercial planting under Directive 90/220.

From the early 1990s, the UK approved many applications for experimental releases, with the Advisory Committee on Releases to the Environment (ACRE) processing applications and advising the Department of the Environment on issuing consents. Most of ACRE's dozen members were academics from the biological sciences, but the panel also included representatives from industry and non-governmental organizations, including the environmentalist, Julie Hill of the Green Alliance. John Beringer, professor at the University of Bristol served as the panel's chair from 1990 to 1998.

Table 4.6 Approvals by the UK Advisory Committee on Releases to the Environment (ACRE) for Commercial Planting of GMOs under Part C of Directive 90/220[76]

Year	Crop	Applicant	Purpose	Decision
1994-95	Oilseed Rape	Plant Genetic Systems	Planting	Yes
	Soybeans	Monsanto	Import	Yes
1995-96	Oilseed Rape	AgrEvo Crop Protection	Import	Yes
1996-97	Maize	Northrup King	Import	Yes
1997-98	Maize	Monsanto	Import	Yes
1998-99	Oilseed Rape	AgrEvo Crop Protection	Import	No

[76] Advisory Committee on Releases to the Environment, *Annual Report Nos. 2-6*, 1995-99.

At the time few of the viable modified crops were suitable for the British climate or ecology. Soya, for example, requires a high temperature. And a popular variety of modified corn, coded to produce the *bacillus thuringiensis* toxin harmful to the European corn borer, had little relevance in the UK where the insect did not pose a threat. "There was not much to market" said Nigel Poole, formerly of Zeneca.[77] "The first crops were not actually of any use to UK agriculture." But when a viable crop for British soil emerged in Plant Genetic System's oilseed rape, ACRE forwarded the application to Brussels in 1994 with a favorable response. It became the first commercial planting application to gain approval.

Many commercial applications reviewed by ACRE during the 1990s came from producers seeking to import foreign commodities for sale in the European market. These included soybeans from Monsanto, corn from Northrup King and Monsanto and oilseed rape from AgrEvo Crop Protection (AgrEvo) – all forwarded by ACRE to Brussels with a positive recommendation.

Former ACRE Secretary Helen Marquard described the panel's early deliberations as extensive, thoughtful and open. "It was certainly step-by-step and case-by-case," said Marquard, who described the panel's reviews as rigorous.[78] In each case, ACRE deliberated on the environmental implications of the release. For example, it investigated whether imported soybeans posed a threat to the environment simply for existing in proximity to either British crops or wildlife. After the review, the panel either forwarded the findings to Brussels with a favorable opinion, or rejected the dossier. Most applications received a green light.

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[77] Poole, Nigel, Interview, July 28, 2010.
[78] Marquard, Helen, Interview, December 16, 2010.

ADVISORY COMMITTEE ON NOVEL FOODS AND PROCESSES
Established: 1988 Chairman: Professor Derek Burke (1988-1997), Janet Bainbridge (1998-2003) Reputation: Composed mostly of university biologists and chemists, with a representative from industry, the panel reviewed applications for modified food products on a voluntary basis until 1997, when review by member state authorities became obligatory under Regulation 258/97. Following BSE crisis in 1996, the panel moved from the remit of the Department of Health and the defunct Ministry of Agriculture, Fisheries and Food (MAFF) to the Food Standards Agency.

Despite its thoroughness in evaluating environmental risks, ACRE did not review the safety of food products for consumption. Moreover, Directive 90/220 did not stipulate a protocol for testing the composition of food, including any changes in toxicity or allergenicity as a result of modification. Although the European Commission had directed DG Industry to author food safety legislation, officials did not complete the regulation until 1997, when the Parliament and Council passed the so-called novel food law, Regulation 258/97.[79] This left a gap of several years in which no common legal obligation existed for safety reviews of modified food products bound for the European market. While member state food policies technically applied, most, including the UK's, did not require mandatory safety reviews for GMOs.

Although the law did not require it, companies aiming to sell GMOs in Europe typically sought to have their products assessed by domestic authorities. "You would have been silly if you didn't get it," said Nigel Poole, a former Zeneca official.[80] In the

[79] EU Parliament and Council, *Regulation (EC) No. 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients*.
[80] Ibid.

UK, applicants looked to the Advisory Committee on Novel Foods and Processes (ACNFP), a panel that advised the Ministry of Agriculture, Fisheries and Food (MAFF). Comprising over a dozen experts from a range of science disciplines, the panel conducted detailed reviews which also included scientific evaluations from a designated assessment team. Professor Paul Burke of the University of East Anglia chaired ACNFP until Janet Bainbridge, a professor from the University of Teesside, replaced him in 1997.

Table 4.7 Approvals of Modified Food Products by the Advisory Committee on Novel Foods and Processes (ACNFP)[81]

Year	Product	Applicant	Voluntary Review	Mandatory Review
1994	Tomato paste	Zeneca	Yes	-
	Soybeans	Monsanto	Yes	-
1995	Maize products		Yes	-
	Tomatoes		Yes	-
	Tomato paste		Yes	-
1996	Maize products		Yes	-
	Maize		Yes	-
1997	Tomato products		Yes	-
	Maize		Yes	-
	Maize		-	Yes
	Cottonseed		-	Yes
	Cottonseed		-	Yes
	Potato		-	Yes
	Maize		-	Yes
1998	Tomato products		-	Yes

The perception of a regulatory gap on product safety was arguably most pronounced for food products not containing live GMOs, including packaged and processed foods. For these, companies had no clear obligations under 90/220, since the sale of a sealed product did not constitute an environmental release. On the other hand, the products clearly contained engineered ingredients. "That would be a gray area," said Nigel

[81] UK Advisory Committee on Novel Foods and Processes, *Annual Reports 1994-1998* (London, Department of Health; Ministry of Agriculture, Fisheries and Food, 1994-98).

Poole, whose company Zeneca created a modified tomato used in a canned paste marketed throughout the UK. The company modified the California-grown tomatoes in the same way as CalGene's "Flavr Savr" variety, to delay ripening.[82] Zeneca volunteered to have it reviewed by ACNFP in 1994. And before the product reached store shelves at Sainsbury's supermarkets in early 1996, Zeneca agreed to label it, posting references to its origin on the tin and store shelf, as well as providing leaflets. "The way we wanted to communicate was to be as open as we possibly could in our own culture," Poole said.[83] Despite containing modified tomatoes, the Zeneca paste sold very well in stores that carried it, including Sainsbury's.[84] "We had 70 percent of the market," Poole said.[85]

Europe (1996-1999)

View from the Farm

Despite the fact that the tomato had become the first genetically modified whole food internationally, the crop arguably failed to provide the yield growth, input savings or quality improvements that would make it competitive with traditionally bred varieties. By the mid-1990s, the most successful engineered crops were herbicide tolerant soybeans and Bt corn engineered to repel insects. However, neither of these was an ideal fit for European agriculture. Soya plants thrive in hot weather; and, European farmers generally produced corn in sufficient quantities already.[86] Moreover, in contrast

[82] Ibid; Poole, Nigel, Interview, July 28, 2010.
[83] Poole, Nigel, Interview, July 28, 2010.
[84] Blythman, Joanna, and Fort, Matthew, "The Trojan Tomato?" *The Guardian*, March 16, 1996.
[85] Ibid.
[86] Bernauer, Thomas, *Genes, Trade and Regulation*, (Princeton, N.J.: Princeton University Press, 2003), 84.

with America, European farms were smaller in size, more numerous and less industrialized.[87]

First Approvals

Because no urgency had existed for European farmers to adopt engineered crops, most of the early market-ready crops came from America as import commodities. Environmental reviews at the European level began in 1995. Although the first applications for commercial cultivation or product sales took longer to get through the system than their American counterparts, they nevertheless ended with approvals, beginning in 1996. Overall, the tortuous path of oversight and large number of institutional veto points meant that potential delays existed at multiple stages of the process.[88]

[87] Ibid.
[88] Other scholars have discussed the number of veto players or veto points in relation to the EU policy, including Pollack, Mark, and Shaffer, Gregory, *When Cooperation Fails: The International Law and Politics of Genetically Modified Foods* (Oxford: Oxford University Press, 2009).

Table 4.8 Applications to Market GMOs in Europe[89]

Crop	Use	Applicant	Member State Authority	Commission Approval	Consent
Oilseed Rape (H)	Cultivation	Plant Genetic Systems	UK 1995	1995-96	UK Feb. 1996
Soybeans (H)	Import	Monsanto	UK 1995	1996	UK May 1996
Chicory	-	Bejo Zaden	Ne. 1995	-	Ne. Aug. 1996
Maize (I, H, A)	Import	Ciba Geigy	Fr. 1996	-	Fr. Feb. 1997
Oilseed Rape (H)	Import	Plant Genetic Systems	Fr. 1995-96	Dec. 1996	-
Oilseed Rape	Import	Plant Genetic Systems	Fr. 1995-96	Dec. 1996	-
Oilseed R. (H)	Cultivation	AgrEvo	UK 1996	-	UK June 1998
Maize (H)	Cultivation	AgrEvo	Fr. 1996-97	April 1998	-
Maize (I)	Cultiv., Import	Monsanto	Fr. 1996-97	April 1998	
Maize (H, I)	Import	Northrup King	UK 1996-97	-	UK June 1998
Maize (H, I)	Cultiv., Import	Pioneer	Fr. 1996-97	-	-
Chicory (H)	Cultivation	Bejo Zaden	Ne. 1996-97	-	-
Oilseed R. (H)	Cultivation	AgrEvo	Ger. 1996-97	-	-
Oilseed Rape (H)	Cultivation	Plant Genetic Systems	Bel. 1996-97	-	-
Potato	Cultivation	AVEBE	Ne. 1997-98	-	-
Carnation	Cultivation	Florigene	Ne. 1997	-	Dec. 1997
Beet (H)	Cultivation	Danisco Seed et al	Den. 1997-98	-	-
Maize (H)	Import	Monsanto	UK 1999	-	-
Cotton (H)	Cult., Import	Monsanto	Sp. 1997-98	-	-
Tomatoes	-	Zeneca Plant Science	Sp. 1997-98	-	-
Cotton (I)	Cult., Import	Monsanto	Sp. 1997-98	-	-
Maize (H, I)	Cult., Import	Dekalb Genetics Corporation	Ne. 1997-98	-	-
Potatoes	Cultivation	Amylogene HB	Swe. 1997-98	-	-
Carnation	Cultivation	Florigene Europe	Ne. 1997-98	-	-
	Cultivation	Florigene Europe	Ne. 1997-98	-	-
	Cultivation	Florigene Europe	Ne. 1997-98	-	-
Oilseed Rape (H)	Cult., Import	AgrEvo	Ger. 1999	-	-
Maize (H, I)	Cult., Import	Pioneer	Ne. 1999	-	-
Maize (H, I)	Cultivation	Novartis	Fr. 1999	-	-
Maize (H)	Cultivation	Monsanto	Sp. 1999	-	-

H = Herbicide Tolerant; I = Insect Repellant; A = Antibiotic Resistant

[89] Data compiled from: UK Advisory Committee on Releases to the Environment, *Annual Report Nos. 2-6* (London: Department of the Environment, Transport and the Regions, 1995-1999).

Table 4.8 shows the historical approvals under the framework of Directive 90/220. After the first applications arrived in Brussels with a favorable opinion from home regulators, the Commission distributed them to other member states for review. In all cases, at least one member state raised an objection, meaning that an individual dossier would have to come before the Regulatory Committee, the large panel of member state experts chaired by a civil servant from DG Environment.[90] Former Commission civil servant Joanna Tachmintzis served frequently as chair until January 1995.[91] The committee met every few months and contained mostly civil servant representatives with varying backgrounds.[92] Most worked in their home state's environment ministry, but others came from agricultural or other divisions.

Reaction

Although the system yielded approvals, controversy plagued it from the start. Environmental groups in multiple countries began to focus on GMOs, staging protests and directly lobbying producers. While media coverage in Germany had begun soon after approvals started in early 1996, outlets in the UK started to focus on GMOs later in the year, when specific products, including imported soybeans and maize, inched closer to arrival.[93]

Indeed, as American soybean growers prepared to ship the first harvest of their Monsanto-developed crops to Europe in the summer of 1996, newspapers swiftly

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[90] Bradley, Kieran, "The GMO-Committee on Transgenic Maize: Alien Corn, or the Transgenic Procedural Maze," in Van Schendelen, M.P.C.M., *EU Committees as Influential Policymakers* (Aldershot, Hampshire: Ashgate Publishing, 1998), 211.
[91] Tachmintzis, Joanna, December 14, 2010.
[92] Ibid.
[93] Karacs, Imre, "Greens Rally Against Invasion of the Killer Corncobs," *The Independent*, June 30, 1996.

alerted readers to their arrival, and to the fact that the crop would come without a label.[94] At the time the US produced an estimated 50 percent of the world's soya, exporting 25 percent of it to Europe.[95] Although only two percent of the American soybean yield possessed engineered varieties, future harvests promised to contain much more. Moreover, US growers, and their backers in government, refused to segregate modified and unmodified varieties, a move that would pre-empt the possibility of labeling.[96] Since an estimated 60 percent of processed foods in British supermarkets contained soya in some form, suddenly a large portion of foods had the potential to contain modified ingredients or their derivatives because producers had insisted on comingling varieties.[97] "Effectively, all soya became GM very quickly," said former Greenpeace UK Executive Director Peter Melchett.[98] "Our food had been changed."

Consumer Uprising

Whereas environmentalists found a natural foe in biotechnology, consumers often took longer to enter the anti-GMO fold. In Germany, where early media coverage and protests were strongest, consumers successfully petitioned large food producers such as Nestle and Unilever to abstain from using engineered ingredients in their products.[99] However, reaction in the UK was more muted initially, with less press coverage, and so consumer boycotts of engineered products would take longer to gain force and

[94] Durham, Michael, "Genetically Engineered Foods Hit Your Local Supermarket Soon. And You Won't Know It's Happening," *The Observer*, August 18, 1996.
[95] Penman, Danny, "Crop Trade Wars and the Maize of Confusion," *The Independent*, May 16, 1997.
[96] Nuttall, Nick, "Stores Lose Fight Over 'Superbean' Labelling," *The Times*, October 10, 1996; Arthur, Charles, "Trade War Threat Over Genetically Altered Soya," *The Independent*, September 30, 1996.
[97] Ibid; Blythman, Joanna, "Just Soy Stories," *The Guardian*, November 30, 1996.
[98] Melchett, Peter, Interview, December 13, 2010.
[99] King, David, "Genetic Engineering: New Beans Means Profits," *The Guardian*, December 11, 1996.

eventually compel many food producers and retailers to block engineered varieties from their brands.[100]

Specter of BSE

Such changes to the food supply came at a time when many Europeans harbored serious concerns about food safety. The crisis over bovine spongiform encephalopathy (BSE), the deadly neurodegenerative disease that had afflicted thousands of British cows in recent years, reached a peak in 1996, when scientists said it had spread to humans, despite government safety assurances.[101] In March of that year, the UK Ministry of Agriculture, Fisheries and Food launched a multi-year eradication program to eliminate several million heads of cattle as a precaution. The same month also marked the beginning of a devastating worldwide ban on British beef which lasted a decade and cost the industry several billion pounds.[102]

UK press accounts drew frequent parallels between GMOs and BSE. And starting in September, anti-biotechnology partisans received a boost when one of the most recognizable figures in Britain, Prince Charles, began linking genetic engineering with BSE, warning about the implications of violating "nature's laws."[103]

Although the engineered soya came with EU approval and scientific vetting by the UK's Advisory Committee on Novel Foods and Processes, government assurances

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[100] Beaumont, Peter, "Greens Target Crop Designers' Homes and Research Stations," *The Observer*, December 15, 1996; Dodd, Vikram, "Sainsbury's Bans GM Food in Own Labels," *The Guardian*, March 17, 1999; Pollack, Mark, and Shaffer, Gregory, *When Cooperation Fails: The International Law and Politics of Genetically Modified Foods*, (Oxford: Oxford University Press, 2009), 67.

[101] The human manifestation of the disease is known Creutzfeldt-Jakob disease (CJD). See: The Phillips Committee, "BSE Inquiry Report" (Her Majesty's Stationery Office, October 2000).
Appleyard, Bryan, "Revenge of the Mutant Organisms," *The Independent*, April 5, 1996;
Gray, John, "Dangers in This Drive for Food Profits," *The Guardian*, September 9, 1996;
Connor, Steve, "'Mad Cow' Link to CJD Proved," *The Sunday Times*, September 28, 1997.

[102] BBC News, Blog Post, "End to 10-Year British Beef Ban," May 3, 2006, http://news.bbc.co.uk/1/hi/4967480.stm, accessed June 19, 2012.

[103] Schoon, Nicholas, "BSE is an Offence Against God, Says Prince Charles," *The Independent*, September 20, 1996.

gave consumers little confidence. Indeed, since in the case of BSE officials' mismanagement had arguably made that crisis worse, many observers openly questioned the wisdom of trusting government safety advice.[104]

Tensions increased in late 1996 with the news that American-grown maize engineered by the Swiss company Ciba Geigy had mixed with unmodified varieties intended for use as animal feed without gaining European approval. UK food safety officials issued an initial warning, and EU officials were still reviewing the variety, which in addition to containing genes for herbicide tolerance and insect resistance also possessed a "marker gene" conferring resistance to the antibiotic ampicillin. Critics worried that the gene could pass to animals and with it the resistance to medicine in case an infection occurred.[105] The perceived link with BSE had grown stronger.

Labeling

Because critics could find no overt dangers in the imported crops, labeling as a matter of consumers' right-to-know quickly emerged as a consensus position.[106] Under growing pressure from interest groups, retailers throughout Europe demanded that the imported soya carry labels, but were often rebuffed by the Missouri-based American Soybean Association, Monsanto, traders such as Cargill and Archer Daniels Midland, and Gene Moos, the US under secretary of agriculture for farm and foreign agriculture service.[107] While the Americans claimed that labeling would inconvenience farmers by forcing

[104] Gray, John, "Dangers in this Drive for Food Profits," *The Guardian*, September 9, 1996.
[105] Burrell, Ian, "Gummer Pledge on Genetic Maize," *The Independent*, December 5, 1996.
[106] Durham, Michael, "Genetically Engineered Foods Hit Your Local Supermarket Soon. And You Won't Know It's Happening," *The Observer*, August 18, 1996.
[107] Arthur, Charles, "Trade War Threat Over Genetically Altered Soya," *The Independent*, September 30, 1996; King, David, "Genetic Engineering: New Beans Means Profits," *The Guardian*, December 11, 1996.

them to segregate varieties, critics suggested that growers could have easily done so and that producers simply wanted to prevent a consumer boycott of modified crops.[108]

From 1996 to 1997 the issue of GMOs and labeling quietly simmered in Britain, rousing less public opposition than in other member states, such as Germany.[109] However, with American farmers set to raise the percentage of engineered soya harvested in 1997 to 40 percent, and with higher percentages expected thereafter, the issue would only grow in salience throughout Europe.[110] Likewise, when the Commission in early 1997 approved the controversial antibiotic-resistant maize by Ciba Geigy, suddenly two engineered varieties threatened to enter the European food supply through processed goods.[111] With time, a steady drumbeat would land the issue firmly on the European agenda and create serious challenges for the regulatory system.

Systemic Weaknesses

The ensuing storm over unlabeled soya and corn revealed a host of systemic weaknesses which officials would struggle to address. On the question of labeling, Directive 90/220 only allowed member states to impose labels in cases of demonstrated risks.[112] Moreover, Europe's much-anticipated product safety regulation, the novel food law, which would take effect in May 1997, stopped short of requiring labels for most products containing corn and soya derivatives. In fact, Regulation 258/1997 exempted varieties which had already gained approval, and required labels for only those foods containing live GMOs. Therefore, even if importers segregated engineered corn and

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[108] Durham, Michael, "Look What's Coming to Dinner... Scrambled Gene Cuisine," *The Observer*, October 6, 1996.
[109] "Food Chain Bans Genetic Food," *The Independent*, March 16, 1998.
[110] Clarke, Angus, "Which Foodstuffs are Modified?" *The Times*, August 15, 1998.
[111] Bellos, Alex, "Mutant Maize to Go on Sale," *The Guardian*, February 18, 1997.
[112] EU Commission, "Report on the Review of Directive 90/220/EEC in the Context of the Commission's Communication on Biotechnology and the White Paper," COM (96) 630 final, December 10, 1996, 9.

soya, producers had no obligation to do the same after converting the grains into processed foods.[113]

Comitology Concern

Another weakness pertained to reviews. Although in theory an applicant could receive permission to plant or market a GMO commercially throughout Europe if a single member state had approved it, in each case one or more countries objected to the evaluation, triggering the comitology procedure.[114] In addition to building lengthy delays into the system, the practice revealed disparities in regulatory reviews and a lack of trust between member states. "It worked well to a point until some member states took a political position of not wanting to approve GMOs as a national policy," said a European Union civil servant who served in the Commission.[115]

Member states frequently collided over interpretations of risk and safety. According to observers, such as HSE civil servant inspector David Bosworth, whom the UK detailed to DG Environment in the 1990s, risk assessments could show that GMOs posed no more danger than conventional varieties, but they could not provide absolute data guaranteeing safety. "It's easy to say GMOs aren't safe," Bosworth said. "You can interpret data in many ways."[116]

But the greatest weakness revealed by the arrival of engineered imports pertained to comitology itself. When opposition to Ciba Geigy's maize led to the Regulatory Committee's failure to produce a conclusive opinion, the application came

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[113] Schoon, Nicholas, "Manufacturers Not Obliged to Label Modified Processed Food," *The Independent*, December 9, 1996; Meins, Erika, *Politics and Public Outrage: Explaining Transatlantic and Intra-European Diversity of Regulations on Food Irradiation and Genetically Modified Food*, (London: Lit Verlag, 2003), 122-123.
[114] EU Commission, "Report on the Review of Directive 90/220/EEC in the Context of the Commission's Communication on Biotechnology and the White Paper," COM (96) 630 final, December 10, 1996, 7.
[115] EU Civil Servant 1.
[116] Bosworth, David, Interview, December 17, 2010.

before the Council. However, when the Council failed to act the measure by law returned to the Commission, which had a statutory obligation to approve it. The Commission did so, but only with a discomfort that would persist as the practice became the common procedure for approvals. "The Commission was put in a very difficult position of being forced by law to take a decision," said a European Union civil servant who worked in the Commission during the late 1990s.[117] The Commission faced strong criticism from within the EU for approving the maize, with the Parliament even casting a symbolic vote of 407 to 2 in April to censure the body for favoring trade matters over health and safety concerns.[118]

Meanwhile, after the Commission approved the controversial maize variety in early 1997, Austria and Luxembourg invoked Directive 90/220's safeguard clause, which prohibited marketing within their borders based on environmental risks.[119] Although the officials who drafted the directive originally intended the safeguard clause for exceptional circumstances only, its use by member states would become common practice.

Revising 90/220/EEC

Following the controversial soya and maize imports, the Commission faced a storm on two fronts: hostility from member states via the Council and Parliament; and, the threat of US-led trade sanctions. To alleviate pressure coming from Europe, officials pledged to revise Directive 90/220, unveiling a proposal in February 1998, which broadly called for labeling of any products containing GMOs, including processed or commingled

[117] EU civil servant 2, Interview.
[118] Penman, Danny, "Crop Trade Wars and the Maize of Confusion," *The Independent*, May 16, 1997.
[119] EU Commission, "State of Play on GMO Authorisations Under EU Law," January 28, 2004.

goods.[120] The draft also sanctioned voluntary labels for products certified as non-modified.

The proposal called in addition for post-market monitoring of products and a change to the comitology procedure that would allow the Council to reject an application with a qualified majority instead of requiring a unanimous vote. In theory, the latter change would have allowed the Council to block the controversial maize application from moving forward the previous year.

While most revisions strengthened restrictions, some aimed to boost efficiency, including a proposal which called for a centralized risk assessment rather than one based on separately-conducted member state reviews and the piecemeal work of Commission scientific committees.[121] Member states consistently mistrusted the existing system. "It wasn't seen as independent enough," said Kathryn Tierney, a civil servant in DG Environment.[122] The draft also included provisions for streamlining approvals for experimental releases, updating risk categories and improving communication between parties.

Commission as Enforcer

While the Commission took steps to alleviate member states' anxieties about GMOs by revising the directive, it also attempted to rein in member state opposition. For example, in 1997 the Commission attempted to prevent Austria and Luxembourg from invoking the safeguard clause, arguing that in each case the nations presented no evidence of

[120] EU Commission, "Proposal for a European Parliament and Council Directive Amending Directive 90/220/EEC on the Deliberate Release into the Environment of Genetically Modified Organism" COM (1998) 85 Final, February 23, 1998, 5.
[121] Ibid, 2; In response to the BSE crisis, the Commission in 1997 created the Scientific Steering Committee, which organized half a dozen smaller advisory panels that addressed aspects of food safety and were staffed by experts based in the member states.
[122] Tierney, Kathryn, Interview, December 10, 2010.

environmental risk. However, the Commission's efforts failed when the Regulatory Committee, and later the Council upheld the member state bans.[123]

Clashes between the Commission and member states continued through 1998 and into 1999, with countries expressing interest in a Europe-wide moratorium, and officials resisting these efforts as illegal.[124] Indeed, the Commission endeavored to keep the regulatory system working, granting new approvals even as officials contemplated reforms. Following the approval of the controversial maize in 1997, the Commission approved varieties of oilseed rape, maize, and several carnations.[125] But with these approvals came further invocations of the safeguard clause: against oilseed rape in France and Greece, and maize in Austria.

Settlement

As opposition intensified, officials in the European Parliament, including Labour MEP Ken Collins, Chairman of the committee on the environment, public health and consumer protection, called for a temporary moratorium in late 1998 until officials completed the redrafting of the directive.[126] But the Commission would continue to resist a moratorium since it would contravene EU law and dampen trade relations with the US.[127]

Officials brought the debate to the world stage in June 1999 when German Chancellor Gerhard Schroeder, host of the Group of Eight Summit in Cologne, brought

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[123] Bradley, Kieran, "The GMO-Committee on Transgenic Maize: Alien Corn, or the Transgenic Procedural Maze," *EU Committees as Influential Policymakers* (1998): 215; Bates, Stephen, "EU Maize Row," *The Guardian*, January 10, 1998; Bates, Stephen, "Why Americans Are Happy to Swallow the GM Food Experiment," *The Guardian*, February 1999.
[124] Hencke, David, "Minister Drops Ban on Modified Crops," *The Guardian*, April 20, 1998; "You Can't Go It Alone, EU Warns Britain," *The Daily Mail*, February 17, 1999.
[125] EU Commission, "State of Play on GMO Authorisations Under EU Law" MEMO/03/221, November 7, 2003.
[126] Walker, Martin, "Brussels to Debate Ban on Mutated Food Crops," *The Guardian*, December 19, 1998.
[127] "You Can't Go It Alone, EU Warns Britain," *The Daily Mail*, February 17, 1999.

up GMO safety under "global threats," which also included AIDS.[128] With Schroeder's Green Party coalition partners reportedly pushing the issue, the world leaders directed the OECD to investigate GMOs' safety, despite vocal support for biotechnology from Tony Blair and Bill Clinton.[129]

The issue spilled over into the Council meeting of European Environment Ministers on June 24 and 25, 1999. At the marathon 20-hour session covering a range of topics, ministers agreed on the need to halt approvals and reform the regulatory system, but they split over how to achieve this.[130] Competing drafts of a formal EU declaration emerged, with ministers from France, Greece, Italy, Denmark and Luxembourg signing on to a version that would suspend approvals pending completion of new labeling and traceability rules. A second declaration, signed by Austria, Belgium, Finland, Sweden, Germany, Spain and the Netherlands, sought to block approvals until officials could demonstrate that GMOs posed no threat to the environment or human health.

Some nations, including the UK, declined to sign either declaration on legal grounds, and pushed instead for a voluntary moratorium, whereby industry agreed to delay applications pending further safety assessment: "I do not think it would be credible for the Council of Ministers to say it would disobey community legislation," the *Independent* recorded one British official saying.[131]

The Council declined to adopt either declaration, or issue a formal moratorium. However, they issued a statement outlining a common position, which pledged to reject applications that failed to address objections or meet the expectations of EU committees

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[128] Hamilton, Sebastian, "UK and Germany Clash Over GM Foods," *Sunday Business*, June 20, 1999.
[129] Ibid.
[130] Morris, Shane, and Spillane, Charles, "EU GM Crop Regulation: A Road to Resolution or a Regulatory Roundabout?" *European Journal of Risk Regulation* 4 (January 2011), 362.
[131] Castle, Stephen and Brown, Colin, "UK Rejects Total Ban on GM Crops," *The Independent*, June 25, 1999.

and member state competent authorities.[132] The statement also affirmed the reforms sought in the proposed revision to Directive 90/220, including mandatory labeling, post-market monitoring and common risk principles. Providing only vague details, the statement clarified the immediate future for GMOs: Applications would not progress.

In fact, the system had effectively stopped working already. In October 1998, officials approved the last GMO, a modified carnation variety, and would make no further approvals for several years. Although the Commission declined to adopt a formal moratorium, a *de facto* one had come into force. Most acknowledged the existence of an EU ban even if they declined to describe it as such for legal reasons. "There will be a moratorium but, clearly, member states cannot say: 'we are not going to apply the law,'" said one unnamed official quoted in the press.[133]

United Kingdom (1996-1999)

Despite ongoing concerns raised by interest groups, 1996 and 1997 brought few changes to Britain's approach to GMOs. Retailers stopped short of blocking engineered soya and corn from store shelves, although many pledged to label select products voluntarily.[134] Politically, most questions about product regulation resided in Brussels, although UK officials did take related action to improve food safety oversight in the wake of the BSE crisis, creating a Food Standards Agency with the power to act against dangerous breaches of the food supply.[135]

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[132] EU Council, "2194th Council Meeting - ENVIRONMENT - Luxembourg", June 24, 1999.
[133] Castle, Stephen, "EU Agrees on Tougher GM Food Control," *The Independent*, June 26, 1999.
[134] Arthur, Charles, "Food Chain Bans Genetic Food," *The Independent*, March 16, 1998.
[135] Cooper, Glenda, "Food Safety Brief Switches to Health," *The Independent*, May 9, 1997.

Focus on Planting

As Brussels grappled with product regulation, policy debates about GMOs in the UK generally involved the provision of consents for commercial planting in the UK already signed off by Europe. Here, the Department of the Environment served as the competent authority, but consulted with other government divisions, such as the Ministry of Agriculture, Fisheries and Food (MAFF).

With approval pending for the first commercial release, Plant Genetic Systems' oilseed rape, the government advisory body English Nature and others warned that increased herbicide use as a result of sowing herbicide-tolerant crops could impact bird and insect populations. [136] They also warned about the potential creation of aggressive weeds. Ministers delayed the approval in early 1998, and would spend the next year debating a moratorium.[137]

Issue linkage

Momentum against GMOs picked up in 1998 on multiple fronts. In addition to the lobbying against Whitehall by environmental groups, Prince Charles re-entered the debate, by urging caution in a letter to 15,000 members of the Soil Association, an organic farming group.[138] On the product front, Malcolm Walker, CEO of the frozen goods supermarket Iceland, reignited the flagging boycott of modified foods by announcing in March that the store would no longer sell modified food products.[139] According to former Greenpeace UK Executive Director Peter Melchett, Walker

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[136] Hencke, David, "Fears Over 'Killer Crops'," *The Guardian*, December 18, 1997.
[137] Hencke, David. "Ministers Put Brake on Genetically Modified Crops." *The Guardian*, February 10, 1998.
[138] Sears, Neil, "Don't Meddle with Our Food, Charles Tells the Scientists," *The Daily Mail*, February 24, 1998.
[139] "Food Chain Bans Genetic Food," *The Independent*, March 16, 1998.

vanquished a key argument being made by Monsanto, the US and UK governments and British retailers: that it was too late to stop engineered foods from entering the food supply.[140]

As spring turned to summer, environmental concerns about modified crops began to conflate with consumer worries about food safety. Although very different, the two issues came to represent the same thing in the public mind, and together fuelled a general opposition to GMOs.

Growing Concern

In early June, Monsanto began a £10 million advertising campaign designed to bolster public support for GMOs in the UK, but the effort arguably had the opposite effect. Nigel Poole, a former spokesman for Monsanto competitor Zeneca, described the advertisements as arrogant, for highlighting the benefits of engineered products without acknowledging or explaining their novelty.[141] "I often wonder if it hadn't been for that sort of hubris whether we could have actually got through it," Poole said.[142] The campaign received heavy criticism, and even drew Prince Charles into a heated palaver with Monsanto after the royal spoke out against the technology and reiterated the comparison of genetic engineering and BSE.[143]

During this time, attacks against experimental crop trials escalated across Britain. Although they had started in the spring, their frequency increased significantly with the launch of Monsanto's campaign and the company's public spat with Prince

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[140] Melchett, Peter, Interview, December 13, 2010.
[141] Vidal, John, "Public 'Wants Labels on Genetically Modified Food'," *The Guardian*, June 4, 1998.
[142] Poole, Nigel, Interview, July 28, 2010.
[143] Hopkins, Nick, "Genetics Firm Accuses Charles of Pandering to Green Lobby, While Opponents of Gene-Modified Food Say His Views Reflect Public Concern," *The Guardian*, June 9, 1998; Arthur, Charles, "Biotech Firms Hit Back at Charles," *The Independent*, June 9, 1998.

Charles.[144] The vandals came from a variety of backgrounds, but typically worked in conjunction with a range of environmental activist groups.[145] Although Charles condemned the violence, some observers viewed his own activism as lending a kind of legitimacy and mainstream support.[146]

Pusztai

Public anxiety reached a climax in August, when Arpad Pusztai, a researcher from the Rowett Institute in Aberdeen, reported that rats fed genetically modified potatoes had suffered from stunted growth and weakened immune systems.[147] Broadcast on ITV's investigative *World in Action* television program, and then again around the world, the findings confirmed Britons' suspicions about GMOs and provided scientific backing for their safety concerns.

Scientists quickly cast doubt on his findings, with Pusztai forced to leave his post within days and the Royal Society later discrediting his research as "flawed in many aspects of design, execution and analysis."[148] Moreover, a June report stated that "no conclusions should be drawn from it."[149] Nevertheless, pockets of support for him endured.[150] But the damage had been done. Helen Marquard, a deputy director at the Department of the Environment, recalled a colleague's briefing upon Marquard's return

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[144] Paterson, Michael, "Eco Warriors or Vandals?" *Mail on Sunday*, June 21, 1998.
[145] Vidal, John, "Analysis: Trashing the Crops," *The Guardian*, July 31, 1998.
[146] Paterson, Michael, "Eco Warriors or Vandals?" *Mail on Sunday*, June 21, 1998.
[147] Radford, Tim, "Minister Rejects Call for Genetic Food Ban," *The Guardian*, August 11, 1998.
[148] Royal Society, "Review of Data on Possible Toxicity of GM Potatoes" (Royal Society, June 1999), 1; Radford, Tim, "Scientists Doubt GM Food Research," *The Guardian*, May 19, 1999.
[149] Ibid.
[150] Waugh, Paul and Michael McCarthy, "Prince's GM Attack Upsets Ministers," *The Independent*, June 2, 1999.

from a business trip. According to Marquard, the colleague said: "Don't expect the UK now to be as you left it because it has changed radically.'"[151]

Government Halts Commercial Planting

In the fall of 1998, the government faced a decision not only on the consent for the first commercial release which officials had delayed earlier in the year, but on a handful of applications already cleared by Brussels, including one from Monsanto.[152] In October, civil servants held separate meetings with environmentalists and industry, and floated a voluntary plan to delay planting for at least several months in order to study the impact of growing a few modified varieties alongside non-engineered ones.[153] Getting firms to delay voluntarily removed a key legal obstacle, since under EU law the government could ban planting only after demonstrating specific environmental risks.

Later in October, Minister of State for the Environment Michael Meacher and Jeff Rooker, the minister for food safety at MAFF proposed the so-called Farm-Scale Evaluations (FSEs), a government-sponsored trial of GMOs involving volunteer producers. "If, during this process, we do find evidence of harm then we can take appropriate action," Meacher told a House of Lords select committee.[154] Reaction to the announcement was mixed. Environmentalists complained that the move would open the door to modified crops.[155] Producers said they had already conducted ample safety trials, and some, including Monsanto and Zeneca, refused to take part, seeing the project as a

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[151] Marquard, Helen, Interview, December 16, 2010.
[152] Arthur, Charles and McCarthy, Michael, "Genetic Crops May Be Banned," *The Independent*, October 10, 1998.
[153] Ibid.
[154] Michael Meacher delivered this statement on 21 October 1998. See: UK Parliament, House of Lords Select Committee on European Communities, *Second Report*, Witnesses October 21, 1998, Question Number 603-619, (London: UK Parliament, Session 1998-1999).
[155] Vidal, John, "Genetic Crops Move Upsets Green Groups," *The Guardian*, October 22, 1998.

cynical ploy by the government. "It was the excuse for politicians not to apply the law," said former Zeneca spokesman Nigel Poole.[156]

Britain Catches Up to the Continent

Public opposition to GMOs grew at a rapid clip in the early months of 1999, as snowballing news coverage dissected all aspects of genetic engineering. In one February *Daily Mail* article, a scientist claimed that genetic modification could create dangerous toxins in food.[157] Another broadly vindicated Arpad Pusztai's controversial findings from the previous summer.[158] Amid the saturation coverage, the supermarket campaign picked up, with large chains, including Marks and Spencer, Sainsbury's, and later Tesco, pledging not to sell engineered foods in their product lines.[159] The stores joined a Europe-wide trade consortium which sourced non-engineered varieties. It seemed Britain's consumer movement had finally caught up with the continent.

As public opposition hardened, the UK government's position remained an open question. Although farm-scale evaluations put the question of GMO approvals on hold, they came with no set time frame. Prime Minister Tony Blair, continued to dismiss requests for a multi-year moratorium, and insisted that GMOs were safe.[160] But after Brussels committed itself in June 1999 to amending its laws, including giving member states more flexibility over commercial applications, Britain began to push for longer delays. In November 1999, officials in Whitehall reached an agreement with industry on

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[156] Poole, Nigel, Interview, July 28, 2010.
[157] Jeffreys, Daniel, "This Terrifying Tampering," *The Daily Mail*, February 8, 1999
[158] Hinsliff, Gaby, and Maguire, Chris, "GM Scientist 'Proved Right'," *The Daily Mail*, February 12, 1999.
[159] Dodd, Vikram, "Sainsbury's Bans GM Food in Own Labels," *The Guardian*, March 17, 1999; Evans-Pritchard, Ambrose, "EU Lifts Five-Year Ban on GM Foods, But Shoppers Will Have Choice," *The Daily Telegraph*, July 2, 2003.
[160] Radford, Tim, "Blair Rules Out Block on New Genetically Modified Crops", *The Guardian*, February 13, 1999.

the farm-scale evaluations.[161] Although supportive of GMOs in theory, the UK would take a strongly precautionary approach.

4.4 Revising the Policy Design and Execution: Europe (1999-2004)

The Commission made no approvals from October 1998 until May 2004. Although the system remained virtually closed throughout the six-year period, no formal ban ever existed. "It wasn't a moratorium," said Kathryn Tierney, a civil servant in DG Environment.[162] However, a *de facto* ban had clearly taken hold, keeping the system operational on paper but not in practice.

Although officials at the June 1999 Council meeting emphasized the need to reform the system and slow down the process, the EU set no official target for commencing approvals. From 1998, a majority of member states on the Regulatory Committee opposed new applications, which under the rules would automatically send them to Council. However, with Council unable to muster a majority for approval, or in some cases declining to vote entirely, decisions bounced back to the Commission.

In theory, the Commission could have forced through approvals as it did with maize in 1997. In fact, under the law officials arguably *should have* done so. However, the experience with maize had so polarized EU institutions, and escalated tensions between Brussels and the member states, that officials declined. "You had how it should be done written down in law and then you had the politics of the situation," said one EU civil servant who served in the Commission.[163]

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[161] Lean, Geoffrey, "IOS Hastens End of GM Crops in Britain," *The Independent on Sunday*, April 4, 2004.
[162] Tierney, Kathryn, Interview, December 10, 2010.
[163] EU civil servant 2, Interview.

Rather than pursue a politically difficult course, officials chose another path: delay. Instead of clearing applications, officials waited on various factors which might collectively persuade members of the Regulatory Committee or Council to vote yes. "It was simply the Commission delaying the decision that needed to be taken because the Council hadn't acted and because there wasn't enough political support for it," said the EU civil servant who served in the Commission.[164]

Thus, approvals remained on indefinite hold until enough political support could make the system function again. While each member state brought its own set of concerns to the table, new approvals would ultimately depend on making substantial and detailed reforms to the system.

A New Directive

For three years between 1998 and 2001, officials in DG Environment and across the Commission worked to overhaul Directive 90/220, and address long-standing problems with the law. Its replacement, Directive 2001/18/EEC, contained a litany of new restrictions, including requirements for clear labeling and traceability of all GMOs, post-market monitoring and a rule that all consents would expire after 10 years.[165]

Although the revised directive contained a few streamlining measures, such as guidance for a common risk assessment, most changes effectively increased the burden on producers and made it easier for member states to reject applications. Among other things, the directive allowed member states to incorporate ethical concerns into their assessment, as well as the "precautionary principle," the legal and philosophical concept

[164] Ibid.
[165] EU Parliament and Council, *Directive 2001/18/EC*, 4.

which justified policymaking delays if unacceptable risk levels persisted in the absence of sufficient data.[166]

Even before the proposal passed or came into force, Commission officials hoped that the provisions would give member states on the Regulatory Committee and Council enough comfort to begin making approvals.[167] David Bowe, the British Labour MEP, who liaised between the European Parliament and the Commission, declared the moratorium "dead" since consumers would have the assurance of an airtight system in place.[168]

Product Safety Redux

But following passage of the directive hopes for a swift resumption of approvals evaporated when a group of member states led by France pledged to block approvals on the Regulatory Committee until the EU enacted further reforms.[169] Despite Directive 2001/18's new and broadly restrictive content, many of its strongest provisions, including those for evaluating, labeling and tracing modified food products, actually required further legislation. While the directive addressed the risks of "deliberate release" of GMOs into the environment and outlined a regulatory system overseen by DG Environment, product safety fell under the purview of the Directorate General for Health and Consumers, or "SANCO" by the French abbreviation.

With DG Environment still *Chef de File* for deliberate releases, SANCO took the lead in crafting two new regulations, which over time would enhance the latter division's control over GMOs and minimize DG Environment's role. Proposed in 2001,

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[166] Ibid, 1; EU Commission, "Communication from the Commission on the Precautionary Principle" COM (2000) 1 Final, February 2, 2000.
[167] Osborn, Andrew, "EU 'Caves in to US Firms' on GM Foods," *The Guardian*, July 20, 2000.
[168] Burke, Jason, "EU Allows in New Flood of GM Food," *The Observer*, February 11, 2001.
[169] Fletcher, Martin, "French Threaten to Thwart Deal on GM Crops," *The Times*, February 12, 2001.

the regulations became law in 2003.[170] The first, Regulation 1829/2003, articulated a more detailed and coherent system for assessing the safety of modified food than the novel food law.[171] Most critically, it called for product reviews by the nascent European Food Safety Authority (EFSA), established in 2002. Based in Parma, Italy, the EFSA replaced the Commission's Scientific Steering Committee, which some member states had viewed with mistrust. The second regulation, 1830/2003, spelled out the legal requirements for comprehensive labeling of all GMOs, as well as for "traceability," or providing information about modified products at all stages of development and marketing.[172]

Trade War

The new regulations passed in September 2003. However, before member states could reflect on their adequacy, long-standing antipathy toward the EU policy boiled over from America. In May 2003, the United States filed a legal challenge against Europe at the World Trade Organization (WTO), citing lack of scientific evidence for the EU's rejections.[173] According to WTO rules, states may ban imports only if they can demonstrate their harmfulness. "We've waited patiently for five years for the EU to follow the WTO rules and the recommendations of the European (Commission), so as to

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[170] EU Commission, "Proposal for a Regulation of the European Parliament and of the Council on Genetically Modified Food and Feed" COM (2001) 425, July 25, 2001; EU Commission, "Proposal for a Regulation of the European Parliament and of the Council Concerning Traceability and Labelling of Genetically Modified Organisms and Traceability of Food and Feed Products Produced from Genetically Modified Organisms and Amending Directive 2001/18" COM (2001) 182, July 25, 2001.

[171] EU Parliament and Council, *Regulation (EC) No. 1829/2003 of the European Parliament and of the Council of 22 September 2003 on Genetically Modified Food and Feed*.

[172] EU Parliament and Council, *Regulation (EC) No. 1830/2003 of the European Parliament and of the Council of 22 September 2003 Concerning the Traceability and Labelling of Genetically Modified Organisms and the Traceability of Food and Feed Products Produced from Genetically Modified Organisms and Amending Directive 2001/18*.

[173] Denny, Charlotte, "America Challenges GM Crops Ban," *The Guardian*, May 14, 2003.

respect safety findings based on careful science," said US Trade Representative Robert Zoellick.[174]

Claiming the *de facto* moratorium cost American farmers £180 million per year in lost revenue from corn exports alone, the US asked for £1 billion in compensation for losses suffered by American farmers as a result of the EU position.[175] US officials also accused the European policy of prolonging famine in Africa by causing countries such as Zambia to reject American food aid in the form of modified crops.[176]

The Moratorium Ends in Brussels

With the EU under growing pressure from outside, openings in the system began to emerge for several modified food products in the year following the US trade complaint. One such product, a sweetcorn variety for human consumption developed by Syngenta, prompted the Commission to make its first approval in six years, even after the Regulatory Committee and Council had failed to approve it. The Commission cleared the tinned maize in May 2004 after the European Food Safety Authority found no objection. "[The] GM sweetcorn has been subjected to the most rigorous pre-marketing assessment in the world," said EU Commissioner for Health and Consumer Protection (SANCO) David Byrne.[177] Calling the maize as safe as any conventional variety, officials sought to shift the discussion away from food safety. "It is a question of consumer choice," Byrne said.[178]

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[174] Ibid.
[175] Watson, Roy, "Europe Sets Rules for Labelling GM Food," *The Times*, July 3, 2003; "Bush Threatens Trade War Over GM Ban," *The Daily Mail*, April 28, 2004.
[176] Mortished, Carl, "GM Crops Policy Shuts Door on Industry," *The Times*, January 15, 2003.
[177] Evans-Pritchard, Ambrose and Clover, Charles, "GM Sweetcorn Given the Go-Ahead as Europe Bows to the US," *The Daily Telegraph*, May 20, 2004.
[178] Browne, Anthony, "Protests After Europe Ends GM Food Freeze," *The Times*, May 20, 2004.

Despite the end of the moratorium, several challenges remained. Approval of the modified products did not necessarily translate to public acceptance. Retailers acknowledged they would have trouble marketing the products, even with clear labeling. "I don't know anyone who will even give it a trial because of the consumer attitude to GM," said David Southwell of the British Retail Consortium.[179] Furthermore, approvals for modified crop varieties would come more slowly, and depend heavily on the political climate within respective nations. The revised legislation gave member states much more flexibility to determine how and whether to accept engineered crops.

Although the moratorium had technically ended, the trade dispute would continue as US officials called for further liberalization by the EU. "The approval of a single product is not evidence that applications are moving routinely through the approval process in an objective, predictable manner based on science and EU law, rather than political factors," one US official in Brussels said.[180] "Our basic concern is that the EU does not have a consistently functioning approval process."

United Kingdom (1999-2004)

During the EU's *de facto* moratorium on new GMO approvals in 1998, the UK concurrently blocked any commercial planting from commencing in Britain; officials placed on hold the handful of commercial planting applications already cleared by Brussels but not yet in receipt of a final consent. The delay allowed the UK to perform further safety studies known as the farm-scale evaluations. The government's five-year, £6 million project spanned 266 trial fields in England, Scotland and Wales, with

[179] Sample, Ian, "EU Approves GM Sweetcorn," *The Guardian*, May 20, 2004.
[180] Browne, Anthony, "Protests After Europe Ends GM Food Freeze," *The Times*, May 20, 2004.

participants mimicking commercial growing conditions, and raising modified varieties alongside traditionally-bred ones.[181]

Farm-Scale Evaluations

The evaluations generated controversy from the start, with industry expressing skepticism about their purpose, and GMO opponents seeking to halt any advance of the technology.[182] Organizers had difficulty recruiting willing farmers, and upon completing the evaluations, the results suggested that only one of the four varieties tested, an herbicide-tolerant maize by Bayer, would have beneficial effects on the countryside.[183] The other three GMOs, including two types of oilseed rape and a beet variety, had an arguably greater environmental impact than non-engineered crops, leaving fewer insects, including butterflies and bees.[184]

For industry, the evaluations delivered a less-than-positive result. But the findings merely added to a list of other woes facing producers, including the routine destruction of crop trial sites, aided in part by a government requirement that firms disclose the exact locations of all trials.[185] The number of participating farmers dropped precipitously.[186]

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[181] Burke, Maria, the Farm Scale Evaluations Research Consortium and Scientific Steering Committee, "Managing GM Crops with Herbicides" (Department for Environment, Food and Rural Affairs, March 21, 2005), 1-2

[182] McKie, Robin, "You Can't Stop Us Growing Gene Crops, Say Food Firms", *The Observer*, October 11, 1998; Vidal, John, "Genetic Crops Move Upsets Green Groups," *The Guardian*, October 22, 1998.

[183] Burke, Maria, the Farmscale Evaluations Research Consortium and Scientific Steering Committee, "Managing GM Crops with Herbicides," 1.

[184] Ibid.

[185] McKie, Robin, "GM Firm Quits as Trials Halt: Crops Firm Blames Move by Beckett," *The Observer*, September 28, 2003.

[186] Brown, Paul, "Despairing GM Firms Halt Crop Trials," *The Guardian*, April 15, 2004.

Ending the Moratorium

Despite opposition from pressure groups and even some ministers, Secretary of State Margaret Beckett announced the approval of the first GMO crop for commercial cultivation in the UK, Bayer's herbicide tolerant maize. But the approval came with numerous restrictions, including one that would require producers to pay into a compensation fund for potential damage caused from cultivating GMOs.

The approval announcement was overshadowed by the company's decision to cancel its growing plans, citing the cumbersome regulations as the reason.[187] A Bayer spokesman described the strictures as suffocating. "New regulations should enable GM crops to be grown in the UK - not disable future attempts to grow them."[188] But in the months that followed, the government showed no signs of easing requirements. "This is the end of GM in Britain," said Soil Association spokesman and former Greenpeace activist Peter Melchett, speaking at the time.[189] The observation, at least in the short term, rang true.

4.5 Conclusion

Attempts to explain Britain's first-generation policy for GMOs typically invite immediate skepticism considering the multiple jurisdictions involved. Indeed, since Brussels designed the framework and played an active role signing off on commercial applications, the policy belonged as much to the EU as to the UK. Therefore, any explanations must account for decisions made by both jurisdictions. Although the UK had developed its own sophisticated policy infrastructure for overseeing GMOs by the

[187] Clennell, Andrew, "GM Giant Abandons Bid To Grow Crops in Britain," *The Independent*, March 31, 2004.
[188] Ibid.
[189] Lean, Geoffrey, "Ministers Forced to Accept That GM Crops Will Never Be Grown in Britain," *The Independent on Sunday*, April 4, 2004.

late 1980s, officials in the following decade deferred to a European-led effort based on a directive crafted by the Commission, Council and Parliament.

The oversight system for commercial planting and sales relied on member states to conduct initial environmental reviews, and voluntary food safety assessments. Successful applications were forwarded to Brussels, where they faced review by the Regulatory Committee and possibly the Council, if any member states objected to them. Following a number of approvals made in the mid-1990s, conflicts within the Regulatory Committee, the Council and the Commission itself effectively halted further consents between 1998 and 2004. Similarly, in the UK, ministers in the late 1990s declined to issue the handful of commercial planting consents which Brussels had already cleared for Britain, citing the need for further studies. Because of the paucity of approvals, this study described Britain's policy, as overseen by Brussels and London, as restrictive.

Considering the complexities of the two jurisdictions, and the three-decade span of policymaking activities, simplistic explanations undoubtedly fail to capture the richness of the case's causal mechanisms. Although scholarly explanations were rarely mono-causal, they generally came in two forms. The first provided a cultural interpretation based on public opinion, viewing the policy as the end result of public opposition to the commercial planting and sale of GMOs. The second explained the restrictive policy in terms of Europe's strong public interest groups and weak biotechnology industry. This study does not aim to contradict these views, but rather to address their limitations and highlight a third explanatory approach which focuses on institutions, and seeks to place all variables in context.

Public Opinion

Any attempt to explain Europe's policy for GMOs would remain woefully deficient without acknowledging the critical importance of public opinion in bringing the issue to the attention of government officials in member states and Brussels, who would take successive steps to restrict the nascent technology. Opposition grew slowly from the mid-1990s, and peaked by 1999, when polls showed that a majority of people opposed engineered food in all EU nations except Ireland, the Netherlands, Portugal and Spain.[190] But opposition never existed in equal measure among member states, with countries on the continent, such as Austria, Luxembourg and Germany, where the supermarket boycott found its first success, showing the most ardent and sustained dislike of GMOs.

Strong opposition from member states filtered into EU institutions designed to reflect their political interests: the legislature, made up of the Council and Parliament; and, the Commission's Regulatory Committee, made up of civil servants. Although the Commission, created to execute the collective goals of the EU, initially supported GMOs, it later relented following criticism from other institutions, including Parliament. Hence, even if opposition permeated EU institutions, the nature of that influence differed depending on the institution.

Furthermore, poll data in Table 4.5 showed that among those who had made up their minds, majority support existed for GMOs in most member states in 1996. Indeed, majority opposition emerged only after the first American imports, including the controversial maize variety, had arrived in Europe and forced their way through the unfinished regulatory system. This suggests that European opposition to GMOs could

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[190] Gaskell, George, Allum, Nick, and Stares, Sally, "Europeans and Biotechnology in 2002: Eurobarometer 58.0, a Report to the EC Directorate General for Research from the Project 'Life Sciences in European Society'," March 21, 2003.

have developed in response to specific events and did not represent an *a priori* factor, allowing for a potentially more dynamic interaction of variables.

Interest Groups

Like public opinion, interest groups also represented a critical variable. Indeed, environmental and consumer groups clearly helped direct public discontent with GMOs to concrete targets, such as government lobbying efforts and boycotts. Indeed, without interest groups, the public opposition to GMOs may not have developed to such a degree or prompted food producers and retailers to keep engineered varieties from store shelves.

Yet the notion that Britain and Europe's environmental and consumer activists possessed an *a priori* power which alone accounted for the restrictive policy approach is difficult to substantiate. Indeed, as this chapter revealed, for most of the 1990s interest groups were unsuccessful in their attempts to raise awareness of GMOs, block engineered varieties from stores or secure mandatory labeling. However, interest groups experienced success after American growers sought to force their commodities through the European system, once various regulatory gaps had been revealed.

Furthermore, interest group successes in the consumer boycotts highlight the importance of the structure of industrial food producers and retailers, and the comparative advantage of launching an anti-GMO campaign in Europe versus the United States. Whereas the United States possessed a larger collection of regional supermarket chains, the European Union had fewer firms controlling the market.[191] Therefore, the decision by grocery giants such as Marks and Spencer, Sainsbury's and

[191] Bernauer, Thomas, *Genes, Trade and Regulation*, 87.

Tesco not to carry GMOs in their own brands virtually blacked out the domestic market in the UK.

A further, and largely credible, extension of the interest group hypothesis suggests that the weakness of industry in Britain and Europe contributed to the restrictive policy result. But even this narrative has limits. Although few modified varieties were suitable to European soils, and American firms held a larger investment in biotechnology than their counterparts overall, producers in Britain and Europe had a serious investment in the technology. Moreover, the international reach of most companies meant that even US-based companies, such as Monsanto, had a significant connection to the European market. Furthermore, as the earlier discussion noted, companies in Europe possessed the same divergence in regulatory priorities as American firms. Some corporations, such as Monsanto, favored more restrictive regulation, because of the competitive advantages it provided over smaller firms which opposed burdensome oversight.

What European firms arguably lacked was a cohesive regulatory paradigm committed to opposing excessive regulation, such as the Reagan Administration approach during the 1980s. Instead they encountered an unfinished regime spread across numerous institutions and apparently susceptible to interest group pressure.

Institutions

Although public opinion and interest groups played a clear role in Britain and Europe's restrictive policy, they do not provide the whole story. Regarding public opinion, the study showed that opposition to GMOs was not a constant factor but one that developed in response to specific events, especially the introduction of American products into the regulatory system without labeling or safety evaluations. Similarly, interest groups

became effective later in the decade in response to the same events, and in a way that capitalized on European regulatory gaps, as well as the structure of continental agriculture and food retailing. Therefore, while explanations based on public opinion and interest group agency describe important mechanisms of the case, they do not provide details about what occurred inside government when American products arrived and caused a stir.

This study hypothesized that institutional explanations significantly expand knowledge of the case, beginning with early biotechnology policymaking in Europe, when officials grappled with the question of how to proceed. While some factions within the Commission pushed for a less burdensome approach based on a flexible, product-based scope, and "vertical" legislation which would distribute oversight responsibilities among directorates general as relevant, officials in power pursued another direction. Indeed, DG Environment, the Council and Parliament secured an approach based on rDNA as the process-based scope for regulation, and horizontal legislation guaranteeing environmental assessments by DG Environment.

While the final directive represented a much more burdensome approach for industry, one of the biggest problems with the policy design was that it did not do enough. Although the policy required environmental reviews for the marketing of GMOs, it made no provision for safety assessments or labeling and left it to member states to provide voluntary reviews. Although Europe would pass subsequent product legislation drafted largely by DG Industry, the policy remained noticeably incomplete when the first engineered foods arrived. Moreover, in addition to leaving gaps in the regulatory system, Directive 90/220 locked in comitology via regulatory committee for approving products when member states disagreed.

The combination of incomplete oversight and comitology, with its multiple veto points, created considerable difficulty for producers seeking approvals to market the first GMOs. Although the system cleared the first dozen applications, approvals ground to a halt when members of the Regulatory Committee, Council and Commission—all susceptible to political pressures at home—declined to take action even when required to do so by statute.

These systemic problems became apparent at a time when Europeans had deep sensitivities about food issues, in part resulting from the crisis of BSE. When applicants such as Monsanto sought to force through the first engineered commodities, member state publics, including Britons, developed a negative opinion of GMOs that quickly hardened.

Pierson's Criteria

These institutional details suggest that the "inside" view of policymaking in Britain significantly contributes to the explanation of causal mechanisms in concert with those based on other factors. However, as a work of social science, this study must do more than outline structural factors impacting the outcome. It must explain how exactly institutions shaped the restrictive policy in Britain. To do so, Chapter One proposed to describe policy development as an increasing returns process that can reveal the early institutional arrangements that drove policymaking later. The following paragraphs apply Pierson's criteria for increasing returns to GMOs in Britain.

Multiple Equilibria

In the UK and Europe, the policy-making path could have gone in multiple directions during negotiations over Europe's draft directives in the late 1980s. Most critically,

officials faced a quandary over the extent of the system's reach, including whether to regulate the process or products of genetic engineering; and, whether the policy should take a "horizontal" form across directorates general, or a "vertical" approach that would allow multiple directorates to play a relevant role. Moreover, if officials embraced horizontal regulation, they faced multiple options in how to structure it. While the Commission's draft proposal maintained a flexible position on these issues, amendments made by the Parliament and Council locked in a scope based on rDNA (meaning that Europe would regulate the process not the products of genetic engineering), and ensured the policy's horizontal reach by requiring assessments in all cases by DG Environment.

Contingency

In the UK and Europe, the crisis over BSE in the period leading up to the mid-1990s represented a critical contingent event for GMOs. Although no scientific link existed between BSE and engineered food, the former arguably heightened public sensitivity to food safety issues throughout Europe, and enflamed concerns about modified crops when imports began arriving without labels. In fact, the BSE experience drove one of the most prominent concerns raised about GMOs from 1996, when critics worried that the "marker gene" added to Ciba Geigy's maize during the process of genetic engineering could cause antibiotic resistance in cattle—a potentially serious risk. In Britain, evidence of post-BSE conditioning further revealed itself when opposition to GMOs rapidly increased in the months after Rowett Institute researcher Arpad Pusztai's controversial safety findings. Although the scientific community quickly dismissed those results, the ensuing uproar fuelled negative media coverage, paralyzed ministers and turned consumers away from GMOs.

Timing and Sequencing

While the United States designed and executed a coherent policy approach well before engineered foods became a reality, the EU system remained a work in progress when two of the first engineered products, imported soya and maize, arrived in 1996. In this way one could describe timing and sequencing as critical. Before Europe's novel food law passed in 1997 no mandatory reviews existed for engineered products. And even after the law changed, reviews performed by domestic authorities lacked uniformity and generated mistrust at the European level, where member state officials on the Regulatory Committee frequently challenged applications and in turn triggered comitology.

The failure to finalize the EU policy before products arrived meant that the system followed the products, rather than the reverse. Officials had no time to troubleshoot the policy before reviewing actual GMOs. Problems, such as with Ciba Geigy's controversial maize, revealed cracks in a system which appeared to be less organized and coherent than the framework established in the US.

In the wake of the BSE crisis in 1996, lack of a finished policy created the appearance of government negligence, which biotechnology opponents could successfully capitalize on. Furthermore, when the still-developing policy began to draw scrutiny, media coverage and interest group lobbying arguably helped tilt policymaking momentum toward more stringent options. However, if Europe had established a trusted and workable system before the BSE crisis, officials arguably could have combatted later criticisms more swiftly and seamlessly.

Inertia

In the UK and Europe, opposition to GMOs built slowly, but after it peaked in the late 1990s, subsequent attempts to liberalize the policy and resume approvals in Brussels were met with automatic opposition from numerous member states. Similarly, after British public opinion hardened around 1998, opposition to GMOs remained constant in the years following, despite support for the technology espoused by members of the government including Prime Minister Tony Blair. In both Brussels and London the perceived cost of reopening the issue exceeded the benefit.

Extending Path Dependence

These applications of Pierson's criteria suggest that an increasing returns process existed in the development of the EU-UK policy for GMOs. On this basis, one should conclude that the restrictive policy emerged not simply from strong public resistance and powerful interest groups but from the early embrace of the EU-UK legislative framework and officials' failure in the wake of BSE to complete their policy before products arrived.

Although Chapter One described Pierson's criteria as sufficient to reveal the institutional influences in policy development, this study proposed a secondary test of path dependence in order to address the question of variation in specific terms that scholars can assess comparatively. The following paragraphs apply this to the decision-making structure, the EU-UK legislative framework, during the policy design and execution phases of the case.

Actor Constellation. Following unsuccessful attempts by the Directorate General for Research to create a more limited regulatory system, DG Environment became *Chef de File* and pursued more sweeping "horizontal" legislation, which applied across DGs, in the form of Directive 90/220. Through the course of normal legislative procedure, officials from several European institutions successfully amended the directive, including those from the Commission, Council and Parliament. The process ensured that key actors represented a wide range of communities, from subject-oriented civil servants working in the DGs to directly elected politicians representing member states.

Perhaps the most significant provision in Directive 90/220 was its requirement that applications to grow or sell GMOs follow the standard comitology procedure. This decision, which created an appeal process in case a dispute arose over specific applications, ensured that a broad range of political actors would have input on the Regulatory Committee and Council.

Balance of Interests. The diverse political actors involved in the drafting and implementation stages of the European policy in turn had a significant effect on the balance of interests. While the United States avoided direct political interference and delays by expediting the process within the executive branch, European officials lacked a similar option, and were required to open the process up to the Parliament and Council.

While the Commission had an interest in creating a system that not only protected the public but allowed applications to move through the system, Parliament and Council were concerned primarily with the political interests of the groups they represented: single district constituencies and member state governments. This was demonstrated in provisions such as Article 16 of Directive 90/220 Part C, allowing

individual member states to opt out of accepting an engineered variety. On such a basis, actors' interests did not shift.

GMOs: The Policy Execution

Actor Constellation. Under Directive 90/220 applications could have moved quickly if member states collectively accepted the environmental reviews conducted by individual authorities. However, the fact that each application met with an objection required approval through comitology in all cases. For each application, the Commission issued a draft decision before sending the file to the Regulatory Committee, the representative panel made up of member state civil servants. If the Regulatory Committee failed to reach a decision the file passed to the Council. And if Council failed to provide a resolution, the matter came back to the Commission.

In other words, the institutions charged with reviewing GMOs resembled those institutions that created the regulatory system. Rather than creating a pool of overseers focused on EU administrative matters, the system empowered a Regulatory Committee made up of officials focused on domestic concerns in their home states. The Council contained politicians from member governments who were similarly concerned with domestic political matters in those states.

In the UK, politicians also had an opportunity to weigh in on applications to plant commercially. Although applicants needed approval from Brussels, UK ministers issued the final consents. However, such an institutional arrangement arguably had important consequences later, since ministers would face their first decisions on consents just as UK public opposition to GMOs reached a peak around 1998.

Balance of Interests. Because disagreement led to comitology in each case, the default approval procedure in Brussels built into every application's trajectory several

political votes which reflected member state domestic interests rather than EU administrative matters. First, member state civil servants could challenge another state's review; second, civil servants from across Europe deliberated face-to-face on the Regulatory Committee; and, if the committee failed to approve an application, the Council of ministers would weigh in. As other scholars have noted, this had the effect of enlarging the number of institutional veto points.[192] But it also deprived the EU of an administrative space capable of shifting priorities from member state interests to those of Europe as a whole.

Although the Commission attempted to balance member state political interests with the interests of the EU, its ability to advocate for both simultaneously suffered considerably when member state regulators declined to approve applications for GMOs. In the end, the Commission refused to challenge member states, which exercised their will through the Regulatory Committee, Parliament and Council. As described earlier, Commission civil servants themselves acknowledged the potential for politics to dominate comitology, a procedure more suited to technical cases, not politically sensitive ones. "It was never designed for this sort of monster political pressure," said an EU civil servant who worked in the Commission.[193] "It's designed...to create the internal market by taking fairly technical decisions on particular products. And it works fine for things up to a medium sensitivity." In other words, comitology worked for some products, but not for GMOs, which over time created insurmountable pressure from member states.

Political dimensions arguably also factored into the UK system for issuing commercial planting consents, albeit less directly. Although ministers received

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[192] Pollack, Mark, and Shaffer, Gregory, *When Cooperation Fails: The International Law and Politics of Genetically Modified Foods* (Oxford: Oxford University Press, 2009).
[193] EU civil servant 3, Interview.

scientific advice, because they possessed sole authority over consents—rather than delegating the matter to a separate or less political body, for example—they became a clear target for interest group lobbying and the media, and were arguably forced to include political considerations into their decision-making as a result.

Secondary Test of Path Dependence

Based on this analysis one can say that the early path adopted in the EU and UK, the EU-UK legislative framework, ensured that policymaking in Brussels became a political process dominated by member state interests. Moreover, a similarly political structure unfolded in the UK, where publicly accountable ministers maintained direct control over planting consents, leaving politics strongly in the decision-making equation.

On this basis, the EU-UK legislative framework arguably led to only limited expansions in the constellation of actors and did not yield significant shifts in the balances of interests during the design and execution phases of policymaking. Although this development does not singularly explain the EU-UK policy, the study suggests that a plausible relationship may exist between the lack of changes in actors and interests and the restrictive outcome. In this way, the secondary test of path dependence provides a specific mechanism for assessing institutional influence along the policy path.

Although it remains unclear what a decision-making structure like the Coordinated Framework may have produced in the EU and UK, one could reasonably conclude that the path taken did not provide a cohesive administrative setting for regulating GMOs. Moreover, under such conditions it seems difficult to imagine how a permissive policy could have resulted. Chapter Seven, the conclusion, will review these findings more closely in a comparative analysis that addresses the broader question of variation in biotechnology policies.

CHAPTER 5: HUMAN EMBRYONIC STEM CELL RESEARCH IN THE UNITED KINGDOM

Table 5.1 Timeline: Human Embryonic Stem Cell Research in the United Kingdom

1984 Warnock Committee endorsed IVF and embryo research under statutory regulation
1985 Enoch Powell's proposed ban on embryo research failed despite its 238 to 66 victory at second reading
1988 Government initiated debate on white paper
1990 Parliament passed HFE Act 1990
1997 Birth of Dolly announced
1999 HGAC/HFEA Recommendations shelved
2000 Donaldson Committee endorsed stem cell research and extending the HFE Act 1990; Commons approved regulations
2001 Lords approved regulations pending committee review
2002 First licenses issued by HFEA

Although human embryonic stem cell research officially began in America, the technology represented an important first for the United Kingdom: Unlike the United States, Britain became one of the first scientific powers to embrace the work politically and financially. Three years after the initial 1998 breakthrough, Parliament voted to support the research by extending the existing *Human Fertilisation and Embryology Act 1990*, a law created to oversee *in vitro* fertilization, to cover embryo research conducted for additional purposes, such as stem cell research. In doing so, British officials legalized an activity fraught with moral controversy, made public funds available and attracted scientists from nations with more restrictive policy regimes.

However, the UK's permissive approach did not translate to a lack of government control. Britain allowed stem cell research to move forward only under strict oversight, requiring a detailed application to the institutional regulator, the Human Fertilisation and Embryology Authority (HFEA), before work could commence. In doing so, the UK gave legal permission and public resources to a wide range of

activities not supported by the United States federal government. Therefore, this study describes Britain's policy as clearly permissive in contrast with the restrictive policy adopted by the United States and discussed in Chapter Six.

Table 5.2 Britain's Permissive First-Generation Policy for Human Embryonic Stem Cell Research

Activity	Policy Document	Policy Outcome
Embryo Research (for the purposes of IVF and related research)	*Human Fertilisation and Embryology Act 1990*	License required from Human Fertilisation and Embryology Authority (HFEA); most relevant applications approved
Embryo Research (for the purposes of increasing knowledge of and treatments for disease)	*Human Fertilisation and Embryology (Research Purposes) Regulations 2001*[1]	HFEA license required; most relevant applications approved

Popular with scientists and patient advocates, the UK policy became a regulatory model for countries similarly concerned with advancing research under set controls. However, opponents described it as a step down a slippery slope that could lead to other moral transgressions in the name of science.

Despite the high volume of journalistic accounts, few scholars have engaged the question of the origin of the UK policy or attempted to describe its causal mechanisms. Some works highlighted the importance of differences in national culture, broadly understood as public opinion, to the policy outcome.[2] Other theorists described the central role of institutions in shaping the policy outcome.[3] Another plausible approach

[1] UK Parliament, *The Human Fertilisation and Embryology (Research Purposes) Regulations 2001*, (HMSO, 2001).
[2] Jasanoff, Sheila, Designs on *Nature: Science and Democracy in Europe and the United States* (Princeton, N.J.: Princeton University Press, 2005); Fink, Simon, "Politics as Usual or Bringing Religion Back In?" *Comparative Political Studies* 41, no. 12 (December 2008), 1631–1656.
[3] Banchoff, Thomas, "Path Dependence and Value-Driven Issues," *World Politics* 57, no. 2 (January 2005), 200-230.

which theorists employ in other contexts could involve tracing the impact (or weakness) of British interest groups, such as religious conservatives.[4]

In accordance with the discussion outlined in Chapter One, this chapter seeks to extend knowledge of institutional influences, and recounts the biography of key policy documents, as it unfolded in historical periods. While two periods actually predated the discovery of stem cells, they nevertheless included key debates about embryo research, which occurred in the context of *in vitro* fertilization. During the first period, from 1982 to 1986, a government-appointed panel led by Oxford philosopher Mary Warnock generated controversy by endorsing regulated experimentation on human embryos for IVF treatment and research. In the second period, stretching from 1986 to 1991, Prime Minister Margaret Thatcher's government unveiled the HFE bill to implement Warnock's proposals, precipitating a battle with "pro-life" partisans in Parliament and ushering in a law that would become an important part of the UK decision-making structure for stem cell research.

During the third period, between 1991 and 2001, successive UK advisory bodies recommended that Parliament extend the HFE Act 1990 in the wake of the first successful derivation of human embryonic stem cells. In 2000, the government introduced a statutory instrument which sparked considerable debate but ultimately cleared the House of Commons in December, and the House of Lords in January 2001. In the fourth period, from 2001 to 2002, a Lords select committee deliberated before giving its final endorsement, allowing the HFEA to issue the first research licenses in March 2002.

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[4] Smith, Alexander, "Faith, Science and the Political Imagination: Moderate Republicans and the Politics of Embryonic Stem Cell Research," *The Sociological Review* 58, no. 4 (2010), 624–638.

5.1 Early Period: the Warnock Report (1982-1986)

Long before embryonic stem cells became a scientific reality, the UK engaged in a vigorous debate over what would become their raw materials: human embryos. This occurred within the context of discoveries in fertility science starting in the late 1970s, when British physicians Patrick Steptoe and Robert Edwards pioneered a successful technique for fusing egg and sperm *in vitro*, and then implanting the fertilized embryo into a woman's uterus. Known as *in vitro* fertilization (IVF), the method famously produced Louise Brown, the world's first "test tube baby," in 1978.

IVF Dilemma

As a signature achievement of British science, with practitioners around the world rushing to emulate the approach, IVF carried the obvious benefit of potentially assisting infertile couples to conceive. But the prospect of creating embryos in a laboratory also presented several negatives in the twilight years of Prime Minister James Callaghan's Labour government. Besides fears of Frankenstein-like human manufacture, officials had to grapple with several ethical quandaries which accompanied the technique: artificial insemination, egg donation and the use of surrogate mothers.

But the greatest quandary of all was embryo research. As researchers made clear, the future success of IVF required further research and experimentation on existing human embryos, a scientific imperative that generated concern among the public, but especially among "pro-life" opponents of abortion, such as Jack Scarisbrick, chairman of the advocacy group LIFE. This key constituency, which had ties with many

Tory backbenchers, opposed research on the basis that life, or personhood, began at conception.[5]

Government in the Middle

PRIME MINISTER MARGARET THATCHER
Party: Conservative In Office: 1979-1990 Reputation: Elected at a time of acute economic turmoil, "Iron Lady" Margaret Thatcher famously initiated a spate of historic domestic reforms to privatize industry and reduce union power, while maintaining a strong anti-communist posture internationally. A former chemist, Thatcher and ministers generally supported scientific innovation, including the landmark discovery in Britain of *in vitro* fertilization, despite opposition from many members of the Conservative Party.

Some scholars viewed the Conservative government elected in 1979 as eager to impose order on the uncertainties created by IVF.[6] At the same time, however, the decision to wait three years into the administration of "Iron Lady" Margaret Thatcher before taking action suggests that officials were in no hurry, and possibly even also had reservations owing to the technology's controversial nature. In any case, when scientists sought to pivot from experimentation to the broader clinical use of IVF in 1982, ministers in the Department of Health and Social Security felt the need to confront the many social, ethical and legal issues raised. "The government was thrown into a frenzy of trying to think what on earth to do about this," said Mary Warnock, a philosophy fellow at St. Hugh's College, Oxford, whom the DOH asked to chair a committee that would examine the issues raised and advise ministers on the potential response.[7]

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[5] Ibid.
[6] Mulkay, Michael, *The Embryo Research Debate: Science and the Politics of Reproduction* (Cambridge: Cambridge University Press, 1997), 15-16.
[7] Warnock, Mary, Interview, July 19, 2011.

DEPARTMENT OF HEALTH (DOH)

Secretary of State for Social Services: Norman Fowler (1981-1987)
Secretary of State for Health: Kenneth Clarke (1988-1990); Alan Milburn (1999-2003)
After administering health services through a variety of bodies in the 19th century, the modern consolidation of government health services occurred with the creation in 1919 of the Ministry of Health, which during its 50-year existence saw the considerable expansion of health care in the UK and the creation of the National Health Service.
In 1968, the UK joined health with social services in the newly created Department of Health and Social Security. The Thatcher Government decoupled the two in 1988.

SOURCE: See note[8]

Despite the moral and political controversy surrounding IVF, the Thatcher government privately signaled its support from the beginning. The then-Secretary of State for Social Services, Norman Fowler, consistently expressed enthusiasm, and there was no indication of disagreement from Prime Minister Thatcher, who herself had begun her career as a research chemist.[9] "My feeling is that [Thatcher] would always be in favour of anything that was good for the prestige of British science," Warnock said.[10] But given the sensitive nature of the issues raised, the government had to proceed with caution. Warnock, writing years later, described ministers as attempting to avoid the appearance of science running amok on the one hand, and the perception that they would simply collapse under the (anti-research) pressure of public opinion on the other.[11] Creating the Warnock Committee in the summer of 1982 served both purposes.

[8] Hennessy, Peter. *Whitehall*, (London: Pimlico, 2001), 418-426.
[9] Ibid.
[10] Ibid.
[11] Warnock, Mary, *Nature and Mortality* (London: Continuum, 2003), 75.

The Warnock Committee

THE WARNOCK COMMITTEE[12]
Members:
Mary Warnock, Fellow, Mistress of Girton College (Chairman)
Q.S. Anisuddin, Legal Executive
T.S.G. Baker, Queen's Counsel
Josephine Barnes, Gynaecologist
M.M. Carriline, Social Worker
D. Davies, NHS Trust
A.O. Dyson, Theologian
N.L. Edwards, Health Administrator
W. Greengross, General Practitioner
W.G. Irwin, Physician
J. Marshall, Professor of Neurology
M.C. Macnaughton, Professor of Obstetrics
Anne McLaren, Biologist
D.J. McNeil, Solicitor
K. Rawnsley, Professor of Psychological Medicine
M.J. Walker, Psychiatric Social Worker
Joint Secretaries:
Mrs. J.C. Croft
J.S. Metters
Legal Adviser:
R.A. Sanders

When DOH civil servants offered Warnock the post in June 1982, the Oxford philosopher already had considerable experience examining moral questions for the government, having chaired a panel on special educational needs, and a separate inquiry into the use of animals in laboratory research.[13] Busy with her regular teaching load and hesitant to accept, Warnock said she agreed to lead the IVF panel because she found the issues too intriguing to pass up.[14]

Warnock met once with officials in July and briefly consulted with them about the committee makeup, suggesting broad categories of potential participants, but not

[12] UK Warnock Committee, *Report of the Committee of Inquiry Into Human Fertilisation and Embryology* (London: HMSO, 1984).
[13] UK Warnock Committee, *Report of the Committee of Enquiry into the Education of Handicapped Children and Young People*, (London: HMSO, 1978); UK Warnock Committee, *Report of the Advisory Committee on Animal Experiments*, (London: HMSO, 1981).
[14] Warnock, Mary, *Nature and Mortality* (London: Continuum, 2003), 73.

specific names.[15] The department announced the other members later that month, selecting 15 participants, including six physicians, three lawyers, two social workers, two health professionals, a biologist and a theologian.

Although the panel included one Catholic member, John Marshall, Professor of Clinical Neurology from the UCL Institute of Neurology, subsequent critics would fault the committee for not including more dissenting voices. David Alton, a pro-life MP from Liverpool who served from 1979 to 1997, described the panel's makeup as exclusionary and undemocratic. "That rang alarm bells for me at the time," said Alton, asserting that the government had marginalized alternative perspectives[16]

Assisted by the support staff of a Department of Health legal advisor and two secretaries (one scientific, one administrative), the committee met several times per year for the next two years, and completed their work sequentially, reviewing all aspects of a single topic before moving to the next. "We did it in bits," Warnock said.[17] Unlike other panels that parceled out specific responsibilities to members, Warnock Committee members covered the same scientific and philosophical ground.

Members faced a steep learning curve, especially those without medical training, including Warnock. To assist panelists with the science, developmental biologist Anne McLaren, stepped into the breach, with charts and tutorials. "She managed to teach all of us," Warnock said.[18] The committee also took oral evidence from representatives from two dozen organizations, and received written submissions from more than 200.[19]

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[15] Ibid, 75-76.
[16] Alton, David, Interview, August 24, 2011.
[17] Warnock, Mary, Interview, July 19, 2011.
[18] Ibid.
[19] UK Warnock Committee, *Report of the Committee of Inquiry Into Human Fertilisation and Embryology,* 95-98.

The Report

Although the panel did not take votes on specific issues, Warnock said members were keenly aware of each others' views. These contrasting perspectives Warnock incorporated into the final report, which she wrote mostly herself, with assistance from McLaren. The scientific secretary Jeremy Metters also contributed technical language.

In the foreword, Warnock made a key distinction between ethics and the law. Although the issues involved presented distinctly *moral* questions, about which people's subjective opinions often differed, the committee had to advise the government about the *law*, which by definition must apply to all people. Panelists could differ in their moral views, but in making laws they needed to consider everyone. All committee members wanted some limits placed on research. "Barriers, it is generally agreed, must be set up; but there will not be universal agreement about where these barriers should be placed," Warnock wrote.[20] In total, the report exceeded 100 pages and contained 64 specific recommendations. It also included three expressions of dissent from members.

On matters of fertility, panelists agreed that IVF should continue, along with artificial insemination and egg donation, but only with licensing by a statutory authority. Such an authority would maintain records of all treatment facilities, set relevant standards and conduct regular inspections. The report provided detailed guidelines for obtaining and using donated *gametes* (eggs or sperm). To the chagrin of some scientists on the panel, Warnock's prior policy experiences had biased her in favor of regulation, and so she aimed to apply the same approach to IVF. "I thought we would never get anywhere if we didn't start off quite early by saying we have got to have regulation,"

[20] Ibid, 3.

Warnock said. "Because otherwise…there would be a free for all and then it would be criminalized."[21]

The panel's opposition to surrogacy prompted the first of three dissenting opinions. While most members of the group, including Warnock, opposed the use of surrogate mothers, they determined that a ban would be impossible to enforce, and recommended prohibiting only commercial surrogacy. In their dissent, scientist David Davies and physician Wendy Greengross, wrote that surrogacy should remain an option for some couples as a last resort.[22]

Embryo Research

The report's most controversial recommendation stated that scientists could receive licenses to conduct research on human embryos through the 14th day after conception. Warnock described this recommendation, intended to improve scientific knowledge and techniques, as the most contentious.[23] Opinions varied considerably, with panelists frequently returning to the philosophical question of when human life begins, a question Warnock found virtually impossible to answer. While some could argue that life began at conception, others said egg and sperm were alive, or that a human was not fully alive until it is born, she explained.

Warnock sought to bypass this quandary by proceeding directly to the question of the embryo's moral status. A small minority of panelists believed that a human embryo after conception deserved the full legal protection of a human being, and that IVF could proceed only if each embryo produced was implanted into a uterus. However, the majority found that the embryo stopped short of full personhood, and that a closer

[21] Warnock, Mary, Interview, July 19, 2011.
[22] UK Warnock Committee, *Report of the Committee of Inquiry Into Human Fertilisation and Embryology*, 87-89.
[23] Warnock, Mary, Interview, July 19, 2011.

examination of the embryo's biological development could determine whether, and under what circumstances, research might be permitted. "What we had to do was decide, given the story of the development of the embryo from fertilization, what was the moral status of it at every stage?" Warnock said.[24] Those panelists not insisting on a black-and-white definition of personhood would have to find a way to draw distinctions within the shades of gray.

14-Day Rule

Following many rounds of discussion, a majority of panelists agreed to a temporal limit and decided on 14 days for two reasons. The 14th day after fertilization coincided with the appearance of the so-called primitive streak, the microscopic precursor to the human fetus, located within the bundle of cells that would become the placenta. The 14th day also marked the point at which the embryo implanted fully into the uterus. Although Warnock acknowledged the arbitrary nature of any chronological cutoff, she defended the ethical foundation of the 14-day rule because of its physiological basis: "There was absolutely no question of any suffering on the part of the embryo before 14 days because it didn't have a nervous system."[25] The rule, which would criminalize research on embryos after the 14th day, also fit well with the law. "It had the merit of being definite," said Warnock, describing the 14-day rule as the most significant feature of the entire report. "The law must have certainty in that sort of situation."[26]

Not everyone on the panel agreed. Three dissenters, Madeline Carriline, John Marshall and Jean Walker, penned a four-page opinion which supported the creation of

[24] Ibid.
[25] Ibid.
[26] Ibid.

embryos but only for implantation in a uterus.[27] Such a position would outlaw all research on embryos, and potentially impede IVF treatment itself, since its future largely depended on further research. Four others, Scott Baker, A.O. Dyson, N. Edwards and Wendy Greengross, wrote a separate, and less restrictive, dissent, approving the use of supernumerary or "spare" embryos leftover from fertility treatments, but opposing the creation of embryos purely for research purposes.[28]

Reaction to Warnock

Released in July 1984, two years after the committee started work, the Warnock Report generated swift criticism on multiple fronts. Many scientists decried the recommendations as burdensome.[29] However, the strongest opposition came from pro-life groups, such as the Society for the Protection of Unborn Children (SPUC) and LIFE, which produced a critique, entitled "Warnock Dissected."[30] Former LIFE Chairman Jack Scarisbrick faulted Warnock's decision to bypass the question of an embryo's personhood as "absurd." "It simply ducked the crucial question," said Scarisbrick, referring to the embryo's personhood.[31] He also challenged the significance of the primitive streak as a temporal marker. "We had scarcely heard of the primitive streak before Lady Warnock discovered it."[32]

Despite the growing opposition of pro-life activists, broader public sentiment remained unclear. While a MORI poll cited at the time of the November 1984 House of Lords debate on the Warnock Report showed that 85 percent of Britons opposed

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[27] UK Warnock Committee, *Report of the Committee of Inquiry Into Human Fertilisation and Embryology*, 90-93.
[28] Ibid, 94.
[29] Mulkay, Michael, *The Embryo Research Debate: Science and the Politics of Reproduction* (Cambridge: Cambridge University Press, 1997), 20-22.
[30] Scarisbrick, Jack, Interview, August 10, 2011.
[31] Ibid.
[32] Ibid; Warnock became a Dame Commander of Order of the British Empire (DBE) in 1984.

experiments on human embryos, news accounts suggest that the public knew little about the technology and were not actively aware of the issue.[33] Moreover, as a Marplan poll cited by research advocates in 1985 revealed, the more people learned about the purposes of research, the more inclined they were to support it.[34]

Noncommittal Government

Following the Warnock Report's release the government remained non-committal. Although Bernard Braine, Chairman of the All-Party Parliamentary Pro-Life Group, said he believed Thatcher would support a ban on embryo research, ministers deflected questions about the report.[35] When pro-life MPs demanded during the November Commons debate that the government recognize the sanctity of human embryos, Secretary of State for Social Services Norman Fowler said members needed to balance the issue against the needs of childless couples.[36] In fact, most support for the government came from Labour members across the aisle.

Warnock, who said Fowler had made favorable comments about the report in their private discussions, believed she had the government's support. "[Fowler] liked it," Warnock said. "I don't think there's any doubt that they wanted the impetus to go on."[37] As a sign of possible support, when the Medical Research Council announced in early 1985 that it would create an interim licensing authority for embryo research, operating on a voluntary basis, the government made no attempt to halt the plan.[38]

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[33] McKie, David, "Gingerly Into the Thickets of Life," *The Guardian*, November 1, 1984.
[34] Mulkay, Michael, *The Embryo Research Debate: Science and the Politics of Reproduction* (Cambridge: Cambridge University Press, 1997), 29.
[35] Veitch, Andrew, "MPs Draw Up Bill to Ban Experiments on Embryos," *The Guardian*, July 21, 1984.
[36] Veitch, Andrew, "Fowler Deflects Tory Embryo Ambush / Commons Debate on Test Tube Babies," *The Guardian*, November 24, 1984; "Anxiety Over Potential Embryo Abuse / Government Reviews Warnock Committee Report on Surrogate Motherhood," *The Guardian*, November 24, 1984.
[37] Warnock, Mary, Interview, July 19, 2011.
[38] Mulkay, Michael, *The Embryo Research Debate: Science and the Politics of Reproduction* (Cambridge: Cambridge University Press, 1997), 24-25.

However, officially, the government refused to take any direct steps to implement the Warnock recommendations.

The Powell Bill

The scattered opposition to embryo research gained momentum when Ulster Unionist MP Enoch Powell, a former Conservative minister, agreed to introduce a ban: the so-called Unborn Children (Protection) Bill.[39] Powell, who was not pro-life himself, said he opposed the research out of a general feeling of repugnance, and agreed to introduce the legislation as a private member's bill.[40]

To the shock of some observers, the measure gained a huge victory at second reading, in a vote of 238 to 66 in February 1985.[41] Scientists and research advocates responded with an organized drive to generate support for work on embryos. The following November, a group of physicians, scientists and MPs formed a group called Progress, aiming specifically to educate and influence Parliament on science issues.[42]

Not surprisingly, the bill's strong showing failed to overcome the fate of most private members' bills which fail because the government declines to allocate time for offering amendments. "A private member's bill needs time to proceed," said former Liberal MP David Alton. "And if governments aren't prepared to provide that time…It can't make progress."[43] The Powell Bill died in June despite attempts by some

[39] Ballantyne, Aileen, "Powell to Seek Embryo Test Ban," *The Guardian*, December 3, 1984.
[40] Ibid.
[41] Travis, Alan, "Embryo Bill Rebels Beat Thatcher / Proposed Legislation to Ban Research on Human Embryos," *The Guardian*, February 16, 1985.
[42] Mulkay, Michael, *The Embryo Research Debate: Science and the Politics of Reproduction* (Cambridge: Cambridge University Press, 1997), 28.
[43] Alton, David, Interview, August 24, 2011.

members to provide time.[44] Several MPs would attempt to resurrect the measure in other private members' bills, but without government time these similarly ended in defeat.

While most parliamentarians basically agreed on the Warnock Report's recommendations for the use of IVF, the parallel question of embryo research made government action impossible in the short term. However, because scientists had insisted that IVF required further research in order to succeed, officials could not approve one without the other.

5.2 Policy Design: The Human Fertilisation and Embryology Act (1986-1990)

Government Delays

Since the question of embryo research prevented action even on the consensus positions on IVF, officials put the issue on the back burner and allowed fertility treatment and experiments to proceed under voluntary licensing controls throughout the mid- to late-1980s. Some saw this as a deliberate strategy designed to avoid a confrontation with anti-research backbenchers, in the hopes of introducing legislation after opposition to research had diminished.[45]

The government's continued inaction prompted criticism from both sides. While supporters complained about the lack of regulation and faltering IVF service standards, opponents sought an opportunity to ban the practice, feeling buoyed by the lopsided victory of the Powell Bill in 1985.[46]

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[44] Brown, Colin, "Powell Bill Fails But Embryo Battle Hots Up," *The Guardian*, June 8, 1985.
[45] Mulkay, Michael, *The Embryo Research Debate: Science and the Politics of Reproduction* (Cambridge: Cambridge University Press, 1997), 36; Scarisbrick, Jack, Interview, August 10, 2011.
[46] "Infertility Service Appalling, Says Labour / Criticism of National Availability of Infertility Treatment," *The Guardian*, July 31, 1986; "Parliament: Embryo Bill for Next Year," *The Times*, July 10,

While ministers certainly wished to avoid controversy, they also made it clear that logistical challenges prevented the advance of legislation. Several spokesmen, and even Thatcher herself during Prime Minister's questions, insisted that a full debate which examined the many complexities of the issue would require a sizeable portion of the always-crowded parliamentary floor schedule.[47] Officials knew the issue would take time, and they saw no need to rush it.

Making the Case

In the years that followed her report, the now-Baroness Warnock, remained busy with the issue, speaking to audiences around the country with fellow panelist Anne McLaren.[48] Also making the case for research in growing numbers were a coalition of doctors, scientists and patients, who helped create a powerful lobbying force for their interests during this time. The partners made their union official in 1988 and formed the Genetic Interest Group, which became known as the Genetic Alliance UK in 2010, according to Alastair Kent, the group's long-time director.[49]

Pre-Implantation Genetic Diagnosis

As patient advocates became more active in the 1980s, they also became more hopeful. Advances in science, such as a technique called pre-implantation genetic diagnosis (PGD), suddenly meant that IVF could assist not only the infertile, but also carriers of congenital maladies such as Huntington's disease and muscular dystrophy. By screening

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1987; Fletcher, Martin, "Delay in Legislation to Curb Embryo Testing Angers MPs," *The Times*, November 14, 1988.

[47] "Parliament: Embryo Bill for Next Year," *The Times*, July 10, 1987; "Parliament: Pledge on Embryo Research - Lords," *The Times*, January 16, 1988.

[48] Warnock, Mary, Interview, July 19, 2011; Warnock became a life (crossbench) peer in 1985.

[49] Kent, Alastair, Interview, August 5, 2011.

fertilized embryos for genetic defects prior to implantation, scientists could help couples produce healthy offspring and increase scientific knowledge of disease.

Although scientists were years away from deriving stem cells from human embryos, science advocates were beginning to articulate the centrality of embryo research to future discovery.[50] But some observers described the new excitement as misplaced. Former pro-life Liberal Democrat MP David Alton described the scientific claims as unfounded, and said the charities had been "taken in by these seductive arguments," and then successfully lobbied "susceptible" MPs.[51] Whether embryo research represented the best path forward or whether patients had overstated the case would become a central debate in the years to come.

White Paper

Despite the government's delays, ministers showed signs of support for IVF and research, releasing a consultation document in December 1986, followed by a white paper a year later.[52] Released in November 1987, four legislative cycles after the Warnock Report, the white paper closely followed the report's recommendations, proposing the establishment of a licensing authority to regulate all aspects of IVF activities.

But on the subject of embryo research, the government took a neutral position. Ministers said they would hold a so-called free vote on the issue, as their Labour predecessors had famously done in 1967 during votes to legalize homosexuality and

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[50] Sherman, Jill, "Embryo Research 'Needed to Defeat Genetic Disease'," *The Times*, November 21, 1987.
[51] Alton, David, Interview, August 24, 2011.
[52] UK Department of Health and Social Security, "Legislation on Human Infertility Services and Embryo Research: A Consultation Paper" (HMSO, December 1986); UK Department of Health and Social Security, "Human Fertilisation and Embryology: A Framework for Legislation" (HMSO, November 1987).

abortion.[53] But the government provided no clear timetable for introducing legislation. Therefore, although some observers saw the white paper as a step forward, in reality it represented limited progress.

Debating the White Paper

The Lords took up the white paper first, ensuring that the opening round would reflect the expertise and relative political remove of the upper chamber. Parliamentary Under-Secretary of State for Health and Social Security, Roger Bootle-Wilbraham, Lord Skelmerdale, opened the debate by citing the broad consensus that existed for creating a statutory licensing authority for IVF technologies.[54] But on the issue of embryo research, the hereditary peer and Conservative Party veteran said the government would remain neutral and allow Parliamentarians to vote with their conscience.

Making the case for research, speakers made clear that improving IVF techniques would require improving scientific understanding of embryos. Failing to allow ongoing research would mean that couples receiving treatments would essentially become research subjects, "guinea pigs" for future advances in the field, said Lord (John) Rea, a physician and hereditary peer from the Labour benches.[55]

But the most emotional argument for research pertained not to IVF but to the promising technique of pre-implantation genetic diagnosis. "We might be nearer to reducing what has been a great fear for many parents of giving birth to a child with congenital abnormalities," said Lord (David) Ennals, a former Labour MP.[56]

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[53] Both the *Sexual Offences Act 1967* and the *Abortion Act 1967* passed as private members bills with government time provided.
[54] Bootle-Wilbraham, Roger, Lord Skelmersdale, House of Lords, *Hansard*, col. 1453, January 15, 1988.
[55] Rea, Lord (John), Lords, *Hansard*, col. 1468, January 15, 1988.
[56] Ennals, Lord (David), Lords, *Hansard*, col. 1455, January 15, 1988.

And since PGD could identify a genetic abnormality before implantation, lords touted the procedure as a way to prevent late-term abortions that might occur after a woman discovered a defect from an amniocentesis. Moreover, since no restrictions on embryo research yet existed, prohibiting PGD could actually increase the number of abortions performed, as Lord Ennals pointed out.

When Does Life Begin?

The central case against embryo research came from those who equated it to killing a human life. "From the moment of its conception...I believe that the human embryo becomes a human being," said Miles Fitzalan-Howard, the Duke of Norfolk and a Catholic.[57] The statement reflected the view of many Catholics. However, subsequent speakers pointed out that although the pope had condemned research on embryos, no consensus existed on the theological grounding of the position. "There is no certainty in official Roman Catholic teaching as to when the soul enters the body," said Frank Pakenham, the Earl of Longford.[58]

On the question of the embryo's personhood, supporters of research first made their case in physiological terms. Speakers described a 14-day-old embryo as no larger than the point of a pin. Moreover, they said before the primitive streak became apparent after the 14th day, no distinction existed between the cells which formed the placenta and those that made up the future-fetus.[59]

Speakers made such a strong distinction between the pre- and post-14-day embryo that some even called the former by a different name: the pre-embryo, a non-scientific term which would generate criticism. And, to draw a further contrast between

[57] Duke of Norfolk, Lords, *Hansard*, col. 1471, January 15, 1988.
[58] Pakenham, Frank, the Earl of Longford, Lords, *Hansard*, col. 1474, January 15, 1988.
[59] Jellicoe, Earl (George), Lords, *Hansard*, col. 1464, January 15, 1988.

the two stages of embryonic development, speakers pointed out that countless embryos, perhaps a majority of those conceived, do not even make it to the second stage, with women losing a potential child before they even knew of the pregnancy. As many would point out, no one mourns the loss of these thousands of embryos lost early and naturally without the knowledge of would-be parents.

The debate also took the discussion of personhood to the religious frontier, when John Habgood, the then-Archbishop of York and a physiologist, challenged the notion that life began at conception. Instead, he defended the primitive streak as the more significant marker of individuality. "This seems to me a biologically and morally more satisfying starting point than the moment of conception," Habgood said.[60] In refuting the assertion of an early embryo's unequivocal personhood, Habgood provided a kind of theological endorsement: "When personal attributes are non-existent and when identity is yet to be established there is room to allow experiment."[61]

Slippery Slope

Among other concerns raised, research opponents expressed unease at the new capacity to manufacture life in the laboratory. "It is an absolutely revolting prospect," said the Earl of Longford, a Labour peer and former minister. "I am very nervous about the situation." Patrick Maitland, the Earl of Lauderdale and a former Conservative MP, compared embryo experimentation to the scientific horrors of the Second World War. "I believe that experiments on embryos and so-called pre-embryos differ only in degree and never in kind from the sickening human vivisection done by the Nazi doctors at

[60] Habgood, John, Archbishop of York, ibid, col. 1462.
[61] Ibid, col. 1463.

Auschwitz, Natzweiler and Birkenau, and by the Japanese at Khandok," he said. "All [of] that was done in the name of science."[62]

Against these suggestions of a slippery slope, research supporters defended embryo experiments by insisting that Parliament would control how far such activities could go. "It would be for Parliament, not possibly for over-eager scientists, to decide whether to descend the slippery slope," said Earl (George) Jellicoe.[63]

Turning Point?

Contrasting with the overwhelming opposition to embryo research voiced by MPs in earlier years, the Lords' debate on the white paper offered research advocates a glimmer of hope: 11 out of 22 speakers supported research, while only six opposed it. Moreover, that strong showing continued when the discussion moved to the Commons less than a month later. Minister for Health Tony Newton opened the debate by touting the considerable consensus which already existed for prohibiting such activities as cloning, commercial surrogacy, animal-human hybrids and the pre-selection of embryos for particular physical characteristics. But on the difficult issue of embryo research, he said the government would remain neutral. Overall, three principles would guide decision-making: respect for human life, assistance for childless couples and the welfare of children.

Although speakers addressed a range of topics, embryo research dominated the discussion. Echoing many of the same points offered in the Lords, pro-research MPs spoke of the need to assist couples, and to prevent the spread of inherited diseases. For the latter, scientists proposed to use technology, not only to prevent individual couples

[62] Maitland, Patrick, Earl of Lauderdale, ibid, col. 1487.
[63] Jellicoe, Earl (George), ibid, col. 1464.

from passing genetic conditions to their children, but potentially to eliminate afflictions such as Huntington's Disease and Muscular Dystrophy from the entire population.[64] Moreover, since pre-implantation screening could obviate the need for a late-term abortion, even pro-life members, such as John Hannam of Exeter, saw the value of embryo research.[65]

Opponents wielded familiar arguments about protecting unborn life, calling the matter a question of human rights and human dignity. "Those embryos have the right to live," said Kenneth Hind, a Conservative from West Lancashire.[66] Others insisted that IVF and medical research could continue without the use of embryos.

Research advocates insisted on the need for research to boost IVF's success rates beyond the one child born for every ten attempts. The debate's most personal comments came from Dafydd Wigley, a Plaid Cymru MP from Caernarfon, whose two teenage sons died years earlier of Sanfilippo syndrome, a congenital metabolism disorder. Wigley spoke of the destructive toll that disability can have on patients and their families, and described a ban on research as "an act of callous and calculated brutality."[67] "[Disability] leads to marriage break-ups and suicides, places tremendous strain on other siblings and has a massive financial, social and psychological effect on the family," Wigley said.[68]

Like the Lords debate, discussion among MPs tilted strongly in favor of research, with 11 out of 20 members supporting the Warnock recommendations on human embryos, and 7 clearly opposing them. More significantly, both sessions marked

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[64] Barnes, Rosie, House of Commons, *Hansard*, col. 1230, February 4, 1988.
[65] Hannam, John, ibid, col. 1237.
[66] Hind, Kenneth, ibid, col. 1247.
[67] Wigley, Dafydd, ibid, col. 1214.
[68] Ibid, Commons, *Hansard*, col. 1216, February 4, 1988.

an important turning point, as the first time research supporters would outshine opponents.

A Bill (At Last)

Despite the white paper's reasonably favorable reception, the government declined to introduce legislation later that year, more likely because of a tight legislative calendar than a desire to delay a decision. But in the summer of 1989 Kenneth Clarke, Secretary of State for the now free-standing Department of Health, announced his intention to bring forward a bill that fall.[69] The government then made the following announcement in the Queen's speech of 21 November 1989: "A Bill will be introduced to institute a legal framework for scientific developments on human fertilisation and embryology."[70] Parliamentarians would have a free vote on legislation based largely on the white paper.

Lords Redux

Like the debate on the white paper, the government brought the bill first to the House of Lords, which arguably had the tactical advantage of both depoliticizing the issue and emphasizing the expertise of that body's accomplished scientists and theologians. "They thought that by beginning it in the Lords that they were more likely to get it through," said Lord Alton.[71] At a minimum, the move gave voice to some of the nation's most prominent, and articulate, research supporters.

John Habgood, Archbishop of York, used the debate at the second reading of the bill to provide a clearer refutation to the notion that life began at conception: "Christians are no more required to believe that humanness is created in an instant than we are

[69] The government bifurcated the Department of Health and Social Security in 1988.
[70] Queen Elizabeth II, House of Lords, *Hansard*, col. 6, November 21, 1989.
[71] Alton, David, Interview, August 24, 2011.

required to believe in the historical existence of Adam and Eve," declared Habgood, who had trained as a physiologist. He urged his colleagues to focus instead on the embryo's changing stages of development. "To me biological gradualism makes much more sense."[72]

On the other side of the issue, peers defended embryos as constituting an individual life, although Lord Kennet, Wayland Young, did concede that an embryo was not entitled to full human rights.[73] Some research opponents stepped away from religion with forceful secular appeals, citing sources such as the World Medical Association's 1949 statement on medical ethics, which demanded protection for the human embryo from conception.[74] Baroness (Sue) Ryder, who had worked behind enemy lines in Poland during World War II and later as an aide worker, described embryo research as "dangerously" close to work done by Nazi scientists."[75]

But supporters of research defended the motives of scientists as noble and sympathetic. In one speech, Lord (John) Walton, the accomplished neurologist, explained in detail how IVF techniques were helping researchers to prevent the transmission of Duchenne's muscular dystrophy, a latent tissue disorder on which he had conducted extensive research. "The situation has now been transformed," Walton said.[76]

The Lords bill survived several attempts to block its key provisions. In February 1990, research supporters rejected an amendment to ban work on embryos in a vote of 234 to 80.[77] In March, a provision to limit research to embryos left over from fertility

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[72] Habgood, John, Archbishop of York, House of Lords, *Hansard*, col. 1021, Dec. 7, 1989.
[73] Young, Wayland, Lord Kennet, ibid, col. 1026.
[74] Gibson, Edward, Lord Ashbourne, ibid, col. 1048.
[75] Ryder, Baroness (Sue), ibid, col. 1067.
[76] Walton, Lord (John), ibid, col. 1053.
[77] Gunn, Sheila, "Embryo Research Backed," *The Times*, February 9, 1990.

experiments also failed. With these battles behind them, the Lords sent the approved bill to the Commons by the end of the month.

Abortion Detour

Once the bill cleared the Lords, opponents in the Commons, such as David Alton of Liverpool, knew they faced an uphill fight.[78] If the nation's leaders in science, law and theology endorsed embryo research, they reasoned, how could MPs oppose it? In any case, the bill's future in the Commons was initially unclear. During the first debate, the number of speeches supporting the legislation roughly matched those against.[79] Research supporters did not take victory for granted.

The Commons also became a focal point for pro-life members seeking to change Britain's abortion law. After failing in 1987 to narrow the window in which a pregnant woman could receive a legal abortion from the current 28 weeks to 18 weeks, anti-abortion activists eagerly looked for suitable opportunities to try again. They found one in the IVF legislation.[80]

While the Lords succeeded in keeping abortion amendments out of the bill, ministers agreed to accept them in the Commons, following discussions between Sir Geoffrey Howe, the Leader of the House and Deputy Prime Minister, and key pro- and anti-research stakeholders. Among other things, Howe's decision reflected a growing support among MPs for lowering the outer time limit for abortions, especially after a recent Lords report called for lowering the existing 28-week limit to 24 weeks, as a way

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[78] Alton, David, Interview, August 24, 2011.
[79] Mulkay, Michael, *The Embryo Research Debate: Science and the Politics of Reproduction* (Cambridge: Cambridge University Press, 1997), 39-40.
[80] Wintour, Patrick, "The Day in Politics: 'Hijackers' Renew Abortion Attack", *The Guardian*, November 24, 1989; Liberal Democrat David Alton of Liverpool introduced the unsuccessful private members bill in 1987.

to address long-standing problems with the Abortion Act 1967.[81] Even the prime minister endorsed a 24-week limit.

Although some research advocates feared that abortion provisions could derail the bill, it arguably had the opposite effect, propelling the legislation forward. First, Howe's decision to hold separate votes on embryo research and abortion helped isolate the bill's controversial elements and ensured that the legislation cleared its second reading. Second, the scheduling of the vote on embryo research for the day before the vote on abortion arguably diverted the focus of pro-life members and campaigners away from the former. Indeed, in the days before the voting, research opponents focused their energies most strongly on abortion, even sending MPs a plastic model of an 18-week-old unborn fetus on the eve of the crucial abortion vote.[82]

Patient Push

The weeks leading up to the vote on embryo research also coincided with an unprecedented display of patient activism. Indeed, Alastair Kent, Director of Genetic Alliance UK, credited the period with establishing supporters of research as a political force.[83] Teaming with scientists and MPs from Progress, the Genetic Alliance targeted undecided members, meeting with them to explain the value of the research.[84] Progress aimed to send an infertile person or a patient suffering from congenital illness to visit every MP.[85]

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[81] Gunn, Sheila, "MPs 'Favour' Cut in Abortion Limit," *The Times*, March 19, 1990.
[82] White, Michael and Wintour, Patrick, "MPs Back Embryo Research," *The Guardian*, April 24, 1990.
[83] Kent, Alastair, Interview, August 5, 2011.
[84] Mulkay, Michael, *The Embryo Research Debate: Science and the Politics of Reproduction* (Cambridge: Cambridge University Press, 1997), 41; Until 2010, Genetic Alliance UK was known as the Genetic Interest Group.
[85] Ibid.

Scientists in the field assisted these efforts by showcasing their research in public. Days before the committee vote on embryo research, Robert Winston, head of Hammersmith Hospital's infertility unit and Progress' President, stood with three women who carried genes for a congenital disorder and announced their successful and disease-free impregnation using PGD and IVF techniques.[86]

The combination of these efforts certainly helped the embryo research provisions gain a strong 364 to 193 victory, a 171-vote majority. Despite the free vote, Secretary of State for Health Kenneth Clarke opened the debate with a strong personal endorsement of research which patient advocates viewed as helpful to their cause.[87] The emotional, seven-hour debate revisited the key arguments about an embryo's status, human rights, childless couples and fighting disease.[88] In the end, Prime Minister Margaret Thatcher and all but four cabinet members voted in favor of research.[89]

A day after MPs approved the embryo research provision they took up the question of altering the 28-week outer time limit on abortion in a complicated series of free votes orchestrated by Leader of the House and Deputy Prime Minister Geoffrey Howe. While pro-life members eagerly sought the opportunity to lower the limit as far as possible, the "pendulum" voting procedure favored the 24 week limit privately supported by most cabinet members and the prime minister.[90]

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[86] Hall, Celia, "Embryo Tests Give Disease Carriers Safe Pregnancies," *The Independent*, April 19, 1990.
[87] White, Michael and Wintour, Patrick, "MPs Back Embryo Research," *The Guardian*, April 24, 1990.
[88] Jones, Judy and Goodwin, Stephen, "Parliament and Politics: Embryo Research Wins Decisive Majority; Human Fertilisation and Embryology Bill: Commons, Committee Stage Debate," *The Independent*, April 24, 1990.
[89] Wintour, Patrick, "The Day in Politics: Thatcher Joins Cabinet Majority in Voting for Embryo Research," *The Guardian*, April 25, 1990.
[90] House of Commons, *Hansard*, col. 267-304.

The heated debate lasted seven hours, and Secretary Clarke personally endorsed the 24-week limit.[91] Voting began at 11 pm, and not surprisingly the 24-week limit garnered the most votes, with 409 in favor and 152 opposed. Pro-life members, who would have preferred to see an 18-week limit, expressed outrage over another amendment which passed on the same night with little fanfare: provision to allow for abortion up until birth in cases of fetal abnormalities.[92]

Passage

HUMAN FERTILISATION AND EMBRYOLOGY ACT 1990[93]

(2) A licence under this paragraph cannot authorize any activity unless it appears to the Authority to be necessary or desirable for the purpose of—
(a) promoting advances in the treatment of infertility
(b) increasing knowledge about the causes of congenital disease
(c) increasing knowledge about the causes of miscarriages,
(d) developing more effective techniques of contraception, or
(e) developing methods for detecting the presence of gene or chromosome abnormalities in embryos before implantation,
Or for such other purposes as may be specified in regulations.

Controversy over the abortion provisions dominated the remaining discussions before the final debate and vote on the overall bill. The government, having fulfilled its promise of providing free votes on embryo research and abortion provisions, imposed a two-line whip for the final vote at third reading. The bill passed overwhelmingly with 303 in favor and 65 opposed.[94]

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[91] Goodwin, Stephen and Jones, Judy, "Parliament and Politics: MPs Back 24-Week Limit on Abortions; Human Fertilisation and Embryology Bill: Commons, Committee Stage Debate," *The Independent*, April 25, 1990; Commons, *Hansard*, col. 272, April 24, 1990.
[92] Wood, Nicholas, "Pressure to Close 'Abortions Up to Birth' Loophole," *The Times*, April 26, 1990.
[93] UK Parliament, *Human Fertilisation and Embryology Act 1990*, (London: HMSO), 35.
[94] Linton, Martin and Newstub, Nikki, "The Day in Politics: Deputy Speaker Intervenes to Break Tied Abortion Vote - Embryo Bill Approved After MPs Block Moves to Re-Introduce Curbs on Pregnancy Termination," *The Guardian*, June 22, 1990.

The *Human Fertilisation and Embryology Act 1990* created for the first time a protection for the human embryo 14 days after fertilization, and a regulatory apparatus to enforce it. In so doing, the government implicitly sanctioned the licensed activities of scientists not only in the field of fertility but congenital disease.

5.3 Extending the Policy Design: HFE (Research Purposes) Regulations (1990-2001)

The first few lines of the new law established the regulatory institution that would enforce it: the Human Fertilisation and Embryology Authority (HFEA), which replaced the voluntary body operating in the interim.[95] While some pro-life MPs during the debates had made calls for direct regulation of embryo experiments by ministers, the government rebuffed these as impractical, saying they had the potential to politicize research.[96]

HFEA

HUMAN FERTILISATION AND EMBRYOLOGY AUTHORITY (HFEA)[97]
Chair: Colin Campbell (1990-94); Ruth Deech (1994-2002); Suzi Leather (2002-06)
Established: 1991
Members: 21 (1998-99); 23 (1999-2000); 25 (2000-01)
Staff: 32 (1998-99); 33 (1999-2000); 34 (2000-01); 45 (2001-02)
Budget: £1,559,000 (1998-99); £1,579,000 (1999-2000); £2,883,000 (2000-01); £2,811,000 (2001-02); £5,533,000 (2002-03)

[95] UK Parliament, *Human Fertilisation and Embryology Act 1990* (London: HMSO); Ballantyne, Aileen, "Health: The Embryo and the Law - When Does Life Begin? In This Age of the Test Tube, it Seems MPs, Not Scientists, Will Have the Final Say," *The Guardian*, September 8, 1989.
[96] House of Commons, *Hansard*, col. 919, April 2, 1990.
[97] UK Human Fertilisation and Embryology Authority, *Annual Report and Accounts*, 1999-2003.

The act stipulated that the HFEA would advise the Secretary of State for Health, and required that its chair, deputy chair and more than half of its 20-something board members had a non-scientific background, and no personal interests in IVF or research. The HFEA's duties included licensing and standard-setting for all clinics and researchers, maintaining confidential fertility records and performing inspections as needed.

Board members directed the organization from a series of committees—including a panel charged with licensing embryo research—with an approximately 30-person executive staff to implement decisions. Members, including the Chair, received only partial remuneration. "It was run on a shoe-string," said Ruth Deech, who served as HFEA Chair from 1994 to 2002.[98] By the late 1990s, the authority had an annual budget of less than two million pounds, a majority of which came from license fees.[99] Deech and others described the HFEA's ethos as committed and passionate about advancing fertility science and medical research.

Admired and defended by its supporters, the HFEA faced criticism virtually from the start. Many anti-abortion activists generally viewed its activities as an abomination, and sought unsuccessfully to place their own partisans among its ranks.[100] Science enthusiasts chaffed at the agency's controls, which they described as too restrictive. In one high-profile example, Nottingham resident Diane Blood sued the HFEA successfully for the right to inseminate herself with sperm collected from her comatose husband shortly before he died.[101] While the HFEA did not see policy-making

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[98] Deech, Ruth, Interview, August 4, 2011.
[99] UK Human Fertilisation and Embryology Authority, *9th Annual Report and Accounts*, 2000.
[100] Suzi Leather, who served as HFEA Chair from 2002 to 2006 confirmed in a July 13, 2011 interview that the organization declined to appoint members who opposed to the basic activities regulated by HFEA.
[101] Davies, Patricia Wynn, "Widow Wins Right to Have Baby from Her Dead Husband; Court Clears Way for Fertilisation Authority to Give Final Go-Ahead," *The Independent*, February 7, 1997.

as its primary role, the agency had latitude in implementing the law across the new frontiers of biomedicine.

Occasionally the law needed some adjusting, and ministers had foreseen this possibility and ensured that Parliament could make subsequent amendments with secondary legislation.[102] In the years after the HFE law took effect in 1991, officials made several minor modifications, including two statutory instruments on embryo storage and one relating to handling.

Dolly

In February 1997, the UK experienced arguably the most high-profile development in biomedical science since IVF: the announced birth of a cloned sheep called Dolly by a process known as somatic cell nuclear transfer.[103] The historic feat, facilitated by Ian Wilmut and colleagues at the Roslin Institute in Scotland, sparked not only a worldwide discussion of the technology's potential to create human beings but a parliamentary review of the UK's regulatory structure.

Public opinion polls revealed considerable opposition to human cloning in the UK, although no evidence suggests it had a serious effect on the upcoming general election, which observers expected the Labour Party to win.[104] The government responded with a statement explaining that the HFE Act 1990 expressly prohibited human cloning.[105] However, several weaknesses in the law surfaced in subsequent meetings of the House of Commons Science and Technology Committee chaired by Sir Giles Shaw.

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[102] UK Parliament, *Human Fertilisation and Embryology Act 1990*, (London: HMSO), 35.
[103] McKie, Robin, "Scientists Clone Adult Sheep," *The Observer*, February 23, 1997.
[104] Rentoul, John, "Labour Enjoys Clear Water for Election Run-in," *The Independent*, March 7, 1997.
[105] UK House of Commons, Science and Technology Committee, "The Cloning of Animals from Adult Cells," March 18, 1997, v.

Most critically, the HFE law did not foresee the creation of a cloned embryo by the combination of an adult cell and unfertilized egg, explained HFEA Chairman Ruth Deech, who appeared as a witness.[106] And, despite the fact that all work on human embryos required an HFEA license, one could argue that embryos produced by cell nuclear transfer did not fit the same legal definition, since fertilization had not actually occurred. "The striking thing about the technique used at Roslin is that it appears to elude so many of the controls of the Act," the committee's report stated.[107] In other words, although the law technically forbade human reproductive cloning, it might not withstand legal challenge. The panel recommended that Parliament reaffirm its opposition to human reproductive cloning through primary legislation.

Cloning Benefits

In addition to the ambiguity on cloning, the committee highlighted another critical fact: The technology used to create Dolly could also advance research on aging and disease. Since Wilmut's team had successfully caused adult cells to revert to an earlier state, researchers believed that future work could restore damaged and diseased tissues using similar mechanisms. "The science is astonishing and its implications profound," the committee report stated.[108]

[106] Ibid, xi.
[107] Ibid, xii.
[108] Ibid, vi.

PRIME MINISTER TONY BLAIR[109]

Party: Labour
In Office: 1997-2007
Reputation: Leader of the "New Labour" landslide that broke the 18-year hold on Conservative Party power in 1997, Blair endorsed a spate of "third way" economic measures, including the weakening of his party's traditional ties with labor unions and support for low taxes and a vibrant (and deregulated) financial services sector.
A strong supporter of science and innovation, Blair spoke out in favor of both stem cell research and genetically modified food products.

The newly-formed government of Prime Minister Tony Blair agreed. In a response issued in December 1997, the Department of Trade and Industry's Office of Science and Technology reaffirmed the government's opposition to human cloning but supported the therapeutic use of cloning techniques as long as they did not produce human beings.[110]

The position created an immediate quandary for policy makers regarding how to encourage research cloning or "therapeutic cloning" while preventing reproductive cloning. What were the scientific, legal and ethical implications? To examine this question, the government created a working group made up of members from two organizations: the HFEA and the Human Genetics Advisory Commission (HGAC), an expert panel formed earlier in the year to advise ministers on fast-moving developments in genetics, including gene therapy.[111]

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[109] Peele, Gillian, *Governing the UK* (Oxford: Blackwell Publishing, 2004), 14.
[110] UK Department of Trade and Industry, Office of Science and Technology, "The Cloning of Animals from Adult Cells, Government Response to the Fifth Report of the House of Commons Select Committee on Science and Technology, 1996-97 Session", December 1997.
[111] Ibid; Chaired by a lawyer called Sir Colin Campbell, who himself had served as HFEA Chairman from 1991 to 1994, the HGAC had no enforcement powers, but provided a forum for producing government advice.

The joint HGAC/HFEA working party quietly sought to sift through the many issues raised by cloning and provide a sober analysis of the issues. It also sought to temper the on-going media controversy, which saw leaders from around the world, including US President Bill Clinton, calling for new safeguards against human reproductive cloning. "We want to put the fantastic scenarios aside, and take a calm look at possible benefits," HGAC Chairman Sir Colin Campbell told journalists.[112] This presented a challenge. As public concern, and eager newspaper editors, generated news stories about human clones, even a few distinguished scientists encouraged speculation by speaking publicly about the benefits of producing human clones, for example, to help infertile couples.[113] The panel was traversing difficult terrain.

HGAC/HFEA CLONING WORKING GROUP (1998)
John Polkinghorne (Chairman), Physicist, Theologian Christine Gosden, Geneticist Anne McLaren, Biologist George Poste, Biologist

The working group consisted of four scientists, including Warnock Committee veteran biologist Anne McLaren and panel chair John Polkinghorne, a physicist, Church of England priest and frequent government collaborator. After issuing a consultation document in January 1998, panelists met regularly amongst themselves and with stakeholder groups before releasing a December report which affirmed the existing protections against reproductive cloning.[114] Officials clarified that any work involving

[112] Hawkes, Nigel, "Advisers Ask for Public's View on Cloning Benefits," *The Times*, January 30, 1998.
[113] Laurance, Jeremy, "Britain Considers Licensing Human Cloning," *The Times*, January 12, 1998.
[114] UK HGAC/HFEA Cloning Working Group, "Cloning Issues in Reproduction, Science and Medicine: A Consultation," January 1998; UK HGAC/HFEA Cloning Working Group, "Cloning Issues in Reproduction, Science and Medicine: A Report," December 1998.

cell nuclear transfer in humans—either for therapeutic or reproductive purposes—would require an HFEA license under current regulations, although they noted that new primary legislation would reinforce these controls.[115]

Both the consultation and report contained a significant inclusion: the government's first mention of stem cells, the pluripotent cells possessing the potential to become any tissue type in the body. Although the report focused on cloning and cell nuclear transfer, research on stem cells would grow in acclaim in the months after the first successful derivation was announced in November 1998 by American research teams.[116]

The report endorsed therapeutic cloning as a way to produce stem cell lines with the matching DNA of patients, but it also highlighted a key legal hurdle: Because the 1990 Act made no allowance for conducting research on embryos for therapeutic purposes, Parliament would have to extend the law before the HFEA could issue a license on such a basis. To fill the gap, the report called for new regulations under the Act.

The Government Delays

Although the working group attempted to allay concern about reproductive cloning by underscoring government opposition and the adequacy of existing prohibitions, the joint report spurred colorful coverage in the media, with many stories failing to distinguish between cloning for reproduction and for research. The stories were enough to compel

[115] Ibid, Section 9.
[116] Wade, Nicholas, "Scientists Cultivate Cells at Root of Human Life," *The New York Times*, November 6, 1998.

Deech to clarify that the research would not lead to reproductive cloning.[117] Many newspaper accounts described plans to create embryonic stem cells with the matching DNA of the patient as an attempt to grow "spare parts" in the laboratory.[118]

Controversy persisted in the ensuing days and months that followed.[119] The government, which had initially refused to act on the report's recommendations, reached a decision in June that reflected both public unease and the government's wariness of controversy: delay. "We believe more evidence is required of the need for such research, its potential benefits and risks and that account should be taken of alternative approaches that might achieve the same ends," Minister for Health Tessa Jowell told the Commons.[120] Since the HGAC/HFEA report had expressly reviewed the benefits and risks already, observers argued that the government had simply wanted to avoid controversy.[121]

Some connected the issue with the public's recent negative reaction to genetically modified food, and said the government wanted to avoid a similar confrontation over embryo research.[122] "I think this is a fallout from GM food, which in itself was a fallout from BSE," Professor David Latchman, vice-chairman of the Parkinson's disease Society's medical advisory panel, told journalists.[123]

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[117] Radford, Tim, "Cloning to Be Used to Fight Disease; Scientists Could Be Employing New Techniques within a Year in Search of Treatments for Parkinson's, Huntingdon's and Alzheimer's," *The Guardian*, December 9, 1998.
[118] Murray, Ian, "Human Spare-Part Cloning Approved," *The Times*, December 8, 1998.
[119] Rayner, Gordon, "The Cloning Watchdogs Who All Think the Same Way; Peer Attacks 'Blatant Disregard for Impartiality'," *Daily Mail*, March 1, 1999.
[120] Hinsliff, Gaby, "Scientists Stunned as Ministers Call Halt to Human Cloning," *The Daily Mail*, June 25, 1999.
[121] "A Cowardly Retreat Over Cloned Embryos," Editorial, *The Independent*, June 25, 1999.
[122] Hawkes, Nigel, "Why Stem Cells Make a Phoney Moral Debate," *The Times*, August 17, 2000.
[123] Boseley, Sarah, "Cloning Brought to a Halt; Temporary Ban on Research Could Leave Britain Trailing," *The Guardian*, June 25, 1999.

DONALDSON COMMITTEE[124]
Liam Donaldson (Chair), Chief Medical Officer
David Baird, Biologist
W.F. Blakemore, Veterinarian
John Burn, Geneticist
Alastair Campbell, Medical Ethicist
Dian Donnai, Geneticist
Martin Evans, Biologist
Brian Heap, Master of St. Edmund's College, Cambridge
David Linch, Haematologist
Robert May, Government's Chief Scientific Adviser
Peter Morris, Professor of Surgery
Derek Morgan, Reader in Law
John Polkinghorne, Scientist, Theologian
David Weatherall, Haematologist

To carry out the government's request for more information, ministers tasked the Chief Medical Officer Sir Liam Donaldson with conducting a formal inquiry, for which he appointed a 13-member panel made up mostly of scientists and doctors. However, the Donaldson Committee also contained one lawyer, one professional ethicist and a priest who had also trained as scientist and served on the HGAC/HFEA panel, Rev. John Polkinghorne. Donaldson, a former surgeon, at one point described the committee almost as a vehicle for calming unease: "We want to have an objective look at the risks and benefits (of therapeutic cloning) and we want to take the public along with us."[125]

But some critics have challenged the sincerity of such efforts to inform the public about government biomedical policies over the years. Josephine Quintavalle, a pro-life activist and founder of Comment on Reproductive Ethics (CORE), suggested that since the 1990s officials have pursued their own pro-research agenda regardless of

[124] UK Department of Health, Chief Medical Officer's Expert Group, *Stem Cell Research: Medical Progress with Responsibility*, June 2000.
[125] Laurance, Jeremy and Arthur, Charles, "Human Cloning Banned in Research Cloning Opponents Welcome Ban," *The Independent*, June 25, 1999.

whether or not the public approved. "CORE was always based on the principle that we can't leave this to the scientists, we can't leave this to the expert," Quintavalle said.[126]

The Donaldson Committee met a half dozen times in the following year, with its chairman keen to complete work as quickly as possible, according to one member, Sir Peter Morris, a surgeon.[127] Panelists engaged in lengthy discussions and made decisions based on broad consensus. They solicited the views of numerous organizations and received feedback from, among others, the Royal Society and Nuffield Council on Bioethics, which both supported research on stem cells under certain conditions.

Not surprisingly, the Donaldson Report, released in August 2000, contained many of the same recommendations found in the HGAC/HFEA effort. Panelists called for expanding the permissible uses of human embryos in research to include work that would increase knowledge of disease and its treatment.[128] To achieve this, they proposed that ministers create regulations to extend the HFE Act 1990, and retain the HFEA as the institutional regulator.

But the Donaldson Report differed from the HGAC/HFEA effort in one key respect: It made stem cell research the express focus, and contained information not found in previous documents, including discussion of the different sources of stem cells and the problems associated with each. It also provided a more detailed discussion of potential applications in medical treatment, listing the dozen cell types which researchers aimed to produce, and the diseases they hoped to address with them. Perhaps most important of all, the report bore the imprimatur of Britain's Chief Medical Officer, lending a sense of urgency to the issue as a matter of public health.

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[126] Quintavalle, Josephine, Interview, August 2, 2011.
[127] Morris, Sir Peter, Interview, September 28, 2011.
[128] UK Department of Health, Chief Medical Officer's Expert Group, *Stem Cell Research: Medical Progress with Responsibility*.

Government Caution

Upon releasing the report, the government strongly reaffirmed its opposition to reproductive cloning and pledged to introduce new primary legislation to address that issue. But in all other respects, ministers proceeded with extreme caution, waiting two months after Donaldson submitted the document in June 2000 to release it during the August recess, and privately disagreeing over how to proceed.[129] Moreover, Secretary of State Alan Milburn's formal response in August merely "accepted" the recommendations and pledged to bring legislation with a free vote.[130] Some observers described the government as hiding behind Donaldson, a strategy that arguably gave ministers flexibility in case the public rejected his recommendations.[131]

But no serious uproar ensued. Although pro-life observers such as Josephine Quintavalle described a "huge resistance" to the Donaldson findings among anti-research partisans, many politicians and campaigners failed to mount fresh arguments or organize effectively.[132] Although newspapers blared the word "cloning" from newspaper headlines, most articles distinguished between reproductive and research purposes. And, perhaps most importantly, since the government offered only the vague promise of unveiling legislation "as soon as the Parliamentary timetable allows," opponents had nothing specific to criticize.[133]

Throughout the autumn months, stem cell research entered the public discourse only occasionally, with research advocates quietly using this period to bolster their case.

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[129] Wintour, Patrick, "Whitehall Split on Cloning Decision," *The Guardian*, July 31, 2000.
[130] Milburn, Alan, *Government Response to the Recommendations Made in the Chief Medical Officer's Expert Group Report "Stem Cell Research: Medical Progress with Responsibility,"* August 2000.
[131] Quintavalle, Josephine, Interview, August 2, 2011; Hawkes, Nigel, "Why Stem Cells Make a Phoney Moral Debate," *The Times*, August 17, 2000.
[132] Hawkes, Nigel, "Experts Back Use of Therapeutic Cloning," *The Times*, August 17, 2000;
[133] Milburn, Alan, *Government Response to the Recommendations Made in the Chief Medical Officer's Expert Group Report "Stem Cell Research: Medical Progress with Responsibility,"* August 2000, 1.

In October, Liberal Democrat from Oxford Evan Harris pushed the issue with a private members bill to permit stem cell research, but with an inconclusive result. With 83 votes in favor and 175 against, even some research supporters had withheld support because they favored a fuller airing of the matter.[134] In November, a Royal Society working group briefed parliamentarians on the promise of the technology, with group chairman biologist Richard Gardner and colleagues explaining that embryonic stem cells offered the best means of combating disease and injury. Moreover, blocking progress could harm British science, they warned.[135]

Debating Stem Cell Research

After discussing stem cell research privately for several months, the government settled on a plan and brought the matter into the public eye in November. Parliamentary Under-Secretary of State for Public Health Yvette Cooper opened the first of three debates on the floor of the Commons by promising regulations to legalize stem cell research, and a free vote for Labour MPs.

Explaining that the 1990 Act permitted embryo research for five purposes, including understanding infertility and the causes of congenital disease, Cooper framed the proposed statutory instrument or secondary legislation as a simple extension of the act to include a further purpose: understanding disease and disorders and their treatment.[136] "Provision was made in the 1990 Act for regulations to be extended in such a way," said Cooper, who emphasized HFEA oversight and explained that by law any research would occur according to the strictures of the 1990 Act, with no embryos kept

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[134] House of Commons, *Hansard,* col. 626-630, October 31, 2000; *Hansard*, col. 1213, November 17, 2000.
[135] Connor, Steve, "Science: Grow Your Own Spare Parts; If Embryo Research Is Extended in Britain, One Day We Could All Be Growing Our Own Set of Organs Ready to Use Should We need a Transplant. But Would It Open the Door to Cloning Humans?" *The Independent*, November 10, 2000.
[136] Cooper, Yvette, House of Commons, *Hansard*, col. 1178, November 17, 2000.

alive after 14 days.[137] "The HFEA must still license every research proposal," Cooper said.[138]

On the same day Cooper began the debates, supporters of research received a boost when the prime minister himself weighed in with a strong endorsement during a speech to European bioscience professionals, warning against the embrace of "anti-science" attitudes.[139]

Assisting the Living

While declaring her respect for opponents of conscience, Cooper emphasized the moral imperative of stem cell research as means of assisting the sick and dying. "The moral arguments cut both ways," Cooper said.[140] "It is important to recognize how many people's lives could be transformed by such a breakthrough."[141] The minister noted that 50,000 people in the UK suffered from spinal cord injuries, 120,000 from Parkinson's disease, 1.4 million from insulin-dependent diabetes—all afflictions which scientists hoped to remedy with stem cell research. A cure for these or other illnesses, including Alzheimer's disease, could have a transformative effect on society, Cooper said: "Nursing homes throughout the country could be emptied."[142]

On the controversial topic of reproductive cloning, Cooper pledged the government's strong opposition. "I want to make it clear that reproductive cloning is illegal," Cooper said.[143] "It will stay illegal." However, since the cloning ban rested on

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[137] Ibid, col. 1176.
[138] Ibid, col. 1178.
[139] Woolf, Marie, "Blair Tells Violent Eco-Warriors They Can't Stop Science," *The Independent*, November 18, 2000.
[140] Cooper, Yvette, House of Commons, *Hansard*, col. 1177, November 17, 2000.
[141] Ibid, col. 1178.
[142] Ibid, col. 1179.
[143] Ibid, col. 1180.

the HFEA's refusal to grant licenses for research involving reproductive cloning, Cooper promised new primary legislation in the future.

Clarifying the difference between cloning for reproduction and for therapeutic purposes, Cooper explained that the 1990 Act did not outlaw the latter, which many hoped would produce stem cells with the matching DNA of ill patients. "Strictly speaking--[cell nuclear transfer] is legal already," Cooper said. Although any work on human embryos required an HFEA license, the technical act of embryo cloning did not.[144] This arguably minimized the degree of perceived change being proposed in the regulations. However, the proposed regulations arguably represented a significant departure from the status quo because they would bring the controversial procedure into more common use.

Opponents of research responded with numerous arguments against the proposal that members would develop further in the weeks ahead. One of these concerned process. Ann Winterton, a Conservative MP from Congleton, faulted the government for releasing the Donaldson Report and the official response during Parliament's August recess, preventing some legislators' from commenting.[145] In a more serious criticism, Winterton denounced ministers for using a statutory instrument to address cell nuclear transfer and cloning, which she said MPs did not discuss in 1990."[146]

Slippery Slope

On matters of substance, research opponents warned that allowing the research could have dangerous consequences. Winterton, who at the time chaired the All-Party Parliamentary Pro-Life Group, raised the specter of reproductive cloning and cited an

[144] Ibid, col. 1181.
[145] Winterton, Ann, ibid, col. 1200, 1203, November 17, 2000.
[146] Ibid, col. 1175 and 1208.

earlier, speculative statement by British research physician Robert Winston, asserting that cell nuclear transfer would lead to the inevitable cloning of a human being.[147] Other MPs alluded to recent concerns about BSE and GMOs, and suggested that society wanted science to slow down. "Much has changed in the climate of public opinion since 1990," said Philip Hammond, a Conservative from Runnymede and Weybridge.[148]

In response to concerns about scientists altering the natural world, other speakers saw man-made changes to the environment as common, reasonable and virtuous. "Part of what it is to be human is that, unlike other animals, we can change the way things are, and we have always done so," said Robert Key, a Conservative MP from Salisbury. "If that were not so, we would have no moral law, no aspirations and no interest in the common good."[149]

Adult Stem Cells

Winterton and Hammond also faulted the proposal as potentially unnecessary, explaining that so-called adult stem cells, plucked from bone marrow, brain, skin and other sources, could provide the same benefits without the ethical concerns. While pro-research speakers warned against closing any doors to embryonic stem cell work, Hammond said Parliament should delay moving forward until advocates could demonstrate that the research was "absolutely required."[150]

Overall, the first debate tilted heavily in favor of research, with seven speakers in support and two opposed. Still, the government hesitated, declining to release the draft proposal, or a timetable for voting. Some ministers privately worried that the

[147] Ibid, col. 1206.
[148] Hammond, Philip, ibid, col. 1184.
[149] Ibid, col. 1216.
[150] Hammond, Philip, ibid, col. 1198.

measure would fail.[151] At this time, Cooper and her counterpart in the House of Lords, Lord (Phillip) Hunt, began canvassing members, writing to all MPs and peers.[152] The government also coordinated with patient advocacy groups, which spurred into action, with letters and visits to constituency surgeries across the UK.

By the start of the second five-hour debate one month later, ministers had unveiled a proposal and finalized its timetable for the vote, which would occur after a third debate the following Tuesday. While the government originally suggested holding the vote at the end of the second Friday debate, ministers moved it to "prime time," after some research opponents complained.[153]

> HUMAN FERTILISATION AND EMBRYOLOGY (RESEARCH PURPOSES) REGULATIONS 2001
>
> (2) A licence may be issued for the purposes of-
> (a) increasing knowledge about the development of embryos;
> (b) increasing knowledge about serious disease, or
> (c) enabling any such knowledge to be applied in developing treatments for serious disease.

Unlike the first debate, the second session featured several strongly worded personal testimonials, including statements from Anne Begg, a Labour MP from Aberdeen confined to a wheelchair, and Fiona MacTaggart of Slough, also from the Labour Party, who referenced her ongoing struggle with multiple sclerosis. However, one of the most emotional speeches came from Anne Campbell, who described seeing her mother ravaged by Parkinson's disease.[154] "In my teenage years, I saw my mother transformed from a happy, outgoing and sociable young woman to somebody who was prematurely old and disabled," said Campbell, a Labour MP from Cambridge. "To

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[151] Dillon, Jo, "Pressure on MPS to Back Genetic Research," *The Independent on Sunday*, December 3, 2000.
[152] Ibid.
[153] Hurst, Greg, "MPs Protest at 'Gag' Over Embryos," *The Times*, December 8, 2000.
[154] Campbell, Anne, House of Commons, *Hansard*, col. 921, December 15, 2000.

someone who develops Parkinson's disease, multiple sclerosis or diabetes in perhaps 10 years' time, it will be hard to explain why we did not take a decision now."[155]

While some research opponents brought up the standard arguments about protecting embryos, since the 1990 Act had already addressed the question of legitimate research, they were essentially moot.

Crossing the Rubicon?

In the second debate, research advocates described the regulations as a logical step for supporters of the 1990 Act. For those who supported research on embryos to combat congenital disease, how could they *not* endorse it to fight cancer, Parkinson's, Diabetes and Alzheimer's? Indeed, the new research had the potential to help even more people and transform their lives.

Cooper developed this logic further in the third and final debate on December 19: "Parliament is not being asked to cross the Rubicon today," she said.[156] "Those who support the current law and IVF should also support the regulations."[157] Because the 1990 Act had addressed the issue of embryo research already, it provided assurance to hesitant members and even obliged them to endorse the proposal.

Opponents of research had arguably only one issue on which to base claims that the proposed regulations did in fact depart significantly from the status quo: therapeutic cloning. Although Cooper had stated that cell nuclear transfer was technically legal under the 1990 Act, speakers pointed out that Parliament did not debate the technology at the time, and indeed, that cell nuclear transfer did not exist. Ann Winterton read from an editorial in the *Daily Telegraph* which accused the government of undue haste: "'It

[155] Ibid, col. 923.
[156] Cooper, Yvette, House of Commons, *Hansard*, col. 213, December 19, 2000.
[157] Ibid.

was never Parliament's intention to allow cloning, even if it had been conceivable. The new regulations are being presented as if they merely clarified the existing law, whereas in reality they mark a radical departure from it.'"[158] The editorial, which described therapeutic cloning as a "cannibalistic" treatment of embryos, urged members to vote no: "'This is a serious abuse of parliamentary procedure.'"[159]

The regulations created a dilemma for members who supported stem cell research but not cell nuclear transfer. In the second debate Ruth Kelly, a Labour MP from Bolton who opposed therapeutic cloning, lamented that the proposed regulations could not be amended and took an all-or-nothing position on research.[160] Kelly also pointed out that using cell nuclear transfer to address diseases of the mitochondria, or within a woman's eggs, would create a more serious moral dilemma. Indeed, if researchers successfully fused a healthy donor oocyte or egg with the nucleus of a disease-carrying woman's egg, it would engineer permanent changes to the germ line, resulting in the first ever genetic modification of humans.

Closing Arguments

In the third debate, research opponents, such as Ann Winterton and Liam Fox, continued to cast doubts on the need for embryonic stem cells in place of work on adult cells, to the chagrin of supporters who marshaled considerable evidence to the contrary. Evan Harris, Liberal Democrat from Oxford, echoed the British scientific and medical community in dismissing the arguments. "It will be possible to realize the potential of [adult stem cell research] only if we get answers from the embryological work."[161]

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[158] Winterton, Ann, House of Commons, *Hansard*, col. 241; "Cloning and Killing," *The Daily Telegraph*, December 19, 2000.
[159] Ibid.
[160] Kelly, Ruth, House of Commons, *Hansard*, col. 900-901, December 15, 2000.
[161] Harris, Evan, ibid, col. 255, December 19, 2000.

Harris said. In other words, even research on adult cells required work on embryos. If one subscribed to Britain's highest authorities, embryonic stem cell research was indisputably the best way forward scientifically.

Also in the final debate, research opponents opened a new line of criticism by accusing research supporters of raising people's hopes without any assurance of success. Winterton accused research advocates of propagating a "cruel hoax."[162] But supporters rejected these criticisms: "We promise to try, but we never promise to succeed," said Michael Clark, a Conservative MP from Rayleigh. "If we do not promise to try, we will never succeed."[163]

By the time Yvette Cooper closed the session, opinion in the Commons had swung even more strongly in favor of research than when the debates had begun. In both the second and third sessions, speakers in support outnumbered those against by four to one. The vote reflected a strong victory for research, with 366 MPs voting in favor, and 174 against.

Consistent with the free vote, many MPs crossed party lines, with 76 Labour members voting against the regulations, and 57 Conservative MPs supporting it. However, a considerable Labour majority, some 75 percent, supported research, while a majority of the Conservatives, 65 percent, opposed it.[164] Most cabinet members voted in favor, with the exception of three ministers, Welsh Secretary Paul Murphy, Trade Minister Helen Liddell and Europe Minister Keith Vaz. The Conservative leader William Hague and all but a handful of the shadow cabinet voted no.

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[162] Winterton, Ann, ibid, col. 244.
[163] Clark, Michael, ibid, col. 250.
[164] Hurst, Greg, "Passions Run High in Stem Cell Debate," *The Times*, December 20, 2000.

Lords Concession

Despite the measure's strong victory in the Commons, its passage in the Lords remained uncertain. Some peers had doubts about opening the door to cell nuclear transfer. And even some supporters of therapeutic cloning nevertheless challenged the government's use of secondary legislation, which provided limited debate time and no opportunity to offer amendments.

In the week before debate opened, a broad coalition of religious leaders, including the Archbishops of Canterbury and York, along with Roman Catholic, Jewish and Muslim leaders, sent an open letter to each peer calling for a delay, and for a Select Committee to look into the matter.[165] "These complex questions deserve to be examined in far greater detail than a brief parliamentary debate on an unamendable order would permit," the letter stated.[166]

When Lord (David) Alton announced that he would introduce an amendment based on the religious leaders' letter, in order to force the government to reintroduce the regulations in a later session, the government responded quickly. Downing Street's spokesman in the upper chamber, Parliamentary Under-Secretary of State for Health Lord (Phil) Hunt, conferred with the Chief Whip Lord Dennis Carter and enlisted the respected scientist Lord (John) Walton to offer a counter-measure that would create a select committee after passage of the regulations.[167] "It would allow the Lords to say: 'Okay, we agree to this, you can get on with it, but we've got the safeguard of this select committee,'" said Lord Hunt, a Labour peer from King's Heath.[168]

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[165] Brogan, Benedict, "Religious Leaders in Cloning Plea," *The Daily Telegraph*, January 17, 2001.
[166] Ibid.
[167] Hunt, Lord Phil, interview, October 18, 2011.
[168] Ibid.

The heated Lords session of January 22, 2001, drew approximately 40 speakers, who voiced a range of concerns, from the destruction of human life to the need to pursue all available research channels. However, the debate ultimately hinged on the question of process: Was a statutory instrument an adequate mechanism for legislation? Alton drew a comparison with a contemporaneous government bill to ban fox hunting and attacked ministers for the protecting four-legged mammals but refusing to do the same for human embryos.[169] But Lord Hunt made the ultimately convincing point that if the regulations passed and the select committee subsequently cast doubt on research, the government would undoubtedly take note. "Quite clearly if the select committee had come back and said we don't think this is a good thing we'd have had to come back, we'd have had to amend the order. I don't think there's any doubt about that."[170] In the end, the peers accepted the compromise, rejecting Lord Alton's proposal with 92 in favor and 212 opposed.[171] The Lords approved the Walton measure without a roll call vote.

5.4 Policy Execution (2001-2002)

Human Reproductive Cloning Act 2001

Although during the debate, Lord Hunt provided further assurance that the government would ban human reproductive cloning by primary legislation, ministers initially showed no urgency in moving forward. This changed, however, in late 2001, when a Court of Appeal sided with the Pro-Life Alliance by ruling that the Act did not have

[169] Alton, David, House of Lords, *Hansard*, col. 24, January 22, 2001.
[170] Hunt, Lord Phil, Interview, October 18, 2011.
[171] House of Lords, *Hansard*, col. 122, January 22, 2001.

jurisdiction over embryos created by cell nuclear transfer, since the legislation had limited its reach to embryos "where fertilisation is complete."[172]

The government responded swiftly with new primary legislation to close the loophole, unveiling a bill to criminalize placing "in a woman a human embryo which has been created otherwise than by fertilisation."[173] While the so-called Human Reproductive Cloning Act provided an immediate answer to the question, the government later appealed the ruling and won, in 2003.[174] The HFEA and the 1990 Act therefore retained the power to regulate all embryos, even those produced by cloning.

Lords Committee

To review the issues arising from the new regulations, the government appointed a Select Committee on Stem Cell Research, which consisted of 11 members chaired by Rev. Richard Harries, the Bishop of Oxford who had served on advisory panels for both the HFEA and Nuffield Council on Bioethics. Although members represented diverse views, most came from backgrounds which typically supported scientific research. The panel convened in March 2001 and deliberated for almost a year.[175] Although the committee saw its central purpose as evaluating whether the extension of the research purposes in the 2001 was justified, members looked broadly at the legislative history, ethical questions and international context. Panelists received over 100 submissions, and held 12 sessions at which 42 people provided oral evidence.

Completing work in February 2002, the committee sided with the government and gave its full backing to the regulations. Although panelists recognized the

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[172] Charter, David, "New Law Will Close Loophole on Human Cloning," *The Times*, April 16, 2001.
[173] UK Parliament, Human Reproductive Cloning Act 2001, December 4, 2001.
[174] O'Hanlon, Kate, "Act Regulates Creation of Live Human Embryos by Cell Nuclear Replacement," *The Independent*, March 18, 2003.
[175] UK House of Lords Select Committee on Stem Cell Research, "Stem Cell Research," February 13, 2002.

importance of adult stem cell research, they concluded that work on embryos should move forward. In a statement, Harries defended embryonic stem cell work as important and necessary.[176]

First Licenses

Officials at the HFEA met immediately to discuss pending applications, ultimately granting the first embryonic stem cell licenses to two research teams. One team based in London and led by researchers Stephen Minger, Sue Pickering and Peter Braude of Guy's Hospital and King's College aimed to create nerve and pancreatic cells to treat Parkinson's disease and diabetes, and to produce new infertility treatments, respectively. A second team led by Dr. Austin Smith of the Centre for Genome Research in Edinburgh aimed to coax stem cells into becoming nerve, heart and blood cells.[177]

In the months that followed, HFEA staff members incorporated the new types of research requests into their standard, committee-driven operating procedures, but few changes to the system were needed. Stem cell lines created from HFEA-licensed embryos were housed in the newly created UK Stem Cell Bank.[178] "I think it worked really well," said Suzi Leather, who replaced Deech as Chair in 2002.[179]

5.5 Conclusion

Although active political decision-making for embryonic stem cell research in the UK occurred in a period of less than two years between August 2000 and February 2002,

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[176] Hawkes, Nigel, "Stem Cell Research on Embryos is Approved by Lords," *The Times*, February 28, 2002.
[177] Highfield, Roger, "Embryo Cell Research Licences Granted," *The Daily Telegraph*, March 2, 2002.
[178] Ibid.
[179] Leather, Suzi, Interview, July 13, 2011.

policy activities in the preceding two decades contributed hugely to the final decision. Indeed, the Warnock Committee and Report, several legislative false starts and the successful passage of the landmark HFE Act 1990 painstakingly reviewed the question of embryo research and affirmed that the work should move ahead.

Similarly, the discovery of cell nuclear transfer in 1997 triggered lengthy deliberations by two expert inquiries, which identified the value of human embryonic stem cell research as well as a viable regulatory route: extending the existing framework to cover stem cell research in the HFE (Research Purposes) Regulations 2001.

Although Britain's permissive policy undoubtedly had multiple influences, two factors stand out in particular for their explanatory power. The first, public opinion, suggests that officials created a permissive policy because the general public supported it. The second, interest groups, implies that the policy reflected the weakness of Britain's religious conservatives.

Public Opinion

Arguably the strongest case for public opinion as the decisive factor in determining the UK policy would proceed as follows: Since the British public clearly supported research into IVF in the late 1980s and on embryonic stem cell research ten years later, officials simply translated these desires into legislation. However, this scenario presents multiple problems. First, the few available opinion surveys suggest that opinion was split, or at least that partisans on either side could claim to have significant public support for their respective positions.

Second, both the Thatcher and Blair governments clearly wavered in their thinking at several points. As documented above, Tory ministers repeatedly hesitated, waiting more than five years in the late 1980s before unveiling legislation. Similarly,

Labour officials delayed action on stem cell research for more than a year in 1999 in order to get a second advisory panel to reaffirm the original findings of the first: that Parliament should extend the HFE Act to cover therapeutic research.

If public opinion clearly supported research or opposed it, the government arguably would not have shown such hesitation. Instead, ministers would have moved forward decisively in favor or against. But the fact that they delayed showed that the government had reservations about supporting research, especially during the late 1990s when activism on GMOs had already created a polarized climate.

Interest Groups

An arguably stronger causal argument comes from an analysis of interest group influence (or lack thereof). According to such an approach, weakness among pro-life activists in Parliament and outside ultimately allowed pro-research forces, such as scientists and patient advocates, to dominate discussion and achieve legislative victory.

Although pro-life forces certainly failed to secure victory in Parliament in 1990 and 2000-01, an explanation based purely on interest groups is problematic for several reasons. First, although Britain's pro-life contingent, made up largely of Catholics, lacked the size of its heavily evangelical Christian counterpart movement in the United States, British pro-life forces nevertheless had a significant degree of power and possessed a strong, non-partisan operation in the All-Party Parliamentary Pro-Life Group. Moreover, pro-life members experienced some success in joining forces with MPs who opposed research for reasons other than abortion, such as opposition to therapeutic cloning, for example.

Second, the successful passage of legislation in both 1990 and 2001 required considerable government maneuvering, meaning successful victory over anti-research

partisans was not assured. In 1990, the government scheduled a vote on embryo research for the day before a vote on abortion, concentrating attention and energy to the latter and arguably securing passage of the former. And in 2001, ministers sought to approve stem cell research by statutory instrument, a strategy that strictly limited debate and prevented amendments. Thus, the government relied strongly on tactical strategy in both votes.

Institutions

Explanations based solely on public opinion or interest groups add important details to the case, but they also have limitations. If opinion alone drove decision-making, officials would not have wavered consistently, moving forward with such trepidation. Similarly, if weak interest group opposition alone explained the case, ministers arguably would not have employed tactical strategies for advancing legislation through Parliament.

This study hypothesized that institutional legacies significantly affected policymaking by shaping the options available inside government. As the preceding discussion revealed, considerable opposition to embryo research existed in Parliament in the years following the Warnock Committee and Report, and MPs would likely have banned the practice if the government had agreed to allot time to a private member's bill proposed by Enoch Powell.

Indeed, despite Warnock's comprehensive review of relevant concerns, MPs still required approximately six years, from 1984 to 1990, to reverse their majority opposition. And when they finally did so, with the HFE bill in 1990, ministers needed to employ legislative tactics such as lowering the abortion time limit and the strategic scheduling of votes in sequence.

The proposed HFE bill itself had at least two important effects on policymaking. First, it allowed for a thorough discussion of issues among relevant parties. During the debates leading up to 1990, a new group of actors comprised of scientists and patient advocates entered the discussion for the first time and highlighted the potential benefits of research. In this way, MPs could systematically address lingering questions about the purpose of the research, the moral status of the human embryo and the nature of the regulatory controls. This led to the second major effect of the HFE bill: By prescribing an institutional regulator for all embryo research, the measure could help depoliticize the issue and shift attention to administration.

Ten years later, the legacy of the HFE Act 1990 similarly impacted the government's proposed regulations. The same coalition of scientists and patient advocates active in 1990 returned in 2000-01. And the proposed institutional regulator, by 2000 the generally respected HFEA, helped address safety concerns about stem cell research.

These effects of the HFE Act 1990, and the fact that the 2001 Regulations represented a mere extension of earlier legislation, suggest a critical role for the sequencing of legislation. Indeed, without the Act in place, *de novo* legislation in 2001 would have required considerable time and resources and may not have succeeded. Moreover, because the Act provided a framework that officials could simply extend, alternative approaches to legalizing stem cell research became immediately impractical.

Like the passage of the Act in 1990, enactment of the 2001 regulations created a profound policymaking shift in that it empowered civil servants to oversee grants for stem cell research in a depoliticized environment. Rather than reflecting partisan divisions which had plagued the technology during legislative debates, HFEA officials based oversight on established principles of law.

Pierson's Criteria

These institutional features suggest that structural factors significantly influenced the policy outcome in the UK. Indeed, as the chapter showed, one can trace the legacy of the 1990 Act throughout policymaking for the 2001 regulations and beyond. But how exactly did institutions impact outcomes? To answer this question, Chapter One proposed to describe policy development as an increasing returns process that can reveal the early institutional arrangements that drove policymaking later. The following paragraphs apply Pierson's criteria for increasing returns to stem cell research in the UK.

Multiple Equilibria

For stem cell research in the UK, one could say that multiple equilibria existed prior to passage of the Human Fertilisation and Embryology Act in 1990. In the years after the 1984 Warnock Report, the future of IVF and embryo research in Britain remained unclear. The strong victory of Enoch Powell's private member's bill at its second reading in 1985 meant that MPs would have likely swung against embryo research if ministers had granted requests for time to debate the matter. Although the HFE Bill eventually passed in 1990, supporters had no assurances that such an outcome would occur. In fact, some observers expected it to fail. Therefore, to the extent that MPs could have voted for an alternative prior to 1990, or for no act at all, one could say that multiple equilibria existed.

Contingency

Regarding stem cell research, one could see contingency in the government's strategy for passing the HFE Act in 1990. Indeed, the decision to allow amendments restricting

abortion arguably compelled many pro-life MPs to support the bill despite its provisions to allow embryo research. Similarly, the scheduling of the vote on embryo research for the day before the vote on the abortion time limit arguably helped draw attention away from the former. Both of these events played a key role in advancing embryo research provisions and the Act itself, such that without them, the legislation would have possibly failed. Furthermore, the failure of the Act could have had a dramatic effect on stem cell research, because the law provided the legal basis for the 2001 Regulations. Indeed, if no primary legislation had existed when officials took up stem cell research in the late 1990s, creating a path for the technology would have added considerable delays to the process as officials would have had to deliberate over whether, how and when to pass legislation.

Timing and Sequencing

For stem cell research in the UK, timing and sequencing provides possibly the strongest application of Pierson's criteria, since the 2001 regulations were based on the 1990 Act. In this way, the Act provided a tested and reliable method of regulation based on the HFEA's track record of approving research under certain conditions. Stem cell research represented a mere extension of existing practice. In addition to conceptual efficacy, the 1990 Act saved the government from having to introduce new primary legislation, a process which requires time for debate and amendments, and can add months, and possibly years to the legislative timetable.

Inertia

During the 2000 Parliamentary debates a kind of inertia developed in the rhetoric of research supporters who told hesitant colleagues that the 1990 Act had already

addressed the question of ethically acceptable embryo research. This approach provided the assurance that the new research would come with a fully fledged system of rules, including the 14-day rule for the use of embryos, and a respected institutional regulator, the HFEA. It also created a perceived obligation among MPs who had backed the 1990 Act to support the stem cell measure.

Extending Path Dependence

These applications of Pierson's criteria suggest that an increasing returns process existed in the development of the UK policy for stem cell research. On this basis, one should conclude that the permissive policy emerged not simply as a result of an undecided public or poorly organized pro-life interest groups but the passage of the HFE Act 1990 with its own institutional regulator that officials could simply extend.

Although Chapter One described Pierson's criteria as sufficient to reveal the institutional influences in policy development, this study proposed a secondary test of path dependence in order to address the question of variation in specific terms that scholars can assess comparatively. The following paragraphs apply this to the UK decision-making structure, the HFE Act 1990 framework, during the policy design and execution phases of the case.

Stem Cell Research: The Policy Design

Actor Constellation. Following the success of the Enoch Powell bill at its second reading in 1985, many in Parliament believed that opposition to embryo research outweighed support. In the years before the 1990 Act, research opponents consisted of resolute pro-life activists but also MPs with more general concerns about the safety and morality of moving ahead. But during the debates on the white paper in 1988, and on

the proposed bill in 1989-1990, an important shift took place. Scientists and patient advocates from nascent organizations, such as the Genetics Interest Group, won the support of many members of Parliament, who in turn telegraphed the many potential benefits of research, including the complete elimination of certain diseases from the population. Parliamentarians also addressed the safety concerns of those who opposed research for reasons other than the life of the embryo, and explained that the government would maintain tight control over experiments through legislation and regulation.

A further group of emerging research supporters included religious figures, such as John Habgood, the Archbishop of York, who articulated a theologically acceptable alternative to the notion that life began at conception. Contrasting the already well-known opposition to research of many religious leaders, including many Roman Catholics, the archbishop encouraged his colleagues to consider the life of the early embryo as a spectrum.

In the years leading up to the 2001 stem cell regulations, the actor constellation largely resembled the one in operation during the 1990 Act deliberations, with scientists and patient advocates playing a high-profile role inside and outside of Parliament. During this time, two further groups of actors entered the scene. The first included the scientists serving on expert committees, who helped draw attention to the issue and lend their professional credibility to research efforts. The second group, which played a large but mostly unseen role, included HFEA officials who factored into Parliamentary discussions based on their mostly positive reputation as regulators of embryo research for the purposes of IVF and congenital disease.

Balance of Interests. Within Parliament the new actor constellation in 1990 played a critical role in shifting the balance of interests from a majority coalition of

research opponents to a majority made up of supporters. This occurred when the new constellations of actors conclusively answered lingering questions, including those pertaining to the purpose of the research, the moral status of the human embryo and the nature of the regulatory controls. Indeed, during the 1990 debates few MPs could easily disregard the benefits of research. And with the sanction of high-ranking church officials and the promise of strong oversight, supporters' ranks rose while the number of opponents fell. On the question of the embryo's moral status, the exhaustive discussion offered numerous moral assurances. Furthermore, in articulating a vision for strong oversight, research supporters successfully addressed other members' concerns about the safety of the research, depoliticizing the issue and shifting attention to administration.

Ten years later, when the same questions recurred during debates over the 2001 regulations, the balance of interests from the 1990 Act discussions remained essentially intact. Indeed, the potential to combat debilitating diseases once again became an effective rhetorical justification for permitting the research. And because the Act had exhaustively addressed the issue of an embryo's right to life, few opponents couched their criticisms in those terms. Furthermore, given the acknowledged success of the HFEA as an institutional regulator, no speaker raised serious concerns about the adequacy of existing oversight.

Stem Cell Research: The Policy Execution

Actor Constellation. Following the approval of the regulations in both houses of Parliament, and by the Lords select committee in 2002, the key actor constellation involved in policymaking became HFEA civil servants who issued licenses to institutional applicants. To the chagrin of many pro-life activists, the HFEA did not

include opponents of embryo research on its licensing committee.[180] The committee included scientists and lay members who supported the concept of embryo research under the conditions stipulated by the HFE Act 1990 and 2001 Regulations.

Balance of Interests. By the time the HFEA began issuing grants in 2002, the balance of interests had shifted dramatically. Because the regulations simply extended the range of permissible activities to include stem cell research, permission to conduct research on embryos for that purpose depended on HFEA approval, and therefore reflected that agency's internal dynamics. Opponents, such as pro-life activists, had limited opportunities to object to specific proposals, and no influence in the grant-making process. Thus, after extensive political bargaining in Parliament, the government had succeeded in creating an administrative and bureaucratic space for overseeing research.

Secondary Test of Path Dependence

Based on this analysis one can say that the early path adopted in UK policymaking, passage of the HFE Act 1990, provided not only a legal justification for embryo research but a trusted regulator, the HFEA, which could simply extend its work to cover new science applications, such as stem cell research.

On this basis, the HFE Act 1990 framework arguably led to significant expansions in the constellation of actors and shifts in the balance of interests during both the design and execution phases of policymaking. Although this development does not singularly explain the UK policy, the study suggests that a plausible relationship exists between changes in actors and interests and the permissive outcome. In this way,

[180] Dame Suzi Leather, who served as HFEA Chair from 2002 to 2006, confirmed this during a July 13, 2011, interview.

the secondary test of path dependence provides a specific mechanism for assessing institutional influence along the policy path.

Without the 1990 Act framework, the government arguably would have needed to pass new legislation, which at a minimum would have added lengthy delays to the process, and could have led to a more restrictive policy result. Chapter Seven, the conclusion, will review this finding more closely in a comparative analysis that addresses the broader question of variation in biotechnology policies.

CHAPTER 6: HUMAN EMBRYONIC STEM CELL RESEARCH IN THE UNITED STATES

Table 6.1 Timeline: Human Embryonic Stem Cell Research in the United States

1979	Carter Administration tentatively approved funding for IVF research
1981	Reagan officials took office, reversing course
1993	Clinton officials opened the door to embryo research
1995	Dickey Amendment affixed to federal budget
1997	Birth of Dolly announced
1998	Thomson and Gearhart successfully isolated human embryonic stem cells for the first time
1999	Rabb Opinion upheld some forms of stem cell research under the Dickey Amendment
2000	Stem cell guidelines developed by Clinton NIH
2001	Bush took office and blocked federal funding for new stem cell derivations

Although the historic creation of human embryonic stem cells for the first time in 1998 represented a landmark achievement in American science, the United States government famously spurned the activity in its policy response. Indeed, President George W. Bush's personal decision to block federal funding for most forms of the research in 2001 had a paralyzing effect on US research, galvanizing political opposition and animating election cycles in 2004, 2006 and 2008.

Table 6.2 United States Policy for Human Embryonic Stem Cell Research

Activity	Policy Document	Policy Outcome
Embryo Research	The Dickey Amendment to the Fiscal Year 1996 Budget[1]	Prohibited use of public funds to create human embryos for research purposes or for research in which embryos are destroyed or discarded
Derivation of Stem Cells	President Bush's Stem Cell Decision of August 9, 2001[2]	Subsequent experiments that derived stem cells from human embryos could receive no federal funds.
Utilization of Stem Cells		Federal funds could sponsor research that utilized only those stem cells derived from embryos before 9:00 pm on August 9, 2001.

Table 6.2 describes the first-generation policy in the US, in place from 2001 to 2009. Although the Bush approach technically granted federal funding for stem cell research for the first time, because it blocked money from work on new stem cells the policy effectively prevented most scientists from carrying out research.

Within weeks of the decision, research supporters denounced it as blatantly favoring the "pro-life" position of religious conservatives, a constituency that Bush's advisers considered crucial to his re-election. Supporters of the Bush policy included those who sought to protect embryos because they equated them with distinct human lives, and those who more generally favored drawing a moral line against descending down a slippery slope.

Some scholars have emphasized the role of culture, broadly demonstrated in differences in public opinion, as a leading factor shaping the restrictive US outcome.[3]

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[1] US Congress, *The Balanced Budget Downpayment Act, I*, Public Law 104-99, 110 STAT. 34, January 26, 1996.
[2] Bush, George W. (Crawford, Texas, August 9, 2001).

Other works highlight the role of interest groups, such as the religious conservatives Bush considered so important.[4] Still other potential explanations, which scholars have applied elsewhere, could focus on the impact of institutions on the policy outcome.[5]

This study hypothesized that institutions played a critical role in shaping the US policy, and aims to make a case based on what occurred inside government, highlighting links between all major influences on the policy outcome. To achieve these aims, this study recounts the biography of the key policy documents, by tracing the process of decision-making in three historical periods. Period one, from 1993 to 1996, actually predates the technology, but includes a policymaking event that would critically impact stem cell research later: passage of the Dickey Amendment in the 1996 budget process.

After the successful isolation of human embryonic stem cells in 1998, officials at the National Institutes of Health (NIH) obtained a legal opinion on the applicability of the Dickey Amendment and drafted guidelines allowing for federally-funded research under certain conditions. However, before NIH could begin distributing funds, Bush assumed the presidency and changed course. The third period, in 2001, details the internal deliberations of the Bush Administration—as the primary decision-making structure, culminating in the decision to revoke the Clinton guidelines and fund research on a small and finite number of stem cell lines.

Throughout this history, the policy question animating debate in the US reflected discussions in other countries save in one key respect: The US policy addressed only

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[3] Jasanoff, Sheila, Designs on *Nature: Science and Democracy in Europe and the United States* (Princeton, N.J.: Princeton University Press, 2005); Fink, Simon, "Politics as Usual or Bringing Religion Back In?" *Comparative Political Studies* 41, no. 12 (December 2008), 1631–1656.
[4] Smith, Alexander, "Faith, Science and the Political Imagination: Moderate Republicans and the Politics of Embryonic Stem Cell Research," *The Sociological Review* 58, no. 4 (2010), 624–638.
[5] Banchoff, Thomas, "Path Dependence and Value-Driven Issues," *World Politics* 57, no. 2 (January 2005): 200–230.

research funded by the federal government. In other words, Bush's decision had no impact on private sector work.[6] While this would seem to lessen the relevance of government action, public funding decisions nevertheless had serious implications. Indeed, most funding for research on stem cells in the United States came from the federal government.[7] Therefore, placing controls on the purse would force researchers to develop alternative funding streams, leave the country or abandon the field. Given the significant consequences of denying federal funds, this study views such a position as a virtual ban on the technology at least for researchers who depended on government funds.

6.1 Early Stages (1979-1994)

Decades before the discovery of human embryonic stem cells, scientists began conducting work on what would become their raw materials: human embryos. Following the discovery of *in vitro* fertilization (IVF) by British physicians Patrick Steptoe and Robert Edwards in 1978, researchers could for the first time produce embryos in the laboratory for further study.

Moratorium

In the wake of the IVF breakthrough, officials in the administration of Democratic President Jimmy Carter began taking steps to provide federal grants for research in the US. First, the Department of Health, Education and Welfare (HEW), precursor to the Department of Health and Human Services (HHS), created rules establishing that any

[6] Unless otherwise noted, all references to US government financial support for human embryonic stem cell (HESC) research will refer to appropriations made by the federal government.
[7] Numerous sources confirmed this assertion, including bioethicist Eric Meslin in an e-mail communication from July 20, 2012.

federally-funded projects required ethical oversight.[8] Then, in May 1979, the department's Ethics Advisory Board (EAB) endorsed IVF techniques under certain conditions. However, before making any grants for IVF research, officials dissolved the board in 1980 for reasons unrelated to embryo research.

The election of Republican Ronald Reagan in 1980 effectively halted the momentum of IVF and embryo research, according to observers such as bioethicist Eric Meslin, of the Indiana University Center for Bioethics.[9] Upon taking office, officials maintained the EAB in name but declined to provide a budget for it to conduct its work and review applications. Meslin speculated that the Reagan administration allowed the panel to fade away because officials implicitly opposed the research. "It was a Washington strategy, that you bleed something of its budget and that's one of the ways that you kill it," Meslin said.[10] From the early 1980s, federally funded research on embryos would languish under a *de facto* moratorium that lasted more than a dozen years.

[8] National Bioethics Advisory Commission, *Ethical Issues in Human Stem Cell Research* (Rockville, Maryland, September 1999), 34.
[9] Meslin, Eric, Interview, September 16, 2010
[10] Ibid.

NATIONAL INSTITUTES OF HEALTH (NIH)

Established: 1887
Budget: $3.4 billion (1980), $7.6 billion (1990), $17.8 billion (2000), $28 billion (2004)
Directors: Harold Varmus (1993-1999), Elias Zerhouni (2002-2008), Francis Collins (2009-present)
Reputation: First conceived in the 19th Century as a one-room laboratory for assessing the infectious diseases of returning merchant sailors, NIH grew to become a large confederation of medical research institutes spread across 45 acres near Washington, DC.
A division of the US Health and Human Services Department, NIH distributes a majority of its budget (83 percent in 2011) via grants to so-called extramural researchers, investigating at various institutions around the country.

SOURCE: See note[11]

The deadlock began to lift after the election of President Bill Clinton in 1992 ended the 12-year hold on the White House by Republicans Reagan and George Bush, and the new administration in 1993 removed the technical requirement for review by the defunct EAB panel.[12] The move cleared the way for NIH Director Harold Varmus to form a new committee, the Human Embryo Research Panel, to make recommendations for ethically acceptable research. The panel published a September 1994 report that recommended federal funding for certain types of embryo research, including a range of fertility experiments, pre-implantation diagnosis and an obscure activity known as embryonic stem cell research. Although researchers knew little about stem cells, they were making rapid progress in the field. Indeed, the following year researchers led by

[11] Department of Health and Human Services, NIH, "OER and You: An Introduction to Extramural Research at NIH," website; NIH, "NIH History," website.
[12] The removal of this requirement occurred as part of the more sweeping *NIH Revitalization Act of 1993*, which Clinton signed on June 10, 1993; see National Bioethics Advisory Commission, *Ethical Issues in Human Stem Cell Research*, 31.

James Thomson of the University of Wisconsin successfully derived a primate stem cell, buoying hopes that scientists could one day do the same for humans.[13]

While the 1994 report highlighted stem cell research as only one of several research priorities, the inclusion is the first government endorsement of the technology. Furthermore, the report supported not only the use of supernumerary embryos leftover from IVF, but embryos created and donated expressly for research purposes.[14] Such an endorsement would have significant political implications later.

Politicization

PRESIDENT BILL CLINTON
Party: Democratic In office: 1993-2001 Reputation: Elected by a plurality in 1992, the former Governor of Arkansas and self-styled "New Democrat" governed largely from the center, especially after the 1994 loss of Congress to Republicans. Indeed, "third way" philosophies arguably accounted for some of Clinton's most significant achievements, including the North American Free Trade Agreement, the crime bill and welfare reform. While Clinton supported abortion rights and funding for science and technology, positions on embryo cloning and stem cell research often reflected the political caution of his other interactions with Republicans in Congress.

Before NIH could take action on the recommendations, politics would intervene. The Clinton Administration, reeling from the Democratic Party's loss of both houses of Congress in the November 1994 elections, fretted about the 1994 report's support for embryo research in light of the new political headwinds.[15] In what some viewed as an

[13] Thomson, James A.; Kalishman, Jennifer; Golos, Thaddeus G.; Durning, Maureen; Harris, Charles P.; Becker, Robert A.; Hearn, John P., "Isolation of a Primate Embryonic Stem Cell Line," *Proceedings of the National Academy of Science* 92 (August 1995), 7844-7848.
[14] Ad Hoc Group of Consultants to the Advisory Committee to the Director, NIH, *Report of the Human Embryo Research Panel* (Bethesda, Maryland: National Institutes of Health, September 1994), 76.
[15] Varmus, Harold, *The Art and Politics of Science* (New York and London: W.W. Norton, 2009).

attempt to appease Republicans in Congress, President Clinton issued a directive in December denying federal funds for the creation of human embryos.[16] However, Clinton left open the possibility of providing federal funds for research on embryos leftover from fertility treatments.

If Clinton aimed to mollify opponents of embryo research, the maneuver failed. Indeed, the issue continued to galvanize religious conservatives who strongly opposed legalized abortion and embraced the view that human life begins at conception. One organization, the National Right to Life Committee, an anti-abortion group with an active policy branch, seized on embryo research and attempted to use Republicans' recent gains in Congress to its advantage.

Out-of-power in Congress for 40 years, members of the Grand Old Party viewed their historic return as nothing less than a "revolution."[17] Below the surface of victory, however, the transition of January 1995 presented numerous management challenges, including the customary burden of filling leadership positions and the majority staffs of dozens of House and Senate committees. "The place tends to be a madhouse," said Tony McCann, former staff director of the Subcommittee on Labor, HHS, Education and Related Agencies.[18] This led to another, more subtle Republican challenge: balancing interests in a party with considerable ideological diversity. While the House leadership and many members of the freshman class of 1994 leaned significantly to the right, many Republican incumbents considered themselves moderates, especially on social issues. In the coming years, "hot button" topics such as abortion and embryo research would test political fault lines and spur battles not only between parties but within them.

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[16] Office of the White House Press Secretary, Statement by the President, December 2, 1994.
[17] Clymer, Adam, "The 1994 Elections: Congress The Overview; G.O.P. Celebrates Its Sweep To Power; Clinton Vows To Find Common Ground," *The New York Times*, November 10, 1994.
[18] McCann, Tony, Interview, May 6, 2010.

6.2 The Dickey Amendment (1995-1996)

When Congressman Jay Dickey received a visit in early 1995 from two staff members of the National Right to Life Committee (NRLC), the conservative Republican from Pine Bluffs, Arkansas, knew little about stem cell research or the use of embryos in experiments.[19] But the legislator with a Southern drawl knew the group well. Indeed, the nation's largest pro-life interest group with grassroots affiliates in all 50 states had helped elect him in 1992, organizing telephone "calling trees" in his congressional district, among other forms of support.[20] Dickey considered the group a political ally, and shared its pro-life views. And after multiple exchanges in his Washington, DC, office, he would come to endorse the group's view of embryonic stem cell research: that such work amounted to killing a human life. "Only after I started getting briefed on it did I realize that it was a life that was being terminated," said Dickey.[21] The group soon had a staunch supporter in the congressman.

Table 6.3 Proposed Appropriations for Fiscal Year 1996[22]

National Institutes of Health	$12 billion
Labor, HHS, Education and Related Agencies	$260 billion
US Government	$1.5 trillion

The National Right to Life Committee had thought carefully about their strategy before approaching Dickey. Rather than seeking to block embryo research with a free-

[19] Dickey, Jay, Interview, May 17, 2010.
[20] The organization refers to itself as the nation's largest pro-life group with affiliates in all 50 states and over 3,000 chapters nationwide. For more information, see www.nrtlc.org. Rep. Jay Dickey served in the House of Representatives from 1993 to 2001, winning elections in 1992, 1994, 1996 and 1998.
[21] Dickey, Jay, Interview, May 17, 2010.
[22] U.S. House of Representatives, "Report of the Committee on Appropriations: Departments of Labor, Health and Human Services, and Education, and Related Agencies Appropriations Bill, 1996" (Government Printing Office, 1995), 5.

standing bill on the House floor that could open the issue up to debate and delays, the group saw a more attractive option in stopping research by starving it of federal funds. As a member of the House Appropriations Committee, Dickey and colleagues had broad authority over the nation's purse strings, overseeing the dozen major spending bills that authorized all expenditures in the federal government's approximately $1.5 trillion budget. Rather than take a chance on the House floor, the group would push for an amendment or rider to the National Institutes of Health's approximately $12 billion budget for 1996. "There's less delays if you go through Appropriations, as well as less dialogue," Dickey explained.[23] A rider would conveniently circumvent the normal procedure for passing legislation. Moreover, spending bills were a safe bet because they had to pass eventually. "They liked the idea of being a parasite, you might say, and that's what they were," Dickey said.[24]

Table 6.4 The Dickey Amendment to the Fiscal Year 1996 Budget[25]

None of the funds made available by Public Law 104–91 may be used for— (1) the creation of a human embryo or embryos for research purposes; or (2) research in which a human embryo or embryos are destroyed, discarded, or knowingly subjected to risk of injury or death greater than that allowed for research on fetuses in utero under 45 CFR 46.208(a)(2) and 42 U.S.C. 289g(b). For purposes of this section, the phrase "human embryo or embryos" shall include any organism, not protected as a human subject under 45 CFR 46 as of the date of enactment of this Act, that is derived by fertilization, parthenogenesis, cloning, or any other means from one or more human gametes.

[23] Dickey, Jay, Interview, May 17, 2010.
[24] Ibid.
[25] US Congress, *The Balanced Budget Downpayment Act, I*, Public Law 104-99, 110 STAT. 34, January 26, 1996.

At first Dickey had declined the group's request and suggested they approach a more senior committee member. But the lobbyists returned empty handed, after more prominent members declined to carry the amendment. "This didn't have a track record so [other members] didn't want to start with something that was going to fail," Dickey said. "Or it just wasn't big enough for them at the time to attract their attention."[26] Rather than see the effort collapse, Dickey agreed to help. "That convinced me that if it was going to get done it was going to get done by me."[27] With Dickey on board, the group had settled on a strategy, and identified a willing agent. With attorneys from Congress' Office of Legislative Counsel, Dickey and company drafted the amendment, a brief two-clause statement calling for a prohibition on "funding to create Human Embryos for research purposes or for research in which human embryos are destroyed or discarded."[28] Then they turned to strategy.

Markup

Like most years, the 1996 federal budget process began with a request from the president in February 1995, followed in the spring by a congressional budget resolution providing an overall monetary target, with caps for each of the 13 major spending bills comprising the government's cumulative expenditure. According to procedure, each bill was drafted by its respective House Appropriations subcommittee, with the full committee expected to vote on each, in a so-called markup. Such occasions represented high-stakes games with real consequences. Winners received funding for supporters' projects. Losers had to face their backers empty-handed.

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[26] Ibid.
[27] Dickey, Jay, Interview, May 14, 2010.
[28] US House of Representatives, "Report of the Committee on Appropriations: Departments of Labor, Health and Human Services, and Education, and Related Agencies Appropriations Bill, 1996" (Government Printing Office, 1995), 214.

Dickey and his Right-to-Life associates faced a critical decision. Although most budget amendments by convention required subcommittee approval, an informal poll of the Subcommittee on Labor, HHS, Education and Related Agencies suggested that his measure would likely fail. But the congressman had another option, and one that carried some risk: Dickey could bypass the subcommittee, and bring the measure to a full Appropriations Committee markup, at which members considered amendments before voting to send spending bills to the full House. Deciding that it was worse to lose at the subcommittee, Dickey decided to try his luck with the full panel.[29]

When the Appropriations Committee opened the first day of marking up the spending bill on July 20, 1995, few people in the Rayburn Building's crowded hearing room knew much about the Dickey Amendment, if they had heard of the measure at all.[30] A range of spending proposals, from abortion to labor relations, lay on the chopping block, as the new Republican majority asserted its priorities and Democrats sought to defend theirs.

During the campaign GOP leaders had pledged to slash spending, and they took broad aim at programs not aligned with party ideology. As the keeper of the purse strings, the Appropriations Committee was a natural focal point for attention. But the health spending bill had an added draw as a forum for battles on the range of social issues covered by it. Some of these battles occurred over subjects which had no specific monetary appropriation, like embryo research, but nevertheless represented a political powder keg due to their controversial nature. In other words, the measures had symbolic rather than practical meaning. "[They] are just simply a pain in the neck because they have nothing to do with what we're trying to accomplish, which is to pass a bill to fund

[29] Dickey, Jay, Interview, May 17, 2010.
[30] McCann, Tony, Interview, May 6, 2010.

the government," said Tony McCann, former staff director of the Subcommittee on Labor, HHS, Education and Related Agencies.[31] McCann knew these amendments well, and considered them a nuisance. Passing a budget was enough of a challenge.

Given the size and complexity of the $260 billion spending bill for health and other divisions, it is not surprising that many of the key players interviewed for this study recalled only aspects of the buildup to the Dickey Amendment's introduction into full committee. For members of Congress who cast hundreds of votes each year, and for the staff members who often spent 14 to 16 hours per day preparing behind the scenes for the markups, specific details about a single vote easily get lost in the "fog of war," according to Tony McCann, who like others active during this time spoke extensively about legislative procedures, but did not recall all events precisely.[32]

Committee Showdown

Although the full Appropriations Committee typically worked its way through each spending bill section by section, Chairman Bob Livingston, a pro-life Republican, told Dickey he could bring his amendment up out of order.[33] Before voting on any amendment, the panel's 56 members needed to hear a legal description of a proposal before casting their vote.[34] Then after receiving the summary, each side took a few minutes to confer.[35]

After a few hours, Dickey rose to offer his amendment. But before the vote on his proposal, John Porter—the pro-choice Republican chairman of the health subcommittee which had drafted the health spending bill (and which Dickey had

[31] Ibid.
[32] Ibid.
[33] Dickey, Jay, Interview, May 17, 2010.
[34] Porter, John, Interview, April 8, 2010.
[35] McCann, Tony, Interview, May 6, 2010.

bypassed)—offered a substitute amendment that would prohibit funding for the creation of research embryos, but not for the destruction of those already created through IVF.[36] "I've always been pro-choice and pro-research, and I was chairman of the [sub]committee, so it made sense to offer the substitute so people had a choice between them," Porter said.[37] The substitute likely required some prior planning, which suggests that the congressman knew Dickey's amendment was coming. Dickey himself suggested that he either told Porter about his amendment or else Chairman Livingston did so through a routine pre-markup briefing of subcommittee chairmen, known as "cardinals."[38] After Porter introduced his substitute, parliamentary procedure required a debate on the proposed Porter Amendment before addressing Dickey's measure.[39]

Passage

Looking back after more than a dozen years, Porter recalled little from the committee discussion of his substitute, including the proposal's narrow failure. With votes deadlocked at 26 in favor and 26 against, the tie vote meant rejection. According to the roll call, 15 Democrats and 11 Republicans supported the substitute, and 20 Republicans and 6 Democrats opposed it. Four members, three Democrats and one Republican, did not vote.[40]

After the Porter Amendment failed, the committee took up the Dickey Amendment, which won comfortably in a vote of 30 to 23. Those voting in favor

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[36] U.S. House of Representatives, "Report of the Committee on Appropriations: Departments of Labor, Health and Human Services, and Education, and Related Agencies Appropriations Bill, 1996" (Government Printing Office, 1995), 213.
[37] Porter, John, Interview, April 8, 2010.
[38] Dickey, Jay, Interview, May 17, 2010.
[39] McCann, Tony, Interview, May 6, 2010.
[40] US House of Representatives, "Report of the Committee on Appropriations: Departments of Labor, Health and Human Services, and Education, and Related Agencies Appropriations Bill, 1996," (Government Printing Office, 1995), 213-214.

included 26 Republicans and 4 Democrats. Opponents of the measure included 17 Democrats and 6 Republicans. Three Democratic members did not vote.[41]

The Dickey Amendment received minimal coverage in media reports, with markup coverage focusing on other matters. Two days after the session, a *New York Times* story on the budget included several paragraphs about abortion-related cuts proposed in the Appropriations Committee, including one to remove mandatory federal funding for low income women seeking an abortion in cases of rape or incest.[42] One sentence in the story alluded to the Dickey Amendment: "Members also voted to ban the use of Federal funds for human embryo research."[43] Although clearly noticed by some, the Dickey measure failed to generate a headline or free-standing news story. It represented one example for a greater storyline that reaffirmed the GOP takeover. "The religious right's bill has come due," Democratic Rep. Nita Lowey told the newspaper. "They handed the new majority an agenda and the Republicans are ticking off the items."[44] At the time, the Dickey Amendment represented only a pebble in the GOP landslide. But it would take on much greater significance in the years ahead.

Becoming Law

After the markup the amendment would face one additional hurdle: Democratic Congressman David Obey, who had served as committee chairman before the Republican takeover, brought an amendment to the House floor to strike the Dickey provision and a host of other items. But the Obey measure failed, and the Dickey

[41] Ibid.
[42] Gray, Jerry, "Senate Approves Cutback In Current Federal Budget," *The New York Times*, July 22, 1995.
[43] Ibid.
[44] Ibid.

Amendment was preserved, with 155 members in favor and 270 against.[45] Then, in the coming months the entire spending bill became a pawn in a wider battle between President Clinton and the new Republican Congress, a battle that would have significant political consequences and lead to a government shut-down over various budget disagreements.[46] Resolution came in January 1996, when after rounds of negotiations, Congress passed and the President signed an omnibus bill containing the health spending bill with the Dickey's language intact.[47] The Dickey Amendment had become law.

The measure would remain in force indefinitely. Although the amendment faced a challenge in the next year's budget when Congresswoman Lowey attempted to strike the amendment with a vote on the House floor, the effort failed 167 to 256.[48] More importantly, the House and Senate leadership made the decision to include the amendment in all subsequent spending bills.[49] Former Appropriations subcommittee staff member Tony McCann worked with Chairman Porter each year to determine which amendments to bring forward in a draft bill. He explained why they included the Dickey Amendment year after year: "There tends to be a fair amount of inertia in the system," McCann said. "Everybody seems to be living comfortably with it, and if you disturb it you will be tangled up for months."[50] In other words, lawmakers viewed the

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[45] For more information on the Obey amendment, H.AMDT.714 (A004), see Roll Call vote 611, US House of Representatives, 104th Congress, August 2, 1995; also see: Anonymous, "Fiscal 1996 Labor, HHS, Education Appropriations - Legislative Riders" *CQ Floor Votes* (Congressional Quarterly, August 2, 1995), 1;

[46] A federal government shut down occurred on two occasions and for a total of 21 days between November 1995 and January 1996, with non-essential employees placed on paid leave. See, Kosar, Kevin R., *Shutdown of the Federal Government: Causes, Effects, and Process* (Congressional Research Service, September 20, 2004).

[47] "Bill Summary & Status - 104th Congress (1995 - 1996) - H.R.2880 - Titles - THOMAS (Library of Congress)," http://thomas.loc.gov/cgi-bin/bdquery/z?d104:HR02880:@@@T.

[48] Anonymous, "Fiscal 1997 Labor-HHS Appropriations" *CQ Floor Votes* (Congressional Quarterly, July 12, 1996), 1.

[49] In common parlance, the measure also became known as the "Dickey-Wicker Amendment," after Republican Congressman Roger Wicker of Mississippi joined Dickey in advocating for the law.

[50] McCann, Tony, Interview, May 6, 2010.

cost of undoing the measure as too dear. "I just don't think there's many members of Congress who are prepared to do that absent some small pressure, and I don't think that pressure exists," McCann said.[51] Therefore, even as the future would bring new technological developments and momentum for stem cell research, once the Dickey Amendment became law it became difficult if not impossible to repeal.

6.3 The Clinton Policy (1998-2001)

Dolly

After the Dickey Amendment became law, only a few months would pass before another biomedical storm gathered: the early 1997 announcement by researchers in Scotland about "Dolly." Although the development stunned scientists in America and polarized opinion around the world on the prospect of cloning humans, the effect on stem cell research remained indirect.

Among other things, Dolly's birth demonstrated that researchers could manufacture a viable embryo with DNA virtually identical to that of a donor organism. The procedure, known as somatic cell nuclear transfer, had the potential to assist stem cell research in at least one critical way: It suggested that one could produce embryos, and therefore stem cells, that possessed the matching DNA of patients. Scientists viewed this as critical since many believed stem cells needed to have the genetic make-up of patients in order to produce successful cures. In theory, sufferers of a disease could have a genetically-identical embryo created to produce stem cells capable of restoring their tissue. However, given that the research had not advanced to the point that scientists could actually create human embryonic stem cells much less know how

[51] Ibid.

they functioned, the cloning of embryos for this purpose remained a strictly academic exercise.

Politically, cloning for either reproduction or embryo research remained deeply controversial. Shortly after Dolly's birth announcement, President Clinton issued a directive banning federal funding for human reproductive cloning, despite the fact that two earlier laws, including the Dickey Amendment and Clinton's 1994 directive, arguably had done this already.[52] Clinton also instructed his newly created National Bioethics Advisory Commission, formed the previous year to explore ethical questions surrounding human subjects in research and the use of genetic information, to change course and review issues in cloning via cell nuclear transfer.[53] Members of Congress also held hearings and proposed a ban on human reproductive cloning similar to the one passed by countless countries and the United Nations.[54]

Stem Cell Breakthrough

After more than a year in which politicians, journalists and the public chewed on cloning, scientists in November 1998 announced the most far reaching stem cell discovery to date: Research teams led by James Thomson and John Gearhart, of the University of Wisconsin and Johns Hopkins, respectively, announced that they had derived pluripotent stem cells from human embryos.[55] To date scientists had only found success using primate embryos. "To most of the scientific community and to the public

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[52] Office of the White House Press Secretary, "Memorandum for the Heads of Executive Departments and Agencies," March 4, 1997; Members of Congress would propose numerous bans on reproductive cloning in the years that followed, but none of these would succeed because opponents of embryo research wanted to include a ban on research cloning in any such proposal.
[53] US Executive Office of the President, National Bioethics Advisory Commission, Annual Report 1996-1997, (Rockville, Md.: March, 1998).
[54] Seelye, Katharine, "GOP Lawmaker Proposes Bill to Ban Human Cloning," *The New York Times*, March 6, 1997.
[55] Wade, Nicholas, "Scientists Cultivate Cells at Root of Human Life," *The New York Times*, November 6, 1998.

at large, Thomson's announcement about human embryonic stem cells was stunning," wrote Harold Varmus, the Nobel Prize-winning director of NIH, in his 2009 memoir.[56] Indeed, after discussing stem cells for years as a mere hypothetical, the successful derivation opened a new door in the race to cure some of the world's most devastating diseases.

Government officials proceeded cautiously following the stem cell discovery. When Massachusetts biotechnology firm Advanced Cell Technology announced that its scientists had created stem cells by cloning a human cell with the use of a cow egg, President Clinton described himself as "deeply troubled," and directed the National Bioethics Advisory Commission to look into the matter, as well as embryonic stem cell research in general.[57]

In the wake of the Thomson and Gearhart discovery, Varmus and policymakers at NIH spied an opportunity: As foreign scientists and non-federally-funded researchers in the United States began to replicate the discovery by extracting stem cells from human embryos, Varmus wanted NIH to find a way to extend federal funding within the current legal constraints. He wagered this was possible so long as the NIH-endorsed experiments strictly limited to already-existing stem cell lines. "Since no further damage would be done to human embryos by working with the newly-produced stem cells, there was no reason to think that federal funding of the research would violate the Dickey-Wicker Amendment."[58] Critically, Varmus made the distinction between the act of deriving stem cells from embryos, which the Dickey Amendment clearly prohibited, and of utilizing the cells in research. Of course, such a view rested on the assumption that a stem cell did not itself constitute a human embryo.

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[56] Varmus, Harold, *The Art and Politics of Science* (New York and London: W.W. Norton, 2009), 218.
[57] Wade, Nicholas, "Clinton Asks Study of Bid to Form Part-Human, Part-Cow Cells," *The New York Times*, November 15, 1998.
[58] Ibid, 219.

Tensions would flare for weeks and months over Varmus' distinction, as research critics insisted that the Dickey Amendment prohibition extended not simply to derivation but to the utilization of stem cells. Proceeding with caution, Varmus decided to seek a legal opinion, and contacted Harriet Rabb, General Counsel of NIH's parent division, the Department of Health and Human Services. It would fall to Rabb and her legal team to determine what the law said.

Rabb Opinion

Varmus' request landed in late 1998 on the desk of Marcy Wilder, Harriet Rabb's deputy counsel whose legal portfolio at HHS included NIH issues and other health matters. As one of three deputies, Wilder under Rabb's direction drafted the memorandum providing the department's legal opinion. "The question was asked: What are we permitted to do?" Wilder recalled.[59] Working in collaboration with Rabb, Wilder said the two spent about two months crafting a memo that provided an answer. Together they considered various interpretations of the law and searched for the best reading.[60] The first sentence of the memo's summary answer revealed the document's main thrust: "The statutory prohibition on the use of funds appropriated to HHS for human embryo research would not apply to research utilizing human pluripotent stem cells because such cells are not a human embryo within the statutory definition."[61] Like Varmus, the Rabb memorandum clearly distinguished between stem cells and the human embryos destroyed to produce them. Such a distinction would allow federally-funded researchers to utilize stem cells, but not to derive them.

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[59] Wilder, Marcy, Interview, April 13, 2010.
[60] Ibid.
[61] Rabb, Harriet, "Federal Funding for Research Involving Human Pluripotent Stem Cells" (U.S. Department of Health and Human Services, January 15, 1999), 1.

The case made in the memo reflected a close reading of key legal texts with a lengthy discussion of definitions. Starting with the language of the Dickey Amendment (see Table 6.4 The Dickey Amendment to the Fiscal Year 1996 Budget), Wilder and Rabb explored the statutory definition of "embryo." While the text defined an embryo as an organism, Wilder and Rabb noted that it failed to define the word "organism," and provided one from a scientific dictionary.[62] Defining an organism as an "individual constituted to carry out all life functions," Wilder and Rabb argued that stem cells did not constitute organisms because they lacked the capacity to function on their own or to develop into an organism that could.[63]

The memo also stated that stem cells fell short of the commonly accepted definition of an embryo: "Pluripotent stem cells do not have the capacity to develop into a human being, even if transferred to a uterus."[64] Therefore, Wilder and Rabb affirmed the legal distinction between stem cells and embryos. Furthermore, if stem cells were not embryos, the authors reasoned that the Dickey Amendment's prohibition would not stop federally-funded researchers from utilizing stem cells.[65]

But the Rabb opinion sparked considerable opposition among those who believed the Dickey Amendment prohibited embryonic stem cell research. Moreover, critics considered Rabb's finding a loophole which contravened the intended meaning of the amendment.[66] "They will destroy the embryos with private funds and experiment on the tissue with public funds," summarized Richard Doerflinger of the Conference of

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[62] Rabb, Harriet, "Federal Funding for Research Involving Human Pluripotent Stem Cells" (U.S. Department of Health and Human Services, January 15, 1999), 2; *McGraw-Hill Dictionary of Scientific and Technical Terms*, 5th Edition, (New York: McGraw-Hill, 1994).
[63] Rabb, 2.
[64] Ibid, 2-3.
[65] Wilder, Marcy, Interview, April 13, 2010.
[66] Wade, Nicholas, "Government Says Ban on Human Embryo Research Does Not Apply to Cells," *The New York Times*, January 20, 1999.

Catholic Bishops in a statement.[67] Further to the point, 70 members of Congress signed on to a February 11, 1999, letter to HHS Secretary Donna Shalala, challenging the opinion: "Any NIH action to initiate funding of such research would violate both the letter and the spirit of the federal law banning federal support for research in which human embryos are harmed or destroyed," the letter stated. [68] Authors faulted the Rabb opinion for its narrow definition of the embryo, saying it was not supported by the law.

Under attack from anti-research partisans, Shalala responded in a February 23, 1999, letter, defending the department's interpretation of the law. Specifically, she noted that the Rabb opinion utilized a definition of embryo provided in the statute itself.[69] Shalala also reaffirmed the distinction between research to derive stem cells and research utilizing them at a different stage. "There is nothing in the legislative history to suggest that the provision was intended to prohibit funding for research in which embryos – organisms – are not involved," Shalala wrote.[70] HHS stood by the findings of the Rabb opinion.

NIH Guidelines

With the legal question answered, NIH moved to draft guidelines, the required protocol which investigators had to follow in order to obtain federal funds. Following the release of the initial draft in 1999, the agency finalized the rules in 2000.[71] Drafted by a working group of the advisory committee to the NIH director, the guidelines reaffirmed that

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[67] Ibid.
[68] Dickey, Jay et al, "Letter to HHS Secretary Donna Shalala," February 11, 1999, from Johnson, Judith, *Stem Cell Research*, CRS Report for Congress (Washington, D.C.: Library of Congress, January 10, 2001), 5.
[69] Shalala, Donna, "Letter to Jay Dickey et al," February 23, 1999, from Johnson, Judith, *Stem Cell Research*, CRS Report for Congress (Washington, D.C.: Library of Congress, January 10, 2001), 5.
[70] Ibid.
[71] US Department of Health and Human Services, NIH, "National Institutes of Health Guidelines for Research Using Human Pluripotent Stem Cells," *Federal Register* 65, no. 166 (August 25, 2000), 51976-51982.

researchers could utilize stem cells derived from embryos left over from fertility treatments, but not derive them themselves or utilize stem cells derived in any other manner. Grantees would need to submit detailed information about the source of their stem cells, including details of the derivation and procurement. The rules also required confirmation of the informed consent of donors and a guarantee that donations occurred for fertility purposes and without monetary inducements. In total, grantees would need to gain approval from four review boards, one at their home institution and three at NIH.[72]

During the guideline drafting phase, research opponents raised repeated objections. Moreover, even supporters of research disagreed about the best way to proceed. In a surprising turn, President Clinton's own National Bioethics Advisory Commission, which strongly supported stem cell research, acknowledged the appearance of contradiction in Rabb's distinction between deriving and utilizing stem cells. "We ought not hide behind the idea that this is just use," said panelist Alexander Capron on the day the committee voted on its position. "That is what the NIH tried to do, but I don't think it will convince the people who need to be convinced."[73] Clearly, the technology remained problematic for both supporters and opponents.

Controversy over how to proceed was also reflected in the question of timing. Numerous observers have argued that NIH officials under Clinton could have implemented the policy as soon as the guidelines were completed in August 2000, five months before George W. Bush took office—an assertion that some Bush officials agreed with, seeing the delay as intentional. "They could have started funding right

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[72] Wade, Nicholas, "New Rules On Use Of Human Embryos In Cell Research," *The New York Times*, August 24, 2000.
[73] Wade, Nicholas, "Advisory Panel Votes for Use of Embryonic Cells in Research," *The New York Times*, June 29, 1999.

away," said Jay Lefkowitz, a Bush aide from January 2001.[74] On the other hand, other observers such as former NIH scientific administrator Arlene Chiu described the timetable as reflecting the normal deliberations of establishing a policy and process to implement funding.[75] Patient advocates watching the process carefully largely agreed. "That's just the normal inertia of bureaucracy at NIH," said former Juvenile Diabetes Research Foundation President Peter Van Etten.[76] In any case, as 2000 drew to a close the framework for federally funded stem cell research was not slated to take effect until the next president assumed office.

[74] Lefkowitz, Jay, Interview, April 16, 2010.
[75] Chiu, Arlene, Interview, October 7, 2010; Wade, Nicholas, "New Rules On Use Of Human Embryos In Cell Research," *The New York Times*, August 24, 2000; US Department of Health and Human Services, NIH, "National Institutes of Health Guidelines for Research Using Human Pluripotent Stem Cells; Correction," *Federal Register* 65, no. 225 (November 21, 2000), 69951; US Department of Health and Human Services, NIH, Office of the Director, "Approval Process for the Documentation of Compliance with NIH Guidelines on the Use of Human Pluripotent Stem Cells in NIH Research Proposed for Support Under Grants and Cooperative Agreements," November 21, 2000; US Department of Health and Human Services, NIH, "Approval Process for the Documentation of Compliance with NIH Guidelines on the Use of Human Pluripotent Stem Cells in NIH Intramural Research," January 16, 2001.
[76] Van Etten, Peter, Interview, September 15, 2010.

6.4 The Policy Design: Bush Deliberates (2001)

Early Days

PRESIDENT GEORGE W. BUSH
Party: Republican In office: 2001-2009 Reputation: Elected by a razor-thin margin of 537 votes in Florida, and in spite of losing the popular vote overall, President Bush commenced his first term in 2001 with vaguely centrist assurances that he would govern from the center in keeping with the "compassionate conservatism" pledged during the campaign. However, various ideological pressures within Bush's own party later ushered in a distinct and conservative agenda on social policy and morality issues. Bush's decision on embryonic stem cell research represented an early struggle over how to achieve the right balance. Although many critics would later deride Bush for inhibiting or ignoring science, some of his decisions actually bolstered research, such as carrying out the planned doubling of NIH's budget.

SOURCE: See note[77]

When President Bush entered the Oval Office in January 2001, human embryonic stem cell research was not a high priority. While the issue had generated considerable interest in the biomedical community and among religious conservatives, news outlets covered it infrequently and the issue received little attention in the 2000 presidential campaign. Although some critics had warned that a Bush victory could slow or stop progress in the fight to cure various illnesses, perhaps the only statement given directly by the candidate came in a questionnaire from the United States Catholic Conference, in which Bush affirmed the group's position: "Taxpayer funds should not underwrite research

[77] Peele, Gillian, "Electoral Politics, Ideology and American Social Policy," *Social Policy and Administration* 39, no. 2 (April 2005), 150–165; Edwards, George, and King, Desmond, *The Polarized Presidency of George W. Bush* (Oxford: Oxford University Press, 2007).

that involves the destruction of live human embryos."[78] Providing only the rudiments of a position on the issue, Bush's statement failed to weigh in meaningfully on the stem cell debate.

After Bush took office, a coalition of pro-life organizations began lobbying the administration to block implementation of the policy, describing the destruction of human embryos as immoral and challenging the Rabb opinion as illegal.[79] As it stood, NIH planned to begin distributing grants for stem cell research later that year. However, social conservatives represented a key interest group that had played a pivotal role in Bush's election. Although the former Texas governor campaigned as a "compassionate conservative" and emphasized his centrist appeal, Bush won the GOP nomination with the support of the party's right wing. Besides espousing conservative positions on economic and foreign policy, he agreed with party chiefs on many social issues, but especially abortion.

Therefore, when activists asked the new president to halt experiments on embryos they had every hope, and some expectation, that he would listen. And to some extent he did. Speaking with reporters in late January, 2001, Bush hinted at a general opposition to stem cell research that destroyed human embryos, with aides promising to review the policy.[80]

But just as conservatives made their requests, research supporters quietly but firmly mounted a vigorous defense of the technology. Although wary at first about pushing too hard, scientists and patient groups worked existing channels and leaned on

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[78] Fox, Michael J., "A Crucial Election For Medical Research," *The New York Times*, November 1, 2000; Lefkowitz, Jay, Interview, April 16, 2010; Toner, Robin, "Bush Caught In the Middle On Research On Stem Cells," *The New York Times*, February 18, 2001; Toner, Robin, "Bush Caught In the Middle On Research On Stem Cells," *The New York Times*, February 18, 2001.

[79] Stolberg, Sheryl Gay, "Transition In Washington: Research And Morality: Stem Cell Research Advocates in Limbo," *The New York Times*, January 20, 2001.

[80] Ibid; Lacey, Marc, "Bush to Attend Democratic Caucuses," *The New York Times*, January 27, 2001.

one of their strongest advocates inside the administration: Tommy Thompson, the new Secretary of HHS, who as Wisconsin's governor had publicly praised the stem cell breakthrough discovery of fellow Wisconsinite James Thomson.[81]

The President Pauses

As public controversy grew, the issue's complexity became apparent and the White House refrained from making further comments. Bush had already stated on the record that he opposed harming human embryos. On its face, acceding to conservative demands made sense politically, even if it meant fighting the inertia of a policy already set in motion by the Clinton Administration. However, the push-back from research advocates made it clear that a restrictive position would have clear political costs. Although the President was not known for his forceful science advocacy, he was not considered an enemy of academic research either, and in fact would later tout achievements such as completing a long-term doubling of NIH's budget begun in earlier years.[82]

Describing the sense of pause inside the White House, Presidential aide Jay Lefkowitz paraphrased Bush's thought process at the time: "It was, 'wow, this looks like a big issue. This looks like one we haven't really thought much about. Let's really learn up on it.'"[83] Indeed, Bush's earliest statements to the press on stem cell research in January 2001 contained the kind of basic (and perhaps understandable) inaccuracies of someone who had not examined the issue in detail.[84]

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[81] Stolberg, Sheryl Gay, "Transition In Washington: Research And Morality: Stem Cell Research Advocates in Limbo," *The New York Times*, January 20, 2001.
[82] Lefkowitz, Jay, Interview, April 16, 2010.
[83] Ibid.
[84] Lacey, Marc, "Bush to Attend Democratic Caucuses," *The New York Times*, January 27, 2001.

Bush's refusal to take immediate action temporarily buoyed researchers.[85] But religious conservatives expressed frustration. Conference of Catholic Bishops spokesman Richard Doerflinger protested that the President had already indicated his support for the group's position. "We are anxiously waiting for action based on that stance," the *New York Times* quoted Doerflinger as saying.[86] Another group, the American Life League, began to question whether it still had the President's support after all. "I think the president is having second thoughts," said spokeswoman Judie Brown.[87] Looking back on the matter, former Bush aide Jay Lefkowitz said that the President had made no firm commitments relating to embryonic stem cell research on the campaign trail.[88] In any case, during the first months of the administration, White House officials were seeking room to maneuver, and they would need it.

Reviewing Rabb

After the early warning shots from rival camps, the White House began working behind closed doors to determine the President's position. The obvious policy options included: taking no action and allowing NIH to implement the proposed Clinton policy as planned; revising the measure; or, blocking it entirely. As it stood, NIH had planned to accept stem cell funding applications through mid-March, with approval pending later that spring. Therefore, the White House would need to act quickly if it planned to act at all. Moreover, in early March a pro-life organization seeking to match frozen embryos with adoptive parents filed suit against HHS to block the policy, an event which

[85] Toner, Robin, "Bush Caught In the Middle On Research On Stem Cells," *The New York Times*, February 18, 2001.
[86] Ibid.
[87] Ibid.
[88] Lefkowitz, Jay, Interview, April 16, 2010.

Lefkowitz said helped spur the White House's involvement.[89] In any case, Bush officials would have until the spring to take action or else decline the right to do so.

After stem cells landed on the agenda, Deputy Chief of Staff Joshua Bolton needed a staff lawyer to review the legal issues involved and to brief the President on his options. So Bolton tapped Lefkowitz, his long-time friend who was serving as General Counsel to the Office of Management and Budget (OMB). While officials had announced publicly that HHS would review the Clinton stem cell policy, Lefkowitz conducted his investigation separately on behalf of the President, and out of the public eye. "He [Bush] wanted it to be very, you know, quiet," said Lefkowitz, who spent several weeks reviewing the statutory history and the Rabb opinion, and speaking informally with attorneys in the Departments of Justice and HHS.[90] Lefkowitz, who often worked up to 14 hours per day at the White House, estimated that he spent about two hours a day on stem cell research at the time.

In the end, Lefkowitz determined that the Rabb opinion stood on firm legal ground. "It was probably the right answer as a legal matter," he said.[91] But the finding did not mean that Bush endorsed the proposed Clinton policy, only that officials would not challenge its legality. Indeed, addressing the matter in later years, Bush officials asserted that the Rabb opinion had violated the spirit of the Dickey Amendment, if not the letter.[92]

Some observers have described the Rabb opinion as creating a political problem for President Bush, in that he would have to take credit—or blame—for any change in

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[89] US District Court for the District of Columbia, "Nighlight Christian Adoptions Et Al V. Thompson," March 8, 2001; Lefkowitz, Jay, "Stem Cells and the President - An Inside Account," *Commentary*, January 2008.
[90] Lefkowitz, Jay, Interview, April 16, 2010.
[91] Ibid.
[92] The President's Council on Bioethics, *Monitoring Stem Cell Research* (Washington, D.C., January 2004); Lefkowitz, Jay, "Stem Cells and the President - An Inside Account," *Commentary*, January 2008.

stem cell policy, rather than looking to the law for justification. "If the law provided a way out for the Bush administration they would have taken that path," said Marcy Wilder, the HHS attorney under President Clinton who drafted the Rabb opinion. "Because it would have been much easier to say, in fact, this is not permitted by the law, and we're done."[93] Indeed, finding a legal error in Rabb would have allowed Bush to halt the proposed Clinton policy without taking responsibility for the change, pleasing conservatives while shielding the President from inevitable criticism. But, as White House officials determined, they would have to base any policy change on Bush's own preferences, not the law.

Briefing the President

After the White House assessed its legal options, officials were in no hurry to weigh in. Indeed, the only hint of the administration's direction came when the Department of Health and Human Services (HHS) directed NIH to delay the panel reviewing grant proposals for several months.[94] From March to July, White House staff worked quietly behind the scenes to prepare the President to make a decision. Former aides described the President's activities as part of a "highly unusual process of deliberation" in which Bush received information and memoranda on subjects as diverse as philosophy and molecular biology; met with experts and interest group activists; and, convened small, informal meetings with his top advisors.[95]

Following his legal review of the Rabb opinion, Lefkowitz served as the President's top aide on the issue. After an initial meeting with the President, he began writing memos for Bush, whom he described as an eager student: "A day rarely passed

[93] Wilder, Marcy, Interview, April 13, 2010.
[94] Wade, Nicholas, "Grants for Stem Cell Work Are Delayed," *The New York Times*, April 24, 2001.
[95] Lefkowitz, Jay, "Stem Cells and the President - An Inside Account," *Commentary*, January 2008.

when he did not call with a follow-up request or a question about something he had read."[96] One morning Bush called at 6:30 am, and Lefkowitz' wife had to fetch the aide from the shower. Overall, Lefkowitz met with Bush an estimated 20 times or more, including half a dozen sessions alone with the President.[97] Other White House staff members discussed stem cell research with the President too, usually in the presence of Lefkowitz. They included White House Chief-of-Staff Andrew Card; Counselor Karen Hughes, a long-time aide; and, Senior Adviser Karl Rove, the President's senior aide, longtime political adviser and "architect" of his re-election.[98]

In June, the White House team began blocking off regular sessions for the President to meet with stakeholders and experts in the field. Guests advocating for stem cell research included staff members of the Juvenile Diabetes Research Foundation, and some of the nation's most prominent scientists: Douglas Melton, the research biologist and co-director of the Harvard Stem Cell Institute; John Mendelsohn, a cancer specialist from the University of Texas; and two top-level researchers on diabetes from NIH, Ron McKay and Allen Spiegel. Visitors opposed to the research included members of the National Right to Life Committee and the Conference of Catholic Bishops. The President also met with bioethicists Leon Kass of the University of Chicago, Daniel Callahan of the Hastings Center for Bioethics and Leroy Walters of Georgetown University. Additionally, aides said Bush discussed the issue with virtually everyone he encountered, including people of diverse age and rank, and nearly every member of his cabinet.[99]

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[96] Ibid.
[97] Lefkowitz, Jay, Interview, April 16, 2010.
[98] US Executive Office of the President, "President Bush Thanks Americans in Wednesday Acceptance Speech."
[99] Lefkowitz, Jay, "Stem Cells and the President - An Inside Account," *Commentary*, January 2008.

Caught in the Middle

The issue moved from behind the scenes to center stage in June 2001. As the summer approached, partisans made their case in the media, and members of Congress and the public started to weigh in, and the President found himself in an increasingly difficult position. Allowing the proposed Clinton policy to move forward would upset social conservatives who insisted he had committed himself to defending unborn life. However, blocking the policy would galvanize the medical establishment against him, and anger countless voters hoping to see cures for the most perplexing diseases.

Despite the political pressure bearing down on Bush, Lefkowitz insisted that politics did not play a large role in decision-making. After all, any action seemed destined to upset one faction or another: "I think from the president's perspective it was kind of a loser issue politically, and it was just a question of doing what he thought was right," Lefkowitz said.[100] In his own account, Lefkowitz wrote that the President once swatted away a polling report, which apparently showed that the country opposed research on human embryos, when a National Right to Life activist handed it to him: "This is too important an issue to take polls about. I am going to decide this based on what I believe is right," Lefkowitz recalled Bush saying.[101] Similarly, the New York Times from the period recounted the President insisting that the issue was "way beyond politics."[102]

However, the notion that political considerations were not a significant factor in White House decision-making is problematic, at least in terms of how stem cell research had arrived on the President's agenda at a time when the proposed Clinton policy was

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[100] Lefkowitz, Jay, Interview, April 16, 2010.
[101] Ibid.
[102] Alvarez, Lizette, "61 Senators Call for Stem Cell Research," *The New York Times*, July 21, 2001.
[102] Lefkowitz, Jay, Interview, April 16, 2010.

set to take effect. Indeed, the President had said almost nothing about the issue during the campaign or after taking office, and only did so after social conservatives raised the matter. Given that Bush provided no independent indication at the time that he objected to the NIH policy, one could plausibly assume that he would have allowed it to move forward if supporters had not pressed him. However, conservatives *did* lobby him, and the potential loss of this key constituency arguably played a significant, if not critical, role in driving the issue on to the President's agenda.

6.5 The Policy Execution: Bush's Decision (2001)

Politics also seemed to factor significantly into White House activities after stem cell research landed on the agenda in June. Some officials clearly aimed to syncopate the President's response with the pulse of key constituencies. As conservatives stepped up pressure in June, one lobbyist explained that Karl Rove wanted to win the Catholic vote in upcoming elections: "I've talked a little with Karl Rove," said Conference of Catholic Bishops spokesman Richard Doerflinger. "He is concerned about the views of the Catholic Church on these issues because Catholic voters are seen as such a swing vote in the elections."[103] With an eye on re-election, Rove indicated that the stem cell issue could have major consequences.

The White House also felt pressure from the other side, from patient advocates not necessarily considered his political base. One activist warned that Bush would have trouble finding a credible scientist to lead the NIH if he banned funding for embryonic stem cell research.[104] While it remains unclear how much officials were listening, one research supporter inside the White House, HHS Secretary Tommy Thompson, told

[103] Pear, Robert, "Bush Administration Is Split Over Stem Cell Research," *The New York Times*, June 13, 2001.
[104] Ibid.

associates that the longer the President waited to make a decision the more likely it was that he would fund some kind of stem cell research.[105]

Patient advocates were arguably the strongest constituency backing research, given that stem cell research remained in its early stages and had not garnered significant attention from industry. Carl Feldbaum, who served as President of the Biotechnology Industry Organization (BIO) during this time remembered urging the White House to "keep the door open," but acknowledged that industry did not play a central lobbying role.[106]

Although polls showed Americans split over stem cells if they had any opinion at all, one political factor the White House clearly did not ignore was the on-going drop in the President's approval ratings.[107] A New York Times-CBS News poll placed Bush's approval at 53 percent, down seven points from March.[108] Although his support remained solid, critics, including some within the President's own party, took aim at the White House for swinging too far to the right, and for relying too heavily on political adviser Karl Rove in making decisions. "We're not unconcerned," said spokeswoman Mary Matalin in July, adding that the administration planned to "recalibrate" its strategic approach.[109]

Some pushes in support of research came from close to home. Nancy Reagan, whose husband former President Reagan famously suffered from Alzheimer's disease, lobbied Bush in support of stem cell research, along with top former Reagan advisers,

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[105] Stolberg, Sheryl Gay; and David E. Sanger, "Bush Aides Seek Compromise On Embryonic Cell Research," *The New York Times*, July 4, 2001.
[106] Feldbaum, Carl, Interview, September 2, 2010.
[107] Clymer, Adam, "Wrong Number; The Unbearable Lightness of Public Opinion Polls," *The New York Times*, July 22, 2001.
[108] Berke, Richard L.; Elder, Janet, "Bush Loses Favor Despite Tax Cut and Overseas Trip," *The New York Times*, June 21, 2001.
[109] Berke, Richard L.; and, Bruni, Frank, "Crew of Listing Bush Ship Draws Republican Scowls," *The New York Times*, July 2, 2001.

Kenneth Duberstein and Michael Deaver.[110] Within the White House, Chief-of-Staff Andy Card also conveyed his support, having witnessed his late parents' suffering from Parkinson's and Alzheimer's diseases. And, of course, the President himself had lost his sister Robin to leukemia during his boyhood.[111]

As the weeks drew on, stem cell research would divide members of the GOP, and not simply along abortion lines. Several pro-life Republicans in the Senate stepped forward to endorse the proposed Clinton policy, including Orrin Hatch, Strom Thurmond and John McCain. By late July, at least 61 senators, and possibly as many as 75, publicly endorsed some form of embryonic stem cell research.[112]

Although former aides downplayed the effect that this growing pressure from both sides was having on the president, Bush's turmoil over stem cell research soon became conspicuous.[113] In fact, some commentators observed the famously easy-going president looking somewhat tense.[114] Inside the White House, aides witnessed Bush going back and forth on the issue. "It's come up in economic policy meetings," said one White House official. "He says, 'Hold on,' and we get back into stem cell."[115] In early July, after a full month of deliberation, reporters asked the President when he would make a decision. "In a while," he said.[116] A few days later, Bush told aides in a meeting

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[110] Bruni, Frank, "From Nancy Reagan, a Nod Toward Embryonic Stem Cell Research," *The New York Times*, July 13, 2001.
[111] Bruni, Frank, "Bush Weighs a Decision on Stem Cell Research Amid Reminders of Suffering," *The New York Times*, July 8, 2001.
[112] Alvarez, Lizette, "61 Senators Call for Stem Cell Research," *The New York Times*, July 21, 2001.
[113] Lefkowitz, Jay, Interview, April 16, 2010.
[114] Dowd, Maureen, "The Relaxation Response," *The New York Times*, July 4, 2001.
[115] Bruni, Frank, "Bush Weighs a Decision on Stem Cell Research Amid Reminders of Suffering," *The New York Times*, July 8, 2001.
[116] Stolberg, Sheryl Gay; and David E. Sanger, "Bush Aides Seek Compromise On Embryonic Cell Research," *The New York Times*, July 4, 2001.

that he needed more time: "I'll make up my mind when I make up my mind -- and then I'll tell you," a staff member recounted.[117]

A Way Forward

As Bush agonized over his options under pressure from polarized factions, the fundamentals of his policy began to emerge. One piece involved the number of stem cell lines researchers would need to do their work. In theory, stem cells are immortal and scientists can extract an unlimited number of cells from a single line. While researchers said they only needed a finite number, no one knew exactly how many. While some researchers described 10 to 15 lines as sufficient, others placed the number between 100 and 1,000 due to the potentially different effects each type could have.[118] Regardless, the White House knew from a relatively early period that an unlimited number was not needed to achieve success.

The notion of limiting the supply of stem cells allowed for the second major policy component: placing a temporal limit on derivations, or permitting federal researchers to use stem cell lines derived only before a certain date. This would allow the President to say that he did not support the further destruction of embryos. The idea became a common parlance in June, and by July, White House staff were discussing various compromise proposals.[119] Although some social conservatives denounced using even cell lines created in the past as unethical, some suggested that they could live with

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[117] Bruni, Frank, "Bush Weighs a Decision on Stem Cell Research Amid Reminders of Suffering," *The New York Times*, July 8, 2001.
[118] Sanger, David, "Bush Leans Against Support for Stem-Cell Research, Aides Say," *The New York Times*, June 22, 2001; Pear, Robert, "Bush Administration Is Split Over Stem Cell Research," *The New York Times*, June 13, 2001.
[119] Ibid; Stolberg, Sheryl Gay; and David E. Sanger, "Bush Aides Seek Compromise On Embryonic Cell Research," *The New York Times*, July 4, 2001.

the notion of a temporal line being drawn.[120] "It would not jeopardize his standing as a pro-life president," said Richard Land, president of the Southern Baptist Convention's Ethics and Religious Liberty Commission, told the *New York Times*.[121] For Bush and his political advisers, limiting funds to cell lines derived after a set point in time represented a strategy that could preserve the support from the conservatives he needed to win reelection.

Only a few days before he announced his decision, the President held a final round of meetings. On August 2, he met in the Oval Office with NIH officials, including Allen Spiegel, who served as director of the National Institute of Kidney, Diabetes and Digestive Disease, one of the largest and most powerful divisions of NIH. Spiegel remembered the mid-day meeting well. "My own speculation has always been that [White House officials] had made up their mind when they invited us in," said Spiegel, who sat on a sofa a few feet away from the President during the 45-minute long meeting.[122] Sitting at the head of the group in twin armchairs were Bush and Lana Skirboll, a former biologist and head of the NIH's Office of Science Policy. Looking back, Spiegel said the most interesting interaction between NIH and the White House was taking place behind the scenes. Skirboll had been working furiously to provide the White House with a concrete number of cell lines already in existence.[123] While the issue of viable stem cell lines would later galvanize countless members of the research community against the President's policy, the White House at the time was attempting to please this constituency, or at least minimize its disappointment.

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[120] Stolberg, Sheryl Gay; and David E. Sanger, "Bush Aides Seek Compromise On Embryonic Cell Research," *The New York Times*, July 4, 2001.
[121] Toner, Robin, "Conservatives Pressure Bush In Cell Debate," *The New York Times*, July 12, 2001.
[122] Spiegel, Allen, Interview, April 15, 2010.
[123] Ibid.

Later in the afternoon of August 2, the President met in the Oval Office with Georgetown bioethicist Leroy Walters, who just a few days earlier had agreed to cut short his vacation in South Carolina after his assistant received a call from Karl Rove, requesting his presence.[124] Viewing the opportunity as one he could not pass up, Walter met with Bush, gave a brief presentation on the President's options and urged him not to ban federal funding outright, saying it would discourage scientists and disillusion those seeking medical cures.[125] Throughout the discussion, aides made a series of comments that, in retrospect, revealed the direction of the policy. Officials said NIH had identified 60 stem cell lines, which surprised Walters: "I said 'That's a much bigger number than I have heard from anybody else.'"[126] At the end of the meeting, the men stood, and, according to Walters, Bush said, "I think the president needs to be a moral educator on a topic like this one. And I am going to try to be a moral educator."[127]

The Decision

President Bush announced his decision in a live speech from his ranch in Crawford, Texas, on Thursday, August 9, 2001, at 9 p.m.[128] As his first prime-time televised address since taking office, the speech and its staging reflected either the high-level of public interest or the White House's desire for a bold statement, or both. Drafted by aides Karen Hughes and Jay Lefkowitz, the speech offered a snapshot of stem cell research and the moral arguments in favor and against.[129] The President delicately

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[124] Walters, Leroy, Interview, April 14, 2010.
[125] Ibid; Walters, Leroy, "Three Policy Options on Human Embryonic Stem Cell Research," August 2, 2001.
[126] Walters, Leroy, Interview, April 14, 2010.
[127] Ibid.
[128] Bruni, Frank, "Of Principles And Politics," *The New York Times,* August 10, 2001.
[129] Lefkowitz, Jay, Interview, April 16, 2010.

walked his audience through the subject, revealing his decision only at the end of the eleven-minute address.

The crux of the speech hinged on two questions: Did frozen embryos in a test tube constitute a human life, and did the fact that these leftover embryos would be destroyed anyway justify their therapeutic use?[130] Rather than provide direct answers, Bush framed the arguments. On the first question, the President explained that while one person could view an embryo in a petri dish as something not yet human, another could argue that every human started out as an embryo. On the second question, he noted that some believed spare embryos destined for destruction should be used for a good purpose, while others argued that killing life for any reason is wrong.

Bush answered the questions indirectly. First, he described himself as a defender of life: "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."[131] Next, Bush alluded to potential excesses of science, like human cloning, and warned about the need for moral vigilance: "Even the most noble ends do not justify any means."[132] Both points affirmed the need to draw a moral line.

Bush described the contours of that line in the speech's denouement. NIH had informed him that approximately 60 stem cell lines already existed worldwide, Bush said. The President would allow federal funding only for research on those lines going forward. In other words, he would adopt the proposed Clinton policy, but with a strict deadline for derivations. "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

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[130] Bush, George W. (Crawford, Texas, August 9, 2001).
[131] Ibid.
[132] Ibid.

least the potential for life," Bush said. The compromise clearly answered the two questions posed earlier: an embryo constituted a human life, or at least a potential one; and, efforts to battle disease did not justify the further destruction of embryos.

In political terms, the compromise dealt a blow to both sides of the debate, but it also seemed to minimize the damage because each side got something in return. The scientific community lost the more permissive approach proposed under Clinton, but would also see federal funding for the first time. "Frankly, we expected a total ban," said Peter Van Etten, President of the Juvenile Diabetes Research Foundation.[133]

Social conservatives would have to live with research on cell lines made from previously destroyed embryos, but they could take comfort in the prohibition against funding for further derivations. Some secular conservatives also praised Bush for drawing a moral line, including *Washington Post* columnist Charles Krauthammer, who supported stem cell research under certain conditions and would have preferred a more permissive approach than the Bush policy.[134]

Thus, the compromise left Bush in a strong place, at least in the short term, since he could take credit both for promoting research and for defending unborn life. He could maintain his credibility as a pro-life conservative from Texas, while temporarily shielding him from charges of being anti-science. At least in the short term, the decision allowed the President to convert a "political loser" into a "win-win" scenario.

Post-Decision

Some benefits of Bush's speech would not last beyond the short-term. While most conservatives would stand by the President in future years, research advocates had a

[133] Van Etten, Peter, Interview, September 15, 2010.
[134] Krauthammer, Charles, Interview, April 12, 2010.

mixed reaction that would harden into steadfast opposition once the promised 60 stem cell lines failed to materialize. The White House, working with NIH Office of Science Policy Director Lana Skirboll, overestimated the number of viable stem cell lines in existence worldwide, apparently including in the figure embryos not yet derived. Researchers later said the true number of cell lines was closer to 20.[135] Looking back, Spiegel said the President's meeting with NIH officials seemed designed to give the appearance that the NIH itself had signed off on the 60 cell lines. [136] In fact, he said, it was the non-research-oriented Office of Science Policy that did so. NIH scientists were not consulted about the adequacy of the lines.

Less than a month had passed after the decision before opponents began a counter-offensive to modify it. But before such efforts could progress, the terrorist attacks of September 11, 2001 shifted the nation's political agenda to national security and the Middle East. Stem cell research would simmer on the back burner for several years but would galvanize opponents of the President's policy, including patient advocates and the scientific establishment, in the election cycles of 2004, 2006 and 2008. These efforts led to numerous successful state funding initiatives, including those approved by voters in California, New York, Wisconsin, Florida, Texas and Missouri.

Although the directive extended only to work receiving government support, because most proposed stem cell work would have occurred at publicly funded research labs and institutes, it forced many researchers to seek alternate funding or pursue their work outside the United States. And, as scientists such as University of Chicago

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[135] Stolberg, Sheryl Gay, "U.S. Concedes Some Cell Lines Are Not Ready," *The New York Times*, September 6, 2001; Stolberg, Sheryl Gay, "Trying to Get Past Numbers on Stem Cells," *The New York Times*, September 7, 2001.
[136] Spiegel, Allen, Interview, April 15, 2010.

geneticist and Presidential Medal of Freedom winner Janet Rowley pointed out, it also stopped many young investigators from entering the field in the first place.[137]

6.6 Conclusion

Although direct policymaking efforts for human embryonic stem cell research in the US took approximately seven months, the first-generation approach built on the activities of at least the previous decade. Indeed, following more than a dozen years of relative inaction under Presidents Reagan and Bush on the question of funding embryo experimentation, the Dickey budget amendment in 1996 severely restricted the activities that the NIH could lawfully support. Thus, even before stem cells became a reality, NIH was prohibited from supporting research on their raw materials: human embryos.

Following the stem cell discovery in 1998, US officials focused their efforts on negotiating a path for research funding around the constraints of the Dickey Amendment. However, before the NIH could implement the policy, President Bush assumed office, halted the proposal and launched his own effort. Whereas the UK policy built on the work of successive advisory committees, legislative activity and the reputation of the HFEA, the US policy, as a presidential directive, required only a handful of White House officials to draft and a select number of NIH staff to administer. Perhaps most critical of all, key decision-making was concentrated in one person, the President himself, and he opted to fund only experiments using stem cells derived before August 9, 2001.

Given the lengthy timeframe of the case, simplistic explanations of the US policy inevitably fail to address its complexity. However, this chapter highlighted two factors as potentially important in shaping the outcome. The first, public opinion,

[137] Rowley, Janet, Interview, April 19, 2010.

suggests that the US public favored a more restrictive approach, or at least did not oppose it. The second, relating to interest groups, points to the power of religious conservatives to influence the President.

Public Opinion

Although partisans on both sides of the stem cell issue cited poll data showing that the US public supported their position, the majority of Americans arguably had not formed a position on the issue when Bush made his decision.[138] According to press accounts, the wording of poll questions may have affected responses. At a minimum, the length of questions indicated public indecision. "The mere fact that you've got to offer a lengthy summary implies that it's too early to sort it out," pollster Bernard Roshco told *The New York Times*.[139] In other words, public opinion was arguably too premature and under-formed to serve as a guide to Bush's decision-making.

Furthermore, the overwhelming support for stem cell research in later years, as epitomized by the numerous funding initiatives at the state level, suggested that the public was actually predisposed to support the technology and oppose Bush's restrictive approach. Therefore, if the White House was principally concerned about public opinion officials would have likely paused before taking action and possibly embraced a more flexible policy.

Interest Groups

Whereas public opinion provides inconclusive insights, interest groups offer a potentially powerful explanation of the Bush policy. Indeed, this chapter showed how

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[138] Clymer, Adam, "Wrong Number; The Unbearable Lightness of Public Opinion Polls," *The New York Times*, July 22, 2001.
[139] Ibid.

social conservatives played a critical if not decisive role in putting the issue on Bush's agenda. But the view of religious organizations "capturing" government is not without problems. First, Bush's strong support for business and industry suggest that the White House would have avoided decisions that could harm innovation. At the same time, given that stem cell research remained at the very early stages, private-sector investment was minimal. Indeed, with such a limited industry stake, lobbyists held back from wielding their full voice.

The second problem with the view that social conservatives determined the US policy is the fact that leading figures in the anti-research movement rejected Bush's compromise as unacceptable. Judie Brown of the American Life League said Bush "can no longer describe himself as pro-life."[140] On the other hand, other social conservatives were pleased that Bush drew a line on derivations, and begrudgingly accepted the policy. In the end, the President won re-election in 2004 with broad support from religious conservatives. Therefore, social conservatives may have failed to get a ban on all research, but the policy nevertheless reflected their interests.

Thus, interest groups provide a compelling explanation of the immediate political motivation behind the Bush decision. However, they do not account for the historical events that created the context for their influence. Scholars must consider the possibility that earlier developments, such as the passage of the Dickey Amendment in 1996, ultimately enabled Bush to take a restrictive position.

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[140] Toner, Robin, "The President's Decision: The Reaction; Each Side Finds Something to Like, and Not," *The New York Times,* August 10, 2001.

Institutions

Although explanations based on public opinion and interest groups add important insights to the US policy for stem cell research, both have limitations. First, public opinion failed to provide a conclusive measure of the country's sentiment, even if the Bush administration had decided to listen. Second, although interest groups clearly played an indisputable role in compelling Bush to take action, the religious conservatives lobbying the President did not get all that they had wanted, and their efforts in 2001 failed to explain the institutional context that allowed Bush to declare himself "a moral educator."

This study hypothesized that institutions played a critical role in shaping the policy outcome and proposed to look deep within government to highlight such effects. The narrative showed how the Dickey Amendment first emerged in 1995, and initially passed only after the Porter substitute, which would have allowed stem cell research funding in subsequent years, failed by one vote. It also explained how the Dickey law became a fixture in annual budgets thereafter, creating a kind of inertia against future changes.

The permanent addition of the Dickey Amendment to US budgets meant that, following the discovery of stem cells in 1998, Clinton Administration officials were forced to spend numerous months in procedural deliberation, delaying the policy and ultimately deferring the matter to the next president. These events take on even greater historical importance considering that if the Clinton administration had completed its policy earlier and issued research grants before Bush took office the US would have in effect embraced a permissive first-generation policy.

When Bush assumed office he had multiple policymaking options: take no action and allow the proposed Clinton policy to take effect, block the policy or alter it.

Bush chose the latter, and the decision would have important consequences. Most importantly, it would confine decision-making to the White House and prevent other actors, such as the NIH's Office of Science Policy, from playing a direct role in the design and execution of the policy. Finally, because Bush alone had made the decision and refused to make any reversals, future changes became impossible, even when the promised 60 cell lines failed to materialize.

Pierson's Criteria

These findings inside government suggest that institutional context played a significant role in shaping the policy outcome in the US. But how *exactly* did institutions affect outcomes? To answer this question, Chapter One proposed to describe policy development as an increasing returns process that can reveal the early institutional arrangements that drove policymaking later. The following paragraphs apply Pierson's criteria for increasing returns to stem cell research in the US.

Multiple Equilibria

Before the Dickey Amendment became attached to the 1996 budget appropriation for health-related divisions, one could say multiple equilibria existed for the US stem cell policy because no restrictions yet applied to human embryo research. If members of Congress and President Clinton had rejected the amendment NIH could have begun funding stem cell research immediately after the 1998 discovery. Instead Dickey's approval created an impediment before scientists could even take up the work.

Contingency

At least two contingent events in the policy-making process arguably had a large impact later. The first occurred during the 1996 House Appropriations Committee markup session when Congressman John Porter's substitute for his Republican colleague Jay Dickey's more restrictive amendment lost in a tie vote, 26 to 26.[141] If Porter's measure had received one more vote, arguably no constraint on destroying human embryos would have followed, clearing a potential path for stem cell research. Instead, the Dickey Amendment set the context in which a stem cell policy could emerge. The second contingent event concerns the NIH's possible delay in implementing the Clinton stem cell policy. As some insiders noted, completing the guidelines earlier could have allowed the agency to begin distributing grants before the next president took office. In other words, the US could have launched a more permissive policy before President Bush had a chance to unveil a restrictive one.

Timing and Sequencing

The timing and sequencing of events helped to shape the restrictive policy outcome for stem cell research in at least two ways. First, because the Dickey Amendment placed a constraint on embryo research before scientists had even discovered human stem cells, Clinton Administration officials were forced to proceed slowly after researchers succeeded in isolating the cells in 1998. Without the Clinton Administration's lengthy deliberations, Bush would not have had the same opportunity to set the course for stem cell research. Indeed, NIH officials were on track to approve the research when Bush took office in 2001.

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[141] U.S. House of Representatives, "Report of the Committee on Appropriations: Departments of Labor, Health and Human Services, and Education, and Related Agencies Appropriations Bill, 1996" (Government Printing Office, 1995), 213.

Inertia

Two historical episodes suggest that inertia prevented officials from deviating from a policy-making path already set in motion. First, once the House Appropriations Committee approved the Dickey Amendment, it became extremely difficult to remove the measure from subsequent budgets. As former staff members described, the committee retained the amendment in spending bills to avoid the potential delays caused by reopening the matter.[142]

Second, after President Bush unveiled his policy with its strict August 9, 2001, time deadline on derivations, he declined to make any subsequent changes even after learning that the promised 60 viable cell lines had failed to materialize. Bush could have brought the deadline forward to include more derived stem cells, but he refused. Making a further accommodation to research meant potentially upsetting social conservatives, as well as going back on his word. In 2006 and again in 2007, Bush vetoed bills that would have made more lines available.

Extending Path Dependence

These applications of Pierson's criteria suggest that an increasing returns process existed in the development of the US policy for stem cell research. On this basis, one should conclude that the restrictive policy emerged not simply from limited public awareness or powerful pro-life interest groups, but from the passage of the then-obscure Dickey Amendment in 1996 and the subsequent failure to begin funding stem cell research before 2001.

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[142] McCann, Tony, Interview, May 6, 2010.

Although Chapter One described Pierson's criteria as sufficient to reveal the institutional influences in policy development, this study proposed a secondary test of path dependence in order to address the question of variation in specific terms that scholars can assess comparatively. The following paragraphs apply this to the US decision-making structure, the Bush framework, during the policy design and execution phases of the case.

Stem Cell Research: The Policy Design

Actor Constellation. In the US, the 1998 breakthrough discovery of stem cells precipitated the emergence of many new policy actors. These included President Clinton's National Bioethics Advisory Commission (NBAC), which advised the White House on new developments in the biomedical sciences, and the NIH's Office of Science Policy, which oversaw a wide range of publicly funded research activities and produced draft guidelines for stem cell research in 2000.

Despite these key additions to the landscape, however, none of the actors in these groups possessed true decision-making authority or directed the course of the US policy. Indeed, their roles remained strictly advisory. Leading actors in the process included not agency officials but aides in the Clinton and Bush administrations who generally lacked specialist expertise.

Balance of Interests. Although staff at NIH and NBAC possessed considerable knowledge resources in terms of bioethics and institutional planning, the White House-centered model ensured that political considerations took precedence over administrative consensus. Following the 2000 election, President Bush himself directly engaged key interest groups, including both the White House's religious allies and patient advocates. Thus, while various government institutions had the potential to shift

the balance of interests, they were ultimately prevented from doing so. As further evidence of this, scholars may look to Bush's personal forays into bioethics. Rather than turning to scientific experts, the President sought to answer the question himself, by devoting countless hours to a process typically administered by specialists. The final result, of course, meant that Bush's personal priorities took precedence over other concerns.

Stem Cell Research: The Policy Execution

Actor Constellation. Just as the Bush White House centralized decision-making and excluded civil servants from designing the nation's approach to stem cell research, officials executed the policy without a significant expansion in the constellation of actors. While officials at HHS and NIH were tasked with implementing the President's decision, they had no discretion over approvals beyond the President's specific rules which blocked funding for all derivations, and for utilizing stem cells derived after August 9, 2001. The Bush Administration even discarded the stem cell guidelines created but not enacted by NIH under President Clinton, paradoxically creating a very restrictive regime with less oversight than the more permissive approach drafted earlier.

Balance of Interests. Because the White House policy left no opportunity for further discussion among actors, the balance of interests remained essentially frozen from August 9, 2001. In such a climate, arguably the only significant shift would occur years later at the state level, when supporters of stem cell research joined forces to pass legislation to create new funding streams.

Secondary Test of Path Dependence

Based on this analysis one can say that the early path adopted in the US, approval of the Dickey Amendment and the failure of the Clinton NIH to begin funding stem cell research, ensured that subsequent policymaking remained a distinctly political activity in the *de facto* control of the White House.

On this basis, the Bush framework arguably led to very few expansions in actor constellations and no significant shifts in the balance of interests during the design and execution phases of policymaking. Although this development does not singularly explain the US policy, the study suggests that a plausible relationship may exist between the lack of changes in actors and interests and the restrictive outcome. In this way, the secondary test of path dependence provides a specific mechanism for assessing institutional influence along the policy path.

Although it remains unclear what a different institutional context would have produced, one could reasonably conclude that the path taken in the US did not provide a cohesive administrative setting for regulating stem cell research. Chapter Seven, the conclusion, will review this finding more closely in a comparative analysis that addresses the broader question of variation in biotechnology policies.

CHAPTER 7: CONCLUSION

This study began with a puzzle: At the turn of the 21st Century, countries were adopting different policies for the same emerging applications of science and technology. Why did this occur? This study has sought to answer this question, not by asserting a general theory for all emerging technologies, but by exploring specific cases that could shed light elsewhere: agricultural genetically modified organisms (GMOs) in food and human embryonic stem cell (HESC) research, two science applications which resulted in different policies in Britain and the United States.

As earlier chapters have shown, varying policies emerged when GMOs and stem cell research became contested in their respective domestic political systems, with some interests favoring "permissive" policy approaches, while others sought "restrictive" ones. Chapter Two described both controversial technologies as "position issues," because of the diverging opinions generated among various constituencies, as opposed to "valence issues," which imply general consensus on policy positions even if management styles differ. While scholars in other disciplines, such as sociology, might explore how and why these two biotechnologies became position issues in the first place, this study sought to address how governments responded to them, i.e. the decisions made in the form of policy outcomes.

7.1 Findings

While conventional wisdom, journalistic accounts and many scholarly works have emphasized the role of factors external to the government machine—particularly public opinion and interest groups—in driving policy outcomes, this study showed that institutions played a critical role as well. Chapters Three through Six developed this

interpretation by showing that, despite the portrait of polarization described in the introduction, respective approaches to each technology began from roughly similar starting points and then diverged based on specific choices and external events that later had the self-reinforcing effect of "increasing returns."

For GMOs, the study described how in the US, Congress and the EPA nearly took the regulatory lead before the White House established the Coordinated Framework (1986), and advanced GMOs well before public awareness of the issue became significant. In the UK and EU, officials debated a range of legislative and non-legislative approaches, including the concertation of national policies, before launching a decentralized system that would remain incomplete when public opposition peaked in the late 1990s.

For stem cell research, the study showed that Britain came close to banning embryo research before approving the *Human Fertilisation and Embryology Act 1990*, a law which later became an advantageous tool that the government could simply extend to stem cells without passing new legislation. In the US, federally funded embryo research remained viable until the Dickey Amendment ban narrowly passed in 1996 and delayed policymaking efforts until President Bush took office.

After describing how policies developed in diverging directions, the study addressed the implications of those paths. In doing so, the thesis described how the Coordinated Framework and the HFE Act1990 framework played such an essential role in securing the permissive policies embraced for GMOs in the US and stem cell research in Britain that neither technology arguably would have moved forward as quickly—or perhaps at all—without them. In contrast, the study also described how a lack of comparable structures for GMOs in the UK and EU, and for stem cell research in the US, may help account for the restrictive policy results in those jurisdictions.

Regarding GMOs, the Coordinated Framework in the US removed policymaking from direct political influences and empowered expert agency civil servants to craft and execute a permissive policy. Without a similar executive branch effort, US officials would have needed new legislation to oversee GMOs. In the EU, by contrast, reliance on an unfinished framework and DG-Environment-led comitology ensured that civil servants and officials negotiated largely on the basis of domestic political interests, rather than to advance an administrative agenda. Similarly in Britain, when ministers lacked the option to delegate the matter to civil servants, they declined to issue planting licenses for modified varieties already approved in Brussels.

For stem cell research, this study showed how Britain's *Human Fertilisation and Embryology Act 1990* framework provided the blueprint and context for the country's permissive policy in part by creating a trusted regulatory system led by civil servants concerned with administrative questions, not political ones. Without the law's comprehensive provisions and its institutional regulator, the Human Fertilisation and Embryology Authority (HFEA), Parliamentarians would have had to start over, first by passing new legislation, which can take up to several years, and then by creating a new oversight mechanism. In the US, the Dickey Amendment prevented the emergence of a comparable structure. Indeed, by blocking NIH civil servants from playing an oversight role, the amendment ensured that stem cell research would remain in the political domain, where President Bush could impose a restrictive policy.

Evaluating Findings

Findings in this study emerged from the empirical research reported in Chapters Three through Six. As Chapter Two highlighted, qualitative research of this kind inevitably raises issues of reliability and validity, and this study sought to address them by

explaining procedures for collecting replicable data—including elite interviews, discussed in greater detail in Appendix Two—and for ensuring that data captured what they were intended to represent.

However, after compiling reliable and valid evidence, this study must verify that the findings which followed from it produced accurate and objective results. Although this study does not constitute a formal test, scholars of research methods have described numerous approaches to evaluating findings, including the identification of empirical evidence which could potentially disprove—or falsify—results if it existed.[1] Because this study relies on mostly non-numeric data sources to support claims about historical causation, precise testing of research findings is difficult. However, providing relevant counterfactual examples can assist those seeking to disprove, and therefore falsify, hypotheses.[2] The following discussion explores counterfactual hypotheses in reference to each of the cases in this study.

GMOs in the United States

To falsify the claim of increasing returns one would require data showing that the US policy was constant in nature, and that an approach similar to the Coordinated Framework could have emerged in later years, i.e. after public awareness of GMOs had become significant. However, the strong opposition which followed the introduction of food products in the late 1990s would almost certainly have bolstered contemporaneous efforts in Congress to pass legislation. Indeed, with enhanced public scrutiny of the policymaking process, White House officials in any administration would have had difficulty avoiding legislation.

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[1] King, Gary, Keohane, Robert, and Verba, Sidney, *Designing Social Inquiry: Scientific Inference in Qualitative Research* (Princeton, N.J.: Princeton University Press, 1994), 100-105.
[2] Fearon, James, "Counterfactuals and Hypothesis Testing in Political Science," *World Politics* 43 (January 1991).

Falsifying the specific importance attributed to the Coordinated Framework would require data indicating that the permissive policy adopted could have resulted from other means. Since legislation represented the primary alternative to executive branch action, one would need to show that the Congress could have passed, and the President would have signed, a bill providing a similarly permissive policy in a comparable time frame. However, because legislation would have codified GMOs as different by means of the process used to produce them, legislation would have created a different, and almost certainly more restrictive, standard under the law.

The legislative route also could have created numerous uncertainties, given the number of institutional veto players involved in normal legislative procedure. Foes of the technology in the Democratically-controlled Congress, including Congressman (and later Senator) Al Gore, would have likely sought to modify any Republican proposal, and deliberations could have added significant delays to the already lengthy time frame required for most successful bills. Delayed action on GMOs would have meant creating a policy after public opposition had hardened, thereby increasing the likelihood for a restrictive approach.

Britain and Europe

To falsify the claim for increasing returns one would need to show that Europe and Britain's restrictive policy approach was constant in nature, rather than one that developed over time and in response to subsequent decisions and events. However, the initial resolve of Commission officials to approve modified crops and food products from the mid-1990s, and the successful introduction of items such as Zeneca's modified tomato paste in the UK, suggest that the restrictive approach emerged later and after opinion hardened.

Falsifying the claim that a lack of a decision-making structure comparable to the Coordinated Framework resulted in the restrictive EU-UK policy would require showing that a structure like the Coordinated Framework would have produced the same policy result. However, at the time of key policymaking events, such a decision-making structure did not exist among the EU-UK policy instruments. Furthermore, scholars could fairly challenge the attempt to test an outcome in which no actor and interest changes in decision-making structures had occurred. Therefore, rather than attempting to describe a hypothetical entity that yielded a restrictive outcome, this study proposes that one could falsify findings by showing that oversight systems in the EU and UK engendered cohesion, and the kind of changes in actors and interests experienced in the other case.

In the mid-1990s, when producers began to market modified products in stores, large gaps still existed in the regulatory process, including the absence of a scheme for reviewing food safety which all member states accepted. Coupled with Britain and Europe's recent experience with BSE, the incomplete policy bolstered GMO opponents' demand that officials halt approvals. The EU stopped clearing products, the UK declined to issue licenses for previously approved crop varieties, and retail food sellers blocked products from their shelves except in a few cases, and even then still required mandatory labels. Therefore, stresses within the regulatory system cast serious doubt on any claims of institutional cohesion.

Moreover, while one could make a case that biotechnology prompted the appearance of new policy actors in Brussels and London, the balance of interests in policymaking did not shift significantly from the views held by the principal political actors, the member state governments. Although the Commission attempted to approach GMOs from a uniform policy perspective, the Regulatory Committee reflected

expressly political interests. In the United Kingdom, although the government assigned numerous civil servants to the GMOs portfolio, because ministers had maintained authority over consents, they prevented a shift in the balance of interests away from politics.

Stem Cell Research in Britain

To falsify the claim for increasing returns one would need to show that in 2000 Parliament and the government could have passed a measure to allow embryo research, to create a new institutional regulator and to allow work on stem cells in a time frame comparable to the HFE Regulations. However, such a legislative effort would have faced numerous challenges. Most critically, the 1990 Act was the culmination of several years of parliamentary debates on embryo experimentation, primarily within the context of *in vitro* fertilization. Without this policymaking precedent, officials taking up stem cell research would have needed to address fundamental questions settled in 1990: When does life begin? When is experimentation on human life justified? Can the government regulate embryo experiments safely? In other words, before officials could address the question of how to govern stem cell research they would need to forge a policy for embryo research. The presumed lack of answers would almost certainly have added considerable delays to the policy path.

In addition to delaying stem cell research for up to several years, one could argue that the absence of a decision-making structure similar to the 1990 Act framework might have led to a more restrictive outcome overall on two accounts: first, because in 1990 the legislative effort succeeded in part as a result of ministerial maneuvering to include a change in the abortion law; and second, because debates over stem cell research in 2000 and 2001 were predicated on the notion that a strong regulator would

oversee embryo research. Without the abortion tactic or the HFEA in place, officials may not have succeeded in passing legislation in the case of embryo or stem cell research. Although one cannot say with certainty, there is no question that, in addition to placing scientific activity on hold for quite some time, *de novo* action on stem cell research would have required careful government planning and time resources.

United States

To falsify the claim for increasing returns one would need to show that the restrictive approach to stem cell research was constant in nature, rather than one that followed from early decisions and subsequent events and choices. However, as earlier evidence revealed, the Bush decision followed only after the passage of time handed the issue from the Clinton administration to its successor. Indeed, efforts by health officials from the discovery of stem cells indicate that without the encumbrance of the Dickey Amendment, NIH would have made grants immediately.

Falsifying the claim that the lack of a decision-making structure comparable to the HFE Act 1990 contributed to the restrictive US policy would require showing that a structure like the HFE Act 1990 would have produced the same result. However, if such a law had existed, or more likely, no ban had existed on embryo research in 1998, officials in the White House would have faced enormous pressure to extend this activity to stem cell research—and would likely have done so.

Scholars could also fairly challenge the attempt to test an outcome in which no actor and interest changes in decision-making structures occurred. Therefore, rather than attempting to describe a hypothetical entity that yielded a restrictive outcome, this study instead proposes that one could falsify findings by showing that the Bush framework fostered institutional cohesion and the kind of changes in actors and interests

experienced in the other case. However, this is difficult to do considering the heavy constraints placed on US oversight by the Dickey Amendment. As Chapter Six described, officials possessed considerable bureaucratic resources in the form of the NIH, but the Dickey measure prevented the Clinton Administration from utilizing them immediately. Forced to obtain a legal opinion, Clinton officials eventually ruled that a narrow form of stem cell research could move forward.

If officials had begun issuing grants under the Clinton presidency then the lack of changes in actors and interests would have been less apparent. But the process took many months, and as NIH officials prepared to start making limited grants in the final days of Clinton's second term, they ultimately deferred to the new administration. After Bush took office in 2001, officials cited the Dickey Amendment as the justification which allowed the President himself to step forward and adjudicate the bioethical quandaries presented by the research. In the end, the White House altered the proposed Clinton NIH policy by placing a severe time restriction on permissible research. Thus, given the significant constraints in the policy path, one could not fairly describe US regulatory oversight for stem cell research as cohesive.

Furthermore, while one could say that the US stem cell policy introduced new actors to the stage, it failed to shift interests away from partisan political concerns. During the policy design phase, we saw that the President acted alone in setting policy, despite the wealth of research expertise on offer. And because President Bush placed such strong limitations on research, civil servant experts played virtually no role in overseeing stem cells thereafter.

Measuring the Variable

While scholars could propose other counterfactual examples, those listed above represent the principal ways of falsifying the main findings of the study, relating to increasing returns and changes in actors and interests in decision-making structures. But even if one accepts this study's principal findings, other questions emerge, notably the degree of impact: How much institutional influence do increasing returns and actor and interest changes actually reveal? Given the significant role attributed to institutions here, this question merits attention, even in a qualitative study.

Although this study was not intended as a formal test, the research sought to demonstrate that each policy case showed increasing returns along the lines described by Pierson. However, because the approach depends on descriptive history, rather than measurable concepts, weighing the comparative influence of early decisions and subsequent events and choices is difficult.

The study can make a clearer statement with regard to other findings, and concludes that permissive policy outcomes for GMOs in the US and for stem cell research in the UK would not have occurred in the same manner—or perhaps at all—without the changes in actors and interests described. However, although the study suggests that a relationship may exist between the lack of actor and interest changes and restrictive outcomes, due to the difficulty of verifying outcomes in which no changes in actors or interests occurred, the research makes no measurement claim regarding GMOs in the EU and UK or stem cell research in the US.

While some critics could describe these conclusions as anecdotal, this study made every effort systematically to acquire relevant materials and conduct germane interviews. In other words, the work behind its production has been focused and purposeful. Moreover, this study aimed to grasp the contours of these cases in order to

identify variable relationships and an analytical approach to explain them in the first instance. In this way it represents an initial step which further research could potentially follow, for example, with efforts to gain a more precise measuring of the variable. The section below on future research directions takes up this issue in greater detail.

Other Factors

References to the centrality of institutions pose the important question of other causal factors shaping policy outcomes. Does the evidence presented in this study necessarily discount other factors, such as culture or interest groups? No, but in some cases it casts doubt on inaccurate generalizations, such as the notion that the US public generally approved of GMOs or that Britons always strongly opposed them. As earlier chapters pointed out, the existence of consistent but diffuse opposition to GMOs in the US, and the success of some popular early engineered food products sold in Britain, cast considerable doubt on such generalizations. In fact, Chapters Three and Four showed that publics on both sides of the Atlantic did not have a strong opinion about GMOs before successive scares in the late 1990s, following a high profile panic over BSE earlier in the decade.

Regarding interest group influence, the evidence presented here similarly challenges the notion that Britain possessed an ineffective pro-life coalition, and that religious conservatives controlled the policy agenda in the Bush White House. As the research showed, Britain actually possessed a sizeable coalition of pro-life MPs, in the All Party Parliamentary Pro-Life Group, which regularly extracted legislative concessions from governments of both major parties. At the same time, careful parsing of the Bush stem cell policy suggests that the President largely personalized the stem

cell decision, treating the issue as a matter of conscience; and, that leading religious conservatives were largely displeased with the outcome.

As noted earlier, factors other than institutions clearly have a role to play in explaining the observed policy outcomes. Indeed, at distinct moments in time, and within certain institutional contexts, both public opinion and interest groups very obviously mattered. What this study cannot assess is exactly how much. Certainly, it is difficult to imagine restrictive policy outcomes for GMOs in Britain and Europe and for stem cell research in the US without the agency of public opinion and interest groups, respectively. But the way those factors played out was significantly mediated and shaped by the workings of government.

Predictions

Like many works of social science, this study was not carried out with the intention of making predictions. Rather the research aimed to bring new empirical and theoretical material to bear in explaining historical events. Nevertheless, the conclusions offered above may have some predictive application, to the extent that other emerging technologies could become "position issues," with large constituencies both in favor and against.

Indeed, one might see such issues arise over technologies as diverse as livestock cloning, human germ-line engineering, artificial intelligence and synthetic biology. And if these science applications generate a diversity of views, the findings presented in this thesis suggest that changes to actors and interests could promote a permissive policy result. Similarly, countries which fail to create administrative infrastructure which can shelter policymaking from direct political forces could be more likely to adopt restrictive policy regimes. But at the same time, the use of actor and interest changes in

decision-making structures to understand policymaking is an approach which has definite limits, creating challenges and opportunities for further investigation that are briefly discussed below in the section on future research directions.

7.2 Theoretical Conclusions

The above discussion addressed the empirical findings of this study, and attempted to falsify results through counterfactual examples. But what are the implications of this study for the theoretical propositions offered in Chapter One, relating to scholarly debates about new institutionalism, bureaucracy and regulation?

Path Dependence

Most propositions in the study concerned the question of how institutions affected outcomes, and the mechanisms of causation. Chapter One proposed path dependence as the key explanatory mechanism. Although James Mahoney and Kathleen Thelen have described path dependent processes as occurring in only rare cases of institutional change, this study embraced Paul Pierson's assertion that path dependence can apply to situations in which time itself helps to explain political phenomena.[3] Moreover, the study echoes the historical institutionalist perspective of Sven Steinmo, and Theda Skocpol and Pierson, who described the concern with asking "big questions" as an intrinsic value, even if it requires successive layers of scholarship to verify results.[4] Along these lines, the attempt to extend path dependence to biotechnology and science

[3] Mahoney, James, and Thelen, Kathleen, *Explaining Institutional Change: Ambiguity, Agency and Power*, (Cambridge: Cambridge University Press, 2010), 3; Pierson, Paul, *Politics in Time: History, Institutions and Social Analysis*, (Princeton and Oxford: Princeton University Press, 2004).
[4] Steinmo, Sven, "What Is Historical Institutionalism?" In Della Porta, Donatella, and Keating, Michael, *Approaches in the Social Sciences*, (Cambridge: Cambridge University Press), 2008; Pierson, Paul, and Skocpol, Theda, "Historical Institutionalism in Contemporary Political Science," in *Political Science: State of the Discipline*, (New York: Norton, 2002).

governance in this thesis is part of an emerging area of development for this analytic approach.[5]

Pierson's Criteria

In order to provide a rigorous elaboration of path dependence, the study proposed to embrace Pierson's interpretation based on the notion of increasing returns and apply it to biotechnology cases.[6] After detailed tracing of decision-making processes, analyses showed that in each case multiple equilibria existed; that contingent events critically impacted later developments; that timing and sequencing were essential; and that once policies started along a certain path the cost of reversal increased significantly.

Indeed, from systematic analyses this study showed that in each case policies for GMOs and stem cell research began from similar starting points but later diverged with early institutional decisions and subsequent contingent events and choices, reinforcing the given policy path in a way that showed increasing returns. Moreover, in describing biotechnology cases as self-reinforcing, Pierson's criteria also revealed the early institutional arrangements that drove policy development later, and in doing so revealed the influence of institutions themselves.

Secondary Test of Path Dependence

Although Pierson's approach based on increasing returns can reveal institutional influences in policy development, it generally does not provide these in terms that scholars can easily compare when addressing the broader question of variation in biotechnology policies. Pierson's criteria can show where policies diverged, but they do

[5] See works below by Pollack and Shaffer, and Banchoff.
[6] Paul Pierson, "Increasing Returns, Path Dependence, and the Study of Politics," *American Political Science Review* 94, no. 2 (June 2000) 251–267.

not provide measures of differences between them, leaving this conception of path dependence open to criticism as being overly broad. Therefore, this study sought to extend the analysis by proposing a secondary test of path dependence that looked to the implications of the policy path described by Pierson.

Decision-Making Structures

To delineate a secondary test of path dependence, the study turned to the key regulatory standard-setting institutions involved in designing and executing policies, and proposed to describe these as "decision-making structures," defined as government regulatory mandates enshrined in a formal or informal institutional agreement. These decision-making structures included, for GMOs, the US Coordinated Framework and the UK-EU legislative framework, and for stem cell research, the HFE Act 1990 framework in the UK and the US Bush framework.

In performing the secondary test of path dependence, Chapters Three and Five found that, within the context of the Coordinated Framework and HFE Act 1990 framework, expansions in the constellation of actors and shifts in the balances of interests apparently moved the policymaking focus from political concerns to administrative ones. This arguably helped facilitate the transfer of authority for controversial technologies from directly elected officials to unelected civil servants. While such a shift removed technology governance from direct democratic accountability, it also neutralized the political interests of those in favor and those opposed, by empowering actors with more oblique policy goals.

Conversely, Chapters Four and Six found that no significant changes in actors and interests occurred within the context of the EU-UK legislative framework for GMOs, and the US Bush framework for stem cell research. In both cases, actor

constellations experienced only limited expansions and the balances of interests failed to shift from political concerns to administrative ones.

Consequently, this study proposed that a causal relationship exists between actor and interest changes and permissive policy outcomes, and possibly between the lack of actor and interest changes and restrictive outcomes. However, as the preceding discussion noted, due to the difficulty of falsifying an outcome in which no actor and interest changes occur, the study can verify the origin of permissive outcomes more extensively than restrictive ones.

Moreover, this study cannot formally test any of these relationships under the parameters established earlier. They are described to identify key variables and to establish the analytical approach. However, subsequent scholarship could examine these relationships in greater detail, as the section below on future research discusses in greater detail.

This account of institutional influences draws from and extends previous scholarship which explained biotechnology policy variation in terms of path dependent processes. Specifically, the study absorbed Banchoff's insights about policymaking for stem cell research in the UK and extended the analysis to the United States, and to genetically modified organisms in food, applying Pierson's criteria for increasing returns.[7] Similarly, the study drew from Pollack and Shaffer's study of GMOs, and sought to deepen the discussion of Pierson's criteria and extend it to stem cell research.[8] The result is arguably the most extensive and systematic account of Pierson's criteria applied to both technologies.

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[7] Banchoff, Thomas, "Path Dependence and Value-Driven Issues: The Comparative Politics of Stem Cell Research," *World Politics* 57, no.2 (January 2005), 200-230.
[8] Mark A. Pollack and Shaffer, Gregory C., *When Cooperation Fails: The International Law and Politics of Genetically Modified Foods* (Oxford: Oxford University Press, 2009).

Moreover, the study also significantly extended the analyses of Banchoff and Pollack and Shaffer by describing the institutional influences behind policy variation in more specific terms that scholars can assess comparatively. Indeed, extending the analysis of Pierson's criteria to reveal explicit changes in actors and interests provides a mechanism for recognizing and understanding policy differences that does not currently exist in other works of scholarship.

Characterizing Behavior

The notion that officials within decision-making structures embodied a specific kind of civil servant behavior evokes a long-running question about these political actors: Can we characterize their behavior? This study proposed in Chapter One that it can be done only to a degree. The chapter described important contributions from theorists of bureaucracy, including Anthony Downs' classic typology of bureaucratic behavior, William Niskanen's account of bureaucratic activity as budget-maximizing behavior and Patrick Dunleavy's well-known bureau-shaping account of bureaucratic behavior, and others.[9] The historical and empirical material in this study brings up numerous cases of bureaucratic politics, notably the turf battles between European Directorates General for Research and the Environment over which division would serve as *Chef de File* for GMOs. And in the US, officials from EPA, FDA and USDA engaged in sometimes "acrimonious" exchanges relating to questions of jurisdiction.

Although officials in those directorates, and the US EPA and FDA, exhibited classic bureaucratic behaviors, others did not, or are more difficult to characterize. For example, although one could view EU member state officials detailed to the Regulatory

[9] Downs, Anthony, *Inside Bureaucracy*, (Boston, Mass.: Little, Brown & Company, Ltd., 1967); Niskanen, William, *Bureaucracy and Representative Government*, (Chicago: Aldine Publishing Company, 1971); Dunleavy, Patrick, *Democracy, Bureaucracy and Public Choice: Economic Explanations in Political Science*, (London and New York: Harvester Wheatsheaf, 1991).

Committee as exhibiting typical bureaucratic behavior with respect to their home institutions, their actions with respect to EU governance suggest a more overtly political role. And in the US, although some officials within the USDA clearly gained from the White House's push to give the reluctant agency control over commercial planting, the impetus clearly came from outside the organization rather than inside.

Regarding stem cell research, while the UK's HFEA leadership may have supported enhancing the agency's duties, the organization already operated on a "shoe-string" and did not actively lobby for the portfolio. Likewise in the US, the NIH under President Clinton arguably could have secured its role as the lead regulator for stem cell research if it had accelerated the grant-making process, but instead the agency deliberated more slowly and ultimately deferred the oversight question to the next president.

Such varied behaviors present a challenge to any simple account of bureaucratic politics. This study merely suggested that some decision-making structures acquired actors with a range of preferences other than direct partisan politics, and that this served to depoliticize position issues, such as genetic engineering and embryonic stem cell research, by shifting the interests of actors overall. This more modest view, however, remains consistent with Moshe Maor's finding that regulatory agencies claim jurisdiction over emerging technologies when their reputations are at stake, either from evidence of a potential harm caused by the technology or a rival regulator's attempt to intervene.[10] Indeed, jurisdiction claiming arguably occurred in the US when EPA and FDA sought regulatory authority over GMOs. Although the USDA did not follow suit, the agency initially did not view GMOs as potentially harmful and resisted regulation.

[10] Maor, Moshe, "Organizational Reputation and Jurisdictional Claims: The Case of the U.S. Food and Drug Administration," *Governance* 23, no. 1 (2010), 133–159.

Similarly, in Europe one could see jurisdiction claiming in the behavior of officials in both the DG Research and DG Environment.

With stem cell research in the UK, officials at HFEA arguably did not make a jurisdiction claim, but since no other potential regulator existed they did not have to. The US situation, on the other hand, is less clear. Although NIH clearly did not make a jurisdiction claim, it remains unclear why not.

Measuring Power

Similar ambiguities arise with regard to the "capture thesis" of regulatory politics. Chapter One described how Marver Bernstein revolutionized perceptions of government in 1955 with his assertion that regulated interests often captured the regulatory bodies overseeing them.[11] This critical insight into regulatory behavior established a research agenda with subsequent scholars both extending and challenging the thesis. One recent example is Daniel Carpenter, who in 2001 argued that some bureaucratic officials acquired autonomy in policymaking by means of their reputations.[12] Carpenter's 2010 study of FDA power extended the concept by revealing how that agency's reputation for consumer protection and scientific expertise gave it a vast and often informal power over the pharmaceutical industry, stretching well beyond US shores.[13]

Of course, Carpenter's findings focused on US policymaking and on select agencies. The cases in this study encompassed a distinct swath of activity. Unlike pharmaceuticals, stem cell research remained a distant commercial possibility at its discovery in the late 1990s, with most work taking place in public research labs. In the

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[11] Bernstein, Marver, *Regulating Business by Independent Commission*, (Princeton, N.J.: Princeton University Press, 1955).
[12] Carpenter, Daniel P., *The Forging of Bureaucratic Autonomy: Reputations, Networks, and Policy Innovation in Executive Agencies, 1862-1928*, (Princeton, N.J.: Princeton University Press, 2001).
[13] Carpenter, Daniel P., *Reputation and Power: Organizational Image and Pharmaceutical Regulation at the FDA*, (Princeton and Oxford: Princeton University Press, 2010).

UK, Parliament moved to bring it under the strict oversight of the HFEA. In the US, no regulation existed for private research, and public-sector work was constrained by the Dickey Amendment and President Bush's decision.

The regulatory framework for GMOs more closely resembled Carpenter's analysis, with seed and chemical companies and food producers making applications to specialist regulators at multiple agencies. In the US, the USDA, EPA and FDA set safety thresholds for all products, with the FDA requiring producers to demonstrate the "substantial equivalence" of engineered foods to traditionally produced ones. Unlike with pharmaceuticals, FDA officials recommended but did not require premarket consultation for GMOs, even as the agency maintained the ability to remove any engineered food from stores that did not meet safety requirements. In Europe, officials relied on home state regulators to conduct reviews until they established the European Food Safety Authority in 2002. Whereas some regimes cleared products rapidly, inconsistency in reviews and conflicting standards contributed to the gridlock which later halted approvals.

Despite the diverse regulatory environments that existed for GMOs and stem cell research, this study proposed that, contrary to Bernstein's assumption that industry would commonly capture government, bureaucratic expertise often translated to political power. In the US, experts from multiple agencies enjoyed significant autonomy to forge a policy for the safe development of GMOs based on their knowledge and experience, challenging suggestions of industry capture portrayed by theorists such as Bernauer and Meins.[14] In Britain, Parliamentarians affirmed the HFEA as an experienced regulator when they decided to place stem cell research under its aegis.

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[14] Bernauer, Thomas, and Meins, Erika, "Technological Revolution Meets Policy and the Market: Explaining Cross-National Differences in Agricultural Biotechnology Regulation," *European Journal of Political Research* 42 (2003), 643–683.

The fact that bureaucratic autonomy developed in countries with permissive policies could lead one to link the two issues, and see outcomes in terms of capacity, i.e. that the expert capacity of the US and UK to oversee GMOs and stem cell research, respectively, accounted for the permissive policies that resulted. However, such an explanation only carries us so far. In the US the NIH clearly had the desire and ability to regulate stem cell research, but the Dickey Amendment constrained it. In Europe, member states clearly possessed the cumulative capacity to regulate GMOs, but actors clashed over political rather than administrative questions. Therefore, expertise alone does not guarantee agency power in all circumstances. However, what does perhaps advance bureaucratic autonomy, on the evidence of this study, is the willingness of political actors to devolve power by creating decision-making structures that engender or at least tolerate changes in the constellation of actors and shifts in the balance of interests.

Future Research Directions

Findings in this study could lead to various new and fruitful lines of research, especially those which examine analytical concepts described but not formally tested here. On the subject of GMOs and stem cell research, one further step could involve testing the Small-N findings of this study through a Large-N analysis that compares, for example, the relationship between bureaucratic capacity and policy outcomes. Scholars might attempt to do this by gathering data that could represent the variable, such as comparative statistics on science expenditures or laboratory employment, and then perform regression analyses to test for correlation. Such an effort could provide quantitative evidence to support and complement the central findings articulated in this thesis. Similarly, one could attempt to create a formal test of the relationship between

actor and interest changes in decision-making structures and policy outcomes. This could perhaps involve creating a numeric measure for respective variables and performing a relevant analysis.

Looking beyond GMOs and stem cell research, one could apply a similar approach to a range of other position issues in which policy variation occurred. Like the cases in this study, scholars could perform analyses to determine whether institutional mechanisms help explain differing outcomes. Among the wide range of possible science applications, those most closely related to GMOs could include dairy products containing the rBST hormone; irradiated food; and, cloned livestock and fish. Science practices addressing issues closer to stem cell research could include pre-implantation genetic diagnosis, gene therapy and abortion. The approach followed here could possibly also apply to position issues resulting from more remote science practices, or from those beyond the realm of science and technology.

But in policy contexts far removed from the world of research and development, emerging position issues may not involve the kind of expertise associated with decision-making structures, meaning that such structures could be expected to have less explanatory power in relation to policy outcomes.

EPILOGUE

Considering the occasional volatility of efforts to craft first-generation policies for GMOs and stem cell research in Britain and the United States, it is not surprising that later policymaking periods contained elements of continuity and change. As earlier chapters described, even the task of identifying and isolating a first-generation approach presented a challenge in some countries, due to frequent shifts in policy within a narrow time frame. To overcome this problem, this study sought in each case to describe the first-generation policy as the first stable and consistent approach to emerge over a period of several years. In some cases, first-generation policies did not fundamentally change in subsequent years. However, others were altered considerably. This epilogue summarizes policy activities in the periods after the first-generation approaches achieved stability, and reflects on how these developments impact the theoretical interpretations presented in this study.

Genetically Modified Organisms

Following the United States' embrace of a permissive policy in the 1980s and 1990s, domestic use of GMOs in agriculture and food products grew steadily. However, despite industry's early hope of transforming a wide range of crops by the start of the 21st Century, only a handful of viable GMOs had emerged in the US market, including soybeans, corn, sugar beets and canola. But American farmers adopted these in high concentrations, leasing seed rights directly from producers. Indeed, less than two decades after their introduction, these engineered crops would capture 90 percent of the

domestic market, compared to traditionally bred varieties.[15] And because food producers used two of these crops--corn and soybeans--as ingredients in countless processed foods, GMOs entered the food supply of most Americans. The success of these crops translated to large profits for Monsanto and DuPont, the chemical agribusiness conglomerates which came to dominate the US market after acquiring many smaller seed companies and biotechnology start-ups. Moreover, although steady consumer opposition to GMOs always existed, US activists generally failed to achieve the organizational strength needed to affect retail chains.

However, GMOs did face difficulties on American soil. Insects and weeds developed a resistance to engineered crop varieties, limiting the effectiveness of certain breeds and requiring ongoing and costly research and development into new crops. Also, the natural spread of engineered plants to nearby fields of non-modified varieties plagued breeders of both, and played out in a series of legal actions.[16] Organic growers battled to keep engineered strains from contaminating their fields, while companies such as Monsanto expended considerable resources investigating farmers suspected of growing engineered crops without a license.[17] Despite the steady approvals, some polls show that the US public continued to have concerns about GMOs. According to one poll by *Thomson Reuters* and *National Public Radio*, 93 percent of respondents said foods containing engineered ingredients should say so on the label.[18]

As new varieties emerged, government regulators at the relevant agencies, including the USDA, EPA and FDA, generally signed off after producers provided sufficient data to demonstrate safety. Although various divisions held up specific

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[15] Moskin, Julia, "Modified Crops Tap a Wellspring of Protest," *The New York Times*, February 7, 2012.
[16] Ibid.
[17] Barlett, Donald, and Steele, James, "Monsanto's Harvest of Fear," *Vanity Fair*, May 2008.
[18] Moskin, Julia, "Modified Crops Tap a Wellspring of Protest," *The New York Times*, February 7, 2012.

approvals in some cases, most applications succeeded eventually.[19] Thus, in the years after formulating its initial policy, the US maintained its permissive approach.

Britain and Europe

Across the Atlantic, a very different story unfolded in Britain and Europe. During the European Commission's six year *de facto* moratorium officials had made no new commercial approvals. But following a legal challenge at the WTO from the US, Europe lifted the ban in May 2004, and began to clear products slowly thereafter. However, the shift failed to change the outlook for GMOs in a significant way. Consumer opposition remained strong, and retailers continued to favor non-modified food products. Most farmers still had little interest in modified crops because few varieties promised to deliver superior yields in European soils. Furthermore, the modest easing of Europe's policy also failed to reverse the trend of biotechnology firms leaving for more favorable political climates. In January 2012, Germany-based BASF, the world's largest chemical company, announced plans to relocate its crop engineering division to America, citing opposition from consumers, farmers and politicians.[20] Britain, which did not oppose GMOs as strongly as some European nations, such as Austria, issued its first consent for commercial planting in 2004. However, given the lack of suitable crops and the weak market for engineered products, the approval did little to advance GMOs in the UK.

But Britain and Europe did not prove to be a wholly hostile environment for GMOs. Although most viable GMOs did not suit European soils, some did, including

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[19] Pollack, Andrew, "U.S. Approves Genetically Modified Alfalfa," *The New York Times*, January 27, 2011.
[20] Kanter, James, "BASF to Stop Selling Genetically Modified Products in Europe," *The New York Times*, January 16, 2012.

varieties of corn grown successfully in Spain, which farmers there sought to use.[21] While this did not significantly alter the approach taken in Brussels, it created small cracks in the continent's wall of opposition. The outlook for GMOs also received a boost from the Commission's own safety studies, performed between 2001 and 2010 at a cost of 200 million Euros, which found that modified crops posed no greater threat to human health or the environment than traditionally bred varieties.[22]

When environmental and consumer interest groups successfully targeted GMOs in the late 1990s, EU officials cited the need to improve its oversight as a reason for halting approvals. After the moratorium, officials had established an independent regulator in the European Food Safety Authority (EFSA) and an enhanced labeling program. They also took steps to make it easier for member states to opt out of commercial planting approvals, which as a rule applied throughout Europe. These steps helped officials move forward with approvals for a limited number of crops. However, applicants faced lengthy delays and no guarantee of approval, indicating that the policy remained significantly restrictive albeit less than between the years 1998 and 2004.

Decision-Making Structures and GMOs

Since the Coordinated Framework remained mostly intact in the years following first-generation policymaking efforts, one can reasonably affirm the theoretical approach articulated in this study with respect to the United States. However, considering that the EU had spent the moratorium years boosting its infrastructure and completing its policy, one could fairly ask why the policy remained restrictive. One answer is that after

[21] Mathiason, Nick, "EU to End Five-Year Ban on New GM Products: European Biotech Firm Beats American Giants to Sell Genetically Modified Corn," *The Observer*, November 16, 2003.
[22] EU Commission, *A Decade of EU-Funded GMO Research (2001-2010)*, 2010.

officials lifted the moratorium the approval system remained political. Member states were free to opt out of accepting GMOs, and few applications gained clearance.

Another problem with this study's approach to explaining the British and European case concerns the effect of Europeanization on the policy outcome. Did Europe's lack of actor and interest changes, which this study identified as critical, simply result from the slow and deliberative process of creating a united Europe? To some degree one could argue the answer is yes. GMOs represented a very early case of European policymaking, and one which occurred without the benefit of numerous laws and institutions created later. However, even after EU officials enacted broad reforms to the regulatory system, the policy approach remained essentially unchanged. This would seem to uphold earlier descriptions of the first-generation policy as stable.

Stem Cell Research

In the years after Britain adopted its permissive policy for human embryonic stem cells, the country became an international hub of research activity.[23] Under the tight controls of the HFEA, the government allowed and provided funding for a wide range of work on human embryos, including efforts to produce stem cells from cloned embryos, the most controversial type of research.[24] With most work taking place in publicly funded laboratories, Britain attracted many top-level scientists fleeing from more restrictive policy environments in countries such as the United States.[25]

But progress on stem cell research came slowly. Despite the hope for rapid cures to debilitating ailments, discoveries occurred incrementally, reflecting the considerable

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[23] Jha, Alok, "UK Opens Pioneer Cell Bank: Decision Places Britain in Front Line of Key Scientific Controversy," *The Guardian*, May 19, 2004.
[24] Henderson, Mark, "Race to Find New Cures Speeds Up as Britain Clones Human Embryo," *The Times*, May 20, 2005.
[25] Radford, Tim, "Scientists Call for UN Compromise on Cloning," *The Guardian*, August 30, 2004.

knowledge gaps that existed for scientists still learning how to use their new instruments effectively. Furthermore, although the UK had a permissive policy, the 1990 Act did not authorize all types of research, such as the creation of so-called hybrid embryos, or embryos produced from human DNA fused with an animal's egg, which scientists wanted to pursue due to the short supply of human eggs.

Several years after establishing the stem cell policy, officials in the Department of Health sought to modernize several provisions in the HFE Act 1990 and proposed a new law which among other changes, would allow work on hybrid embryos.[26] The subsequent HFE Act 2008, which passed comfortably through Parliament despite objections from religious authorities, also relaxed laws relating to the creation of so-called savior siblings, and gave female same sex couples legal rights over children born from donated sperm.[27] Although government officials proposed numerous organizational changes in later years, including a plan to disband the HFEA as part of Prime Minister David Cameron's promised "bonfire of the quangos," Britain's policy remained fundamentally permissive.[28]

United States

Contrasting with Britain's permissive policy, President Bush's move to restrict federal research funding in the United States had an immediate impact on the medical and scientific communities. Beginning in 2001, many researchers left the country or sought alternate sources of funding. Those who stayed often worked in laboratories which by

[26] Connor, Steve, "Medicine Needs Hybrid Embryos, Scientists Say," *The Independent*, April 5, 2007.
[27] UK Parliament, *Human Fertilisation and Embryology Act 2008*, 13 November 2008.
[28] Gentleman, Amelia, "A Quiet Battle for Life: IVF Regulator Aims to Show Its Worth," *The Guardian*, January 10, 2011.

law strictly segregated resources involving stem cell research.[29] In 2005 and 2007, Congress passed bills to permit limited work on stem cells per the NIH guidelines under President Clinton, but Bush blocked these, with the earlier bill providing the occasion for his first ever legislative veto.

However, displeasure with the Bush policy among clinicians and patient advocates ultimately drove efforts to create public funding streams at the state level, including in New Jersey $10 million from the 2004 budget, and a successful ballot initiative in California the same year which financed $3 billion in bonds for research.[30] In subsequent years, a number of other states followed suit, including Connecticut, Florida, Illinois, Massachusetts, Missouri, New Hampshire, New York, Washington, Wisconsin and Texas. Moreover, by the end of the decade, stem cell research had added to the well-documented pressure building against Bush and the conservative coalition.[31]

Pro-research momentum culminated when the newly elected President Barack Obama reversed the Bush policy, in a move consistent with other campaign promises, and enacted one similar to what the NIH proposed years earlier.[32] Under the Obama NIH plan, and consistent with the Rabb opinion in 1999, researchers could not use federal funds to derive stem cells from embryos. However, no limitation existed on the use of stem cells already created from supernumerary embryos.[33]

The Obama policy opened the door to research significantly, enough to describe the US policy as "permissive" under the criteria discussed in Chapter Two. However, the policy was still much less permissive than its British counterpart. Moreover, the

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[29] Kaplan, Karen, and Levey, Noam, "Obama to Reverse Embryonic Stem Cell Research Policy," *The Los Angeles Times*, March 7, 2009.
[30] Waldman, Meredith, "Stem Cells: Stuck in New Jersey," *Nature* 451 (February 6, 2008), 622–626.
[31] Peele, Gillian, and Aberbach, Joel, *Crisis of Conservatism: The Republican Party, the Conservative Movement, and American Politics After Bush* (Oxford: Oxford University Press, 2011).
[32] Jacobs, Lawrence, and King, Desmond, "Varieties of Obamaism: Structure, Agency, and the Obama Presidency," *Perspectives on Politics* 8, no. 3 (September 2010), 793–802.
[33] US Department of Health and Human Services, NIH, "National Institutes of Health Guidelines for Human Stem Cell Research," *Federal Register* 74 (July 7, 2009), 32170.

future of stem cell research remained uncertain as long as Congress continued to include the Dickey Amendment prohibition in the annual budget. In fact, a US judge stunned researchers in 2010 by issuing an injunction on NIH research grants, ruling that even the utilization of stem cells derived using non-governmental funds violated the Dickey Amendment.[34] Although a federal appellate panel later reversed the decision, the matter revealed the precarious foundations of the US policy.[35]

Decision-Making Structures and Stem Cell Research

Policy changes in the years after the first-generation approach could lead some to question the explanations embraced in this study. In the UK, for example, one could ask whether the relatively easy passage of a new act in 2008 reduces the significance of the 1990 framework, through which stem cell research became legal in 2002 owing to regulations rather than a freestanding bill. Along these lines, one could assume that if Parliament managed to pass legislation pertaining to embryo research in 2008 they could have done so in 2000-2001, apparently minimizing the importance of the HFE Act 1990 framework on the policy outcome.

However, this view overlooks the differences between the 2002 Regulations and the 2008 Act. Because the 2008 Act did not include anything as controversial as the embryo research provisions in the 2002 Regulations, it does not represent equivalent legislation. In fact, one could view the fact that officials proposed legislation in 2008 but not for the much more controversial stem cell provisions in 2002 as indicative of the

[34] Harris, Gardiner, "U.S. Judge Rules Against Obama's Stem Cell Policy," *The New York Times*, August 23, 2010.
[35] Harris, Gardiner, "Court Lets U.S. Resume Paying for Embryo Study," *The New York Times*, April 29, 2011.

latter's political vulnerability. Bringing a free-standing bill for stem cell research would have opened up the issue to considerable scrutiny, amendment and delays.

In the United States, Obama's reversal of the Bush policy casts a potentially larger shadow over the explanatory approach embraced in this thesis. How do we account for the change in policy direction? Because earlier chapters described how the lack of actor and interest changes in decision-making structures accounted for the restrictive outcome, one would expect the permissive Obama policy to have followed from actor expansions and interest shifts. To a degree, this is precisely what occurred.

Although the Dickey Amendment prohibition delayed and ultimately prevented NIH officials from moving ahead with stem cell research before President Bush assumed office and restricted it, the US possessed considerable resources at the NIH for overseeing research funding. When President Obama reversed the Bush policy he simultaneously extended NIH oversight to all publicly funded research. However, the US policy still had numerous gaps, including the Dickey Amendment's ban on public funding for both stem cell derivations and the cloning of embryos to produce stem cells with the matching DNA of patients. Moreover, the US policy remained highly vulnerable to future legal challenges. And, as stated elsewhere in this study, it left private sector research entirely unregulated.

Overall, the subsequent pattern of events described in this epilogue was broadly consistent with the interpretations of the thesis. As we saw, permissive policies for GMOs in the United States and for stem cell research in Britain remained essentially stable. But even jurisdictions that changed course uphold the story told here. Indeed, Britain and Europe's slight easing of their restrictive approach to GMOs, and the United States' reversal of its virtual ban on stem cell research, represent changes that the analysis of institutional agency as articulated here can explain.

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APPENDIX ONE

This section describes coding techniques used to create two tables from Chapter Two. The first, Table 2.3 First-Generation Policies for Agricultural Genetically Modified Food Crops and Products (1990-2005), required data from multiple sources. For laws governing planting and sale of GMOs, this study utilized numerous entries from the Center for Environmental Risk Analysis' comprehensive database: http://www.cera-gmc.org/?action=gm_crop_database (accessed January 26, 2012). Specifically, the table drew from the following entries:

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Gerdung, Anja, "Germany's Liability Law for GMO Cultivation," June 2006, http://www.sustainabilitynz.org/docs/GermanLiabilityLawforGMCultivation.pdf, accessed January 26, 2012;

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James, Clive, *Preview: Global Status of Commercialized Biotech/GM Crops: 2004*, ISAAA Briefs (Ithaca, NY: ISAAA, 2004).

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Details relating to the Cartagena Protocol were obtained from:

Secretariat of the Convention on Biological Diversity, the Cartagena Protocol on Biosafety to the Convention on Biological Diversity, "Status of Ratification and Entry Into Force," December 4, 2011, http://bch.cbd.int/protocol/parties/, accessed January 25, 2012.

Coding for the second table from Chapter Two, Table 2.4 First-Generation Policies for Human Embryonic Stem Cell Research (1999-2005), is as follows. The study started with existing compilations, such as those provided by the Hinxton Group, an informal consortium of academics affiliated with Johns Hopkins University, which provided very detailed analyses of world stem cell policies on its website: www.hinxtongroup.org. Where necessary, this study augmented the data with government, scholarly and journalistic accounts, obtained from the Internet search engine "Google" during the month of January 2012. For a complete listing, see:

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APPENDIX TWO

Interviewees:

Ager, Brian, November 12, 2010—Former UK Health and Safety Executive (HSE) civil servant, seconded from 1988-1990 to the Concertation Unit for Biotechnology in Europe (CUBE), Directorate General for Science, Research and Development (DG XII), European Commission; and after 1990, a Brussels-based lobbyist for the biotechnology and pharmaceutical industries.

Alton, David, August 24, 2011—Life peer (Liberal Democrat) and former UK Member of Parliament from Liverpool.

Bosworth, David, PhD, December 17, 2010—Molecular biologist (carcinogenesis specialist), and UK HSE civil servant, seconded to the Directorate General for the Environment, European Commission, between 1996 and 1999.

Cantley, Mark, August 11, 2010—Former European Community civil servant, Concertation Unit for Biotechnology in Europe (CUBE), Directorate General for Science, Research and Development (DG XII), European Commission.

Chiu, Arlene, PhD, October 7, 2010—Neurobiologist and former NIH scientific administrator.

Cohrssen, John, September 1, 2010—Former White House staff attorney under President Ronald Reagan.

Deech, Ruth, August 4, 2011—Lawyer; life peer (Crossbench); and, Chair of the UK Human Fertilisation and Embryology Authority (HFEA) from 1994-2002.

Dickey, Jay, May 14 and 17, 2010—Businessman and former Republican member of the US House of Representatives from Arkansas' 4th District (1993-2001).

EU Civil Servant 1—European Commission.

EU Civil Servant 2—European Commission.

EU Civil Servant 3—European Commission.

Feldbaum, Carl, September 2, 2010—Former President of the Biotechnology Industry Organization (BIO), Washington, DC.

Flamm, Eric, PhD, September 11, 2009—Microbiologist and US Food and Drug Administration (FDA) civil servant.

Hunt, Phil, October 18, 2011—Life peer (Labour) and UK National Health Service official.

Jenkins, Dan, August 31, 2010—Business executive, Office of Regulatory Affairs, Monsanto, Washington DC.

Kahl, Linda, PhD, September 11, 2009—Biochemist and US FDA civil servant

Kent, Alastair, August 5, 2011—Director of the UK Genetic Alliance, known as the Genetic Interest Group before 2010.

Kingsbury, David, PhD, January 21, 2010—Microbiologist and former acting chair of the White House Domestic Policy Council Working Group on Biotechnology.

Krauthammer, Charles, April 12, 2010—Physician and *Washington Post* columnist.

Lefkowitz, Jay, April 16, 2010—Attorney and former White House Office of Management and Budget General Counsel and aide.

Leather, Dame Suzi, July 13, 2011—Former Deputy Chair of the UK Food Standards Agency and Chair of the UK HFEA from 2002-2006.

Marquard, Helen, PhD, December 16, 2010—Molecular biologist and former Deputy Director of the UK Department of the Environment and Secretary of the Advisory Committee on Releases to the Environment.

Maryanski, James, PhD, August 30, 2010—Microbiologist; consultant; and, former Biotechnology Coordinator, US FDA.

McCann, Tony, May 6, 2010—Former staff director of the US House Appropriations Subcommittee on Labor, HHS, Education and Related Agencies.

Medley, Terry, September 16, 2009 and September 10, 2010—DuPont company executive and former US Department of Agriculture staff attorney and official.

Melchett, Peter, December 13, 2010—Organic farmer; Soil Association Policy Director; former executive director of Greenpeace UK; and, Labour minister (hereditary peer) in the Wilson and Callaghan governments.

Mellon, Margaret, PhD, September 18, 2009—Molecular biologist and senior scientist, Union of Concerned Scientists, Washington, DC.

Meslin, Eric, PhD, September 16, 2010 (and an e-mail communication from July 20, 2012)—Bioethicist; professor and former executive director of the US National Bioethics Advisory Commission.

Milewski, Elizabeth, PhD, September 9, 2009—Molecular biologist and civil servant in US National Institutes of Health (NIH) and the Environmental Protection Agency (EPA).

Morris, Sir Peter, September 28, 2011 (e-mail communication)—Surgeon and member of the UK Chief Medical Officer's Expert Group on Stem Cell Research, 1999-2000.

Poole, Nigel, PhD, July 28, 2010 and April 11, 2011—Microbiologist; former researcher and executive, ICI Seeds; former executive, Zeneca Plant Science.

Porter, John, April 8, 2010—Attorney and former Republican member of the US House Representatives, from Illinois' 10th District (1980-2001).

Quintavalle, Josephine, August 2, 2011—London-based pro-life activist and founder of Comment on Reproductive Ethics (CORE).

Rissler, Jane, PhD, September 21, 2009 and March 11, 2010—Plant pathologist; senior scientist, Union of Concerned Scientists; and, former EPA civil servant.

Rowley, Janet, PhD, April 19, 2010—Geneticist, cancer specialist, University of Chicago professor and Presidential Medal of Freedom winner.

Scarisbrick, Jack, PhD, August 10, 2011—Historian and founder and chairman of LIFE, a UK charity.

Schneider, William, PhD, September 11, 2009 (e-mail communication)—Scientist and EPA civil servant.

Speight, Paul, December 1, 2010—European civil servant, Directorate General for the Environment, European Commission.

Spiegel, Allen, April 15, 2010—Endocrinologist and former Director of the National Institute of Diabetes and Digestive Diseases and Kidney Diseases.

Tachmintzis, Joanna, December 14, 2010—Former European civil servant, Biotechnology Sub-unit, Directorate General for Environment, Nuclear Safety and Civil Protection.

Tierney, Kathryn, December 10, 2010—European civil servant, Directorate General for the Environment, European Commission.

Trippier, Sir David, July 29, 2009—Former UK Minister of State for the Environment and Conservative MP from Rossendale, 1979-1992.

Van Etten, Peter, September 15, 2010—Former President, Juvenile Diabetes Research Foundation.

Walters, Leroy, PhD, April 14, 2010—Bioethicist and professor, Georgetown University.
Warnock, Mary, July 19, 2011—Philosopher; life peer (Crossbench); and, Chair of the Warnock Committee.
Wilder, Marcy, April 13, 2010—Attorney and former deputy counsel, US Health and Human Services.

Interview Protocols

This thesis incorporated primary source material from approximately 40 semi-structured interviews conducted and digitally recorded between July 2009 and October 2011 in Washington, DC, London, Brussels and via telephone. (In exceptional cases, noted above, interviewees responded to questions via e-mail.) The following discussion provides details on interview protocols, and coding and use, both of which comported as far as possible with key social science methodological concepts, such as reliability and validity, and triangulation.[1]

Selection: This study selected interviewees based on their relevance to historical events in the policymaking process, including their centrality to and/or knowledge of activities pertinent to document biographies. Although many individuals initially solicited declined requests or failed to respond, those willing to participate often provided suggestions for further contacts, and the study proceeded under this "snowball" approach, with the intention of conducting approximately 10 interviews for each of the four main case studies. Although additional interviews would have provided even further insights, this target number represented a satisfactory compromise, considering the time-intensive demands of preparing for, conducting and transcribing interviews. All interviewees consented to participate in research prior to interviews.

[1] Berry, Jeffrey, "Validity and Reliability Issues In Elite Interviewing," *Political Science and Politics*, vol. 35, no. 4 (December 2002), 679-682.

Sessions. Each interview on average lasted approximately one hour, although some were concluded in less than 20 minutes and others spanned almost three hours in length. Interviewees were informed at the beginning of the interview that the session was being recorded. Some interviewees placed specific conditions on the use of their remarks, such as requests to review comments before publication, and these were incorporated into the preparation of this thesis. However, most interviewees made no such stipulations.

Questioning. Questions for interviewees fell into four broad categories: historical, interpretive, counterfactual and triangulating. Historical questions aimed to elicit both general and specific details missing from the study's working narrative: "What happened in Year X?" "Why did officials take no action?" or, "Did Concern Y factor into your thinking?" In most cases, answers to historical questions were the easiest to verify because their content in most cases corroborated intuitively with input from other sources. Occasional contradictions usually reflected memory losses or other errors, and were typically caught in cross-referencing.

Interpretive questions asked interviewees to give more directly subjective value judgments about historical events: "How much did Factor A influence decision-making?" "Which of the following events was the most important?" Unlike historical answers, responses to interpretive questions required more careful triangulation with other sources. In general, sources tended to corroborate each other. However, when other evidence contradicted interviewee statements, I typically obtained further evidence and evaluated reliability and validity accordingly.

Counterfactual questions presented hypothetical scenarios to assess potential probabilities and therefore the importance of specific factors and events: "If Measure X had not existed what would have happened?" "If officials had followed Route Y what

would have been the result?" Whereas interpretive questions solicited subjective value judgments about historical events, counterfactual ones asked interviewees to give their opinions about hypothetical events. Like other questions, counterfactuals generally yielded corroborated responses, however in some cases more evidence was required or else the material was excluded.

Triangulating questions specifically aimed to corroborate other evidence, including documents and other interview findings. For these I generally questioned interviewees directly about the facts or information in question in the first instance, and on occasion followed up by mentioning the specific interpretation of documents or individuals (preferably unnamed): "What caused Outcome X?" "Do you agree with other sources who have said Y?" Overall, triangulation worked very well as a general research strategy, and was particularly effective when applied across fields, i.e. to partisans with differing views. In a minority of cases, some evidence was difficult to triangulate due to a paucity of corroborating sources, and so the material was generally not used.

Interview Coding and Use

This study manually coded all interview transcripts by marking passages relevant to the draft narrative before their inclusion so that contents could be cross-referenced with other evidence, including transcripts from other interviews. In some cases, I placed key words next to passages to correspond with sections of the draft narrative.

In most cases, this study quoted sources directly and with attribution, a strategy which arguably bolsters claims to reliability and validity. Quoted and attributed statements are not only replicable to the degree that they can be used elsewhere but they allow both the source and the reader to judge their accuracy and validity. In a minority

of cases, interviewees were paraphrased with attribution, or quoted or paraphrased without attribution per the conditions set during the interview.

As discussed above, the study actively triangulated evidence during interviews by means of the questions asked. However, triangulation also occurred regularly during the writing process, when multiple sources were utilized to recount specific events in a comprehensive but accurate way. For example, interviewee evidence often helped to contextualize documents that on their own provide little details about how and why they emerged. Moreover, as a general rule the study cited interviewee evidence only when it provided a superior account of decision-making.