Comparative Biomedical Policy

Governing assisted reproductive technologies

Edited by Ivar Bleiklie, Malcolm L. Goggin and Christine Rothmayr

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Comparative Biomedical Policy presents the first comprehensive and systematic cross-national analysis of assisted reproductive technologies (ART) policy. Based on original and detailed research, the authors collected here discuss the policy implications of the interaction of advanced technology, ethics and democratic policy-making.

The high-profile ART policy issue has captured the attention of scientists, ethicists, social scientists, policy-makers, the media and the public. This up-to-date volume establishes a knowledge base for understanding debates on topics such as embryonic stem cell research and human and therapeutic cloning as well as how access is regulated.

Containing case studies of Belgium, Italy, Canada, the US, Spain, the UK, France, the Netherlands, Germany, Switzerland and Norway, the book explains how, and why, policy-makers within a country designed ART policy the way they did.

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Series editor's preface

Only very few issues affect the fundamental and vital aspects of human life as much as reproductive technology does. Although techniques like donor insemination have been practised since the 1960s, public controversies started with the fertilisation of life outside the woman's body and the birth of the first 'test-tube baby' in England in 1978. The rapid development of biomedical research in the last decades – including work on embryonic stem cells, genetic selection, and cloning – calls for political regulation and guidelines. Answering extremely difficult ethical and medical questions in this area cannot be left to the traditional self-regulatory power of the medical profession. Undesired practices must be prevented, and access to modern techniques by potential users guaranteed.

The contributions to this volume all deal with so-called assisted reproductive technology (ART), covering human fertilisation and reproduction techniques through medical intervention instead of sexual intercourse. The authors, however, do not restrict themselves to the consequences for policy-makers of the application of these techniques or of the public debates in many countries. They all deal with ART as a wide and diffuse policy domain covering a number of difficult medical, ethical, legal and budgetary issues. The goal of this volume is much more ambitious than simply presenting an overview of very different national policies. In order to deal with the many aspects of ART policies in diverse national contexts, an analytical framework of the policy process is developed and applied by each contributor in each country. In this way, the search for common developments and general findings does not disappear into the ocean of country-specific details that usually characterises cross-national empirical studies. Instead, the crucial question can be confronted: how can these differences between policies in various countries be explained?

Before the national ART policies in eleven countries are presented, Malcolm Goggin, Deborah Orth, Ivar Bleiklie and Christine Rothmayr offer an overview of the main aspects of these techniques in their introductory chapter. Furthermore, they present a common analytical framework of the policy process based on the autonomy of the medical experts on the one hand and the access to ART by potential users on the other.

The first four chapters dealing with specific countries address policy-making processes resulting in permissive regulations. Nathalie Schiffino and Frédéric Varone show that Belgium ART regulations function without legal frame (Chapter 2), while Celina Ramjoué and Ulrich Klöti demonstrate that a lack of comprehensive regulation in Italy results in moderate access by users only (Chapter 3). Éric Montpetit presents a highly interesting discussion of the way 'non-decisions' resulted in a lack of regulation in Canada (Chapter 4). Permissive policies in the USA are mainly the result of the absence of a regulatory regime at the national level, leaving states the opportunity to adopt their own rules (Chapter 5). The next four contributions focus on countries with intermediate levels of regulatory ART policies. Julien Dubouchet and Ulrich Klöti start this part with a discussion of the Spanish case, where legislation and liberal policies were adopted early (Chapter 6). In a very different situation, Robert Blank examines the rather strong regulatory mechanism in the United Kingdom and its effect on experts and users (Chapter 7). Isabelle Engeli describes the comprehensive and strict regulatory framework for ART practices in France (Chapter 8), and Arco Timmermans tries to answer the question as to why the Dutch policies in this area are so much more restrictive than, for instance, abortion and euthanasia regulations in The Netherlands (Chapter 9). The third part of the volume deals with three countries that have developed clearly restrictive ART policies. Christine Rothmayr and Celina Ramjoué present a concise overview of the delicate attempts to adopt restrictive regulations in Germany without blocking research completely (Chapter 10). In a fascinating analysis of policy design in Switzerland, Christine Rothmayr and Uwe Serdült make it clear that direct democracy severely affects the agenda for ART policies (Chapter 11). In the last contribution to this part, Ivar Bleiklie discusses the way increased politicisation has contributed to the restrictive policies adopted in Norway (Chapter 12). Finally, Christine Rothmayr, Frédéric Varone, Uwe Serdült, Arco Timmermans and Ivar Bleiklie return to the central question of this volume – how to explain cross-national differences in ART policies – in their extensive concluding chapter.

This volume offers much more than a highly needed overview of ART policies in various countries. The concluding chapter especially shows that the efforts to describe and analyse the peculiarities of eleven national regulative regimes in great detail on the basis of a common analytical framework is very rewarding. Assisted reproductive technology has raised more questions than answers, and many medical, ethical and legal issues are still unresolved. With the further development of ART, the appeal for political regulations and guidelines will increase. The information presented in this volume should play a key role in further debates on the development and prospects of ART policies.

Jan W. van Deth, *Series Editor*
Mannheim, May 2003

Acknowledgements

Unlike many other research projects the one on which this book is based has been a bottom up undertaking, based neither on a project plan nor on a common funding source, but on a mutual interest in working together emerging from a workshop on policy design in 1997. The project was developed gradually as we went along. During a number of meetings over the following years a topic, assisted reproductive technology was agreed upon, then a theoretical framework and methodological design was gradually developed while the research team grew from nine to thirteen members and the number of countries increased from seven to eleven. Finally, data collection was undertaken in the last couple of years.

The project organisation has been democratic and egalitarian in the sense that there has been no clearly defined leadership or central authority predefining topic, theoretical framework or methodological design. The members have engaged in discussion and intellectual exchange from which a common project finally emerged. It has been pushed forward by common intellectual interests, the joy of working together and a belief in the project and its feasibility.

The research for this book has been supported by numerous funding sources and has received help, advice and inspiration from a great number of colleagues and friends.

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Ivar Bleiklie, Malcolm L. Goggin, Christine Rothmayr

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Abbreviations

AI	Assisted Insemination
AIC	Association for the Involuntary Childless
AID	Artificial Insemination with Donor
AN	Alleanza Nazionale (National Alliance)
AP	Alianza Popular
ART	Assisted Reproductive Technology
BelRAP	Belgian Register for Assisted Reproduction
BGE	Bundesgerichtsentscheid (Swiss Federal Supreme Court: jurisprudence)
BR-Drs.	Drucksache Bundesrat (Germany: printed matter of the Upper Chamber)
BT-Drs.	Drucksache Bundestag (Germany: printed matter of the Lower Chamber)
CCNE	Comité Consultatif National d'Ethique pour les sciences de la vie et de la santé
CDA	Christen-Democratisch Appel (Christian Democratic Party)
CDU	Cristiani Democratici Uniti (United Christian Democrats)
CDU/CSU	Christlich Demokratische Union Deutschlands/Christlich Soziale Union (Germany: Christian Democrats)
CECOS	Centres d'étude et de conservation des œufs et du sperme humains
CECOS Italia	Centro Studio e Conservazione Ovociti e Sperma Umani (Italian Centre for the Study and Conservation of Human Oocytes and Sperm)
CFAS	Canadian Fertility and Andrology Society
CIHR	Canadian Institutes of Health Research
D66	Democraten 1966 (Liberal Democrats)
DC	Democrazia Cristiana (Christian Democracy)
DDC	Democratici di Centro (Democrats of the Centre)
DRG	Diagnosis Related Group
DS	Democratici di Sinistra (Democrats of the Left)
EC	European Community

EDI	Eidgenössisches Departement des Innern (Department of Home Affairs, Switzerland)
EEC	European Economic Community
EFRA Italia	European Fertility Research Associates Italy
EJPD	Eidgenössisches Justizdepartement (Departement of Justice, Switzerland)
EschG	Embryonenschutzgesetz (Germany: Embryo Protection Act)
ET	Embryo Transfer
FDP	Freie Demokratische Partei (Germany: Liberals)
FI	Forza Italia (Go Italy)
FmedG	Bundesgesetz vom 18. Dezember 1998 über die medizinisch unterstützte Fortpflanzung (Fortpflanzungsmedizingesetz), Switzerland
FmedV	Fortpflanzungsmedizinverordnung vom 4. Dezember 2000, Switzerland
FNOMCeO	Federazione Nazionale degli Ordini dei Medici Chirurghi e degli Odontoiatri National (Federation for the Orders of Doctors and Dentists)
GG	Grundgesetz (German Basic Law)
GIFT	Gamete Intrafallopian Transfer
GPC	Grupo Parlamentario Centrista
GPM	Grupo Parlamentario Mixto
GPMC	Grupo Parlamentario Minoría Catalana
GPNV	Grupo Parlamentario Nacionalista Vasco
GPP	Grupo Parlamentario Popular (Popular Parliamentary Group)
GPS	Grupo Parlamentario Socialista (Socialist Parliamentary Group)
HIV	Human Immune Deficiency
HPC	Health Policy and Communication Branch
ICSI	Intra-Cytoplasmic Sperm Injection
INAMI	National Institute for Disease and Invalidity Insurance
IVF	In Vitro Fertilisation
KUL	Katolieke Universiteit Leuven
LO	Landsorganisasjonen (Trade Union Association)
LTRA	Ley sobre Técnicas de Reproducción Asistida
MP	Member of Parliament
MSI	Movimento Sociale Italiano (Italian Social Movement)
NAC	National Action Committee on the Status of Women
NCCB	National Consultative Committee for Bioethics
NHO	Næringslivets hovedorganisasjons (Employers' Association)
NR	Nationalrat (Switzerland, lower chamber)
NVOG	Nederlandse Vereniging voor Obstetrie en Gynaecologie (Dutch Association of Obstetricians and Gynaecologists)

NVRB	Nederlandse Vereniging voor Reageerbuisbevruchting (Dutch Association for In Vitro Fertilisation)
OECD	Organisation for Economic Cooperation and Development
ONSS	National Office of Social Security
PCI	Partito Comunista Italiano (Italian Communist Party)
PDS	Partito Democratico della Sinistra (Democratic Party of the Left)
PID	Preimplantation Diagnosis
PNV	Partido Nacional Vasco (Basque National Party)
PPI	Partito Popolare Italiano (Italian Popular Party)
PR	Proportional Representation
PSOE	Partido Socialista Obrero Español
PvdA	Partij van de Arbeid (Social Democratic Party)
R&D	Research and Development
RC	Rifondazione Comunista (Communist Refoundation)
RD	Royal Decree
SAMW	Swiss Academy of Medical Sciences
SIBI	International Society on Bioethics
SPD	Sozialdemokratische Partei Deutschlands (Germany: Social Democrats)
SR	Ständerat (Switzerland, upper chamber)
SSN	Servizio Sanitario Nazionale (Italian National Health Service)
StZG	Stammzellengesetz (Germany: Stem Cell Research Act)
TRA Forum	Forum per la Tutela della Riproduzione Assistita (Forum for the Protection of Assisted Reproduction)
VFJ	Verening voor Familie- en Jeugdrecht (Association for Juvenile and Family Law)
VKE	Vereniging voor Klinische Embryologie (Association of Clinical Embryologists)
VNEK	Verordnung vom 4. Dezember 2000 über die nationale Ethikkommission im Bereich der Humanmedizin, Switzerland
VUB	Vrje Universiteit Brussel
VVD	Volkspasrtij voor Vrijheid en Democratie (Liberal Party)
ZIFT	Zygote Intrafallopian Transfer

1 The comparative policy design perspective

Malcolm L. Goggin, Deborah A. Orth, Ivar Bleiklie and Christine Rothmayr

Six years ago, the editors of and many of the contributors to this volume met at a policy workshop of the European Consortium for Political and Social Research (ECPR) in Bern, Switzerland. As the meeting came to a close, workshop participants decided to organize a collaborative cross-national research project focusing on policy design and re-design. This book is the product of that six-year collaboration, called the Comparative Policy Design Project, or CPDP. Here we report research findings from this comparative study of how our first chosen field – assisted reproductive technology (ART) policies – is governed in nine European and two North American countries.

Comparative Biomedical Policy: governing assisted reproductive technologies is the result of six years of systematic theory-driven empirical research undertaken by a team of thirteen scholars. Herein we report the results of a comprehensive cross-national analysis of a field that has become an important policy issue. As we enter the twenty-first century, almost twenty-five years after the birth of Louise Brown, the first baby born from in vitro fertilization, countries across Europe and North American have adopted very different policy designs for governing ART. One goal of analysing and comparing the adopted policy designs is to establish a knowledge base for understanding current high profile policy debates such as the current discussion of embryonic stem cell research and human and therapeutic cloning in North America and Europe.

Comparative Biomedical Policy has two other purposes. One is to use our analytical framework as a guide to understanding design and re-design in the ART policy domain. ART is a relatively young policy area with an identifiable starting point in the 1970s. Furthermore, there is considerable variation in ART policy design across the eleven countries included in this comparative study. Thus it provides an ideal vantage point for dealing in a systematic comparative way with basic questions in policy research, such as:

- How are new policies made?
- To what extent are policies framed and defined by established institutions and policies?

- To what extent are policies the outcome of identifiable actor strategies and choices?
- To what extent do specific new policy areas, like ART, have characteristics that make them special?

The fact that ART is a new field makes the application of existing assumptions and theories about policy design particularly interesting and fruitful for future studies of policies dealing with biomedicine. We argue that even though we are dealing with a new and emerging policy field with unique characteristics, such as a high rate of scientific innovation, and touching upon fundamental ethical questions about human life, we expect the application of existing assumptions from the field of policy design to contribute to explaining and understanding current policy choices.

The comparative analysis of policy design and re-design in advanced industrial democracies also allows us to contribute to theory development, the third purpose of this collaborative project. We have limited our study to advanced Western industrialized democracies in order to have comparable cases with respect to, first, the level of technological development in biomedicine, and second, the dominant Christian religious tradition as a general context variable.

In this introductory chapter, we briefly describe the field of Assisted Reproductive Technology and discuss why it is an important policy domain for comparative study. Then we present the analytical framework and the data collection and measurement strategies that guide our comparative case study research. We believe that what makes this collection of original essays by country specialists unique is that it represents a carefully designed and centrally coordinated and controlled programme of research. All the original essays in this proposed book use a common analytical framework; the coding and survey instruments used to collect data in all eleven case studies are identical. Finally, we sketch out the book's organization.

What is ART and why is it an important policy domain?

The last decades have witnessed rapid developments in biomedicine, in particular in the fields of reproductive technologies, genetic screening, genetic engineering and organ transplantation. Despite the considerable amount of political activity and the public attention surrounding these biomedical issues, there is little political science research on this topic. As Blank and Hines (2001: 107) observe:

> There is already a fairly well-developed debate over biopolicy issues, and political scientists, those supposedly trained to deal with such concerns, are largely absent. Resolving these issues requires sensitivity to

> the political dimension. The literature is rife with confusion, often consciously imposed, over what is meant by government intervention, what the policy process is and how the political system works.

This absence of empirical political research on biomedicine is particularly evident if we compare the body of literature in the growing fields of bioethics, biolaw and bioeconomics (Blank and Hines 2001: 10–11; Rothmayr and Varone 2002).

In our research, we focus on one domain within the biomedical field, assisted reproductive technology. Assisted reproductive technologies are defined as those techniques where egg and sperm are not brought together (or an embryo is not created) through sexual intercourse, but rather through medical intervention; ART also includes research and social issues related to the application of these techniques.[1] Currently, human cloning and stem cell research are notoriously at the centre stage of public controversy and political regulation. In all the countries studied in this volume, this is not the first time that medical practice and research in ART have led to public debate, however. The invention of the technique of in vitro fertilization (IVF),[2] i.e. fertilization outside the women's body 'in a glass' (in vitro), in the late 1970s and its routinization in the mid-1980s elevated the issue of ART on the global political agenda. In vitro fertilization also created the basis for new practices in ART[3] as well as for new research related to reproductive technologies, such as embryonic stem cell research and cloning. Other techniques, namely insemination[4] by donor, have been practised since the 1960s without leading to larger debates.

Empirically we delimited our field of analysis by defining a number of techniques and issues to be included. We studied all policies addressing what we labelled *basic techniques*, consisting of artificial insemination (AI), in vitro fertilization (IVF) and Gamete Intrafallopian Transfer (GIFT).[5] Then we included some issues and *techniques related* to these basic techniques: surrogacy arrangements,[6] and the issues of donation (sperm, egg, embryo), cryopreservation, gender selection,[7] genetic selection, preimplantation diagnostics[8] and ICSI. Finally, we looked at what we labelled *research and experimental techniques*, including genetic engineering (on gametes and embryos), embryo research, cloning (reproductive and therapeutic) and chimera and hybrid building.[9]

The ART policy field is important for a number of reasons. By choosing ART we have deliberately avoided the traditional sector-oriented comparisons. Instead, we have selected a policy domain that is under-studied as well as politically salient, controversial, involves issues that involve strong beliefs and moral convictions, and engages experts who often play a crucial part in the policy designing process. ART is part of a growing number of issues, dealing with fast-changing technology, which raise basic ethical questions about the engineering of human life. The ART policy

domain allows us, therefore, to focus on questions regarding policy implications of the interaction of advanced technology, ethics and democratic policy-making. The ART domain not only raises the question of whether and how to regulate science and technology, but also raises health policy issues such as quality and safety of treatment, patient informed consent and child well-being, to name a few examples.

The medical sector has a particularly strong tradition of professional autonomy and self-regulation (Hassenteufel 1997). Professional autonomy means that physicians self-regulate their profession in order to guarantee quality of treatment and respect of ethical standards. Self-regulation might therefore be understood as the control over knowledge, which can be structured along three arenas of activity: creation (research), transmission (teaching) and application (performance) (Salter 2001: 872). In the field of ART, two arenas of activity were at centre stage in the debates on ART: research, or the creation of knowledge and technology, and the application of the new techniques. Strong beliefs and moral convictions regarding the science and technology of ART have led some to question the merits of expert autonomy and self-regulation (Hassenteufel 1997: 203–60; Salter 2001: 872).[10] Indeed, one might wonder to what extent ART policy affects the autonomy of the medical profession.

Autonomy

By autonomy we mean the amount of freedom that doctors and researchers as the main target groups for ART policy enjoy, either to practise ART or to conduct related research, respectively. In practical terms, autonomy refers to a physician's freedom to decide matters such as what ART to practise and how to practise, who can practise ART, and how compliance with practice guidelines is assured. Autonomy also refers to a researcher's freedom to decide what type of research to conduct, how to conduct it, who can and cannot conduct research, where to publish findings, and how to secure quality of research. Finally, there is the question of the extent to which researchers and practitioners act as implementers of policy, and how much autonomy they enjoy in their role as implementer.

Access

Physicians and researchers are not the only target groups ART policies are addressing. There are also infertile couples and anyone who might want to make use of ART to have offspring – i.e. the 'clients'. Access refers to the extent to which potential users of ART may avail themselves of such technologies. Currently, these users are mainly seeking to produce children. However, as technologies develop other users (for example, those suffering from diabetes or Parkinson's disease) may seek therapies derived

from embryonic stem cells. Policies may also regulate access by defining eligibility criteria – for example, age, marital status or sexual orientation – used to approve the application of the person seeking infertility treatment. Access is also a function of the amount of private or public insurance or funding that is provided to users for ART-related techniques.

Public policies for ART can be compared along the dimensions of autonomy and access, using the permissive–restrictive continuum that characterizes the governance of much science policy in general and biomedical policy in particular. More permissive policy goals grant wide access and facilitate a high level of autonomy; more restrictive policies result in more limited access and less self-regulation.

Policy designers, or those who govern in each of the eleven countries in this project, have come up with their own answers to the questions raised by ART. Physicians and researchers are granted varying degrees of autonomy to practise ART or pursue knowledge without outside interference across these eleven countries. The conditions for those who seek access to ART equally vary across countries in terms of what technologies are available and who can profit from them, as well as financial conditions offered by governments and insurance plans in terms of support and coverage.

What might account for this variation in autonomy and access across countries? The following framework proposes different explanatory variables for analysing the designing process and the resulting policy design along the two dimensions of autonomy and access.

What is the Comparative Policy Design Framework?

The Comparative Policy Design Framework (CPDF) guides our collaborative study of ART policy design and helps to explain the resulting policies as well as the similarities and differences across countries. Our approach is the result of both a cooperative and cumulative effort. What we present in this chapter is based on cooperation in the sense that in the process of developing this framework over a period of years, we have depended on our colleagues – both inside and outside the CPDP project – to critique our ideas. The framework is also cumulative: it incorporates, synthesizes and extends three of the dominant approaches to the study of policy-making – institutional analysis, the advocacy coalition framework, and the policy design literature (Linder and Peters 1984, 1987, 1991, 1992; Ostrom 1986, 1990, 1999; Ostrom *et al.* 1993; Sabatier 1988, 1999a; Sabatier and Jenkins-Smith 1993, 1999; Schneider and Ingram 1988, 1993, 1997; Weimer 1992).

Figure 1.1 identifies a set of variables and relationships that are the important factors characterizing the policy-designing process and resultant policy designs. The framework seeks to explain policy design, which includes goals, the means (or instruments) chosen to achieve them, and definition of target groups. The framework posits that these design

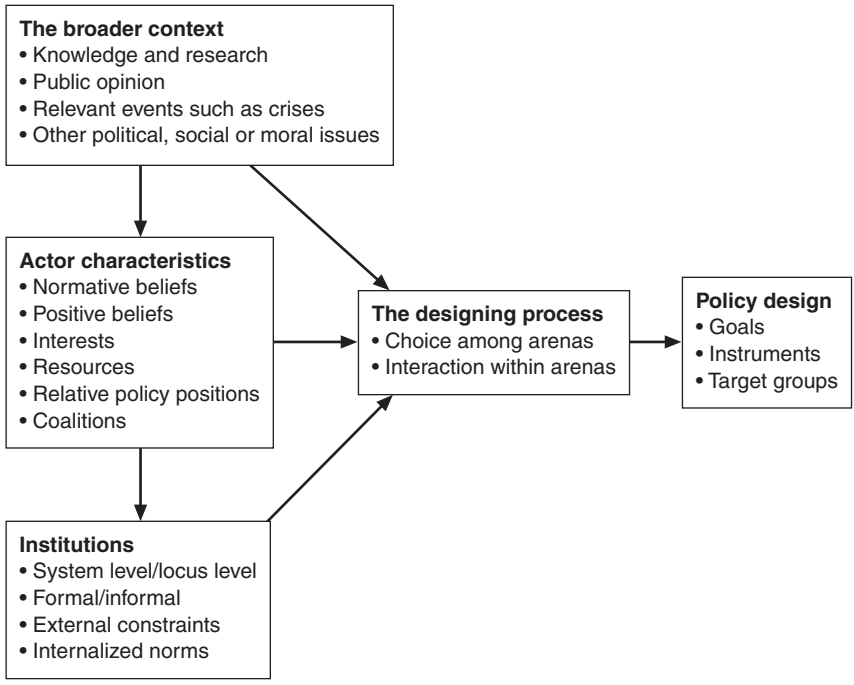

Figure 1.1 The CPDP Framework.

choices will be the product of: (1) characteristics of the participating *actors*, including their beliefs, interests, resources, and relations with each other; (2) *institutional rules, norms, and habits* that either constrain or shape the designing process and resulting design choices; (3) the nature of the *policy designing process itself*, which, though structured by predictable factors, is nonetheless dynamic and probabilistic; and (4) the *broader context* of circumstances, knowledge and opinion, which influences the beliefs, interests, and resources of the participants, and therefore their relations with each other.

We provide operational definitions of our key concepts. Using Figure 1.1 as our guide, we begin with the dependent and intervening variables, policy design and the policy-designing process, respectively. Then, moving from right to left in the figure, we describe and operationalize the three independent variables: actors and actor configurations; institutions; and the broader context.

Policy design

We use the policy-design literature to inform our conceptualization of the *dependent variable* – the goals, instruments and portrayal of target groups

that make up policy content. This literature is rooted in the policy sciences of Lasswell (1971) and Dror (1971). Driven by a concern for the relationship between the policy-making process and the policies that result, and between the content of policies and their consequences, the policy design literature has a strong normative tradition – a quest for the attributes and facilitators of 'good policy' (see, for example, Bobrow and Dryzek 1987; Dror 1971; Dryzek 1983; Dryzek and Ripley 1988; Goggin 1987; Ingraham 1987; Ingram and Schneider 1990, 1991, 1993; Lasswell 1971; Linder and Peters 1984, 1987, 1988, 1989, 1991, 1992; May 1991; Orth 1999; Schneider and Ingram 1988, 1990a, 1993, 1995, 1997). This evaluative focus led policy-design theorists to emphasize the analysis of the content of policy. Through this analysis, two types of insights have been gained. First, by comparing the consequences of policy with its content, we learn about the causal drivers actually at work and their effects in the real world. Second, policy content can be mapped back to the policy-making process that created it. This comparison provides important evidence about the workings of the political process, including which actors have power, what beliefs hold sway, and how information is used. The research that is reported in this book aims at producing this second insight.

Policies, or policy designs, are *authoritative decisions,* meaning that the decision-makers have the power – or can delegate power to others – to force compliance through sanctions. These binding decisions can take a variety of forms, for example statutes, official government regulations, executive orders, court decisions, or formal written agreements reached between political or administrative elites and other public or private actors. These are the receptacles for formal statements of policy goals, as well as the instruments and any organizational arrangements to achieve them, and the choice of target groups to be affected.

Goals are intended consequences. Goals can vary enormously in both form and content (Goggin 1987). For example, goals, in terms of form, can be single or multiple, stated in ambiguous or unambiguous terms, internally consistent or inconsistent, short or long term, or incremental or non-incremental. In the ART policy domain, the goals of policy designs range along a continuum from permitting and promoting the widespread use of available technologies, to regulating their use, to restricting or prohibiting access to certain kinds of technology or access by certain classes of people. We return to further discussion of the permissive–restrictive continuum later in this chapter.

Instruments, the second component of a policy's design, are the tools put at the disposal of the implementers or administrators of authoritative decisions in order to achieve policy objectives (Elmore 1987; Hood 1986; Howlett and Ramesh 1995; Ingram and Schneider 1990, 1991, 1993; McDonnell and Elmore 1987; Schneider and Ingram 1990b, 1993, 1995, 1997; Woodside 1986). Instruments are directed at influencing behaviours

of implementers and target groups in order to achieve policy goals. There are numerous ways in which instruments have been classified. One way to think about them, which is particularly relevant in our case, is that they can be arranged on a continuum from the most to the least coercive (Howlett and Ramesh 1995; Schneider and Ingram 1997).

Target groups are operationalized as those groups that are affected, either negatively or positively, by a policy. Examples are many; in the case of ART, these groups include the authorities who interpret and make operational the authoritative decisions (or the implementers), the clients who seek infertility treatment, the fertility clinics where services are provided, and the physicians who provide the services. According to Schneider and Ingram (1997), target groups can be categorized depending upon the power of the group and whether it is positively or negatively constructed. Explaining why particular 'constructions' or images are chosen and promulgated, and how these choices influence policy outcomes, might be helpful for understanding ART policy.

Policy output can be compared along these four designing elements. For the final comparison, however, we chose to assess the degree of autonomy and access on the basis of the combination of instrument choice and goals, in order to be able to compare the countries along the permissive–restrictive continuum (see Appendix).

The policy-designing process

The designing process has two major components: the choice made by actors about the arena to be engaged, and the behaviour and interaction of actors within that arena, namely coalition building. An *arena* is a context – that is, formal or informal, highly institutionalized or temporary and *ad hoc* – where policy-making is attempted and where policies are crafted and/or chosen. The arena is defined by the place or venue chosen – for example, the legislature, a referendum, the courts, or the meetings of an appointed advisory committee – and the policy-relevant interactions that take place there. Note that the arena is a narrower construct than the *policy domain*. All issues, ideas and participants relevant for a particular substantive policy area define the domain, and multiple arenas or venues for decision-making are likely to be available in most policy domains.

In most political systems there are multiple arenas that might be engaged, each with different potential rules and norms governing the range of acceptable actor interactions and decisions. Actors therefore have choices among these potential arenas. Their own characteristics and their relations with other actors in coalitions, for example, along with the rules and norms governing each arena will influence these choices. These choices, in turn, will have consequences for the policy designs that result.

The second major component of designing behaviour is the interaction among actors within a given arena. We expect this behaviour to be influ-

enced by actor characteristics, relations between actors such as the diversity of policy positions, the cohesion among and polarization between coalitions, and institutional conditions – the rules and norms affecting interaction in the arena. It is this interaction that is the proximate cause of policy design. We expect that choice among arenas and interaction within arenas may be partly intentional and goal-oriented that is, designing behaviour will be strategic and involve coalition building and partly guided by routines and norms. However, this is an empirical question that is addressed in the chapters referring to specific countries later in this book.

Actors and actor configurations: beliefs, interests and resources

The role of beliefs in the policy-making process is perhaps best developed by Sabatier (1988, 1999b) and Sabatier and Jenkins-Smith (1993, 1999) in their advocacy coalition framework (ACF). The ACF continues to undergo revision. The version here is based on Sabatier and Jenkins-Smith's 1999 presentation. The framework emphasizes the beliefs of policy-makers and the networks of these actors that develop within policy domains or subsystems. The ACF operationalizes these networks as comprised of coalitions of actors working in concert to achieve mutually desired ends. During periods of subsystem stability one coalition or, more specifically, its beliefs will define policy. Policy re-designing occurs when subsystems change, which is to say that the set of prevailing beliefs changes due to policy-oriented learning, turnover of participants in the subsystem, or to a change in the external environment. The role of beliefs in motivating individual and collective behaviour, and therefore policy outcomes, is central to the ACF approach. There are several types of actors, including (but not limited to) legislators, bureaucrats and spokespersons for organized interests, corporations, members of the media and policy experts, some of whom could be implementers. Implementers at both the national and sub-national levels of government form an important set of actors. Examples of implementers abound, from the German medical societies to Canada's Royal Commission on Reproductive Technologies to Cantonal health departments in Switzerland. There are three attributes of these individuals and organizations of individuals that interest us here: beliefs, interests and resources.

A belief is an idea about or a mental image of how the world is structured, how it works, and how it should work (Converse 1964; Putnam 1976; Young 1977). In our theory, beliefs are fixed (or at least relatively stable) in the short term; however, individual beliefs may change and actors may develop new beliefs as situations change and as new information is acquired and processed. We expect that as beliefs change and as coalitions grow or shrink, changes in the designing process, and in policy designs themselves, follow. Beliefs may change as a result of policy-learning

(Sabatier 1988; Sabatier and Jenkins-Smith 1993), either on the basis of experience with the effects of existing policy, or as a result of new information derived from empirical research.

Interests arise from the incentives experienced by the actors in the policy-making domain and in their larger environment. These incentives in turn have multidimensional origins. For example, representational considerations like constituent preferences or the prospect of electoral gain or loss focus the mind of elected actors and parties. Other sources for interests include organizational incentives and rules, professional norms or benefits, or a stake in relevant costs and benefits to be determined through decisions about policy design. Interests can be imputed and they can be self-reported. Along with beliefs, interests influence the goals, relationships and behaviour of actors, and therefore the policy designs that result from these behaviours.[11]

Resources include power, status, money, information and prestige. For example, in the context of policy designing in the US, legislators possess both formal and informal resources that can be used to get other actors in the policy domain to do what they might not otherwise do. Resources are conceptualized as a tool that, to varying degrees, gives an actor the ability to pursue his or her goals in the policy arena effectively.

We make a number of assumptions about actors. Actors can be either individuals or groups of individuals. Actors hold beliefs and have interests and resources that are known or knowable. Actors are aware of relevant attributes of and changes in the broader context. Actors know the rules of the game in all arenas and are aware of rule changes. Actors are aware of the policy positions of other actors in the issue domain. However, they face cognitive limits. They are rationally bounded. The policy-designing process can be dominated by either goal-oriented or rule-oriented behaviour (Bleiklie *et al.* 2000: Ch. 1).

Institutions as constraining rules and normative orders

While the policy-design literature and advocacy coalition framework offer strong analytical tools for understanding policy content and policy-making behaviour, each neglects the importance of the institutional context for policy-making.

One way to view institutions is as *rules* that structure how actors interact and what choices they have as they attempt to pursue their policy goals. Institutional rational choice theory explicitly addresses how institutions and individual characteristics interact in decision-making contexts. The fundamental insight animating the institutional rational choice approach is that *institutions* – organizations characterized or defined by rules and norms – structure the behaviour of decision-makers by defining incentives, structuring processes and motivating strategies for achieving goals. In the policy-making arena, the institutional context within which policy-

makers operate influences the amount and distribution of information available, the amount and distribution of power and control, and the costs and benefits to be derived from alternative decisions. These factors influence outcomes – and, specifically, the content of policies chosen.

In their framework for institutional analysis, Elinor Ostrom and her colleagues define three conceptual tiers of decision-making, where each tier is characterized by a set of rules.[12] The first is the constitutional level, where rules govern who may participate in policy-making and how decisions will be made. Rules at this level structure the next, collective-choice level. At the collective-choice level decisions are made that define the rules and policy content governing the final, operational level.

This conceptualization of institutions-as-rules defines supra-system, system and domain-specific rules as important constraints on the policy-design process. Hence, institutions are organizations or sets of organizing procedures that form arenas characterized by rules and norms that are used to manage conflict and facilitate resolution of conflict. They structure decision-making. Rules also advantage or disadvantage actors as they act intentionally to seek their goals. Rules may operate at system level or at locus level. System-level rules are those to which everyone is exposed – for example, a constitution, federalism, or national electoral laws. We might compare these rules across systems, but unless they change over time they are constants when examining one political system. Locus-level rules are embedded within the various organizations below the system level. A locus is a place to which some or all relevant actors may have access, that is, a venue, organization, or institution, where authoritative decisions about policy designs are made. They can be formal or informal; however, in either case institutional rules structure decisions.

Formal and informal rules are expected to influence the arenas (institutions or venues for policy designing) engaged by actors, and these choices among venues may be strategic – that is, intended to enhance the individual actor's or a coalition's ability to achieve his or her goals. Rules also influence the behaviour and interaction of actors within arenas by determining who is advantaged or empowered and who is not, how resources may be used, and what criteria govern a binding decision. For a given case of policy designing there may be a number of arenas of interaction – for example, the British House of Lords, the Swiss courts, or the Italian National Health Service.

In contrast to conceptualizing institutions as constraining design choices, institutions may also be conceived as *normative orders* that shape behaviour through their capacity to socialize their members (March and Olsen 1989). In this view, an institution is defined as a collection of values with corresponding norms and routines by which those values are enforced and implemented (Peters 1999: 29). Institutions as normative orders may operate through various mechanisms. First, they shape members' preferences. Second, the actors themselves are carriers of

normative expectations, and by expressing and communicating their expectations they develop, reinforce or shape institutions (Peters 1999: 57, 107). In our analysis normative orders are first and foremost seen as beliefs. However, in order to understand why actors in a polity collectively may accept and support certain institutionalized rules we need to take into account that they are embedded within normative orders and are not atomistic utility maximizers.[13] Furthermore, preferences are not externally given, but depend on the context in which actors find themselves and how they interpret their interests within and ascribe meaning to that context.

We will focus on how rules at the system and domain levels affect policy design. The analysis of possible effects of system-level characteristics (state structure, political system, type of democracy) and rules on policy design will be particularly studied in the comparative analysis. At the domain level we will concentrate on decision rules as they are expressed by the majoritarian winner principle and the consensus-oriented power-sharing principle. The former may be considered a 'lax' rule in the sense that the majority has a relatively high degree of freedom to impose their view, whereas the latter power-sharing principle may be considered a 'tight' rule in the sense that decision-makers, regardless of the majority behind them, are constrained by a power-sharing principle (Lijphart 1999; Timmermans 2001). One interesting feature of the institutional analysis is that it allows us to clarify the extent to which domain-specific rules are determined by or reflect rules at the system levels. In this context there are two important questions to clarify: to what extent do institutional rules facilitate or hamper actor preferences to be transformed into policy, and to what extent do the rules favour or disfavour specific actors and preferences to make an impact on policy design? Finally, the rules themselves have a normative underpinning, and it would, for instance, be impossible to explain why actors obey rules that do not serve their interests without taking into account the way in which the rules are embedded within normative orders.

The broader context

Sabatier and Jenkins-Smith argue that in the case of policy change, or redesign, the external environment matters.[14] The same logic would apply to the initial design of what John Kingdon (1995) calls 'novel' policies. We identify several aspects of the broader context that ought theoretically to affect policy-making: (1) the development of knowledge and research, both basic and applied (Gottweis 2002) and (2) relevant events, such as crises, well-publicized court cases, media attention to relevant experiences, and elections might influence the designing of policies, namely agenda-setting and the timing of decision-making; (3) public opinion and changes in public opinion are taken into account by actors and might influence their strategies; (4) other relevant political, social or moral issues discussed in the past that might frame the ART issue for debate

(see, for example, Rose and Davies 1994), for example abortion, women's rights, other green or red biotechnology issues, or competing issues on the public and or governmental agenda; (5) other issues that have been raised about ART in the external environment that can be found in the decisions and actions of the European Union, the European Parliament and the European Commission. Policies already adopted in neighbouring countries also influence the policy solutions considered. These examples raise questions about policy diffusion and policy learning (see Bennet and Howlett 1992; Hall 1993; May 1992; Rose 1993; Schneider and Ingram 1988) that are addressed in some of the eleven case studies that follow. In each instance, it is a *change* from the status quo that may impact the beliefs, interests, resources and policy positions of actors and, through these actors, the policy re-designing process and policy re-designs.

Summary

To summarize, we have explicated the Comparative Policy Design Framework that can be used to help explain ART policy design choices, both within and across countries. The framework accounts for the selection of policy goals and instruments, as reflected in content. Essentially, we have posited a behavioural framework that focuses on behaviour that is directed at affecting outcomes of the policy-designing process, including the level of client access and autonomy for physicians and researchers. Our line of argument is that decisions and actions – and resultant levels of access and autonomy – are explained in terms of the policy positions of actors; the rules, norms, procedures and habits shaping the institutional context; and relevant attributes of the external environment. The case studies that follow this chapter will show the extent to which ART policy actors and actor configurations, institutions and the broader context influence design decisions and actions.

What is the comparative case study method?

Our framework has directed us to shine a spotlight in certain directions, and now we need to translate this guidance into the set of specific questions that were used to guide the empirical research that is reported in the next eleven chapters in this book. Here we rely on the advice of Alexander George and Richard Smoke (George and Smoke 1974: 95–103). In their award-winning book on deterrence, George and Smoke (1974: 96) argue for a 'focused comparison of cases' where:

> '[a]ll cases are approached by asking identical questions. This standardized set of questions or hypotheses insures the comparability of results. (Additional questions, of course, may be asked of any given

case if it seems desirable to bring out unique features it may possess, so that the method has some built-in flexibility.)

In the following section of this chapter, we offer the set of questions that guided the empirical research on assisted reproductive technology policy design. We divide our questions according to the dependent, intervening, and independent variables in the model that is schematized in Figure 1.1.

Questions about policy design

Earlier in this chapter, we defined policy design as the goals, instruments, rationales and portrayal of target groups. This operational definition suggests three empirical questions for research. First, what goals did policy-makers adopt? Second, what instruments did they employ to achieve these policy goals? Third, who are the relevant target groups and how were they portrayed?

These policy-design attributes are measured through direct and indirect observation. Goals and instruments are uncovered by analysing authoritative decisions for content. The way that target groups are identified, 'socially constructed' and emphasized is determined by analysing the language of documents and by interviewing participants in the policy-designing process.

More specifically, each instance of a policy design or re-design constitutes one observation, and data concerning the variables in the CPDP framework for that case are collected systematically. For example, in one state there may have been three instances of policy design and re-design directed at regulating surrogacy: the initial design, and two modifications. These constitute three observations. While data are collected at the case level (i.e. the case as the unit of analysis), data are also reported and analysed at the national and, in the case of federal systems, at the sub-national level. Case-level data collection preserves a finer grain of variation and this proved to be helpful, particularly when changes in the explanatory variables drove change in other variables and, ultimately, policy designs.

With some slight variations, field researchers in each of the eleven countries represented in the CPDP project used the coding sheet, with instructions about how to use it. The primary purpose of coding was to analyse each authoritative decision for four components of content: (1) the specified types of assisted reproductive technologies that were affected by the decision; (2) the specified instruments (or means) that were used to achieve the objectives that were specified in the decision; (3) the specified target groups affected by the decision; and (4) the specified goals that this decision was designed to achieve. The coding sheet was also designed to record instances where there are clear causal relationships, or linkages, among technologies, goals, instruments and target groups. It was also constructed to offer the option to add unanticipated provisions, that is closed-ended responses where we have sufficient information and open-ended responses where we do not.

Questions about access and autonomy

On the basis of the detailed coding on policy instruments and the techniques and issues they address, each of the cases was interrogated first about the *level of access* afforded to various clients, including the techniques and funding or coverage for ART available to them, in order to determine the level of access and level of autonomy (see Appendix). Then, addressing the *level of autonomy* provided to the practitioner and researcher communities, we assessed, on the grounds of the policy instruments chosen, how much freedom practitioners and researchers have to decide: which ART to practise and what type of research to conduct; how to practise medicine or conduct research; who can practise ART or conduct research; how to assure compliance with possible policy designs on ART or how to secure the quality of practice and research; and to what extent the researcher and practitioner communities are involved in implementing the policy design (see Appendix).

Using a multi-method approach to collect data that combine interview data with documentary research, we categorized each country in terms of autonomy and access and arranged them along a permissive–restrictive continuum.

Questions about the policy-designing process

In the first section of this chapter, we put forward the argument that the policy-designing process is an intervening variable between actor characteristics, institutions and the external environment on the one hand, and policy design on the other. Here we identify two questions relating to the policy-designing process that each of the authors of the case studies has addressed: which arenas are engaged in the policy-designing process, and what is the nature of the behaviour and interaction of actors within that arena?

Through interviews and secondary sources (for example, news reports and public documents) the researchers in this collaborative project have ascertained which, if any, venues or arenas were intentionally chosen for strategic purposes. From these sources, an account of the designing process – that is, the sequence of important communications, actions and decisions – was reconstructed for each 'case' in each country. This latter collective behaviour is referred to in Figure 1.1 as *interaction within arenas*. The crucial question turns on how actors and institutional conditions interact and shape the designing process.

Questions about actor characteristics

Each investigator in the CPDP project used the answers to questions in a common interview schedule to map the relative policy positions of actors – for the most part, organizations – in each network in much the same way

that 'influentials' are mapped in network analysis (Eulau and Prewitt 1973). Once the map was completed, the network was described in terms of such attributes as the distance between positions of actors in the network (from congruent to divergent); the nature of aggregation (a continuum from individual to alliance); level of aggregation (from 'tight' policy communities to 'loose' issue networks); and distribution of influence (domination by the political institutions, local non-governmental institutions, elites or interest groups). In this manner, coalitions – with their shared beliefs and/or interests – were identified and recorded. To corroborate the findings about actors and their interactions with others from interviews, documentary evidence was also collected and analysed systematically.

From the Comparative Policy Design Framework, we formulated a number of additional questions about actors and their individual-level attributes to guide our empirical research. Which actors have been influential in designing or re-designing policy? What are their beliefs, interests, and resources? How have their beliefs, interests and resources changed over time?

In order to define the set of relevant actors and their organizations within a policy domain, we used the 'reputational' approach (Waste 1986).[15] The reputational approach assumes that the influence of an actor within a policy domain can best be assessed by the judgment of all the other actors within the domain or by 'neutral' experts. Laumann and Knoke (1987) have developed a reliable procedure for constructing a list of relevant actors and organizations.

Once a list of influential actors had been generated for each country, the country specialists interviewed – either face-to-face or by telephone – primary policy designers and other actors in the policy domain, at all levels of government. The interview schedule that was used in this project included questions about actor normative and positive beliefs, positions on relevant issues, rationales, perceptions of target groups, and resources available. Open-ended questions about the actor's role in the policy process were also included in the interview schedule. To increase the level of confidence in inferences drawn from interviews, wherever possible we used 'triangulation' (Singleton *et al.* 1993: 391–2) or a dissimilar method of data collection, for example by analysing for content documents such as committee hearings, actors' public statements, and unpublished reports and analyses.

Questions about institutions

The rules and norms that structure decision-making are important, as are the routines and habits, or 'rules of thumb', that individuals rely upon when making choices. They represent a major set of explanatory variables. The Comparative Policy Design Framework suggests a number of research questions related to institutions: What institutions are engaged? At what

level are rules, norms, routines, and 'rules of thumb' engaged? What types of institutions are used to structure or shape behaviour? To what extent can winning coalitions be explained in terms of stable configurations of rules that structure power, resources and policy options? To what extent does the winning coalition represent shared or contested norms and values with regard to policy goals and policy instruments?

Various arenas of interaction may exist for a given case of policy designing. For example, in the United States, in one of the fifty states during one time period, individual litigants may engage the courts while the legislature writes new law. In general, one or a very few political institutions will constitute the arena. Documentary materials and interview data were used to identify the institutional venues engaged in each case of policy designing and re-designing. In most cases these institutions are obvious and can be inferred from the authoritative decision itself. Investigators also looked for less obvious arenas and venues, such as scientific advisory committees or commercial research enterprises.[16]

How might one go about identifying and measuring levels, and the types of rules, procedures, routines, and habits within levels? Documentary materials and interview data were used to identify the institutional venues engaged in each case of policy designing and re-designing. Systematic primary document analysis was also used to identify the absence or presence of each of different types of institutions. This analysis was supplemented by answers to questions on the interview schedule. Again, we relied on historical records and elite interviews in order to identify any significant rule changes. Informal and *ad hoc* structures were also taken into account whenever these appeared to be crucial to understanding what was going on. Here 'triangulation' and corroboration of evidence is of paramount concern.

Questions about the external environment

There are a number of questions about the external environment that each author asked of his or her case. Chapter authors asked about what relevant knowledge and research, both basic and applied, are germane; the nature of public opinion about ART, and how it has changed over time; how relevant national or international events might have affected the choice of policy design; and what other issues might colour the debate over ART policy design.

Measuring these contexts requires historical reconstruction – from published research and reports, relevant public opinion polls and journalistic accounts. Government statistics were also used to measure changes in other relevant aspects of the external environment at both the national, and in the case of federal systems, sub-national levels of government – for example, the Swiss canton, the Canadian province, the American state or the German Länder.

Summary

All the original essays in this book employed the same strategy for gathering data, consisting of a combination of documentary analysis, interviews and the reputational approach. Thus, the coding and survey instruments used to collect data in all eleven case studies were identical. Where adjustments to the country specific situation were necessary, these are marked in the endnotes to the cases.

How this book is organized

Chapters 2 to 12 are devoted to explaining how and why policy makers *within a country* initially designed ART policy the way they did and how ART policy is currently governed. The chapters also examine and explain why ART policy design within the country has changed over more than two decades. The chapter sequence is organized according to whether we found a liberal or restrictive ART policy design. Thus we start with a group of countries – Belgium, Italy, Canada and the United States – that have no or very limited regulation at the national level, and grant high autonomy to professionals and easy access to patients (Chapters 2–5). Then follows a group – Spain, the United Kingdom, France and the Netherlands – where a more elaborate policy design limits autonomy and access to some extent (Chapters 6–9). Finally we discuss a group – Germany, Switzerland and Norway – that have put in place restrictive policies through tough national legislation (Chapters 10–12).

The final chapter in this edited volume, Chapter 13, compares ART policy design and re-design across the eleven European and North American countries in the study. The countries included in our comparative analysis vary considerably in terms of the scope of policies, the biomedical policy governing regimes, the autonomy of medical experts, and user access to technologies. How do we explain these cross-country differences?

Considering each of the main groups of explanatory factors in our model, we can distinguish three main explanations. One possible explanation is that institutional differences, rules and norms, at systems or domain level, account for differences in policy design choices. Another possible reason for design differences is that the normative and positive beliefs of key actors differ across the eleven countries included in the comparison. Finally, scientific discoveries, medical 'breakthroughs' and new ethical and moral concerns that are all part of the external environment may very well affect ART policy design differently across nations. However, our model emphasizes the possibility that the explanations may be more complex. In the last chapter we will argue that the explanatory factors in our model combined to produce varying conditions of policy design across countries that resulted in a few major types of policy design processes: designing by non-decision, designing by experts, designing by

mobilization and consultation and designing by party politics. These processes in turn tended to be associated with certain policy designs. The type of policy-design process cannot fully explain the content of policies that we observed, and we did not find a perfect match between policy design along the permissive–restrictive continuum and the type of design process. Yet we do believe that our findings indicate that we have identified a number of conditions for policy design that are helpful for understanding the capacity of states to make design public policies, and the processes through which policies are made.

Notes

1 In vivo or in vitro, with the goal to induce pregnancy or for research purposes.
2 IVF: fertilization outside the woman's body 'in a glass' (in vitro) and transferring the embryo into the uterus (embryo transfer) includes several steps from ovarian stimulation and egg collection to embryo transfer.
3 There are several techniques that might be applied with IVF to ease the access for sperm through the shell of the oocyte (zona pellucida) by micromanipulation, such as zona drilling, partial zona dissection, subzonal insemination (SUZI), intracytoplasmic sperm injection (ICSI, a micromanipulation whereby a single sperm is captured in a thin glass needle and injected directly into the zooplasm of the egg to overcome severe sperm dysfunction) as well as techniques for assisted sperm retrieval, such as microepididymal sperm aspiration (MESA) and testicular sperm extraction (TESE). The technique of assisted hatching is used to improve the implantation rates through creating an opening in the zona pellucida (a developing embryo must 'hatch' out of the zona pellucida before it can implant in the uterus).
4 Placement of a sperm sample, intracervical, intrauterine or intratubal, by using either the sperm of the partner or donated sperm.
5 Gamete intrafallopian transfer (GIFT) involves the injection of one or more eggs mixed with prepared sperm directly into the fallopian tubes, so fertilization occurs in vivo. A variation is the zygote intrafallopian transfer (ZIFT), where eggs are retrieved and fertilized in vitro as in IVF, but the embryo is transferred at a very early stage (as zygotes) into the fallopian tube.
6 Surrogate parenting is not defined through any of the above assisted reproductive technologies; it is rather an arrangement between the intended parents and a woman who agrees to bear a child for the future parents. Two types of surrogacy exist; in the first type, the surrogate mother receives the child through artificial insemination of the sperm from the future father, and is therefore the genetic as well as the gestational mother. In the second type, the surrogate mother receives an embryo fertilized in vitro, stemming either from the gametes of the intended parents or from gametes of one or two donors, whereby the surrogate mother is not the genetic mother.
7 Gender selection includes any measures to choose the sex of the future child in connection with insemination, GIFT/ZIFT or IVF. Choosing the sex of the child is applied in certain cases to avoid the transfer of severe hereditary illnesses.
8 Pre-implantation diagnostics is the genetic screening of the embryo after fertilization in vitro and before transferring into the women's body (embryo transfer) in order to determine whether an embryo should be transferred or not. A totipotent cell is split from the embryo in order to undergo genetic analysis.

9 Genetic engineering involves transferring, modifying or replacing human genes in a strand of DNA; in connection with ART in particular germline therapy (micro-injection of foreign DNA into an early embryo, so that it becomes incorporated into the germline of the individual, and thus stable inherited in subsequent generations). Different techniques have been labelled as cloning: the first one consists of splitting or twinning an embryo, which means inducing an embryo to divide into multiple embryos in an early stage of its development; another technique is to remove the nucleus from an egg and insert the nucleus of a cell taken from an IVF-created embryo. The most discussed type of cloning is a variation of the aforementioned technique, whereby the nucleus of a somatic cell stemming from an already existing person is used. Chimera-building and hybrid means bringing together human and non human gametes for fertilization (hybrid) or bringing together totipotent cells from genetically different zygotes to create one embryo (chimera).

10 Some argue that there has been a 'deprofessionalization'; at least there are various indications that authority and self-regulation is more contested nowadays. Patients are more ready to challenge physicians, they have also become better organized in several countries, and alternative medicine has gained in importance.

11 Although interests as motivators of policy designing were neglected in earlier versions of the ACF, in later versions Sabatier and Jenkins-Smith include the role of individual or organizational self-interest, in addition to beliefs, in explaining individual behaviour in the policy process. For example, when actors within coalitions share beliefs but have divergent interests, coordination will be more difficult. The CPDP identifies beliefs, interests and resources as actor characteristics likely to be important for designing behaviours and policy content. Critiques by Schlager (1995) and Schlager and Blomquist (1996) pointed out that beliefs alone were not sufficient to overcome the collective action problem; divergent interests could motivate.

12 Elinor Ostrom and her colleagues have developed a detailed analytic framework for empirically investigating the premises of institutional rational choice theory (Ostrom 1986, 1990, 1991, 1996; Ostrom *et al.* 1993), and this framework has now been tested in a variety of different policy contexts and countries. The approach has been labelled the Institutional Analysis and Development Framework (IAD).

13 Theories about organizational culture also focus on normative orders and behaviour, but whereas organizational culture approaches lean more towards individualist imagery, institutionalism invokes institutions as causes (Jepperson 1991: 153).

14 According to ACF, policy change is *more* likely to occur as the result of some 'perturbation in noncognitive factors external to the subsystem'. (Sabatier and Jenkins-Smith 1999: 123).

15 This is in contrast to the 'positional approach', which depends on the relational data about the policy network itself, and the much narrower 'decisional approach'.

16 We consider informal and *ad hoc* structures only if these appear to be crucial to understanding what has been going on – for example, if a special commission is created not only for expert advice but also to design a policy.

2 ART policy in Belgium

A bioethical paradise?

Nathalie Schiffino and Frédéric Varone

Introduction

At first glance, Belgium seems to be a bioethical paradise for those who want to practise and enjoy Assisted Reproductive Technology (ART) with a minimum of restrictions. As a matter of fact, there are no substantial authoritative decisions on ART or on scientific research in that field. Access to ART practices (who has the right to ask for artificial insemination or in vitro fertilization, for instance) and the scope of techniques physicians can use are not formally regulated. There is no legal framework regulating the status of the embryo, scientific research on human beings and their embryos, or the re-utilization of humans' organs for research aims. This means that everything is allowed, since nothing is strictly forbidden.

However, the reality is somewhat more complex, mainly for two reasons. First, certain procedural norms have been adopted at different periods of time (such as the licensing of ART centres). Second, the autonomy of the medical community is self-limited by different formal and informal rules that tie the practitioners on the one hand to the code of conduct of their professional 'corps', and on the other hand to the ethical principles of their hospital or clinic.

Besides the adoption of these few authoritative decisions, it is also important to note the parallel non-decision process (Bachrach and Baratz 1970: 7). In Belgium, the rather thin policy design (as an output) combines with a significant non-decision flux (as a designing process). Indeed, since 1982,[1] several bills for the substantial regulation of ART in Belgium have been introduced without having actually been adopted. Policy-makers had the capacity to keep issues off governmental and parliamentary agendas. This chapter aims at describing, interpreting and explaining the specific Belgian situation. First, we describe the leadership position of Belgium in terms of scientific development as well as market extension. Second, we analyse policy design in terms of its process and outputs, and codify the few procedural authoritative decisions made. Third, we attempt to explain the limited policy design aided by six hypotheses: (1) the reluctance of the

Social-Christians to confront the bioethical issues of ART; (2) the well-organized interest of the medical practitioners; (3) the lack of group pressure among ART patients; (4) the multi-level governance games in a federal State; (5) the inter-policy coordination with other 'death and life' issues (e.g. abortion, euthanasia); and (6) the restricted impact of external events in Belgium.

Three research questions guide this chapter: why are there so many non-decisions in Belgium? Why are the authoritative decisions mainly procedural? Is Belgium really a bioethical paradise?

'State of the ART' in Belgium

Historically, Belgium has been among the leading countries in the development and commercialization of ART. This pioneering status applies to artificial insemination (AI) as well as to in vitro fertilization (IVF). Since the 1960s, Pr R. Schoysman has been developing AI in the Vriije Universiteit in Brussels (VUB). By 1986 he had already achieved 2,000 pregnancies. In 1988 there were some twenty centres answering between 500 and 1,000 demands for AI a year (CEDIF 1988), and each centre owned its own sperm bank. In 1983, after the UK and France, Belgium was the third country where a test-tube baby was born following IVF performed at the Katolieke Universiteit in Leuven (KUL). In 1988 there were a dozen centres practising IVF and there were approximately 2,000 demands for it per year. These techniques have been steadily developing, and at the same time new technologies are being implemented. Today intra-cytoplasmic sperm injection (ICSI) is a well-known technique; it was first used at the VUB by Pr Devroey and Van Steirteghem's team. In 1992, they reported the first birth to succeed by this technique. In 2001, 2,840 babies were born using ICSI in the ART centre of VUB.[2]

ART centres developed without licensing until 1999. Following a national report (BelRAP 1995–96), thirty-five centres were active in 1996 with approximately the following regional distribution: twenty-four in Flanders, six in Brussels and five in Wallonia. For a long time this situation has meant that Belgium has the highest density of ART centres around the world. Even following the regulations that were adopted in 1999, the country is still facing an 'over-supply' if we consider that the world-wide average is one centre per 700,000 inhabitants while Belgium still has twenty-one official centres (one centre per 500,000 inhabitants) with different types of ART programmes. Moreover, there are also eight human genetic centres (one centre in each of the eight universities with a medicine faculty) with which the ART centres practising IVF are legally obliged to work.

Statistics on ART practices in Belgium depend on a voluntary provision of information by the centres themselves. The difficulty of collecting recent official data can be explained by several hypotheses. First, only a

relatively recent policy requires a 'Physicians' College' to set up a database in order to evaluate the external quality of the medical practices,[3] although this newly created organization has no power to coerce the centres. Second, before the decision about the 'Physicians' College' came into force, the Belgian Register for Assisted Reproduction (BelRAP) gathered – on a voluntary basis – data from about 90 per cent of all hospitals involved in the medical and research uses of ART. Due to the rapid evolution of ART technologies, the collected statistics suffered a delay of two to three years (i.e. it is nearly impossible to carry out research like ours with up-to-date data). Third, the centres face at least three situations that prevent them from releasing figures too quickly: (1) the over-supply situation described above; (2) a tension between University centres and smaller non-University centres; and (3) an economic competition between the most efficient centres. Meanwhile, collaboration between BelRAP and the Physicians' College currently aims at establishing an on-line register. Tables 2.1 and 2.2 give a short overview of ART development in Belgium.

Policy design

In this section, we describe the design process (as a non-decision process) and present the rare design outputs (as procedural authoritative decisions). Then, we codify this rather thin policy design according to the

Table 2.1 Number of cycles

	1990	*1991*	*1992*	*1993*	*1994*	*1995*	*1996*
IVF	2,685	3,151	4,319	3,265	3,681	3,767	3,488
ICSI	–	296	732	1,557	2,806	3,956	3,870
MESA/TESE	–	–	–	–	–	–	531
Total of fresh cycles	2,685	3,447	5,051	4,822	6,487	7,723	7,889
Cryotransfers	498	670	1,110	1,347	1,533	1,610	1,709
Total of all cycles	3,183	4,117	6,161	6,169	8,161	9,333	9,598

Source: Belgian Register for Assisted Reproduction (BelRAP) *Annual Report* 1995–96.

Table 2.2 Cryopreservation of embryos and results of cryotransfers

	1990	*1991*	*1992*	*1993*	*1994*	*1995*	*1996*
Embryos frozen	–	–	–	–	11,617	12,157	15,735
Embryos thawed	–	–	–	–	4,794	–	8,437
Embryos placed	–	–	–	–	2,188	–	3,024
Transfers	498	670	1,110	1,347	1,533	1,610	1,709
Pregnancies	73	78	136	148	163	210	268
Live births	55	59	100	121	115	93	198

Source: BelRAP, *Annual Report* 1995–96.

autonomy attributed to the medical community to decide upon practices of ART and research, and according to the level of access afforded to the various eligible patients.

Designing process: stages and arenas

We identify four historical stages in the designing of ART policy in Belgium. A specific issue that is debated within a specific decision arena dominates each of the four main phases in the policy design.

The first phase runs from the 1960s until the 1980s: it is the period of *AI development self-limited by the physicians*. Forging Belgium's leading role in developing new techniques and the absence of legal decisions to clarify them was the National Council of the Medical Order, which in 1975 introduced Article 88 into its Medical Deontology Code. It stipulated that AI with donor (AID) was limited to married couples, who must give their written and informed consent while the sperm donor remained anonymous. Furthermore, the physician should investigate the motives of the married couple as well as the good health of the donor. Since then, while the anonymity of the sperm donor remains the official rule (it was never questioned and even reassessed in the media in 2001 by the Minister of Social Affairs, Public Health and Environment), the condition of marriage has become more lenient. The deontological article, newly formulated, focuses on the well being of the child to be born; the necessary competencies of the physicians; and the role of the ethics committees.

The second phase of the policy design covers the period from 1982 – a first attempt to regulate AID at the sub-national level – to the *paternity order protected by a revision of the Civil Code* in 1987. In 1982, a bill was introduced in the Parliament of the French Community, a sub-national entity within the federal system of Belgium, for the purpose of regulating sperm donation and conservation (i.e. banks of sperm, prohibition of commercialization); AID (physicians and ART centres, written and informed consent of a married or stable couple, anonymous donor); and the question of paternity in the case of AID (i.e. that the husband is the legal father and that he cannot contest his paternity if he has given his written and informed consent for the AID). The requested opinion of the State Council was negative because the French Community, as a sub-national entity, has no formal power for the modification of the Civil Code that is *de jure* necessary for regulating the paternity order. Thus, the bill was never adopted. Elements of this first bill were reintroduced several times in new bills (for instance on 6 April 1987) and even enveloped other themes in an attempt to settle substantial regulations about ART, but none of the bills were adopted until recently. Meanwhile, a federal law relating to the first bill was enacted on 24 February 1987 in order to modify Article 318 §4 of the Civil Code. Since then, the husband who gives his written and informed consent to AID cannot contest the paternity of the child (of his wife).

The third phase (1986–95) is characterized by the *creation of the National Consultative Committee for Bioethics* (NCCB). Since May 1984 the idea of creating such a Committee had been discussed at the federal level (e.g. bill propositions on 24 May 1984 and 24 March 1988). After quite a complicated but generally consensual debate between all the involved political entities (i.e. the federal level on the one hand and the French, Flemish and German Communities on the other hand), the law that institutionalized the Consultative Committee for Bioethics was adopted on 6 March 1995. Several regulations (decrees of April 1997 and May 1997) then established the composition and the day-to-day functioning of the Committee.

Apart from this institutional design, several substantial ART regulations were also proposed during this phase; however, none were accepted. Two identical rather 'restrictive' bills on a mandatory system of licensing and reporting for ART centres that practise AI, IVF and embryo transfer (ET) were proposed in February 1987, April 1987 and March 1988. Three rather 'permissive' bills on AI, IVF, ET, genetic screening and research on supernumerary embryos were proposed in June 1992, June 1995 (with a direct reference to the law enacted on 20 December 1988 in France regarding medical research on human beings) and February 1997. These 'non-adopted' bills form part of the procedural (versus substantive) decision process about ART in Belgium.

It is also interesting to note the rarity of case law. Only two decisions by the Judiciary, in March 1993 and June 1996, are linked to ART: two opposite judgements were delivered by the Youth Tribunal of Brussels regarding adoptions after recourse to surrogate mothers.

The fourth phase began in 1997 and is still continuing: the period when the policy agenda is focusing primarily on the *research on human embryos* and on *cloning*. This issue is linked to two European initiatives. First, the Council of Europe issued, on 4 April 1997, the Convention on Human Rights and Biomedicine (with Article 18 on embryo research), which was then amended with an additional protocol on the prohibition of the cloning of human beings in January 1998. Second, the European Directive 98/44/CEE (6 July 1998), based on the legal protection of biotechnological inventions, excludes the human body and processes of human cloning from patents and the human embryo from use 'for industrial or commercial purposes' (Articles 5 and 6). European initiatives form part of the debate about ART in Belgium. The Social Affairs Commission of the Belgian Senate has produced a report on Article 18 of the Convention on Human Rights and Biomedicine. Ten bill propositions on embryo research and cloning were introduced in both the Senate and the Chamber between July 1997 and April 2001.

Under the current legislature, a Senate Special Commission on bioethical matters was established on 8 February 2001. The representatives of the different political parties immediately proposed several bills to this Special

Commission. One of the texts (on 20 March 2001) was considered consensual enough to be chosen as the basis for the Senate debates. The discussions could possibly lead to a federal law regarding research on in vitro embryos and cloning, but it should be noted that the process is being considered separately from a law on ART. For the moment Belgium has not yet signed the Convention on Human Rights and Biomedicine, and it still does not have substantial regulation on ART.

Design as outputs: a few authoritative decisions

In terms of formal regulations, the policy design comprises the federal modification of the Article 318 §4 of the Civil Code (24 February 1987) that protects – under normal conditions – the parenthood of a child born by AI; the decree of 14 December 1987 regarding the licensing of the human genetic centres; the federal law of 6 March 1995 creating the NCCB; the decrees of 10 June 1991 and 21 March 2000 and the ordinance of 17 September 1999 on Social Security insurance and ART; and the decrees of 15 February 1999 regarding the licensing of ART centres and the creation of a Physicians' College.

According to a detailed content analysis of these regulations, the constitutive elements of the policy could be summarized in the following way. In terms of goals, no particular consequences or substantial objectives (such as, for example, protecting human dignity, promoting a determined family model) are explicitly developed in the decision-making process. The same conclusion applies to the policy rationales: no justifications for the choice of goals or instruments are explicitly expressed in the official decisions taken.

The main target groups are, without doubt, physicians, hospitals with ART centres, and human genetic centres. The patients may also be considered as an indirect target group insofar as the reimbursement of ART costs are concerned.

Licensing and reporting systems are the two main policy instruments. On the one hand, the composition and formal functioning of the NCCB are regulated by royal decrees. On the other hand, formal procedures and specific conditions must be respected by a hospital if it wants to get an official licence for practising – with the obligation of annual reporting – genetic analysis and counselling (by the human genetic centres), gametes conservation (by the ART centres with programme A) and IVF (by the ART centres with programme B).[4] Techniques of ART that are regulated are listed in Table 2.3. This Table also indicates the conditions that a hospital must respect in order to receive an ART Centre licence.

The implementers of the licence and reporting instruments are mainly the Social Affairs, Public Health and Environment Ministry (for its role in Public Health in this case), but also the Social Affairs and Retirement Ministry (especially for the health-care insurance in the ART field), and even

Table 2.3 ART definition and licensing conditions (according to the decrees of 15 February 1999)

Reproductive medicine	*Programme A centre (without an ART laboratory)*	*Programme B centre (with an ART laboratory)*
Techniques	• Information/ accompaniment, check-up, diagnosis and treatment because of sterility problems • Super-ovulation treatment • Gametes punction and transfer to a B programme	• Gametes treatment in order to practise IVF • Embryos re-implantation • Embryos and gametes cryopreservation
Conditions to be fulfilled in order to get the licence	• One programme for 700,000 inhabitants • Infrastructure, specialized practitioner • At least 3 years practising ART	• One programme in each of the universities with a medicine faculty (NB: max. one non-university programme by Province and at least one public hospital by region) • ART laboratory • At least 6 years practising ART • Agreement with one human genetic centre (in a university hospital)

the Justice Ministry or the Science Policy Ministry (signing the decisions taken in relation to the NCCB). The NCCB and the Physicians' College advise the Social Affairs, Public Health and Environment Ministry as well as the Social Affairs and Retirement Ministry.

Codification of policy design: large autonomy for medical and research sectors, medium access for patients

In terms of policy design, the situation described above leads to a strong autonomy for practitioners. They are self-regulated according to the hospital rules.

As mentioned above, the National Council of the Medical Order introduced in its Deontology Code Article 88 on AI in 1975. The NCCB also influences the centres' practices. This is especially the case in its sixth opinion (in June 1996) regarding the arguments for the optimization of the supply and functioning of the IVF centres. Moreover, local ethics committees (in hospitals) provide advice to the centres regarding their practices and even their research (should the centres develop it). In any case, a medical team including physicians and psychologists whose guidelines are internally codified makes decisions regarding ART patients.

This enlarges access to ART for patients. Married or cohabiting

couples, single parents, and hetero- or homosexual couples choose from among the centres the one that meets their specific demand. However, the democratic character of access is conditioned by several social factors. For instance, economic constraints reduce access, as the Social Security system limits insurance coverage. To summarize, currently, medical acts (gynaecological practices and medicines) are reimbursed but technical manipulations in laboratories (such as ICSI) are not. On average, a patient must pay €375 for IVF, €575 for ICSI and €7.5 for cryopreservation.

Tables 2.4 and 2.5 give details regarding the consequences of the Belgian ART policy for both access and autonomy. These clearly show the importance of the non-design policy in Belgium.

Table 2.4 Access to ART in Belgium (according to the ordinance of 17 September 1999 regarding Social Security insurance and ART)

		Access	
Basic techniques			
Insemination (1)	With gametes of the couple (1a)	3	ND
	With sperm donation (1b)	3	ND
GIFT/ZIFT (2)	With gametes of the couple (2a)	3	ND
	With sperm donation (2b)	3	ND
IVF/ET (3)	With gametes of the couple (3a)	1	L
	With sperm donation (3b)	1	L
	With egg donation (3c)	1	L
	With embryo donation (3d)	1	L
Max. 24: 0–3 no or close to no (N), 4–11 low (L), 12–19 medium (M), 20–24 high (H)		*16*	*M*
Related techniques			
Surrogacy (4)			ND
Cryopreservation (6)	Sperm (6a)		ND
	Egg (6b)		ND
	Of impregnated eggs (6c)		ND
	Embryos (6d)		ND
Pre-implantation diagnostics (7)			ND
Genetic selection (8)			ND
Gender selection (9)			ND
ICSI (10)			ND
Max. 27: 0–4 no or close to no (N), 5–13 low (L), 14–22 medium (M), 23–27 high (H)			
Total of both groups of techniques (max. 6): 0 no (N), 1–2 low (L), 3–4 medium (M), 5–6 high (H)			

Notes
L, low; M, medium; H, high; ND, no design; 1 = low; 2 = medium; 3 = high.
There is no Belgian regulation about who has the right of access to ART. Explicit limitation of the health coverage regarding IVF: at least two unsuccessful cycles to get reimbursement.

Table 2.5 Autonomy in Belgium (according to the decree of 15 February 1999; programmes A and B centres)

		Autonomy	
Basic techniques			
Insemination (1)		3	H
GIFT/ZIFT (2)		3	H
IVF/ET (3)		3	H
Max. 9: 0–1 no or close to no (N), 2–4 low (L), 5–7 medium (M), 8–9 high (H)		*9*	*H*
Related techniques			
Surrogacy (4)		3	ND
Donation (5)	Sperm (5a)	3	H
	Egg (5b)	3	H
	Embryos/impregnated eggs (5c)	3	H
Cryopreservation (6)	Sperm (6a)	3	H
	Egg (6b)	3	H
	Impregnated eggs (6c)	3	H
	Embryos (6d)	3	H
Pre-implantation diagnostics (7)		3	ND[a]
Genetic selection (8)		3	ND[a]
Gender selection (9)		3	ND[a]
ICSI (10)		3	H
Max. 36: 0–5 no or close to no (N), 6–17 low (L), 18–29 medium (M), 30–36 high (H)		*36*	*H*
Research/experimental techniques			
Genetic engineering (11)	On gametes/germ cells (11a)	3	ND[a]
	On impregnated eggs, embryos (11b)	3	ND[a]
Research (12)	On gametes/germ cells (12a)	3	ND
	On impregnated eggs, embryos, zygotes (12b)	3	ND
Cloning (13)		3	ND
Chimera and hybrid building (14)		3	ND
Max. 18: 0–2 no or close to no (N), 3–8 low (L), 9–14 medium (M), 15–18 high (H)		*18*	*ND*
Total of all three groups of techniques (max. 9): 0–1 no or close to no (N), 2–4 low (L), 5–7 medium (M), 8–9 high (H)		*9*	*H*

Notes

L, low; M, medium; H, high; ND, no design; 1 = low; 2 = medium; 3 = high.

a Indirect effect: the decree of 15 February imposes collaboration between the programme B centres and the human genetic centres (Decree of 14 December 1987) which are in charge of the genetic medical activities.

Explaining policy design

In this section we briefly discuss six hypotheses in order to attempt to explain on the one hand the predominance of non-decisions during the whole designing process, and on the other hand the procedural character of the outputs in the policy design. We analyse the interests, beliefs and values of the following actors: political decision-makers (e.g. political parties, government coalitions); implementers of the few rules in use (e.g. federal and regional administrations); social groups who are targeted by the policy instruments (e.g. hospitals, medical and research sectors); and beneficiaries of the ART policy (e.g. patients, pressure groups that are active in the health-care sector). Furthermore, we take into account the institutional rules providing both opportunities and constraints for these actors who seek to design an ART policy within different arenas (e.g. legislatures, executives, courts, regulatory agencies, committees, etc.).

Our methodological triangulation (decisional and reputational approaches) confirms the existence of a rather restricted policy community. Thus it seems appropriate to focus our explanations on the role of political actors (parties, parliamentarians and administrations) and on medical actors (practitioners, hospitals). In fact, six actors clearly appeared as the leaders of the design process. These most influential actors are located in the political arena (leadership is used in terms of bills for political parties or giving advice to the NCCB) or in the medical arena (leadership is used in terms of their competencies, their national and international reputation, and the social network for the ART centres).

Moreover, we also examined contextual variables like the policy regulations of other – but strongly related – bioethical policy fields (e.g. abortion, euthanasia) as well as international pressures and events (e.g. European regulations, policy design in other countries, new ART development in research and medical practices).

The Social-Christians as smooth gatekeepers (hypothesis 1)

Or first explanation relates to the 'parties matter' hypothesis (see, for example, Schmidt 1996). It emphasizes the impact of political parties on the policy design, whereby the ideology of the governing political parties influences the choice of policy instruments.

A general background may be useful to understand better how the various Belgian political parties have tackled bioethical issues. Belgium has experienced conflict along three major cleavages (Rokkan 1972) – in chronological order, the confessional line, the socio-economic line and the cultural line. The cleavages are linked with the emergence of several social groups: Catholics vs seculars, left vs right, Walloons vs Flemish. These lines are partially institutionalized in that 'pillars' or 'sociological worlds' have long been recognized. However, the cross-cutting cleavages

softened the conflict between the different groups. Moreover, there is no structural homogeneity between these groups. For instance, the three traditional political families (Catholic, Socialist and Liberal) do not necessarily cover the Walloon and the Flemish ones. Along the socio-economic cleavage, the Catholics have historically occupied the centre position. In Belgium, being leftist doesn't automatically mean being socialist. Catholics as well as seculars have their own left and right. Belgium can also be considered as a consociative or consensus democracy (Lijphart 1977, 1999: 34–41). Indeed, the political system allows compromises to resolve the conflict among such a plural and segmented society as the Belgian one. It is by negotiating, and *not* by imposing the opinion of the majority, that the groups – and mainly the political parties – overcome their oppositions.

With respect to bioethical issues, the main historical cleavage divides the Catholics (Social-Christian political parties[5]) and the seculars (Socialist and Liberal parties as well as, more recently, the Green parties). The general trend of the bills proposed by the former parties has been the limitation of both the practitioners' autonomy (embryo's status as a person) and access to ART (married couples). The general trend of the bills proposed by the latter parties has been to increase practitioners' autonomy (freedom for scientific research) and to increase access to ART (i.e. not only for married couples).

Historically, the Social-Christian parties have been leading decision-makers: over more than half a century (from 1945 to 1999) they have played the key role in the governmental coalitions. During this period, the limited number of decisions taken regarding ART have aimed either at protecting a traditional conception of the family (paternity acknowledgement in case of AID in 1987) or at fixing procedural rules (licensing system in 1999) to guarantee the quality of the medical care in ART centres.

The main phenomenon to explain is the non-decision process. Clearly, the interest of the Social-Christians – while they were the central coalition's partners – was to avoid putting bioethical matters on the political agenda, mainly for two reasons. The first reason was to protect the internal cohesion of the Social-Christian parties. If the parties adopted a radical position on bioethical matters, they would *de facto* reduce themselves to a conservative nucleus. If they softened their position, they would lose one of their major differentiating characteristics and therefore another part of their electorate.

The second reason was to preserve the governmental coalitions that have united Catholics and seculars since World War II.[6] Because the parties adopt divergent religious–philosophical guidelines, the coalitions have always been at risk when problems along a religious–philosophical cleavage appear on the political agenda. Following the crisis over the abortion law in 1990, two significant events supported this assumption. In

March 1992, the governmental agreement stated that consensus would prevail at both governmental and parliamentary levels for matters such as bioethics, which did not explicitly form part of the governmental agreement. During the electoral campaign preceding the election held in June 1999, the president of the Flemish Social-Christian party declared that no bioethical question would be included in a governmental agreement while its party formed part of a coalition (see Dumont and De Winter 1999).

In July 1999, for the first time in fifty-four years, a coalition was constituted by the Socialists, the Liberals and the Greens (without the Social-Christians). In the field of ethics, this resulted in a change in the government's agenda. The process of euthanasia de-criminalization appears to be coming to an end, a Senate Special Commission on bioethical matters has been set up, bills on embryo research are being debated, and a law allowing homosexual marriage has been adopted (but is leaving aside the question of child adoption by homosexual couples) in spite of opposition from the State Council wishing to protect a traditional concept of the family.

In this new political context, other decisions regarding ART could be taken. However, one must take into account that the Greens (a member of the government coalition) are divided on bioethical issues (although this was not the case in connection with the abortion issue: the Flemish Greens adopted the abortion de-criminalization law with a unanimity at the Senate level and a majority at the Chamber level, and the Walloon Greens adopted it unanimously in both Chambers). The current process is mainly driven by the Liberals and the Socialists while the Social-Christians play an opposition role (especially the Walloons: the recent bill about research on embryos proposed by the Flemish Social-Christians is more liberal).

The important number of non-decisions and the procedural character of the decisions may be explained by the dominant position of the Social-Christians in government. They tended to avoid putting bioethical matters on the political agenda, and they tried to protect the internal cohesion of their parties in Flanders and Wallonia and of governmental pluralistic coalitions at the federal level. This assumption is confirmed by taking into account their attitude following the abortion crisis as well as the change in the political agenda since the alternative coalition came to power in July 1999. According to the experts interviewed, this conclusion has to take into account the rather rapid evolution of the sociological Catholic family in the last few decades. In the field, practitioners of Catholic ART centres have made decisions involving ethical re-positioning. Their main objective was to follow the rapid evolution of techniques. In the political arena, the debate on the Convention on Human Rights and Biomedicine promoted by the Council of Europe began in 1998, and the decrees regarding the licensing of ART centres were adopted in February 1999, at a time when the Social-Christians were still in power. These facts imply that the debate

about research on embryos did not reach a conclusion and that the authoritative decisions regarding the licensing were essentially procedural rather than substantial.

'Tit for tat' strategy within the medical sector (hypothesis 2)

Our second hypothesis examines how the practitioners belonging to different sociological families practise ART in a cooperative way based on reciprocity, in spite of their antagonism (Axelrod 1984).

At the level of the medical sector as a whole, self-regulation is restricted. Indeed, the only rule in use is Article 88 of the Medical Deontology Code. The Code has no legal authority and Article 88 only regulates the conditions under which AID is practised (especially the anonymity of the donor). However, at the level of ART centres, self-limitation combines with a non-State legitimization of current practices (sometimes written), as local ethics committees were created in the 1980s by university hospitals on a voluntary basis. With the decree of 14 August 1994, they became compulsory in all hospitals. The purpose of these local ethics committees is to provide advice about the ethical aspects of care in hospitals, help make decisions in individual cases, and give opinions about experiment protocols on human beings and on human reproductive material.[7]

The restricted self-regulation of the medical sector is due to the pluralism of values and interests held by the different hospitals. This forms part of the historical process by which citizens are integrated within pillars where political parties occupy a central position and pressure groups work as relays between the citizens and the political system (Meynaud *et al.* 1965). In the health field, each sociological family owns its mutual insurance institution and its hospitals (Catholic or secular). Thus, each ART centre belongs to a hospital located in a 'pillar' which – according to the famous 'pillarization' (*verzuiling* in Flemish) definition of Lijphart (1975) – has its own political party, interest group and media. The religious or philosophical trend of the pillar influences the practices of the centre, via the local ethics committee among other mechanisms. Such a process combines with institutional pluralism: the different ART centres agree to 'live and let live' (Axelrod 1984), i.e. to let the other centres practise ART following their own deontology provided that they benefit from the same freedom. At the individual level, this means that practitioners are able to accept or refuse to perform any kind of ART treatment following the principles of their sociological family (the same applies to abortion and euthanasia).

Due to the 'over-supply' situation, the leading ART centres agreed with the political parties to set up a regulation process. The main official argument of the medical sector was to guarantee the quality of ART procedures. An unofficial (but forceful) argument was the economic

competition between the centres and their growing numbers, especially in Flanders. While the decision-making process was going on, the parliamentarians introduced a political argument: to guarantee regional representation by having a clear notion of the repartition of centres between Flanders and Wallonia and by having a hospital in each Province (to protect hospitals within the parliamentarians' regions). Taking into account the sixth recommendation of the NCCB, the process led to the decrees of 15 February 1999.

To conclude, the interest of the practitioners in having their sector regulated is limited, mainly for two reasons. First, they hold a world-leading position in the ART field and wish to retain this position, especially following the rapid evolution of techniques (more rapid than regulations can follow). Second, their fragmentation hampers self-regulation of the sector or substantial State regulation. However, they do agree on the licensing procedure that protects the ART market (the shares of the different hospitals and clinics).

Missing any bottom-up pressure (hypothesis 3)

Our third explanation for a rather thin policy design in Belgium is linked to the traditional problem of collective action. It stresses that ART in Belgium is a 'policy without public' (May 1991), i.e. the 'issue network' is very poorly developed and the political dynamic is dominated by a technocratic expertise rather than public mobilization.

In Belgium, there is no formal organization of the final policy beneficiaries. A handful of ART patients' associations exist but they have a very limited range of action: they do not exert pressure on the politicians, they are not audited by the Parliament's Commissions, they are not interviewed by the media, and their links with practitioners are limited to certain types of activities (such as inviting them to rather small audience conferences, and so forth).

The rarity of authoritative decisions is partly due to the fact that ART patients do not succeed in putting on the political agenda collective problems such as sterility treatment. Infertility still belongs to the private sphere rather than to the public sphere: the issue of infertility is still taboo. Moreover, the public opinion concerned with ART focuses on other ethical issues such as cloning, abortion or euthanasia.

ART patients' organizations do not claim reimbursement for ART practices from the social insurance system. This is partly linked to the complexity of the health-care system as a whole. For all health services, the main costs covered for any patient are medical consulting, the cost of prescription drugs, hospitals costs, and compensatory indemnity in cases of illness or invalidity. The public sector, through the National Office of Social Security (ONSS), finances several areas of Social Security (including health) by taking the area's needs into account. Care is covered by

mutual insurance institutions with specific rules of coverage ('nomenclature') and up to a fixed amount: the patient only pays a *'ticket modérateur'*. The nomenclature is established by the National Institute for Disease and Invalidity Insurance (INAMI), where the different actors are represented (e.g. physicians, chemists, trade unions and mutual insurance institutions). Patients who want insurance coverage for complementary costs (for example, to pay for a single room while in hospital) can affiliate with private insurance companies.

For the ART sector, the INAMI has not established a specific set of regulations. Currently, only medical acts are covered by social insurance. Mutual insurance institutions are starting to take into account other types of practices, but health expenditure in general is strictly constrained. For instance, private insurance companies generally do not cover sterility treatment. ART patients' organizations do not intervene in this debate, and nor do they participate in the larger discussion about the patients' rights that has been launched by the present Social Affairs, Public Health and Environment Ministry.

Neither feminists nor gay associations consider the ART issue to be a priority (homosexual couples are free to receive ART treatment in Belgium). Moreover, a number of ART patients come from abroad, especially from France, which borders Belgium and implements a much more restrictive legislation regarding ART. In Belgium, for instance, a single woman can receive AID, which is not the case in France. These foreign patients do not try to exert pressure on Belgian politicians or on the Belgian ART sector. Conversely, leading Belgian ART centres maintain links with public opinion abroad: they publish their performance in foreign media (*Le Monde*, for instance), they affiliate with the French main pressure group in the ART sector ('Association Pauline et Adrien'), and, they collaborate with French colleagues.

To summarize, the lack of 'grass-roots' pressure explains both the autonomy of doctors and researchers (because there are no fundamental demands regarding ART by organized groups) and the medium access for patients (because there is no pro-active lobbying for ART insurance coverage by organized groups).

Multi-level governance of health care (hypothesis 4)

Multi-level governance is commonplace in Belgium, due to the recent federal structures of the political system. In both Southern and Northern Belgium, demands for political autonomy arose by the end of the nineteenth century. However, the organization of the country as a federal state was only put in place during the second half of the twentieth century. This very slow process of 'federalization' was the result of a long drawn-out divorce between two cultural groups, French and Dutch. The complexity of the Belgian institutional regime resulted from a compromise between

two contradictory concepts. The Flemish nationalists defended the idea of a federal structure with two components (Flemish and Walloon) based on the existence of two distinct cultures or even nations. The Walloon movement was in favour of autonomy and supported the idea of delegating economic matters to three regions (Flanders, Wallonia and Brussels), which would each control their own economic development.

This explains why there are two different kinds of federated entities, making Belgian federalism as incongruent as possible: three Communities (French-, Flemish- and German-speaking), which are responsible for cultural, social and educational matters; and three Regions (Wallonia, Flanders and Brussels-Capital) governing matters concerning economic and regional development, environmental protection, public transportation and housing.

In comparison with other federal States, Belgium's federalization is very recent. If the Regions and Communities were already planned in the 1970 constitutional reform, the federal structure only unfolded in 1980 and the actual power of the federal entities only became significant from 1989 onward, when their financial resources were increased.

Thus, the formulation, adoption and implementation of various policies require proactive coordination between the various levels of government: the federal State, Regions, Communities, provinces and municipalities. The multiplicity of government levels goes together with a fragmentation of the policy and decision-making processes. Indeed, each level of power has its own policy responsibility.

The responsibilities for health care are shared by both the federal and the federated government levels. The 1980 reform of the Belgian State delegated powers (person-related matters) to the three Communities (French-, Flemish- and German-speaking communities). The Communities shifted these policy responsibilities to the three Regions in 1993 due to their budget deficits. The local municipalities and the provinces can also make decisions affecting social help associations.

As far as ART are concerned, this gradual – and mostly confrontational – federalization process has clearly delayed substantial policy-making. The failure of the first substantial bill on AI, which was introduced at the Parliament of the French Community, was due to a conflict of responsibilities between the federal level (exclusive responsibility for modifying the Civil Code) and this sub-national entity (Community responsibility for person-related matters).

Today, the multi-level governance structure still causes a complex repartition of policy responsibilities. Theoretically, the law on the responsibility transfer (August 1980) states that the federated entities can develop a policy both within and outside of the hospitals. *De facto*, the federal level has a predominant role by deciding the programming (e.g. number of centres) as well as editing the rules. The Regions deliver the licence to the ART centres, but the federal State controls the quality of the care as a

result of the recently constructed Physicians' College. This example of vertical fragmentation explains the lack of control by the various levels of power. In any case, the different governments do not take counsel together as to how to act: unlike other health sub-sectors, there are no inter-Ministers' conferences on ART.

Moreover, health policy in general and ART policy in particular are traditionally unplanned (compared to the French model, for example): generally, the federal policy legally ratifies the medical practices that have been used for a long time. The politicians adopt authoritative decisions a posteriori – i.e. they grant licences to well-established medical practices rather than anticipating or dramatically modifying them.

This process is strongly influenced by the logic of power sharing and compromise (to guarantee that various entities have their say) and by the lobbying of groups (especially the physicians and the university hospitals in this case). One case illustrates particularly well this bargaining situation: an ART centre was created in Wallonia when the decrees of February 1999 were adopted. In the context of an over-supply, this centre was not created owing to quality standards but rather to political will in respect of equilibrium between the different Provinces as well as to allow an important ART centre in Brussels to continue as a result of its formal association with a Provincial hospital.

Fragmentation of policy responsibilities and lack of proactive collaboration between the different levels of government also led to disparities among the federated entities. In 1993, 1997 and 1998, Flemish authorities adopted regulations regarding their human genetic centres.[8] A similar decision was not officially taken in the Walloon part of the country.

To conclude, the 'federalism hypothesis' explains the thin design of ART policy by the delay induced by the institutional struggle linked to the federalization of Belgium (mainly from 1970 to 1993) and by the vertical fragmentation of the policy and the decision-making process: the sharing of responsibilities is not symmetrical; there is no cooperative counselling structure between the levels of power; and, the ART policy was not well planned in advance.

Inter-policy coordination (hypothesis 5)

It is difficult to understand the design process of the ART policy without considering 'policy inheritance' (Rose and Davies 1994). Thus our fifth hypothesis is based on three phenomena: first, the legacy of other bioethical issues, especially the abortion crisis in Belgium; second, the competition between issues on the political agenda; and third, the limited influence of 'policy entrepreneurs' (Kingdon 1995) within 'advocacy coalitions' (Sabatier 1988).

The first bioethical issue to be debated and regulated was abortion, in relation to the law that de-criminalized it in 1990.[9] Apart from the fact that

abortion as well as ART are concerned with the embryo status, the abortion policy influences the policies of other bioethical issues in relation to the way decision-makers have dealt with it. Political mechanisms have been established to avoid new crises on ethical matters.

It is quite plausible that euthanasia also has an influence on the agenda of ART. Euthanasia as well as ART (and related issues: research on embryos and cloning) are discussed in the same main policy arena, i.e. the Senate. Until the discussion on euthanasia comes to an end, the debate on ART will be pushed into the background.

As previously mentioned, the present alternative coalition (secular) is managing several ethical issues at the same time. However, the decisions regarding the different issues must come in sequential order depending, among other things, on the public opinion. The work of the Senate Special Commission regarding research on embryos was mainly done *in camera*; the media were not allowed access, partly because of the collective fears regarding cloning but also because of the will for a rapid consensual agreement among the political parties.

The logic of compromise as well as concern about the electorate (to adopt unpopular measures has an electoral cost) determines the role played by policy entrepreneurs and advocacy coalitions. The same actors often intervene in different issues (especially euthanasia and ART if we consider the bills proposed by some liberal and socialist Senators, for example), but the presence of leading actors does not automatically encourage a rapid adoption of authoritative decisions.

To summarize, the ART policy design is influenced by the inherited critical character of bioethical matters; the priority of other issues on the political agenda; and the restriction of the impact of policy initiatives.

External events with a limited influence (hypothesis 6)

Three factors related to events abroad could influence the ART policy in Belgium. The first is the development of research in foreign countries. As Belgium holds a leading position in the field of ART, its practitioners are interested in the findings and performance of their foreign counterparts. Leading ART centres' directors participate in scientific congresses. However, this factor does not have a direct effect on ART regulation. Events reported by the media, such as the birth of the cloned sheep Dolly or the project of the Italian doctor Antinori to clone human beings, seem not to have directed the already advanced practices of the medical sector or the political decision-making process.

The second factor is the pressure for 'harmonization' exerted by international organizations such as certain European bodies. Here, there is a direct struggle between on the one hand the interest of Belgium to sign and ratify the Convention on Human Rights and Biomedicine, and on the other hand the debate launched in 1998 in the Belgian Senate regarding

research on embryos. In this case, the objective of the decision-makers is to participate in the coordination efforts at European level while taking care of the Belgian ART sector peculiarities. This last point is still predominant, as Belgium (like most other industrialized countries) has not yet signed the Convention on Human Rights and Biomedicine.

A third factor could be 'lesson drawing' (Rose 1993) from the policies that the foreign countries (and especially bordering ones) adopt. We interviewed experts and also investigated a parallelism between the French and the Belgian regulation process and the French and the Belgian authoritative decision-making. Within this comparison, the 'lesson drawing' variable is not relevant to explain the Belgian situation. While France developed substantial restrictive laws on abortion as early as 1975 and on ART in 1994, Belgium adopted a de-criminalization law on abortion as recently as 1990 and adopted procedural norms in 1999 for ART concerns. References to French regulations are made by some bill proponents, but there is obviously not a strong argument for law adoption in Belgium.

To conclude, pressure at the international (and especially at European) level, regulations by foreign countries and external shocks reported in the media are not sufficient to trigger a substantial design process.

Final interpretation

The six hypotheses discussed above tend to have a one-way direction effect despite the fact that they are not always concomitant. They sometimes combine. All in all, ART policy appears to be a typical design process and result for the traditional cleavage politics in Belgium.

According to our interpretation, there is a predominance of 'non-decisions' regarding ART in Belgium because:

- until 1999, it was against the interest of the government coalitions and especially against the partisan interest of the Social-Christians to regulate it;
- the self-limitation of medical practices hampers a values conflict;
- the absence of an organization and therefore of a certain demand by the ART patients leads to an 'over-supply' driven policy;
- the abortion crisis locked any decision-making process on bioethics while the Social-Christians were members of a governmental coalition; inversely, the debate on euthanasia and on ART (research on embryos) is possible under a new secular coalition;
- other bioethical issues have priority on the government's agenda (euthanasia);
- the process of policy transfer and of influence from foreign actors has been very limited.

The few authoritative decisions are procedural rather than substantial because

- the fragmentation of the medical sector – reflecting the value pluralism of society itself – hinders a consensus on the substantial regulation of ART;
- the medical sector, and especially the university ART centres, support a procedural design that favours market share redistribution;
- the complexity of multi-level governance hampers coordination towards substantial regulation; this coordination is made possible when the political will sustains it (as is the case for the creation of the NCCB) and the necessity to respect the logic of compromise impedes debate on substantive issues (on which agreement seems impossible);
- the growing importance of research on embryos, the will to follow up on the evolution of techniques, the existence of well-established practices among ART centres and the accepted autonomy of the sector favour a simple formal procedure of licence;
- the limited influence of decisions made at the international level – and especially at the European level – allows a rather large degree of freedom to national decision-makers.

Conclusions

There is one (more normative) question left to answer: is Belgium really a bioethical paradise? The main point to be considered here is that substantial policy design has not always proved to be more regulatory than procedural policy design.

Regarding the autonomy of the medical sector, Belgium is a bioethical paradise with a border. The rules in use among the ART centres, the local ethics committees and the NCCB lead to legitimization but also to the limitation of acknowledged practices. In that sense, they have a regulatory impact. They allow a double-direction autonomy for the doctors: practitioners have the right to practise or not to practise acts depending on their individual values and on the ART centre deontological principles.

In the legitimation process, some events act as a foil to the policy-makers. Some research and medical practices are finally recognized if they permit avoidance of others. For example, cryopreservation was promoted in order to limit the risks of super-ovulation for women. More recently, therapeutic cloning appears as a legitimate choice to avoid the infamous human (reproductive) cloning.

ART practitioners benefit from such a reputation and such support that they can develop their own policy in their own sector. We could speak of a 'non-design by experts'. Physicians act as beneficiaries of the policy, but also as experts whose opinions must be taken into account by the political

decision-makers. This focuses the debate on the status of science and expertise in the policy design.

Regarding the access for patients, Belgium is a bioethical paradise at a price. Nearly any category of patients (married couples or cohabitants, homosexual or heterosexual, single, young or up to a certain age) can legally purchase a broad range of techniques. The access of patients to ART is mainly restricted by economic constraints, since insurance coverage is only partial. Incomplete reimbursement could be an alternative mechanism to the substantial regulation of ART. In this case, procedure is also regulatory. However, it puts into question the democratic character of access to ART.

Notes

1 Bill of 24 June 1982
2 *Le Monde*, 17 July 2000.
3 Decree of 15 February 1999.
4 The regulations of 15 February 1999 distinguish the centres with Program A from the centres with Program B following the technical and medical acts they are (not) allowed to practice. Program A mainly allows ovarian stimulation, gamete punction, their transfer to a centre with Program B. Program B represents gamete treatment, embryo re-implantation, cryopreservation.
5 We refer to the traditional parties in plural form because they have divided themselves along linguistic lines, in 1968 for the Social-Christians, in 1972 for the Liberals and in 1978 for the Socialists.
6 Only two historical examples of secular governments (without the Social-Christians) exist: during the 'Royal Question' (1945–47) and during the second 'School War' (1954–58).
7 Decree of 14 August 1994.
8 Decrees of 3 May 1995, 17 December 1997 and 23 July 1998.
9 The Social-Christian parties have strongly opposed the pro-legislation position views of the Socialist and Liberal parties. They succeeded in removing the issue of abortion from the agenda until 1988 by burying it in parliamentary and other committees. Finally, a private members' bill for de-criminalization of abortion was introduced by a Socialist MP (in the government coalition) and a Liberal MP (in the opposition). King Baudouin I refused – for 'reasons of conscience' – to sign the law, which was adopted by a 'majority of substitution': the Flemish Social-Christians unanimously refused to vote on the bill. An unprecedented constitutional crisis broke out. In order to solve it, the Monarch was declared 'temporarily incapable' to govern; thus the government unanimously signed the bill and then both chambers declared that King Baudouin I was fit to reign again.

3 ART policy in Italy

Explaining the lack of comprehensive regulation

Celina Ramjoué and Ulrich Klöti

Introduction

Italy is often described as the 'Far West'[1] of assisted reproductive technology (ART) since, to date, it does not have a law or comprehensive regulation on ART ('Il far west della sterilità' 18 Oct. 1994).[2] Three ministerial circulars and three ordinances covering specific issues instead of ART as a whole are the only generally binding rules on assisted reproductive technology. A number of court rulings[3] on questions related to ART have to some extent contributed to the overall ART policy design.[4]

In the context of this regulatory vacuum, Italian doctors practising ART enjoy a high level of autonomy: while the handful of ministerial regulations limits only a few specific activities, medical and ethical decisions in non-regulated areas are left to doctors. The level of patients' access to ART, however, is only medium. Although Italian policy design is fairly permissive due to the lack of comprehensive regulation, not all patients have the same level of access to all technologies.

The purpose of this chapter is to explain: (1) why Italy lacks a comprehensive regulation or law on ART; (2) why doctors' autonomy in practising ART is high; and (3) why patients' access to ARTs is only medium. We suggest that the lack of a comprehensive law or regulation on ART can be explained by cross-cutting cleavages: the secular versus Catholic divide in the field of ART and the centre-right versus centre-left division reflected in Italy's polarized multi-party system. A further element explaining the lack of a law on ART is the institutional hurdle of 'perfect bicameralism'. We suggest that the medical community's high level of autonomy is a result of non-regulation – a status quo fostered by doctors' internal division and lack of participation in ART policy-making – and of weak self-regulation. Finally, we argue that medium access is caused by Italy's dual ART market, which took shape due to the restricted ART coverage that Italy's National Health Service foresees in the absence of legislation.[5]

Italy's policy design on ART

Authoritative decisions

In Italy, to date, authoritative decisions on ART have come from the Ministry of Health in the form of three circulars and three ordinances. In 1985, about two years after the first birth in Italy resulting from in vitro fertilization (IVF) and in the context of the increasingly rapid spread of ARTs, the Ministry of Health issued the first attempt at regulating ART, the so-called 'Degan Circular'. Instead of issuing general guidelines on the practice of ART, this establishes which ART the Italian National Health Service should pay for in the context of existing laws and norms, thus also determining which ART is offered in public ART centres. The Circular sets up the following provisions for ART covered by the National Health Service:

- Access: non-separated married couples have the right consensually to request methods of artificial insemination in order to overcome infertility.
- Protection of the embryo: the creation and cryopreservation of embryos for deferred implantation, industrial use and research are prohibited.
- ART with donated gametes is not admissible.

In 1987, the Ministry of Health issued a second Circular entitled 'Measures of prevention against the transmission of the HIV virus and other pathogenic agents through human sperm used for artificial fertilization'. In 1992, this Circular was updated and extended to cover organ, tissue, and bone marrow donation. The 1987 and 1992 Circulars both open with a reference to the absence of norms as the main motivation for formulating a series of technical guidelines, applicable in all ART centres, to prevent the spread of sexually transmittable diseases.

In 1997, Minister of Health Rosy Bindi issued an ordinance, valid for ninety days, entitled 'Prohibition of commercialization and advertising of human gametes and embryos'. One of the events that prompted the issuing of this ordinance was the publication of a private ART centre's advertisement offering money for gametes in the Roman newspaper *Portaportese* (Soldano 1999: 102). To date, the ordinance has been renewed on a regular basis and contains the following provisions:

- prohibition of 'any form of remuneration, direct or indirect, immediate or deferred, through money or any other form, for the transfer of gametes, embryos, [. . .] or [other] genetic material';
- prohibition of any incitement of and advertising linked to the offer of gametes, embryos and genetic material;

- the obligation for all public and private ART centres and institutes to report basic information on their activity to the Ministry of Health and the competent regional ministry.

Together with the ordinance prohibiting the commercialization and advertising of human gametes and embryos, Minister Bindi signed a 'Prohibition of practices of human or animal cloning'. As a reason for this measure, the Ministry cited 'the alarming [...] coverage of repeated episodes of animal cloning [...] or of scientific declarations on the possibility of extending this practice to the human species'. Indeed, this Circular was a response to the February 1997 birth of Dolly the sheep, the world's first clone of an adult mammal.

Like the ordinance prohibiting the commercialization and advertising of gametes and embryos, the ordinance prohibiting animal and human cloning has been regularly renewed since 1997. In January 2002, however, the ban on animal cloning was lifted. Finally, in July 2001, the Italian government issued an ordinance that bans the import and export of cryopreserved embryos.

This overview shows that, to date, authoritative decisions issued by the Ministry of Health have been formulated in response to specific and urgent needs and intended as temporary measures to fill the regulatory void until comprehensive legislation is in place. This explains why these documents cover only specific issues, and some of them have only limited validity. Since the Italian Parliament has not yet passed a law and since the Ministry of Health has not yet issued a more comprehensive regulation, the documents described are still in force. The 1985 Circular remains the most comprehensive authoritative decision on ART, although it addresses only the question of which ART should be covered by the National Health Service. Table 3.1 summarizes Italian ART policy as described above, making the distinction between ART practice covered by Italy's National Health Service (delivered mostly by the public sector) and that paid for by patients (delivered by the private sector).

High autonomy, medium access and Italy's 'mixed' National Health Service

For the Italian case, both doctors' autonomy in the field of ART and clients' access to treatment must be analysed with special attention to Italy's 'mixed' National Health Service, which has important implications for ART in practice. The Italian Servizio Sanitario Nazionale (SSN) was created in 1978 as the first National Health Service on the European continent. The SSN differs from a pure National Health Service in that public health care is not delivered by public facilities only; it may also be obtained in private facilities, where it can be paid for with private funds or by the SSN (in structures which adhere to a convention with the SSN).

Public facilities offer only services that the SSN covers, but patients can choose to pay for them if they wish to obtain special services (this usually also leads to bypassing long waiting lists). Italian doctors can practise in the public and private sectors simultaneously. According to data collected by the Italian National Institute of Health, 63 per cent of ART centres (offering ART beyond simple artificial insemination without cryopreservation) are private (client pays) and 31 per cent are public (SSN pays). The remaining 6 per cent are private centres that offer publicly funded services alongside treatment paid for privately.

In the light of this strong dual public–private structure, doctors' autonomy and clients' level of access must be assessed separately for ART funded by the National Health Service (referred to as 'public sector' below) and for ART paid for with private funds (referred to as 'private sector' below).[6]

Table 3.2 summarizes our findings for clients' level of access to ART based on the content of Italy's authoritative decisions. Clients' access in terms of civil status and sexual orientation is very low (its score is 0 or 'non-existent') in the public sector as the 1985 Circular grants only married couples treatment. In the private sector, on the other hand, access in terms of civil status and sexual orientation is high for both basic and related techniques. Access in terms of financial coverage is low in the public sector, while it is non-existent in the private sector. In sum, the level of access to both basic and related techniques is low in the public and high in the private sector (rates of 1 and 12 respectively on a scale of 1–15). In order to determine a single value for access in Italy which can be placed on a numerical continuum, we established a weighted average in approximate accordance with the numbers of public and private ART centres, giving the public sector approximately one-third and the private sector two-thirds of the weight. The weighted average is 8.3, a 'medium' on our 1–15 access scale.

Table 3.3 summarizes doctors' level of autonomy with respect to the practice of ART. In all three of the ART categories defined (basic, related, and research/experimental techniques), doctors enjoy a high level of autonomy in the private sector (rating 9 out of 9). In the public sector, doctors obtain an autonomy score of 6. The weighted average for doctors' autonomy is 8, a 'high' on our 1–9 autonomy scale. In many cases, both in the public and private sectors, high scores for autonomy are due to the fact that there is no design. The only field in which all doctors' activity is severely restricted is cloning (prohibition).

The lack of comprehensive regulation on ART

The failure to pass a law on ART

Within the history of attempts to legislate on ART, the 13th Legislature (1996–2001) has to date come nearest to passing a law. The main

Table 3.1 ART policy in Italy. Based on the provisions foreseen by Italian authoritative decisions on ART (legally binding for all individuals). When no explicit policy exists, the table indicates whether the technique is practised or not.

Assisted reproductive technologies		*Coverage by National Health Service (mostly public sector)*	*No coverage by National Health Service (private sector)*
Basic techniques			
Insemination		Practised under the following conditions: • couple must be married (Circular 1985) • only husband's sperm can be used (Circular 1985) • series of mandatory tests for husband and wife (Circulars 1987/92)	No explicit design,[a] practised, series of mandatory tests for husband/male partner/sperm donor and wife/female partner (Circulars 1987/92)
GIFT/ZIFT IVF/ET		Practised under the following conditions: • couple must be married (Circular 1985) • only couple's gametes may be used (Circular 1985) • series of mandatory tests for husband and wife (Circulars 1987/92)	No explicit design,[a] practised, series of mandatory tests for husband/male partner/sperm donor and wife/female partner (Circulars 1987/92)
Related techniques			
Surrogacy		Implicitly prohibited through limitation to using couple's gametes (Circular 1985)	No design,[b] not practised (except in isolated cases)
Donation	Sperm	Implicitly prohibited through limitation to using couple's gametes (Circular 1985)	Series of mandatory tests for husband/male partner/sperm donor (Circulars 1987/92)
	Egg	Implicitly prohibited through limitation to using couple's gametes (Circular 1985)	No design, practised, but less than sperm donation
	Embryos/ impregnated eggs	Implicitly prohibited through limitation to using couple's gametes (Circular 1985)	No design,[b] practised very rarely or not at all
Cryo-preservation	Sperm	No design, practised	Mandatory for ART using donated sperm (Circulars 1987/92)
	Egg	No design, practised	No design, practised
	Impregnated egg	Implicitly prohibited (the fertilization of excess egg cells not destined for immediate transfer is not permitted) (Circular 1985)	No design, no reliable information available as to whether practised or not

	Embryo	Prohibited for industrial use, research or deferred implantation (Circular 1985)	No design, practised
ICSI		No design, practised	No design, practised
Pre-implantation diagnosis		No design, practised in few centres	No design, practised in few centres
Genetic selection		No design,[b] not practised	No design,[b] practised very rarely or not at all
Gender selection		No design,[b] not practised	No design,[b] practised very rarely or not at all
Research/experimental techniques			
Genetic engineering	On gametes/ germ cells	No design, not practised	No design, not practised
	On impregnated eggs/ embryos	No design,[a] practised very rarely or not at all	No design,[a] practised very rarely or not at all
Research	On gametes/ germ cells	No design, practised (especially sperm)	No design, practised (especially sperm)
	On impregnated eggs/ embryos/ zygotes	No design, not practised	No design, probably some practise (insufficient data)
Cloning		Prohibited (Ordinance 1997 – Cloning)	
Chimera/hybrid building		No design, not practised	
Other			
Commercialization/ advertisement/export/ import of genetic material		Prohibited[b] (1997 Ordinance – Commercial use; 2002 Ordinance – export, import)	
Creation of embryos for research		Prohibited (Circular 1985)	No design,[b] practised very rarely or not at all
Denial of paternity		De facto prohibition (Supr. Ct. of Const. Matters, decision 347, 26 Sept. 1998; Supr. Ct. of Appeal, decision 2315, 16 March 1999, Supr. Ct. of Appeal, decision 3529, 17 May 2000)	

Notes

a Self-regulation provisions (conditions or partial prohibition) provided by National Federation for the Orders of Doctors and Dentists' Code of Medical Ethics (not legally binding for all individuals).

b Explicitly or implicitly prohibited by National Federation for the Orders of Doctors and Dentists' Code of Medical Ethics (not legally binding for all individuals).

Table 3.2 Access to ART in Italy[a]

		Access			
		Civil status (1)		*Finance (2)*	
		Public funding	*Private funding*	*Public funding*	*Private funding*
Basic techniques					
Insemination (1)	with gametes of the couple (1a)	1	3	2	0
	with sperm donation (1b)	0	3	0	0
GIFT/ZIFT (2)	with gametes of the couple (2a)	1	3	2	0
	with sperm donation (2b)	0	3	0	0
IVF/ET (3)	with gametes of the couple (3a)	1	3	2	0
	with sperm donation (3b)	0	3	0	0
	with egg donation (3c)	0	3	0	0
	with embryo donation (3d)	0	3	0	0
Max. 24: 0–3 no or close to no (N = 0), 4–11 low (L = 1), 12–19 medium (M = 2), 20–24 high (H = 3)		*3* *N = 0*	*24* *H = 3*	*6* *L = 1*	*0* *N = 0*
Related techniques					
Surrogacy (4)		0	3	0	0
Cryopreservation (6)	sperm (6a)	1[b]	3	2	0
	egg (6b)	1[b]	3	2	0
	impregnated eggs (6c)	0	3	0	0
	embryos (6d)	0	3	0	0
Pre-implantation diagnostics (7)		1	3	2	0
Genetic selection (8)		0	3	0	0
Gender selection (9)		0	3	0	0
ICSI (10)		1	3	2	0

Max. 27: 0–4 no or close to no (N = 0), 5–13 low (L = 1), 14–22 medium (M = 2), 23–27 high (H = 3)	*4* *N = 0*	*27* *H = 3*	*8* *L = 1*	*0* *N = 0*
Total of both groups of techniques (max. 6): 0 no (N), 1–2 low (L), 3–4 medium (M), 5–6 high (H)	*0 + 0 = 0* *= N*	*3 + 3 = 6* *= H*	*1 + 1 = 2* *= L*	*0 + 0 = 0* *= N*
For Element 1: Weights for total of both groups of techniques (N = 0), (L = 4), (M = 8), (H = 12)	*0*	*12*		
For Element 2: Judgement for financial coverage of ART (0–3)	*1*	*0*		
Total of Element 1 and Element 2 (0–15)	*1*	*12*		
Weighted average access				
(1/3 public centres–2/3 private centres)	*8.3*			

Element 1: Access in terms of civil status/ sexual orientation	*Element 2: Access in terms of financial coverage*
0 = full prohibition 1 = only married couples 2 = stable heterosexual couples 3 = civil status and sexual orientation do not matter	0 = patient(s) pay(s) 1 = limited coverage by National Health Service 2 = National Health Service covers most of treatment 3 = National Health Service takes over all expenses

Notes

L, low; M, medium; H, high; N, no or close to no; 1 = low; 2 = medium; 3 = high.

a Please note that this table reflects what is foreseen *in theory* in the authoritative decisions coded. *In practice*, levels of access to ART might differ depending on diverging interpretations that individual doctors and ART centres give authoritative decisions and the doctors' Code of Medical Ethics (see below for a discussion of this document).

b In some centres, patients wanting to 'preserve' their fertility before surgery or chemotherapy have access to gamete preservation regardless of civil status and sexual orientation.

Table 3.3 Autonomy in Italy[a]

		Autonomy			
		Activity covered by SSN		*Activity not covered by SSN*	
Basic techniques					
Insemination (1)		M	2	H	3
GIFT/ZIFT (2)		M	2	H	3
IVF/ET (3)		M	2	H	3
Total 9: 0–1 no or close to no (N), 2–4 low (L), 5–7 medium (M), 8–9 high (H)		*M*	*6*	*H*	*9*
Related techniques					
Surrogacy (4)		N	0	ND	3
Donation (5)	sperm: 5a,	N	0	H	3
	egg: 5b	N	0	H	3
	of embryos/impregnated eggs: 5c	N	0	ND	3
Cryopreservation (6)	sperm: 6a	H	3	H	3
	egg: 6b	ND	3	ND	3
	of impregnated eggs 6c	N	0	ND	3
	embryos: 6d	N	0	ND	3
Pre-implantation diagnostics (7)		ND	3	ND	3
Genetic selection (8)		ND	3	ND	3
Gender selection (9)		ND	3	ND	3
ICSI (10)		ND	3	ND	3
Max. 36: 0–5 no or close to no (N), 6–17 low (L), 18–29 medium (M), 30–36 high (H)		*M*	*18*	*H*	*36*
Research/experimental techniques					
Genetic engineering (11)	on gametes/germ cells (11a)	ND	3	ND	3
	on impregnated eggs, embryos (11b)	ND	3	ND	3
Research (12)	on gametes/germ cells (12a)	ND	3	ND	3
	on impregnated eggs, embryos, zygotes (12b)	N	0	ND	3

Cloning (13)	N	0	N	0
Chimera and hybrid building (14)	ND	3	ND	3
Max. 18: 0–2 no or close to no (N), 3–8 low (L), 9–14 medium (M), 15–18 high (H)	*M*	*12*	*H*	*15*
Total of three groups of techniques (max. 9): 0–1 no or close to no (N), 2–4 low (L), 5–7 medium (M), 8–9 high (H)	*M*	*6*	*H*	*9*
Weighted average autonomy in Italy (1/3 public practice–2/3 private practice)	*8*			

Notes

L, low; M, medium; H, high; N, no (full prohibition); ND, no design; 1 = low; 2 = medium; 3 = high.

a Please note that this table reflects what is foreseen *in theory* in the authoritative decisions coded. *In practice*, degrees of autonomy in the field of ART might differ depending on diverging interpretations that individual doctors and ART centres give authoritative decisions and the doctors' Code of Medical Ethics (see below for a discussion of this document).

contentious questions debated both in the Social Affairs Committee and in the Assembly concerned the status of the human embryo, whether unmarried couples should have access to treatment, and whether ART using donated gametes should be allowed.

In July 1998, the Chamber's Social Affairs Committee presented a relatively permissive unified text to the Assembly, which then proceeded to reverse most of its permissive clauses, thus reshaping it into a restrictive bill. It approved amendments giving the protection of the newborn precedence over that of the other subjects involved in ART treatment and prohibiting ARTs with donated gametes, the latter of which prompted the resignation of the bill's rapporteur. In March 1999, a further amendment was passed limiting the production and transfer of embryos to three per cycle and prohibiting their cryopreservation. On 26 May 1999, over two years after the parliamentary debate on ART had commenced, the Chamber of Deputies finally approved a relatively restrictive unified text.

As is required by the Italian legislative process, the bill (S. 4048) was passed on to the Senate for debate and approval. The upper chamber, however, once more went about reversing the bill's key provisions due to the fact that it had a stronger centre-left majority than the Assembly. In particular, it passed an amendment overturning the Assembly's controversial provision prohibiting ART with donated gametes. The highly ideological and emotional context of the debate illustrated to what extent the issue divided members of Parliament and society. It was within this climate that the Senate voted to suspend the debate on 21 June 2000.

After an eighteen-month legislative standstill on ART, the 14th Legislature, elected in May 2001 and dominated by the centre-right, took up the issue of ART in late 2001. After several months of debate on the issues that had caused deadlock during the 13th Legislature, the Assembly passed a new relatively restrictive text in June 2002. The Bill promotes the Catholic point of view in that it prohibits ART with donated gametes and the cryopreservation of embryos, and grants the 'conceived' the right to be born. Its only secular provision is that it grants non-married stable couples access to ART. At the time of completing this chapter,[7] the new bill awaits its reading in the Senate.

Government's reticence to regulate ART

Despite Parliament's failure to pass a law on ART and repeated requests from organizations and individuals involved in the field, the Italian government has, to date, failed to issue a comprehensive regulation on ART. As the paucity and limited scope of the Ministry of Health's decisions on ART illustrate, the Italian government's position has been not to pronounce itself without there being a societal or at least legislative consensus to build on.

An equally reticent actor closely linked to the government was the National Bioethics Committee, a permanent governmental committee created in 1990. The National Bioethics Committee has produced a series of opinions on ART and related subjects, including 'Techniques of assisted procreation' (June 1994) and 'Identity and status of the human embryo' (June 1996). While on other ethical issues the Committee is often able to agree unanimously on a text, opinions on ART often contain presentations of diverging viewpoints and fail to articulate recommendations on particularly controversial questions.

Cross-cutting cleavages and institutional hurdles: explaining the lack of comprehensive regulation on ART

A deeply divided society: Catholicism versus secularism

A first important element explaining the lack of a law or comprehensive regulation on assisted reproductive technology is that the Italian debate on ART is characterized by a deep cleavage between Roman Catholicism and secularism, which runs through society and institutions alike. Because these sectors are more or less equally powerful and hold equally strong views on the controversial issues at stake, agreement on how to regulate ART is extremely difficult to reach.

Before IVF was introduced in Italy in the 1980s, the Roman Catholic Church (referred to as 'the Church') categorically condemned artificial insemination, the type of ART then most widely practised, based on the argument that it was an unnatural form of procreation.[8]

The starting point for the Vatican's and therefore the Church's doctrine on ART is the belief that human life begins at the moment of fertilization. The embryo thus enjoys the rights and level of protection of a human being. The Church opposes recourse to ART outside of matrimony, since this would conflict with the right of the child to be born into a family. ART in which fertilization occurs outside the body, e.g. IVF followed by embryo transfer, is not acceptable to the Church because the excess embryos often produced are frequently destroyed. ART using donated gametes is equally unacceptable from the Church's point of view since it denies the newborn's right to a clear legal status and identity. The only form of ART that the Church does not categorically exclude is artificial insemination with the husband's sperm. On the issue of how ART should be regulated, the Church would prefer a comprehensive and long-lasting law addressing ethical issues rather than a minimalist law or technical regulation.

The impact of the Vatican's doctrine in Italy is considerable, a fact strongly linked to Italian history. Catholic beliefs and principles introduced many centuries ago are strongly entrenched in Italy's contemporary society. The Church has constructed a respected parallel system of services

alongside that of the State (e.g. schools, hospitals), and has succeeded in putting in place a powerful organization of Italian society. Moreover, the Church has developed an impressive capacity to communicate its doctrine to the Italian people with the help of official publications and media appearances of the Pope, who enjoys a high level of moral authority.

A powerful link between the Church and Italian society is provided by political parties founded on Christian values. Until recently, the largest and most important Catholic party was Democrazia Cristiana (DC), which dissolved in the mid-1990s with the end of the First Republic. Its main political opponent, the Italian Communist Party, was essentially secular and based on a non-Catholic ideology. In contrast, the Second Republic features neither a main Catholic nor a large non-Catholic party. Instead, most of the new parties have come to embrace and promote religious values to some extent.[9] Today, the popular and new Christian democratic parties are the strongest representatives of Catholic values. In Italian politics, however, Catholicism to a certain extent cuts across political party lines, and is therefore represented within all political groupings, including Leftist parties. As a result of the influence of Catholicism in Italy, the Church's positions matter for politics and policy, and hold a particular weight in ethical issues such as ART.

In addition to this important indirect power wielded by the Vatican's doctrine, some actors involved in and experts observing the debate on ART recount that the Church resorts to exerting active pressure on parliamentary and ministerial decision-making processes. This phenomenon has been noted in particular since the change from the First to the Second Republic in the mid-1990s, and even more strongly since Silvio Berlusconi's centre-right party Forza Italia took power in mid-2001 (Mantello 2001). Some of our interviewees suggested that the Church may be a key force blocking the path towards a comprehensive law or regulation on ART. The thesis underlying this view is the following: the Church understands that chances of obtaining a regulation or law restrictive enough to abide by its doctrine are low, and therefore prefers to prevent the passage of a law altogether.

Moreover, some critical observers of the Italian political system contend that the passage from the First to the Second Republic, marked by fundamentally changed party and electoral systems, has led to heightened Catholic fervour by centre-right parties. According to this point of view, during the First Republic, Italy's Christian Democrats, though clearly a party inspired by Catholic values, respected the separation of Church and State established by the Constitution more consistently than parties drawing on Catholic values do today.

Secularists, in contrast to Catholics, believe that a regulation or law on ART should not attempt to settle ethical issues, i.e. who should have access to which types of ART. They contend that this type of regulation is unacceptable because it violates individuals' privacy and freedom to choose or

reject a certain ART according to their personal beliefs (Caporale 'Meglio nessuna legge' 1998). Their point of view is that a law or regulation on ART must first and foremost protect the health of all individuals involved in ART treatment (couples, women, men, newborn children) by establishing what is medically safe. Therefore, ART in which fertilization occurs outside the body, ART with donated sperm, as well as cryopreservation of embryos are acceptable to secularists as long as patients' and newborn babies' health and safety are guaranteed. Most secularists adhere to the view that the human embryo does not attain the status of a human being until the fourteenth day after fertilization.[10] Furthermore, secularists believe that a law or regulation on ART must protect patients against the economic exploitation that can occur in the private sector by ensuring an adequate level of coverage through the National Health Service. In accordance with these views, secularists would prefer ART to be regulated by a permissive and 'light' law or technical regulation that would provide guidance for ART centres' activities and protection for patients without stating who should have access to what type of ART treatment (Rodotà 1998).

The most important extraparliamentary representatives of secular views on ART within civil society are patient groups,[11] women's organizations,[12] research institutions and ART clinic associations,[13] as well as a certain number of prominent individuals from various fields (doctors, legal experts, etc.).[14]

A further actor that might be expected to voice a strong secular opinion is the pharmaceutical industry, which has an interest in selling expensive fertility drugs and technical equipment used for ART treatment. Surprisingly, our research has not revealed a particularly active pharmaceutical industry in the ART policy process. Our interviewees stated that industry is an actor with important financial interests in the field of ART, but did not give concrete examples of actions suggesting clear position taking. We tentatively conclude that industry has sizeable interests in promoting a secular regulation of ART, but that these interests may for the time being be sufficiently represented by private ART clinics and secular doctors, thus allowing industry to refrain from aggressive lobbying.

A polarized party system: centre-right versus centre-left

A further feature that, combined with Italy's Catholic–secular societal divide, plays a key role in explaining why Parliament has to this day not been able to pass a law on ART is the country's fragmented and polarized party system. This system mirrors a deep ideologically and economically motivated left–right division within Italian society. From the birth of the Italian Republic in 1946, the country's policy-making process has been intimately linked with and often dominated by Italian political parties. For

this reason, Italy is often referred to as a 'partyocracy' (*Partitocrazia*), in which parties gain the upper hand over institutions. According to Giovanni Sartori, Italy's party system can be characterized as a polarized multi-party system (Verzichelli and Cotta 1997: 547) consisting of many small parties grouped around two larger ones. During the First Republic, Christian Democracy dominated the centre/centre-right pole, while the Italian Communist Party (PCI) was the largest party of the left.

After the 1994 elections, a reformed electoral system,[15] parties' financial difficulties and their discrediting through corruption scandals resulted in a changed political party landscape. Parties dissolved, split into factions or were renamed, but the polarized multi-party structure has remained. The DC has vanished, giving birth to the Italian Popular Party (PPI), the Democrats of the Centre (CCD), the United Christian Democrats (CDU), and other residues of the centre-right bloc. The PCI renamed itself Democrats of the Left (DS, previously PDS), and lost a more leftist faction, the Communist Refoundation (RC).

The extreme right Italian Social Movement (MSI) renamed itself National Alliance (AN) and, in the mid-1990s, made a short entry into government together with Forza Italia (FI), a large centre-right party created only a few months before it won the 1994 elections. Another relatively new centre-right party strengthened through the disappearance of the DC is the Northern League, which advocates federalism and, during the first years of the Second Republic, favoured the secession of the Northern Italian regions.

As the next section will show, the combination of the two cleavages described above (Catholic/secular and centre-right/centre-left) combines to explain why Italian institutions have experienced difficulties in developing comprehensive regulation on ART.[16]

Catholicism vs secularism and centre-right vs centre-left: cross-cutting cleavages

The Catholic and secular camps in Parliament differ fundamentally on the same issues as the Church and secularists do within civil society, with the distinction that the Catholic coalition in Parliament does not suggest that all forms of extra-corporeal ART should be prohibited. However, the Catholicism versus secularism divide and the centre-right versus centre-left divide coincide only to a certain degree. The centre-left contains Catholic elements, just as the centre-right can include secular forces (although this is the case to a lesser degree). For example, Italy's Popular Party, which was part of the governing centre-left coalition of the 13th Legislature, was influenced by the Catholic stance on ART, as were some members of Parliament belonging to the Democrats of the Left.

This constellation goes a long way in explaining why the debated bill on ART was not passed. Indeed, the result of the cross-cutting Catholi-

cism/secularism and centre-left/centre-right cleavages has been fragmentation and internal division within political coalitions and parties. Specifically, divisions within the centre-left coalition and the main centre-left party, the Democrats of the Left, help to illuminate why the centre-left, which held a majority during the 13th Legislature, was not able to pass a law on ART.

The governing coalition was made up essentially of the Democrats of Left and the Popular Party, and several smaller parties and parliamentary groups (Greens, Social Democrats, etc.). In the Senate and in the Chamber of Deputies, the centre-left coalition had a solid majority. If the governing coalition had been in agreement, passing a law on ART should not have presented a problem. The PPI, however, whether by conviction or as a result of efficient lobbying on the part of the Catholic Church, upheld a Catholic position on ART and sided with the centre-right in voting almost unanimously in favour of the proposal including the prohibition of ARTs with donated gametes and of embryo cryopreservation. The fact that the PPI voted against the DS, an important coalition partner, also suggests that the DS did not see the issue of ART as being important enough to provoke a political struggle within the fragile centre-left majority coalition.

Another reason for the failure of the centre-left to pass a law was the division within the DS. Taking into account the ideological heterogeneity of the party (i.e. the fact that the party includes both secularists and Catholics),[17] as well as the delicacy of the issues at stake, the DS group declared that its members should vote in accordance with their own conscience. The votes on amendments concerning the most controversial points were secret. As a result, when the chamber voted on the unified text in May 1999, of 163 DS group members, 6 voted against their group, 48 either abstained or were not present to vote, and only 109 members of the DS group voted against the law (i.e. with their group). The centre-right's groups' votes were far less divided, and thus sufficient to pass the controversial unified text with a relatively wide majority.

Perfect bicameralism as an institutional obstacle

Italy's legislative decision-making process also contributes to its failure to produce a law on ART. This process, in which the main actor is Italy's Parliament (consisting of the Chamber of Deputies and the Senate of the Republic), foresees so-called 'perfect bicameralism'. This means that both parliamentary chambers have identical rights and weight in the formulation and passing of laws. The consequence of this institutional rule is that, before a law can be passed, the Chamber of Deputies and the Senate must both approve it in identical form. If one of the two chambers amends a proposal previously approved by the other, the changed provisions (but not the whole bill) must once more be debated and approved by the first chamber.

This back-and-forth legislative process, known as *navette*, continues until a compromise is reached and passed by both chambers. In both the Chamber and the Senate, a law is adopted by a simple majority of the members present. The advantage of perfect bicameralism is that a law emerging from this process is usually a strong and widely supported text. A disadvantage is that political parties can use this institutional feature to lengthen or even block the legislative process. This is what happened in the case of the legislative process on ART during the 13th Legislature.

A divided medical community and weak self-regulation: explaining doctors' high autonomy

The first and most obvious reason for doctors' high autonomy in the field of ART is the lack of a law or comprehensive regulation on ART. Since regulation on specific ARTs is sparse or non-existent, doctors are, at least in theory, left free to decide whether and how to practise any ART that is not regulated. This holds true especially for doctors practising within a private structure, but to a certain extent also for doctors within public ART centres.

Whether intentionally or not, the Italian medical community fosters and upholds the non-regulated status quo through its absence from the debate on a law on ART. This in turn points towards a lack of effective and/or determined organization. Although Italian ART physicians (especially those working in private practice) have considerable financial interests to protect in the field of ART practice, they appear to cultivate and uphold a high degree of individualism – a feature specific to the Italian case.

Indeed, a closer look at recent decision-making processes in Parliament reveals that doctors are not a cohesive group representing a clearly defined set of beliefs and interests. In spite of the fact that they are well represented in political institutions, through the lobbying of the National Federation for the Orders of Doctors and Dentists (FNOMCeO) and due to the fact that many parliamentarians and government officials are doctors, there is no clear evidence in Parliament of a united doctors' lobby that promotes a certain type of legislative solution.

Moreover, our interviews suggested that doctors' personal beliefs in the field of ART differ widely. Many doctors follow a Catholic orientation, while just as many have secular convictions. A further observation made by an interviewee is that doctors who are not politicians might explicitly choose to distance themselves from the political debate on ART, since they do not agree with the way ART is dealt with by politicians and feel at the same time that the intervention of a practising doctor would have little impact. These elements to a certain extent dispel the widespread idea that Italian fertility doctors are ruthless moneymakers with weak ethical standards.

A second reason for the medical community's high autonomy is that the relatively weak self-regulation by the Italian medical community does not fill the regulatory void on ART. In 1995, in the light of a series of scandals in the field of ART, the Federation for the Orders of Doctors and Dentists[18] adopted a new article on ART that was added to the Code of Medical Ethics. It prohibits surrogate motherhood, post-menopausal treatment, post-mortem ART, the commercial use of gametes and embryos, and the production of embryos for research. It also determines that access to ART should be restricted to heterosexual couples. The FNOMCeO invites local orders to sanction members who do not abide by the principles on ART spelled out by the Code of Medical Ethics.

The Code, then, does not have the status of a law or binding regulation. As a result, doctors in the field of ART interpret its meaning for their practice in different ways. While some view it as establishing clear rules leading to sanctions if broken (permanent exclusion from the Order would be the most serious penalty), others point out that the Order applies its rules arbitrarily. In addition, the procedures for suspension from the Order are long and complicated, sometimes involving the Ministry of Health, and thus allowing for ample time to collect political support for or against a suspension. Faced with this unclear situation as to the actual impact of the Code of Medical Ethics, many doctors do not necessarily feel bound by the rules it sets forth.[19]

Italy's two parallel ART markets: explaining patients' medium access

The fact that patients' access to treatment is only medium is largely due to the 'dual nature' of Italy's ART market. In the context of Italy's mixed National Health Service, the 1985 Circular results in unequal access to ART. Wealthy patients can afford faster access to a wider range of ART than those who depend on the SSN for treatment and financial coverage. In the absence of a comprehensive regulation on ART, many techniques are available to a few, and few are available to many. This makes for a medium level of client access to ART despite the wide range of techniques offered.

Since Italy has, to date, not passed any legislation or comprehensive regulation on assisted reproduction, the main binding text remains the 1985 Circular, which focuses on the question of coverage by the SSN.[20] The text's main provisions are that the SSN will finance only married couples resorting to ART, and only ART using the couple's gametes. Non-married couples and couples wishing to resort to ART using donated gametes cannot obtain coverage from the SSN. Moreover, the SSN does not cover the cryopreservation of embryos.[21] As a result, public ART clinics can offer only a limited variety of ART.

A further limitation found in public ART centres is that they often have

long waiting lists of several months or more. A couple that decides to resort to ART often feels a psychologically motivated urge to act quickly and is therefore frequently not prepared to wait for treatment in a public centre. Many couples interested in ART first get information about treatment in the public sector, and about SSN coverage, but then resort to private facilities for faster service.

Private ART clinics may offer faster and more varied services than public centres, but they are also relatively expensive.[22] Since the law does not forbid techniques such as gamete donation, access for unmarried couples and the cryopreservation of embryos, they are widely practised in private fertility clinics. Observers of the Italian case state that the 1985 Circular led to a rapid development of the private ART sector which, as a rule of thumb, offers anything that the SSN does not cover (as well as what it does cover). Private centres can count on wealthy patients' business, and therefore usually do not offer SSN-covered services (this would be possible through a convention with the SSN).

Conclusion

Italy's lack of regulation can be explained by a combination of two cross-cutting cleavages: (1) a deeply entrenched division between Catholics and secularists on the issue of ART, apparent both in civil society and in Italy's political institutions; and (2) a strong centre-left/centre-right divide reflected by the political party system. The institutional feature of 'perfect bicameralism' presents a further obstacle to the passage of a law. These factors, taken together, have resulted in Parliament's failure to pass legislation on ART, and in governmental reticence to address the issue.

High autonomy is mainly the result of the lack of a law or regulation – favoured by a medical community divided on the issue of ART – together with the medical community's weak self-regulation. Medium access is explained by the inequalities that the dual Italian ART market has led to, in which public centres offer almost fully covered, limited and relatively slow service, and private centres offer a wide range of fast services and cater to wealthier patients.

It is difficult to predict what will happen to the new relatively restrictive bill on ART, introduced in late 2001 and currently awaiting its reading in the Senate. In light of what this study has concluded for previous legislative processes, however, two elements might make it easier for a law to be passed during the 14th Legislature than during the previous one. First, Berlusconi's new centre-right government was elected by a solid majority and thus enjoys strong parliamentary backing and has a powerful tool to pass legislation. Second, the current centre-right majority seems to be relatively united on the values relevant to assisted reproductive technology. Indeed, the current centre-right majority is strongly Catholic, and is much less divided by the Catholic–secular cleavage than the former

centre-left coalition was. This might offer the current centre-right majority a window of opportunity to pass a restrictive law on ART inspired by Catholic beliefs.

Notes

1 According to Neresini and Bimbi (2000: 220), 'Far West' is the most often used metaphor in connection with ART policy.
2 This chapter covers Italian ART policy in its entirety, i.e. since the mid-1980s when ART became more and more common and when Italian legislators and the government first dealt with the issue. However, since the main developments in the debate surrounding ART regulation have taken place over the past five years, a certain emphasis is placed on this period.
3 In Italy's legal system, court decisions do not establish generally binding precedents, and are thus not interpreted as authoritative decisions in this chapter. Decisions of the higher courts may, however, establish principles that are in practice considered to be generally applicable. In the field of ART, a decision by the Italian Supreme Court of Appeal established the principle that an adoptive father's claim for paternity has precedence over that of a biological father (i.e. a sperm donor) (number 3529, 17 May 2000). For overviews of court activity on ART, see Baldini 1999.
4 For a definition of 'policy design' as well as other theoretical and methodological terms and concepts used in this chapter, see Chapter 1.
5 The results presented in this chapter are based on (1) detailed coding of Italy's authoritative decisions on ART, (2) a questionnaire sent to experts to identify relevant actors in the field of ART in Italy ('reputational approach'), (3) extensive documentary analysis (primary and secondary sources), and (4) a series of interviews with experts in the field of ART in Italy.
6 When determining levels of access and autonomy, we do not take into account the Federation for the Orders of Doctors and Dentists' Code of Medical Ethics or the TRA Forum's Code of Auto-regulation, as these are not 'authoritative decisions' according to our definition.
7 The present version of this chapter was finalized in November 2002.
8 The most comprehensive account of the Church's position on ART can be found in a document published in 1987 by the Church's Congregation for the Doctrine of the Faith and entitled 'Instruction on respect for human life in its origin and on the dignity of procreation'.
9 For example, while the former Communist Party was basically secular, its successor parties – the PDS (Democratic Party of the Left) and later the DS (Democrats of the Left) – not only turned away from their secular stances but also developed (in part already existing) Catholic elements, partly as a result of their alliance with the Italian Popular Party (PPI). A further example is Forza Italia, which was born as a neo-liberal, anti-DC and not explicitly Catholic party: it began to emphasize Catholic values after its failure to govern together with the anti-Catholic Northern League in 1994.
10 This approach was established by the British Committee of Inquiry into Embryology and Human Fertilization (1982–85), also known as the 'Warnock Committee'. The rationale behind it is that the neural system of the embryo begins to form after about ten to fourteen days.
11 Examples of patients' organizations are l'Ape Sapiente, l'Altra Cicogna and Madre Provetta.
12 Secular women joined the debate on ART as the Tavolo di donne sulla Bioetica. On the issue of ART, however, Italian women were and remain divided by

the Catholic–secular cleavage. They did not rally around the issue of ART as they did around the issue of abortion during the 1970s and 1980s. Calloni suggests that 'influence of the women's movement was limited to the defence of an existing law [partially decriminalizing abortion]; it did not extend to blocking a new restrictive pro-life law on assisted procreation' (2001: 198).

13 Important research associations and ART clinic associations involved in the debate include CECOS Italia (Centro Studio e Conservazione Ovociti e Sperma Umani) and EFRA Italia (European Fertility Research Associates Italy). Data on the nature and amount of research conducted in Italy are hard to come by. Since there is no official research programme in the area of ART, there are no official numbers. Our interviewees hypothesized that both the public and private sectors probably maintain some level of research activity within the realm of what authoritative decisions do not prohibit.

14 Prominent figures include Stefano Rodotà, a long-time parliamentarian, legal expert on biotechnology and privacy issues, and currently the president of the Italian Authority for Privacy; Giovanni Berlinguer, also a long-time parliamentarian and former President of the National Bioethics Committee (1999–2001); and Carlo Flamigni, one of the pioneers of ART in Italy and a professor and practitioner at the University of Bologna.

15 Before 1993, parliamentary seats were distributed through a system of proportional representation (PR). A major 1993 reform replaced PR with a mixed system of majority vote and PR. Today, Italians vote for three-quarters of their parliamentarians in one-man constituencies through a majority vote system. They elect the remaining quarter of their members of Parliament through a PR-list system with a 4 per cent threshold.

16 Some experts of Italian politics also underline the importance of Italian parties' tendency to use issues such as ART – ethical issues and issues that are relatively unimportant in terms of national priorities – to negotiate and obtain other legislative objectives instead of attempting to resolve them by passing a law.

17 The DS is made up of (a) former members of the Communist party and other leftist parties; (b) a diverse group of collective and individual actors from within civil society who had not engaged in party politics before the transformation of the party system in the mid-1990s (e.g. anti-Mafia groups, ecologists, etc.). The DS, then, is a large, heterogeneous centre-left movement that accommodates a wide range of issues and ideologies, whereas the traditional Italian left was organized around and inspired by Communist values and principles.

18 Italian doctors must be members of the Order to be able to practise.

19 A further attempt at self-regulation took the form of a Code of Auto-regulation announced in November 1998 by a series of research institutes, patients' organizations and ART clinic associations, the so-called 'Forum for the Protection of Assisted Reproduction' (Forum per la Tutela della Riproduzione Assistita, TRA). The TRA Forum's Code establishes a set of rules that guarantee deontological behaviour in the field of ART. Like the Code of Medical Ethics the Code of Auto-regulation is not generally binding, since only ART centres that adhere to it actually commit to following it.

20 As a result of the lack of legislation or comprehensive regulation, the Ministry of Health has not yet established an official classification of medical interventions (known as a Diagnosis Related Group, DRG) in the field of ART covered by the SSN. Instead, ART interventions covered by the SSN are included in other DRGs and carry denominations that are not specific to ART. For example, an egg retrieval following ovarian stimulation may be classified as an 'intervention on the female uterus', an 'intervention on the female reproductive apparatus', or a 'chirurgical intervention' (Fattore and Lazzaro 1998).

21 These statements hold true as a general rule and are the facts upon which this paper builds its analysis. However, in interviews, technical experts in the field of ART have suggested that certain public ART centres apply the 1985 Circular in a more flexible manner than others. Indeed, in individual public ART centres couples requesting treatment are not asked to provide a marriage certificate, and even ART with donated gametes and cryopreservation is offered in a few cases. Therefore, what techniques are available and covered varies from public centre to public centre.

22 According to data collected in 2000–2001 and experts interviewed in Autumn 2001, a one-cycle IVF in the private sector costs at least between 2,600 and 3,000 euros, and is in most cases paid for entirely by the patient. More complex ART interventions can reach around 15,500 euros. In contrast, in the public sector a one-cycle IVF costs between 1,600 and 2,600 euros, of which the patient pays only around 250 euros ('Il far west della sterilità' 1994; Panzavolta 2001: II.3; Pizzini and Lombardi 1999: 97).

4 Policy networks, federalism and managerial ideas

How ART non-decision in Canada safeguards the autonomy of the medical profession

Éric Montpetit

Policy-making for Assisted Reproductive Technology (ART) in Canada amounts to a clear case of non-decision. Since the early 1990s, the federal government has attempted to pass a comprehensive legislation twice in this sector, but each time has decided to delay adoption. After a first attempt in 1997, a new and comprehensive ART bill was introduced in the House of Commons in May 2002 and again it was abandoned when the government decided to end the parliamentary session. Clearly, the non-decisions that have characterized policy-making in this area thus far leave medical specialists with a wide autonomy to practise ART and do little for patients seeking a better access to the technology.

The explanation of the non-decisions (particularly the 1997 non-decision) developed in this chapter stresses a symbiosis between the physician network's power, the Canadian division of responsibilities in health care and new managerial ideas. The physician network displays an unambiguous preference for self-regulation and establishes a close connection to the state through parliament. The division of responsibilities between provinces and the federal government over health has significantly constrained the designing of an attractive ART legislation by Health Canada. Unattractive, the legislation turned out to be opposed even by groups holding values and having interests sharply diverging with those of physicians, the main target of Health Canada. Current managerial ideas hold as unacceptable any such opposition to policy initiatives.

The absence of a federal ART legislation has meant leaving this sector almost entirely to self-regulation by province-based medical colleges and other professional institutions. In other words, the physician network, the prevailing division of powers over health and new managerial ideas have thus far offered efficient protection to medical and research autonomy against potentially intrusive interventions by the Canadian federal government. This argument was developed after a careful analysis of official documents and parliamentary briefs and a series of confidential interviews conducted with government officials and interest group representatives. I

begin with a presentation of a detailed analysis of the current ART policy design in Canada.

Absence of a grand design

Canada, at the federal as well as the provincial levels, has a Westminster type of parliamentary system whereby single-party governments exercise a tight control over legislative activities. Party discipline in the House of Commons and in the provincial legislative assemblies enables first ministers of majority governments to control the designing, introduction, debates (to an extent) and adoption of bills (Savoie 1999). In such a parliamentary system, the government is assisted in policy designing by a bureaucracy. Each minister normally has, within his or her department, a policy branch staffed with policy analysts responsible for the preparation of new policies or the amendment of existing ones.

This briefly sets the stage on which Canadian policy-makers have tried but, up to now, failed to adopt a comprehensive legislation to regulate ART. This non-decision is surprising in many ways. As just explained, the Canadian parliamentary institutions concentrate power in the hands of the Prime Minister. Thus, one would expect a motivated Prime Minister to possess the capability to adopt a law on ART. The motivation to act should have been also present, as a Royal Commission, the Royal Commission on New Reproductive Technologies, released a report in 1993 stressing the urgency to draft a framework legislation enabling the prohibition of a number of practices and the regulation of others. The Commission has been unusually controversial, but very few groups stand against the idea that a comprehensive Act is required in this area. In short, the government has had over eight years to adjust or simply reject some of the 293 recommendations of the Royal Commission.

To be fair, the review of these recommendations was undertaken by the government bureaucracy responsible for preparing health-related policies, namely Health Canada's Health Policy and Communication Branch (HPC),[1] which by 1996 had already prepared a bill echoing some of the concerns expressed by the Royal Commission. Bill C-47, or the Human Reproductive and Genetic Technologies Act, sought to protect human dignity and health, especially that of women and children, via the prohibition of several reproductive and genetic practices. Cloning, sex selection, the creation of embryos for research and the commercialization of ovum and sperm are among the practices considered for prohibition under the bill. Had bill C-47 been adopted, severe fines and imprisonment terms would have applied to offenders. It is in virtue of its criminal law responsibilities that the federal government introduced the Human Reproductive and Genetic Technologies Act in Parliament. In addition, upon introducing the bill the Minister of Health announced that C-47 was to be followed by an enabling legislation for the regulation of those

practices deemed legal (Government of Canada 1996). C-47, however, never saw the light of day: a year after its introduction in the House of Commons, the government allowed the bill to die on the order paper.

Without C-47, Canada is left with very few coercive measures to prevent ethically unacceptable ART. Three such measures exist at the federal level. First, a 1996 regulation, the Processing and Distribution of Semen for Assisted Conception Regulation, enabled by the Food and Drug Act, ensures a higher quality of the sperm utilized in artificial reproduction. The regulation requires the selection of sperm donors based on medical testing, imposes a six-month quarantine, a labelling method, and demands tight book-keeping on the part of sperm-banks. To increase compliance and thereby prevent the spread of infectious diseases, Health Canada has developed and implemented a sperm bank inspection strategy. Second, the Excise Tax Act exempts imported human sperm from border tax, but imported sperm is subjected to the requirements of the Processing and Distribution of Semen for Assisted Conception Regulation mentioned above. Although not explicitly stated in the law, the tax exemption signals that sperm, just like any other body part, including blood, should not be the object of commerce. Unlike other body parts, however, no federal legislation prevents sperm banks from commercializing sperm. The Canada Customs and Revenue Agency works closely with Health Canada to ensure the enforcement of regulations on the import of human sperm. Lastly, the Canadian Institutes of Health Research (CIHR) have published guidelines for the ethical conduct of research on stem cells to clarify the so-called Tri-Council Policy Statement. While the Tri-Council Policy clearly prevented the use of public funds for research projects resorting to commercial transactions to obtain gametes and projects resting on the creation of human embryos, clones or human/animal hybrids, the guidelines now impose strict informed consent requirements from women who participate in embryo or fetal tissue research. Ethical concerns, of course, form the basis of such government research funding restrictions. Privately-funded research, however, remains unconstrained.

The coercive policies of the federal government thus cover a very narrow scope of assisted reproductive practices. To obtain a full portrait of Canadian ART policy it is essential to consider non-authoritative decisions, at the federal but also at the provincial level. A voluntary moratorium called in 1995 forms the main decision of the federal government on ART. The voluntary moratorium covers nine applications of reproductive and genetic technologies:

1 Sex selection for non-medical reasons
2 Commercial pre-conception or surrogacy arrangements
3 Buying and selling of eggs, sperm and embryos
4 Egg donation in exchange for in vitro fertilization services
5 Germ-line genetic alteration

6 Ectogenesis, or the development of a foetus in an artificial womb
7 Human embryo cloning
8 Formation of animal-human hybrids
9 Retrieval of eggs from foetuses and cadavers for purposes of donation, fertilization and research.

The moratorium was presented by Diane Marleau, then Minister of Health, as a temporary measure awaiting the adoption of a comprehensive Act on ART. In her presentation of the moratorium, Minister Marleau insisted that the objective was to ensure, in the short term, that research on reproduction and genetics remains in line with the values of Canadians. A year later, in 1996, Health Canada created the Advisory Committee on the Interim Moratorium on Problematic Reproductive Technologies to monitor compliance. The Committee, composed of university professors and researchers and of some people who have had personal experiences with ART, meets roughly twice a year to prepare reports for the Minister on compliance with the moratorium, but also on the development of questionable practices which should be considered for inclusion in the moratorium. The Committee has few resources to fulfil its mandate.

Most of the responsibilities for the provision of health care in Canada are provincial responsibilities. Nevertheless, provinces also have very few coercive measures applying to ART. First, provinces can decide whether or not assisted reproductive interventions are covered under their health insurance plan. Ontario was the only province (Shanner 1995: 832), to list in vitro fertilization without restriction among the services covered by the provincial health insurance. Utilizing a recommendation of the Royal Commission, however, the province decided to terminate this coverage in 1994. As a result, provincial health insurance policies, as far as ART is concerned, are harmonized covering artificial insemination and in vitro fertilization only when fallopian tubes are blocked. Second, medical clinics, including fecundity clinics, are subject to provincial permit requirements and sanitary inspections, which do not include norms specific to ART. Specialized units of health ministries are in charge of implementing this policy. Third, one province and one territory, namely Newfoundland and Yukon, have amended their respective family law to recognize the male partner of the inseminated women as the legal father of the child.

Parenthood rights have been defined slightly more extensively under the Civil Code in Quebec, the only province to rely on codified civil law and not on common law. A reform of Quebec's Civil Code in 1992 created a first opportunity to involve the National Assembly in matters pertaining to ART. Articles 538 to 540 of the Civil Code deny parental rights to donors and grant these rights to the beneficiaries of assisted reproductive services. Article 541 denies legal status to any surrogacy arrangement. Article 542 protects the confidentiality of the donors, while permitting children born out of ART access to medical information if necessary.

Lastly, article 25, some legal specialists argue, would prevent the commercialization of human gametes and embryos. It has been suggested that provincial legislations in English Canada concerning organ donations could also be used in court cases to prevent similar commercialization. Courts, however, have yet to test this hypothesis (Mykitiuk and Wallrap 1999: 315).

Potentially more significant in terms of scope are provincial non-coercive measures. Broadly speaking, two such measures can be identified. First is professional self-regulation for medical practices. Provinces view fertility treatments solely as a medical practice and consequently consider that regulatory authority rests with medical colleges. In fact, all provinces' Health Service Acts delegate the authority to regulate medical practices to province-based medical colleges, formally recognized under Provincial Profession Acts. Medical colleges license physicians and therefore can remove a licence to sanction anyone resorting to non-condonable medical practices. The colleges, therefore, have the responsibility to keep their members informed about the best available practices, a task accomplished through the preparation of deontology codes and practice guidelines. Medical colleges have produced few such practice guidelines concerning ART, preferring to refer physicians to specialist organizations. Nevertheless, it is widely accepted that controversial practices such as human cloning fall outside professional norms, and as such are unacceptable to medical colleges.

Second, public health institutions, including research institutions, are required to have an ethics committee to develop ethical standards by which researchers and practitioners must abide. The work of these committees has not been coordinated and consequently very little is known about the standards each institution applies. In addition, it is not clear how many of the institutions involved in reproduction and genetics have developed standards pertaining to ART (Conseil du Statut de la femme 1996: 20).

The absence of comprehensive Acts prevents federal and provincial governments' interference in individual physicians' and researchers' decisions to conduct any kind of reproductive and genetics research and to practise given fertility interventions. Physicians and researchers' autonomy can only be constrained by peers, who, thanks to provincial self-regulation regimes, establish norms defining which ART is acceptable and which is not. In other words, if the individual autonomy of physicians and researchers can be constrained, the collective autonomy of the profession is safe. Following a procedure developed by the CPDP, each policy measure just discussed was carefully assessed for its effect on collective professional autonomy and patient access. The results are presented in Tables 4.1 and 4.2.

If the absence of a grand policy design is overall positive in terms of professional autonomy, the picture regarding access for couples suffering

Table 4.1 Autonomy in Canada

		Autonomy	
Basic techniques			
Insemination (1)		3	H
GIFT/ZIFT (2)		3	H
IVF/ET (3)		3	H
Total 9: 0–1 no or close to no (N), 2–4 low (L), 5–7 medium (M), 8–9 high (H)		*9*	*H*
Related techniques			
Surrogacy (4)		2	M
Donation (5)	sperm: 5a,	2	M
	egg: 5b	3	H
	of embryos /impregnated eggs: 5c	3	H
Cryopreservation (6)	sperm: 6a,	2	M
	egg: 6b	3	H
	of impregnated eggs 6c	3	H
	embryos: 6d	3	H
Pre-implantation diagnostics (7)		3	H
Genetic selection (8)		3	H
Gender selection (9)		3	H
ICSI (10)		3	H
Max. 36: 0–5 no or close to no (N), 6–17 low (L), 18–29 medium (M), 30–36 high (H)		*33*	*H*
Research/experimental techniques			
Genetic engineering (11)	on gametes/germ cells (11a)	3	H
	on impregnated eggs, embryos (11b)	3	H
Research (12)	on gametes/germ cells (12a)	2	M
	on impregnated eggs, embryos, zygotes (12b)	2	M
Cloning (13)		2	M
Chimera and hybrid building (14)		2	M
Max. 18: 0–2 no or close to no (N), 3–8 low (L), 9–14 medium (M), 15–18 high (H)		*14*	*M*
Total of all three groups of techniques (max. 9): 0–1 no or close to no (N), 2–4 low (L), 5–7 medium (M), 8–9 high (H)		*8*	*H*

Note
M, medium; H, high; 2 = medium; 3 = high.

from infertility is mixed. First, the limited insurance coverage restrains access to fertility treatments to those who can afford them (Table 4.2). Second, Family Acts and court cases have not permitted any clarification as to who can access fertility treatments. While this is computed as positive for access in Table 4.2, it should be noted that it leaves clinics free to have either open policies or discriminatory policies based on the marital status of patients, their sexual orientation, and their age (Shanner 1995: 827).

Table 4.2 Access to ART in Canada

Access			
B*asic techniques*			
Insemination (1)	with gametes of the couple (1a)	H	3
	with sperm donation (1b)	H	3
GIFT/ZIFT (2)	with gametes of the couple (2a)	H	3
	with sperm donation (2b)	H	3
IVF/ET (3)	with gametes of the couple (3a)	H	3
	with sperm donation (3b)	H	3
	with egg donation (3c)	H	3
	with embryo donation (3d)	H	3
Max. 24: 0–3 no or close to no (N = 0), 4–11 low (L = 1), 12–19 medium (M = 2), 20–24 high (H = 3)		*H*	*24*
Related techniques			
Surrogacy (4)		M	2
Cryopreservation (6)	sperm (6a)	M	2
	egg (6b)	H	3
	impregnated eggs (6c)	H	3
	embryos (6d)	H	3
Pre-implantation diagnostics (7)		H	3
Genetic selection (8)		H	3
Gender selection (9)		H	3
ICSI (10)		H	3
Max. 27: 0–4 no or close to no (N = 0), 5–13 low (L = 1), 14–22 medium (M = 2), 23–27 high (H = 3)		*H*	*25*
Total of all two groups of techniques (max. 6): 0 no (N), 1–2 low (L), 3–4 medium (M), 5–6 high (H)		*H*	*6*
For Element 1: Weights for total of all two groups of techniques (N = 0), (L = 4), (M = 8), (H = 12)		*H*	*12*
For Element 2: Judgement for financial coverage of ART (0–3)			*1*
Total of Element 1 and Element 2 (0–15)			*13*

Note
M, medium; H, high; 2 = medium; 3 = high.

Legal specialists argue that the 1982 Charter of Rights and Freedoms might be used by citizens who were victims of clinic discrimination, notably by construing Section 7 as a right to procreation. The traditional Canadian judicial restraint, however, was maintained in a first case involving ART in 1997 when a Nova Scotia court ruled against a plaintive seeking a judicial review of the province's decision not to cover intracytoplasmic sperm injection under its public insurance scheme (Mykitiuk and Wallrap 1999: 328–9). In short, the absence of a grand policy design has clearly served well the interests of the medical profession, but it is not so clear when it comes to those of the patients.

How can this situation be explained? Can it be explained solely in

terms of the sheer power of the medical profession? Can we say that the institutional context of parliamentarianism and federalism served well the interests of the medical profession?

Explaining the absence of a comprehensive policy design

An issue framed by a Royal Commission

It was a coalition of individual women and feminist groups, effective at getting the attention of key politicians, that in 1989 obtained from the Conservative Government of Brian Mulroney a decision to create the Royal Commission of New Reproductive Technologies (Eichler 1993: 196).

The government gave the Commission the wide responsibilities:

> to inquire into and report on current and potential medical and scientific developments related to new reproductive technologies, considering in particular their social, ethical, health, research, legal and economic implications and their public interest, recommending what policies and safeguards should be applied.
>
> (Royal Commission on New Reproductive Technologies 1993: 2)

Although the appointed Chair of the Commission, Patricia Baird, was rapidly associated with the bio-optimistic view of the medical profession because she is a paediatrician and a geneticist (Vandelac 1993: 255), the Royal Commission was initially composed of members with various backgrounds, including law, sociology and religion (Eichler 1993: 197). The scope of the mandate and membership of the Commission certainly served to mobilize a wide range of civil society groups, drawing from a variety of expertise, experience and interests (Scala 1997: 117–18).

Such mandate comprehensiveness and membership diversity have, however, contributed to the difficulties and controversies encountered by the Commission. The report was produced only after four out of the seven members were fired and additional powers were granted to the Chair through a government decree (Kondro 1992: 1214–15). Although raising serious concerns regarding a number of reproductive and genetic practices, the overall tone of the report has been categorized as bio-optimistic. The report surely recommends the prohibition of certain practices, but its main recommendations to create a regulatory commission to monitor the practice of assisted reproduction and research has been viewed as a legitimization of ART. After a careful analysis of the recommendations of the report, Arseneault (1994: 102) concluded that '...the Commission has given priority to the medical and technology approach, leaving aside the ethical approach and all the questioning this latter approach inherently involves'.

Since the publication of the report, medical and research autonomy has figured prominently as a means to encourage scientific advances in the area of genetics and reproduction in ART policy designing in Canada. Restrictions on the autonomy of the medical profession have only been considered to the extent that some specific practices are clearly ethically and morally non-condonable.

Access has figured as a marginal concern of the Commission. The Commission has even had a slightly restrictive effect on access, as it recommended that provinces should not cover IVF under their health insurance plans (unless required because of blockage of fallopian tubes) given the low rate of success of the practice. Ontario, the only province where IVF was entirely listed, responded quickly by de-listing the practice. No single event has attracted media attention and therefore has influenced ART policy-making in Canada more than the Royal Commission.

The actors' networks

Networks establish various routines of state/civil society connections and more or less efficiently anchor cohesive policy beliefs. According to Marsh and Smith (2000: 6), actor networks 'involve the institutionalization of beliefs, values, cultures and particular behaviour'. Following these characteristics, the British literature on policy networks defines a continuum that ranges between two ideal types of policy networks: the policy community and the issue network (Rhodes 1997: 44). Policy communities are closed to a limited number of actors, are tightly interconnected, and normally comprise influential state actors. Therefore, they serve as efficient anchors for cohesive policy beliefs and are often responsible for path-dependent policy trajectories. In contrast, issue networks are open to a large array of actors and are loosely interconnected. Issue networks normally embody fragmented and changing sets of policy beliefs.

Raising novel issues, the Royal Commission has encouraged the formation and strengthening of interest groups, notably fertility groups (see Table 4.3). However, primarily concerned with increased access for patients, these groups possess few resources and still have to institutionalize efficient patterns of relationship with state agencies. Consequently, they have been able to do very little to improve access to ART. The Royal Commission has also mobilized a number of existing networks over ART. Three such networks became particularly active: the physicians' network, the women's network and the pro-life network. The physicians' and the pro-life networks closely correspond to policy communities, while the women's network, perhaps not quite an issue network, appears more fragmented.

Table 4.3 classifies interest groups active regarding ART according to the network to which they belong. Because Table 4.3 lists only those groups that presented briefs during the parliamentary hearings held

Table 4.3 Policy preferences of Canadian groups by networks

Networks	*Interest groups*	*Autonomy*	*Access*
Physicians' networks	Canadian Medical Association	+ +	+
	Society of Obstetricians and Gynaecologists of Canada	+ +	+
	Canadian Fertility and Andrology Society	+ +	+
	Association des obstériciens et gynécologues du Québec	+ +	+
	Canadian College of Medical Geneticists	+ +	+
	College of Family Physicians of Canada	+ +	0
	National Council on Bioethics in Human Research	+ +	+
	Canadian Nurse Association	+	+
	Canadian Public Health Association	0	+
Women's networks	Feminist Alliance on New Reproductive and Genetic Technologies	–	+
	National Action Committee on the Status of Women	—	0
	National Association of Women and the Law	–	+
	Women's Health Clinic	—	+
	Winnipeg Women's Health Clinic	–	0
	The National Council of Women of Canada	–	0
	REAL Women of Canada	—	—
Pro-life networks	Alliance for Life	—	—
	Canadian Conference of Catholic Bishops	—	—
	Evangelical Fellowship of Canada	—	—
	Catholic Health Association of Canada	—	–
Groups outside the three main networks	Gamete Donation Advocacy and Support Group	+	+
	Infertility Network	+	+ +
	The New Reproductive Alternative Society	0	+ +
	Infertility Awareness Association of Canada	0	+ +
	Parent Finders	0	0
	Council of Canadians with Disabilities	—	+
	Canadian Cystic Fibrosis Foundation	+ +	0
	Canadian Bar Association	0	+

Notes
0 = no clear position
+ = hold positive views on autonomy or/and access
+ + = hold very positive views on autonomy or/and access
– = hold restrictive views on autonomy or/and access
— = hold very restrictive views on autonomy or/and access.

about C-47, it may fail to offer a complete picture of the three policy networks. However, it surely encompasses all the groups most committed to influencing ART policy designing. Their respective policy preferences were identified after a careful analysis of the briefs presented to Parliament.

The pro-life network is the least influential of the three networks. Comprised of groups closely associated with religion (see Table 4.3), the network serves as a solid anchor for the belief that life begins at conception and it has therefore cohesively yielded restrictive positions on ART. The main connection this network enjoys with the state is through a relatively new political party, the Canadian Alliance (formerly known as the Reform Party), which thus far has remained a regional and powerless opposition party. Therefore, the translation of the restrictive preferences of the actors who belong to this network into a restrictive bill and eventually a restrictive Act has been impossible.

In contrast, the women's network has solid connections with the state through Health Canada. Health Canada's Women's Health Bureau has mobilized several groups for whom women's health is a primary concern. Certainly the Health Policy and Communication Branch (HPC), the government bureau responsible for ART policy designing, has been responsive to several of the concerns expressed by women's groups. However, the women's network is not as cohesive as the pro-life network. Committed to decision-making through dialogue and exchange of views, several women's groups (particularly the National Action Committee on the Status of Women (NAC)) have been particularly tolerant of diverging beliefs and ideas (Vickers *et al.* 1993). This commitment is clearly reflected in the brief prepared by NAC as a response to C-47. While NAC stresses that ART is of particular interest to women, the group also argues that the stakeholder consultation approach, an approach based solely on interest, is inadequate because it is too exclusive. A broader span of views, the group argues, should be allowed to enter a dialogue over ART. Diverging views appear welcome even within the network. While NAC endorses the criminal prohibitions contained in C-47, the group insists that there is no consensus on this issue among women, as groups such as the Feminist Alliance on New Reproductive and Genetic Technologies, and the National Association of Women and the Law, claim that criminal law should be used with more caution. As illustrated by this example and Table 4.3, the policy preferences within the women's network are inconsistent.

This is not without an effect on the policy influence of the network. In HPC's New Reproductive and Genetic Technologies: Setting Boundaries, Enhancing Health, a policy document which announced the government's projects, the special interest of ART for women is acknowledged and a specific emphasis is placed on the goal of protecting women's and children's health (Government of Canada 1996: 16, 19). However, when it came to specific policy recommendations HPC had to look elsewhere, given the inconstancy within the women's network.

The Royal Commission's report ended up providing direction to HPC. Some staff members at HPC had either worked for the Commission or had been close to it. HPC officials surely undertook countrywide consulta-

tions to verify the validity of the report's recommendations, but without intending to accept serious challenges (Montpetit 2003). Not surprisingly, Health Canada reported:

> These consultations expanded upon the work of the Royal Commission and confirmed, among other things, that Canada needs a legislative and regulatory infrastructure to deal with NRGTs [New Reproductive and Genetic Technologies]. The consultations also confirmed that the federal government should exercise national leadership in setting boundaries around NRGTs by prohibiting certain unacceptable practices and regulating others.
>
> (Government of Canada 1996: 14)

Consistent with the recommendations of the Royal Commission, Health Canada has proposed two major initiatives: to prohibit 'unacceptable technologies through legislation', and to develop a 'legislated regulatory regime to manage acceptable technologies' (Government of Canada 1996: 5). C-47 corresponded to the first proposal and was to be shortly followed by an amendment to implement the second.

Of all three networks, the physicians' network has been the most influential. The influence of the network rests with both its cohesion and the interconnection it provides between professional groups and the state. First, the network embodies firm beliefs in scientific and medical progress, and has therefore been capable of producing highly cohesive policy positions (Table 4.3). Although groups of physicians agree that *some* practices should be banned, they disagree with the scope of the list of practices the government was contemplating for prohibition in Health Canada's policy document and C-47. For example, preventing all forms of payments in exchange for gamete donation, they argue, would significantly increase the difficulty of finding donors, especially women donors. This would not only harm research, physicians' groups suggested, but it would also reduce access to practices such as donor insemination and in vitro fertilization. Physicians are also particularly concerned with the possibility that the government may employ criminal law to enforce prohibitions. They fear that subjecting medical practices to criminal law – a severe measure given the low rate of delinquency – would risk tarnishing the reputation of all physicians and, by extension, the relationship of confidence they have built over the years with patients. Lastly, physicians' groups have also positioned themselves in favour of the establishment of a regulatory body – an initiative, however, that should complement, not duplicate, the work already accomplished through so called self-regulation (Canadian Fertility and Andrology Society 1994).

Second, the physicians' network provides for a close interconnection with the state through parliament. A study by Carty (1991: 203–5) reveals that riding (i.e. electoral constituency) associations increasingly interact

with interest groups. The study further suggests that groups are particularly active over abortion, an issue often associated with ART. When asked which groups were most influential regarding the abortion issue, Carty pointed at physicians, a group particularly trusted by Members of Parliament (MPs).[2] It is not uncommon for MPs to approach the physicians they know in their riding for policy advice on health-related matters. They are therefore naturally predisposed to listening to physicians at parliamentary hearings. An interviewee confirmed that the opposition to C-47 expressed during parliamentary hearings by groups associated with the physician network had a strong effect on MPs. In short, while the women's network exercised a relative influence on policy designing, the physicians' network had a decisive influence on political ratification and thus on the failure of C-47.

This is not to say that the absence of a grand ART policy design in Canada can be simply explained in terms of the sheer power of a medical profession that is protective of its autonomy. The medical profession, while certainly relieved that C-47 was abandoned, did not get its way completely. As emphasized above, the profession would welcome the creation of a regulatory body capable of appeasing the fears of the public while preserving the autonomy of physicians and researchers. To explain non-decision regarding this issue, one must examine, in addition to networks, Canadian institutions, party politics and new managerial ideas.

Canadian institutions, party politics and new managerial ideas

Two institutional factors have combined to enable non-decision over ART: federalism and the specificity of Westminster politics in Canada. I will discuss these factors in turn and explain the managerial ideas they embody.

The constitutional division of responsibilities between at least two levels of government, inherent to any federal system, shapes policy networks in ways that may strengthen or weaken them (Montpetit 2002). Despite constraining the creation of a federal regulatory body, the division of responsibilities prevailing over health care in Canada serves the physicians' network well, and the medical autonomy it promotes, in comparison to the other two networks. By attributing hospitals, as an area of responsibility, to the provinces, the constitution limits federal interventions over health care. Provinces are responsible for the regulation of medical practices. This division of responsibilities has been favourable to medical autonomy because all provinces and territories have delegated the regulation of medical practices to their respective medical colleges, composed mainly of physicians. Possessing the licensing authority, medical colleges are responsible for the quality of medicine practised in their respective province and territory. While potentially constraining the autonomy of individual physicians, such self-regulation ensures a high level of collective medical autonomy.

This division of responsibilities over health care leaves the federal government with a narrow margin for regulatory manoeuvring. Often in cooperation with the provinces, the federal government has nevertheless adopted narrowly focused regulations to promote health. The use of the Food and Drug Act to regulate sperm banks is an example of such a policy. Because they are narrowly focused, these measures are normally easy to adopt, often corresponding to simple 'spot contracts' (Scharpf 1997: 125–6). A spot contract can occur when the costs and the benefits of a well-defined object are obvious. Giving up sperm-bank inspection, the type of measure people tend not to notice, is a small price for provinces to pay in exchange for relief of responsibility in the eventuality of a tainted sperm scandal.

In contrast, the development of a comprehensive ART policy involves far more difficult 'distributive bargains' (Scharpf 1997: 126–30). Knowledge of the difficulty of negotiating with provinces to create a federal agency to regulate ART has spurred Health Canada's decision to split policy designing into two steps. As explained above, C-47, which contained criminal prohibitions only, was to be a first step followed by a second step establishing a regulatory regime. In criminal law, the first step clearly falls within federal jurisdiction. The second step, which involves the regulation of medical acts, expands into provincial responsibilities. Preliminary consultations served as a serious indication that provinces would not easily agree to federal interventions in this area of provincial responsibility. After receiving several negative responses from provincial officials, Health Canada could only underline in *New Reproductive and Genetic Technologies: Setting Boundaries, Enhancing Health* that the establishment of a regulatory regime will require time and solid intergovernmental consultations (Government of Canada 1996: 10). The Privy Council Office, a central agency notably responsible for intergovernmental relations, served Health Canada several reminders that any regulatory regime would have to depend on intergovernmental cooperation. Under these circumstances, it is not surprising that Health Canada chose to act within federal jurisdiction first, before contemplating a regulatory regime.

This decision to split criminal prohibitions and the creation of a regulatory regime served physicians' autonomy, as it attracted opposition to C-47 even from groups that generally support restrictions to physicians' autonomy. The absence of the regulatory regime from C-47 made the bill wholly unacceptable to groups generally supportive of the prohibition of certain practices, because it leaves unattended a wide range of ART. For example, in its brief on C-47, the Feminist Alliance on New Reproductive and Genetic Technologies wrote: 'Bill C-47 will prove to be a completely ineffectual piece of legislation in the absence of a regulatory framework'. Feminist groups that adopted a cautious approach towards criminal law, and which consequently demanded that some practices considered for criminal prohibition under C-47 fall instead under a regulatory regime,

saw this first step, which rested solely on the federal criminal law jurisdiction, as alarmingly small. In short, Health Canada's decision to split policy designing into two steps, a decision commanded by the particular constitutional division of powers in the health-care sector, fuelled opposition in Ottawa.

Serious opposition from interest groups should not, however, be a problem in a system characterized by few veto points (Tseblis 1995). In fact no one could have vetoed the Prime Minister, had he decided to adopt C-47. Even the jurisdiction-concerned Bloc québécois argued in the House of Commons that it was the federal government's responsibility to ban unacceptable practices such as human cloning. This type of analysis, centring on the formal powers of the Prime Minister, fails to consider the importance accorded to the idea of public consultations by central agencies and the nature of the federal party system in Canada. Beginning with Public Service 2000, launched in 1989 to change the public service culture in Ottawa, the promotion of greater proximity between citizens and government has become a major concern of central agencies (Phillips and Orsini 2002). In 1997, incidentally the same year that C-47 died on the order paper, Privy Council Office and Prime Minister Office officials met in a closed retreat to discuss citizens' engagement. The retreat concluded, Savoie reveals (1999: 110), 'with a call for more research on the topic and to identify "change" agents in departments to promote the concept further'.

The public hearings regarding C-47 came as a revelation that Health Canada had not taken civic engagement very seriously during bill designing. Several groups complained of the limited nature of the consultations undertaken by Health Canada during the preparation of its policy report and C-47 (Montpetit 2003). The National Association of Women and the Law, for example, began its brief by stating that they:

> are concerned [. . .] about the short time frame provided to respond to these proposals. The possible ramifications of some of the proposals put forward in this document and in Bill C-47 are both far-reaching and difficult to gauge. What is needed are very carefully considered solutions that are modulated and proportional to the problems posed. In order to make the appropriate decisions about how the law should operate in this difficult and complicated area, much time, study and consultation is needed.

The National Action Committee on the Status of Women concluded its brief with a complaint about the consultation process conducted by Health Canada:

> Unfortunately, due to the very limited nature of the consultative process engaged in by the federal government in the development of

> the legislation, we have had little opportunity to work in a constructive and cooperative manner toward the development of appropriate legislative means.

Physicians also noted consultation deficiencies during the process engaged in by Health Canada. In its brief on Bill C-47, the Canadian Medical Association claimed that the 'government fails to provide convincing evidence that there is widespread agreement about prohibition'. The Canadian Fertility and Andrology Society (CFAS) wrote:

> in drafting Bill C-47, Health Canada consulted only superficially with key groups. For example, no CFAS scientist or physician with expertise in the treatment of infertility reviewed Bill C-47 prior to its submission to Parliament. At no time did Health Canada bring stakeholders together to achieve consensus and provide feedback.

After these public testimonies, central agencies in Ottawa could only conclude that Health Canada had failed to conduct appropriate public consultations and could only press the Prime Minister to delay the adoption of C-47.

Ideas such as placing a wide public at the centre of policy-making only become more prominent when supported by interests (Hansen and King 2001). Incidentally, Prime Minister Chrétien, who is not a natural enthusiast for new managerial ideas (Savoie 1999: 360), had an interest in supporting the drive of central agencies in favour of public consultations. In fact, Chrétien ought to be concerned about any failure to create policy consensus, if only because of the nature of the Canadian party system. The two political parties that have won elections in Canada, namely the Progressive Conservative Party and the Liberal Party of Canada, are described as brokerage parties – that is, they do not win elections by proposing a coherent set of policy ideas, but by brokering a sufficiently large coalition of disparate interests across the country. To do so, the parties must avoid controversial issues, certainly including issues of life and death. Therefore, once in power, these parties have no mandate to act on these issues (Clarke *et al.* 1996). Incidentally, the Liberal Party's documents offer no indication of preferred policy directions on ART.

Under these circumstances, public consultation can play a large role in deciding which projects the government can legitimately contemplate and which it cannot. Over issues that raise serious ethical concerns, one might say that brokerage politics has made ideas of citizen engagement and even consensus creation popular in Ottawa – a surprising occurrence in a Westminster type of parliamentary system (Aucoin 1986). In light of the abortion policy experience of the early 1990s, one thing appears clear in Ottawa: waiting until a consensus emerges on ethically controversial issues is a wise strategy, to avoid harming chances of re-election.

The Parliamentary hearings over C-47 began nine months prior to a federal election. As central agencies presented it to the Prime Minister, the hearings revealed severe divisions among interest groups. Moreover, the official opposition in the House of Commons, the Reform Party (the Canadian Alliance since 1999), an openly pro-life political party, was fully ready to place the government in a difficult position by moving the debate regarding ART onto abortion. To avoid this controversial issue, the Prime Minister was certainly receptive to the Privy Council Office's suggestion that deficient public consultation was a problem.

In summary, the federal arrangement in health care constrained Health Canada to an unattractive two-step policy design, a design certain to displease several groups. Displeasing groups in a Westminster type of parliamentary system might appear to be unproblematic (Tseblis 1995), but in this case it was. Powerful central agencies increasingly value citizen's engagement, and party leaders are interested in such an idea because they become and stay Prime Ministers when capable of keeping disparate coalitions happy. Needless to say, these institutional and ideational circumstances are more favourable to the physicians' network, despite its preference for a non-intrusive regulatory arrangement, than to either of the other two policy networks, which demand restrictions on physicians' autonomy.

Conclusion

The absence of a grand policy design regarding ART in Canada translates into wide autonomy for the medical profession, which, through province- and territory-based medical colleges, self-regulates the quality of services offered to patients. To the extent that physicians are free to perform a wide range of assisted reproductive interventions, one might argue that patients' access to services is relatively permissive. While this appears to be true, the absence of a grand policy design leaves clinics free to discriminate against patients based on their civic status, sexual orientation or age. Furthermore, the absence of public health insurance coverage creates discrimination in favour of patients who can afford expensive treatments. Given the limited power of groups representing patients, it is not surprising to find that their concerns have not been addressed by Canadian policy-makers. The total absence of a comprehensive policy design for ART, however, can appear mysterious in a political system such as that of Canada, which concentrates power in the hands of a single person (Savoie 1999).

A simple explanation in terms of the sheer power of the medical profession might be attractive (Cobern *et al.* 1983). In possession of specialized knowledge, physicians might claim that they constitute the only source of legitimate authority. From the evidence presented in this chapter, however, physicians' power does not constitute a sufficient explanation for

the failure to make any kind of significant decision on ART. Women, it should be noted, also had an influential network establishing close relationships with Health Canada. While the physicians' network and the linkages it establishes with Members of Parliament help in understanding the failure of C-47, federalism has also worked to prevent policy-makers from making decisions on ART (some of which had obtained the support of physicians). In fact, the constitutional division of powers over health care in Canada have discouraged the regulatory option in the short term, channelling policy-making efforts into criminal prohibitions – an unacceptable option even to groups favourable to restraining the autonomy of physicians and researchers. In other words, the constitutional division of powers has reduced the capacity of the federal government to design an attractive ART policy.

Some authors view political institutions as bundles of rules essentially creating veto players (Tseblis 1995). Following this perspective, one might say that, all other things being equal, Westminster parliamentarianism creates fewer veto players than American presidentialism. This perspective suggests that Canada should have faced less difficulty in adopting ambitious (or unattractive) ART policies than did the United States. This book reveals the opposite situation. The government of Canada was not even able to adopt Bill C-47, a bill of limited scope that fell clearly under the federal criminal law jurisdiction. This might indicate that institutions deserve deeper investigation. In addition to proclaiming rules, institutions embody specific ideas, beliefs and cultural norms. Non-decision in Canada makes sense only after one understands how the ideas widely held by the staff of central agencies, ideas supported by the brokerage practices that characterize the Canadian political party system, have worked to make successful public consultations a pre-condition for policy decisions.

Notes

1 Previously named the Health Policy Division.
2 This comes from a discussion with Carty.

5 The United States

National talk and state action in governing ART

Malcolm L. Goggin and Deborah A. Orth

Introduction

This chapter describes and explains initial policy design and subsequent re-designs in policy toward ART in the United States. The story begins in the mid-1970s, in the immediate post-*Roe V. Wade* period,[1] when the US Congress imposed a moratorium on fetal research and the federal bureaucracy required Ethical Advisory Board (EAB) review and approval before federally-funded in vitro fertilization research could proceed in 1974 and 1975. Our story ends with the most recent (2003) attempts in the US Congress to ban human cloning. It is a fascinating story, with many twists and turns. Some of the advances in human reproduction show a great deal of promise at providing safe and effective treatment for infertility. Other scientific "breakthroughs," such as cross-species fertilization, tubal surgery, egg donation, embryo splitting, and post-humus reproduction, and sperm sorting to increase the odds of having a child of a specified gender, raise either safety or thorny ethical questions.

We begin the chapter with a description of the goals of policy design as of 31 December 2002, and the means that policy-makers have chosen to achieve those goals. The second section traces today's policies to their origins by presenting a chronology of policy designs – authoritative decisions that constitute national and state policy toward ART in the United States. We identify the arenas engaged in the policy process, and the nature of interaction within those arenas. The list of national authoritative decisions is short, whereas the list of state laws regulating ART is relatively long. In the third section of the chapter, we offer explanations for this absence of a regulatory regime at the national level and the presence of many more and far more restrictive policies at the level of state government. We compare the beliefs, interests, and resources of influential actors and assess the extent to which policy design choices are influenced by these beliefs; we also examine and explain these choices in terms of institutional characteristics and the external environment in the United States.

Argument in brief: national talk but state action

Our argument is that within the major national arenas in the United States – the US Congress, the federal courts, and the national executive – the past thirty years have been characterized by a lot of national talk but little action. For example, members of Congress introduced hundreds of ART-related bills between the 93rd (1973–74) and 107th (2001–02) Congress, but only a handful of these bills became law. On the other hand, the fifty American states and the District of Columbia have been very actively engaged in governing assisted reproductive technology. Between 1973 and 2002, state legislatures passed more than 200 laws affecting ART. The evidence that we have gathered is consistent with Robert Blank and Janna Merrick's observation about US ART policies that:

> [d]espite the appearance of reproduction-assisted technologies on the national agenda in the late 1980s, the regulation of infertility services has largely rested with the states through their authority to protect the public health and their power to control familial relations, medical practice, the licensing of health personnel and facilities, and contracts. Public policy-makers have frequently deferred to professional organizations to develop and apply guidelines for assisted reproduction services.
>
> (Blank and Merrick 1995: 97–8)

What are the consequences of this pattern of policy-making? One consequence of ART authoritative decisions in the US is that, with few exceptions, infertile couples, regardless of age, sexual orientation, or marital status, have relatively easy access to artificial insemination, in vitro fertilization, GIFT, ZIFT, and surrogate parenthood, as long as the client has the financial means to pay for infertility treatment.[2] However, access has become easier as more and more states pass laws that remove financial barriers to infertility treatment by mandating that private insurance companies operating within the state either offer to cover or cover the cost of such treatment.

ART policy design provides a high degree of autonomy to ART researchers and practitioners. In the United States, federal government agencies have been used to protect human subjects and guarantee the autonomy of scientists as long as these researchers are not asking for federal funds to conduct research on fetal tissue or embryonic stem cells, or to experiment with human cloning. Physicians who practice ART are essentially self-regulated, thus ensuring their autonomy, at least in the sense that they can decide what ART to practice. They also have control over the content of practice guidelines and how they are interpreted and made operational. However, practitioners are still subject to federal and state licensing laws and reporting requirements.

What explains the US brand of ART policy design, that is, relatively easy access to the technologies and considerable autonomy for researchers and practitioners, with certain restriction attached to certain kinds of research? One explanation can be found in the US Constitution. It protects a woman's right to privacy; it also guarantees First Amendment provisions for freedom of speech; therefore, a researcher's freedom of inquiry is constitutionally protected. The US system of federalism, where power is shared between national and sub-national levels of government, gives states autonomy to regulate ART, especially in the areas of health and safety. States also have a traditional state responsibility for licensure. In fact, state discretion has increased over decades of devolution and increasing state policy-making capacity and activity. Moreover, in the area of assisted reproductive technology, federal laws have protected states from federal pre-emption.

Another factor that accounts for ART policy design in the United States is a faith in science and technology – and especially biotechnology – to solve the nation's health problems. This reflects a utilitarian view – a contract between science and society – that giving scientists the freedom to pursue knowledge without government interference is in the public interest. It is this shared value that has contributed to the unique ART design choices that characterize this case (Goggin 1987, Ch. 1; Robertson 1977–78).

Access would be even greater and restrictions on scientific research less if it were not for the framing of the issue of ART as an "embryo's issue" (Bonnicksen 1989: 98), thus linking ART inexorably to the politics of abortion and the right to life, including the life of the yet unborn. This political connection between ART and abortion was made in the early 1970s and has continued as controversial issues such as stem cell research and human cloning have moved up on the national agenda in recent years. However, despite strong opposition to ART from fetal rights groups, throughout the last three decades public opinion has been positive toward assisted reproductive technology in general, and IVF in particular. This widespread public support for the technology has neutralized some of the more strident opposition to its use from pro-life pressure groups (Ethics Advisory Board, 4 May 1979).

How much access and how much autonomy?

The principal ART policies in place in the United States have been directed at spawning a large, profitable industry, with at least 8,500 embryologists and other physicians providing treatment for infertility in approximately 400 infertility clinics across the states to about 15 percent of women of childbearing age (US Dept of Health and Human Services, Centers for Disease Control 1999).

Table 5.1 shows that the authoritative decisions governing assisted

Table 5.1 Access to ART in the United States

		Access	
Basic techniques			
Insemination (1)	with gametes of the couple (1a)	3	ND
	with sperm donation (1b)	3	ND
GIFT/ZIFT (2)	with gametes of the couple (2a)	3	ND
	with sperm donation (2b)	3	ND
IVF/ET (3)	with gametes of the couple (3a)	3	ND
	with sperm donation (3b)	3	ND
	with egg donation (3c)	3	ND
	with embryo donation (3d)	3	ND
Max. 24: 0–3 no or close to no (N = 0), 4–11 low (L = 1), 12–19 medium (M = 2), 20–24 high (H = 3)		*3*	*H*
Related techniques			
Surrogacy (4)		3	ND
Cryopreservation (6)	sperm (6a)	3	ND
	egg (6b)	3	ND
	impregnated eggs (6c)	3	ND
	embryos (6d)	3	ND
Pre-implantation diagnostics (7)		3	ND
Genetic selection (8)		3	ND
Gender selection (9)		3	ND
ICSI (10)		3	ND
Max. 27: 0–4 no or close to no (N = 0), 5–13 low (L = 1), 14–22 medium (M = 2), 23–27 high (H = 3)		*3*	*H*
Total of all two groups of techniques (max. 6): 0 no (N), 1–2 low (L), 3–4 medium (M), 5–6 high (H)		*6*	*H*
For Element 1: Weights for total of all two groups of techniques (N = 0), (L = 4), (M = 8), (H = 12)		*12*	*H*
For Element 2: Judgement for financial coverage of ART (0–3)		*0*	*L*
Total of Element 1 and Element 2 (0–15)		*12*	*H*

Note
L, low; H, high; ND, no design; 1 = low; 2 = medium; 3 = high.

reproductive technologies in the United States make most technologies accessible to many infertile couples. Table 5.2 shows that doctors and clinics are self-regulated and provide a large number of services – for example, artificial insemination, in vitro fertilization, GIFT, ZIFT, and surrogacy – to any infertile person who either can afford to pay for the technology or has private health insurance that covers infertility treatment.[3] Thus, ability to pay appears to be the main criterion for eligibility for infertility treatment.

Despite repeated attempts by members of the US Congress to establish a national policy regulating surrogacy, there is none. Surrogate parenting

Table 5.2 Autonomy in the United States

		Autonomy	
Basic techniques			
Insemination (1)		2	M
GIFT/ZIFT (2)		2	M
IVF/ET (3)		2	M
Total 9: 0–1 no or close to no (N), 2–4 low (L), 5–7 medium (M), 8–9 high (H)		*6*	*M*
Related techniques			
Surrogacy (4)		3	ND
Donation (5)	sperm: 5a,	3	ND
	egg: 5b	3	ND
	of embryos/impregnated eggs: 5c	3	ND
Cryopreservation (6)	sperm: 6a,	3	ND
	egg: 6b	3	ND
	of impregnated eggs 6c	3	ND
	embryos: 6d	3	ND
Pre-implantation diagnostics (7)		3	ND
Genetic selection (8)		3	ND
ICSI (10)		3	ND
Max. 36: 0–5 no or close to no (N), 6–17 low (L), 18–29 medium (M), 30–36 high (H)		*36*	*H*
Research/experimental techniques			
Genetic engineering (11)	on gametes/germ cells (11a)	3	H
	on impregnated eggs, embryos (11b)	3	H
Research (12)	on gametes/germ cells (12a)	3	H
	on impregnated eggs, embryos, zygotes (12b)	1	L
Cloning (13)		3	H
Chimera and hybrid building (14)		3	ND
Max. 18: 0–2 no or close to no (N), 3–8 low (L), 9–14 medium (M), 15–18 high (H)		*16*	*H*
Total of all three groups of techniques (max. 9): 0–1 no or close to no (N), 2–4 low (L), 5–7 medium (M), 8–9 high (H)		*8*	*H*

Note
L, low; M, medium; H, high; ND, no design; 1 = low; 2 = medium; 3 = high.

is regulated by the states, with strict criminal penalties for "baby selling." However, there are two controversial reproductive technologies that fall under a strict regulatory regime at the national level: the first is a restriction on embryonic stem cell research that is undertaken with government funds; the second is a proposed ban on human cloning.

What are ART policy goals and how are they to be achieved?

For analytical purposes, we have divided policy design for artificial insemination (AI), in vitro fertilization (IVF), and surrogate parenting into one group; and fetal tissue research, embryonic stem cell research, and human and therapeutic cloning into a second group. What follows is a brief summary of the goals and instruments of policy design, organized around these two groupings.

Goals and instruments for AI, IVF, and surrogacy

The goals of the US policies regulating AI, IVF, GIFT, ZIFT, and surrogacy are to provide infertile individuals with the opportunity to exercise their right to have children while protecting the health and safety of donors, recipients, and offspring. The private physicians and the private fertility clinics that provide these services are licensed, but are mostly self-regulated. Practice and ethical guidelines issued by professional associations like the American College of Gynecologists and Obstetricians (ACOG) and the American Society of Reproductive Medicine (ASRM) serve as the instruments of choice. Clinics are also licensed by states and monitored by the federal Centers for Disease Control and Prevention (United States, Department of Health and Human Services, Centers for Disease Control and Prevention 1999). In the case of surrogate parenting, criminal penalties and prohibitions that are codified in state statutes are used to prevent "baby selling" and protect the parties in the transaction from exploitation.

Goals and instruments for embryonic stem cell research

On 9 August 2001, US President George W. Bush announced his administration's policy toward stem cell research (White House Press Release 2001a, 2001b) that permits research on more than sixty genetically diverse stem cell lines that already exist "where the life and death decision has already been made" (White House Press Release, Office of the Press Secretary 2001a, 2001b). With pressure from religious conservatives and fetal rights groups to deny federal funds for this type of research, and counter-pressure from various patient advocacy groups and professional organizations to fund stem cell research with federal dollars, the Bush position balances two imperatives: the need to advance scientific research for the benefit of mankind on the one hand, and the desire to protect the rights of the unborn on the other. Bush's utilitarian argument highlights the faith of the American public in science and technology to improve life *and* a belief in the fundamental value and sanctity of life.

Goals and instruments for human cloning

As of early 2003, the Bush administration goal of the design of policy toward human cloning is to ban both reproductive and therapeutic human cloning. According to President Bush's 28 January 2003 State of the Union Address, which links human cloning to the controversial practice of partial-birth abortion,

> By caring for children who need mentors, and for addicted men and women who need treatment, we are building a more welcoming society – a culture that values every life. And in this work we must not overlook the weakest among us. I ask you to protect infants at the very hour of their birth and end the practice of partial-birth abortion. [Applause.] And because no human life should be started or ended as the object of an experiment, I ask you to set a high standard for humanity, and pass a law against all human cloning. [Applause.]
>
> (Bush 2003)

The day after the President's address to Congress and the nation, the US Senate took up the issue of human cloning. However, this was not the first time the US Congress had tried to pass a public law affecting human reproductive and therapeutic cloning. In 2001, the House of Representatives in the United States Congress passed by a more than 100-vote margin HR 2505, a bill to ban both therapeutic and reproductive cloning. Yet the US Senate could not agree on how to bring two competing bills to the floor for a vote, thus making it impossible to pass a bill during the 2002 session. Meanwhile, several states, including Michigan, California, Louisiana, Missouri, Rhode Island, and Virginia, passed laws to ban cloning of human beings. With the exception of Missouri, these state laws provide for fines of up to $10 million for violating the law.

How have the US authorities governed ART since 1973?

Compared to other nations in this comparative study, in many respects the policy-designing process in the United States is not unique. However, whereas the *actors* may be similar to those in other countries, the *institutions of government* that operate within legislative, executive, and judicial arenas must be understood within the context of a compound republic of federalism. In the US, power is shared across levels of government and the powers of different branches of government are separated; this aspect of the policy design process goes a long way toward explaining ART policy-designing behavior in the USA. In the ART policy domain, in the late 1990s and early 2000s, policy-designing behavior was characterized by both pluralistic and ideological bargaining (Goggin 1993: 14–15). Pluralistic bargaining consists of multiple, disparate groups with cross-cutting

membership and shifting alliances trying to reach a compromise or accommodation. In contrast, ideological bargaining is characterized by polarized coalitions of groups who are interested in neither compromise nor pleasing all groups. Pluralistic bargaining leading to accommodation best describes the AI, IVF, and surrogacy policy-designing process, whereas ideological bargaining that is based on attempts at persuasion is typical of the fetal tissue research, stem cell research, and human cloning policy-designing process. Certain aspects of the external environment, for example public opinion and defining events, may also be determinant. In the next section, we report on the few authoritative decisions – the policy design – affecting ART that the federal executive, legislative, and judicial branches of government made during the twenty-eight years between the monumental 1973 *Roe v. Wade* decision and the end of 2002. These authoritative decisions were coded for content using the instrument designed by the CPDP team of scholars. The following section summarizes the results of this systematic coding.

ART policy design in the 1970s

As discussed above, the 1973 Supreme Court decision in *Roe v. Wade* framed the national debate over human reproduction, especially when federal funds were to be used to support research using fetal tissue. In 1974, Congress created the National Commission for the Protection of Human Subjects as part of the National Research Act (PL 93-348). The public law prohibits discrimination against individuals or institutions for engaging or not in any lawful health service or research activity because of religion or moral conviction.

The Act that created the commission included a provision for a moratorium on fetal research. At about the same time, the NIH developed guidelines for research with human subjects and regulations for research involving human embryos and IVF, including mandatory EAB approval. However, no ethics advisory board was set up until 1978, and then it only had a two-year mandate (Federal Register 1978). The EAB issued a controversial report on 4 May 1979, which triggered more than 12,000 letters to the Department of Health, Education, and Welfare, mostly from those who wanted a ban on ARTs. In 1980, the Secretary of Health and Human Services, under President Jimmy Carter, did not renew the mandate. So federally funded IVF research could not be conducted because there was no ethics board to approve it.

During the 1970s, Congress held lots of hearings, but produced only a few authoritative decisions affecting ART. However, states were much more productive during this same period. In the years immediately following *Roe v. Wade,* twenty-three states were busy enacting laws forbidding fetal or embryo research. During the decade of the 1970s, approximately sixteen pieces of state legislation in fifteen states were adopted that

addressed assisted reproductive technologies. Most legislation addressed artificial insemination or assisted insemination, with or without donors of egg and sperm. The primary focus seemed to be on establishing parental rights to the husband of a woman who is inseminated with sperm donated by a man other than her husband. The language of much of this legislation was similar across states: state laws were designed for the purpose of protecting children created from these new technologies. Additionally, most of the state statutes mandated consent by both parties prior to an ART procedure.

ART policy design in the 1980s

In 1985, Congress adopted the Health Research Extension Act (PL 99-158), which amended Title IV of the Public Health Service Act. PL 99-158 restated rules regulating fetal tissue research. Researchers were the target group for this provision, a general prohibition of research unless it may enhance the well being of the foetus or pose no additional risk, suffering, injury or death.

Three years later, Congress passed and the president signed PL 100-607, the Health Omnibus Programs Extension of 1988. Embedded in this massive nine-title amendment to the Public Health Service Act was Subtitle L, which sets at twenty-four months after enactment of this Act the termination of the moratorium on the Secretary's authority to grant, under specified federal regulations, a modification or waiver for fetal research. When combined with a newly established March 1988 NIH Human Fetal Tissue Transplant Research Panel, this provision set the stage for possible fetal tissue research. However, in late 1989 the Secretary of Health and Human services extended the ban on fetal tissue research from induced abortions indefinitely.

Again, as in the 1970s, talk about a national policy design for ART took place at the federal level of government, but most of the action during the decade was in state legislatures. The decade of the 1980s had at least fifteen new states designing some form of ART legislation. Additionally, several states that passed laws in the 1970s amended their state statutes to include new technologies such as IVF, and cryopreservation, or they added laws regulating surrogate parenting. State legislatures were also writing new laws and amendments requiring testing of donors and donor specimens, a likely result of the AIDS epidemic in the early 1980s.

ART policy design in the 1990s and beyond

As described above, a moratorium on fetal tissue research had been in place since 1974 and continued through the 1980s. On 19 May 1992, President George Bush Sr issued an Executive Order establishing a fetal tissue bank to collect fetal tissue from ectopic pregnancies and sponta-

neous abortions so as to meet the needs of the research community. Also in 1992, Congress passed the Fertility Clinic Success Rate and Certification Act (PL 102-493), a law to provide for reporting of pregnancy success rates of ART programs and for the certification of embryo laboratories. The law also included a directive to the Secretary of DHHS to develop a model program that states could use to certify embryo clinics. To achieve this goal a number of instruments were referenced in PL 102-493, including reporting and documentation, controls through certification, penalties for non-compliance, and quality standards.

In 1993 and 1994, Democrats in both chambers of Congress introduced several bills affecting infertile couples, including six different health insurance bills that would have mandated IVF coverage. One of these bills (S.1) became Public Law 103-43, the National Institutes of Health Revitalization Act of 1993. Section 111 of that law authorized and regulated research on human fetal tissue transplantation as long as it met certain criteria, and declared ineffective an Executive Order relating to a fetal tissue bank. PL 103-43 also nullified the Ethics Advisory Board at NIH, thus opening the door to NIH review and approval of grant proposals to carry out research on human reproduction with federal dollars.

Just after taking office in January of 1993, Bill Clinton instructed his Secretary of DHHS to lift the moratorium on fetal tissue transplantation research. Two weeks later DHHS Secretary Donna Shelala officially rescinded the order, but it was not until January of 1994 that the NIH funded its first human fetal tissue research project. In December of 1994, Clinton announced that NIH could not use federal funds to create embryos for purely research purposes. Two years later, Congress passed a bill regulating embryo research. Section 512 of H.R. 3755 bans the use of federal funds for human embryo research, and is aimed at ART researchers.

Much of the action in the 1990s took place in the legislative arena. However, as we saw above, the executive branch was also engaged. The first Executive Order of the 1990s was to establish a national bioethics committee. The first order affecting ART directly was signed on 4 March 1997. The authoritative decision was triggered by a 24 February 1997 announcement that scientists at the Roslin Institute in Edinburgh, Scotland had cloned a sheep. The directive took the form of Bill Clinton's Executive Memorandum prohibiting the use of federal funds for cloning human beings. The memorandum affected both embryonic stem cell research and human cloning, and was designed to protect the rights of the unborn and protect human dignity. Clinton's memorandum could not have been clearer as to its goal: Clinton wanted to make absolutely certain that no federal funds would be used for human cloning. As the decade came to a close, members of Congress shifted their attention to two other issues: first, revisions of the United States Code that pertained to insurance coverage; and second, the use of federal funds for research

on human embryonic stem cells. The FDA closed out the decade by proposing a rule to require manufacturers of products based on human cellular tissue to screen and test donors. The rule was approved on 17 December 1999.

States were very active in the ART policy domain in the 1990s. More states added IVF, as well as GIFT and ZIFT, to the list of technologies covered by state law. State legislatures also paid more attention to donor eggs, compared to an earlier focus in the 1970s and 1980s on artificial insemination and donor sperm. Many state surrogate-parenting laws that regulated contracts also marked the decade. States turned their attention to the care and sale of embryos as well. By mid-decade, approximately half the states had enacted legislation, ranging in effect from permissiveness to prohibition (Stith-Coleman 1998).

By the end of the decade, fourteen states had addressed mandates to cover or offer insurance for the treatment of infertility. The state of Arkansas is fairly typical. Arkansas passed a law that requires all health insurers that cover maternity benefits also to cover the cost of IVF, as long as the procedure is performed at a medical facility licensed or certified by the Arkansas Department of Health. However, because of ERISA, HMOs are exempt from the law.[4] Patients also have to jump through a number of hoops to qualify for infertility benefits. Illinois has a state statute that requires insurance policies that cover more than twenty-five people and provide pregnancy-related benefits to cover the costs of diagnosis and treatment of infertility. Coverage for IVF, GIFT, and ZIFT is required only if the procedures are performed at facilities that conform to standards set by the America Society for Reproductive Medicine or the American College of Obstetricians and Gynecologists. In Massachusetts, state law provides that insurers may, but are not required to, cover experimental procedures, surrogacy, and reversal of voluntary sterilization or cryo-preservation of eggs.

What has happened since George W. Bush was elected president in November of 2000? The US Congress and the President have recently made two authoritative decisions that have profoundly affected the status of ART research. We describe them briefly here in terms of their goals, instruments, and target groups. The first authoritative decision occurred on 31 July 2001, when the US House of Representatives voted 251–176 to prohibit the creation of cloned human embryos. Called the Human Cloning Prohibition Act of 2001, the bill restricted the autonomy of ART researchers; it also prohibited the importation of any medical treatments created abroad from cloned human embryo cells, thus restricting access to some medical treatments. In 2002, the US Senate considered a similar bill, S. 790, but it never reached the floor for a vote. The Senate bill expressed the sense of Congress that the federal government should advocate for and join an international effort to prohibit human cloning and the president should commission a study by the National Bioethics Advisory Com-

mission to examine both sides of the issue. President George W. Bush has also taken positions on human cloning and the use of federal funds to support stem cell research. On 9 August 2001, Bush announced that he strongly opposed human cloning. On 28 January 2003, he called for a ban on all human cloning.

What explains how the US governs ART?

What explains the US brand of ART policy design, that is, relatively easy access to the technologies and considerable autonomy, with certain restrictions attached to certain kinds of research? Which actors and beliefs have been influential in shaping policy design and re-design? How have US institutions affected policy? How has the policy-designing process worked? For example, does command, bargaining, or persuasion characterize the ART policy-designing process? What factors in the external environment have had a bearing on the form and content of policy governing ART?

Who are the actors?

Here we provide a brief description of the principal actors in the US ART policy-designing process, grouped into four categories: professional associations, advocacy groups, private sector actors, and public sector actors.

Professional associations

The American Society for Reproductive Medicine (formerly named the American Fertility Society) is a multidisciplinary professional association that has more than 8,500 members who work to advance knowledge and expertise in reproductive medicine and biology. The Society for Assisted Reproductive Technology (SART) is one of its affiliates. ASRM's mission is to advance the art, science, and practice of reproductive medicine. Throughout the 1990s, the ASRM issued a number of influential practice guidelines and its Ethics Committee issued a number of definitive position papers.

The American College of Obstetricians and Gynecologists (ACOG) is another professional organization that has influence in the choice of ART policy design. Together with the American Fertility Society, ACOG founded the National Advisory Board on Ethics in Reproduction in 1992. ACOG has prepared and presented testimony to Congress and prepared guidelines for practitioners. ACOG is also encouraging insurers to cover infertility, because most people cannot afford to pay for it themselves.

Advocacy groups

RESOLVE is a national organization representing the interests of infertile couples. It serves as a "consumer voice" providing information and support for people experiencing infertility or reproductive disorders. Established in 1974, with currently fifty local chapters in thirty-eight states, RESOLVE has become one of the leading national and local advocates for comprehensive insurance coverage of infertility.

Because of the way the issue of human reproductive technology policy has been framed, the National Conference of Catholic Bishops and a number of fetal-rights groups are also important players in the ART policy arena. The National Conference of Catholic Bishops, who joined with United States Catholic Conference in July 2001 to form the United States Conference of Catholic Bishops, is working to promote the greater good of the church and humankind by teaching respect for all humans and by protecting the unborn, disabled, elderly, and dying. The organization treats human life as a gift from God, believing that each person has the responsibility to protect and sustain human life at every stage of its existence.

Private sector actors

Fertility clinics are, for the most part, private sector actors, and most clinics are organized to make a profit. Privately funded organizations engaged in research, such as Advanced Cell Technology, are major players in ART policy design as well. Because of the nature of the United States' free enterprise system, the government has no statutory license when research is funded entirely by the private sector. Thus, it is strictly a private matter whether, and under what terms, new intellectual property is made available to others for commercial or research purposes. The United States is one of the few countries in this cross-national research project where the government takes a "hands off" approach to research done with private funds. Technologies that are developed from privately funded science are the property of the corporation who has funded the research.

Public sector actors

The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research was established by an act of Congress in 1974. Title II of Public Law 93-348, enacted on 12 July 1974, established the National Commission. PL 93-348 also required grantees and contractees under the Public Health Service Act to establish Institutional Review Boards (IRBs) to review research involving human subjects. In 1979, the President's Commission for the Study of Ethical Problems in

Medicine and Biomedical and Behavioral Research was created when Congress passed PL 95-622; its first meeting was held in January 1980 and its last meeting was in March of 1983. Congress also created its own Congressional Biomedical Ethics Board in 1985, but the Board was paralyzed by infighting over the abortion issue ("A once and future biomedical ethics board," Hastings Center Report 1988). Hence, the board was not an effective overseer of research in the ART policy domain.

The National Bioethics Advisory Commission (NBAC) was created in 1995, pursuant to President Bill Clinton's Executive order 12975 of 3 October 1995. The authority of the NBAC expired on 3 October 2001, and President George W. Bush did not renew its charter. Instead, on 9 August 2001, the president created The President's Council on Bioethics, chaired by Dr Leon Kass, an expert in biomedical ethics and a professor at the University of Chicago. The purpose of the new council is to study the human and moral ramifications of developments in biomedical and behavioral science and technology, with emphasis on issues of human reproduction such as embryo and stem cell research, assisted reproduction, and cloning.

Other government actors in this policy domain include the Department of Health and Human Services (before 1997, named the Department of Health, Education, and Welfare) and within DHHS, the National Institutes of Health (NIH), the Centers for Disease Control and Prevention (CDC), and the Food and Drug Administration (FDA). Here we describe briefly the role that each has played in the ART policy-designing process.

The US Department of Health and Human Services has played a significant role in designing and implementing policy for insemination, in vitro fertilization, surrogacy, and embryonic stem cell research. Within the DHHS, the National Institutes of Health's mission includes funding research that is aimed at alleviating health problems, including research that improves the success of treatment for infertility. The NIH division that has traditionally played a prominent role in ART policy design and redesign since the early 1970s is the National Institute of Child Health and Human Development (NICHD). This government agency has been influential in both the legislative and executive arenas throughout the past quarter-century.

Since the 1990s the NIH has been particularly influential in US policy governing research with human embryos. The issue of research with human embryos surfaced in 1993, and Congress passed the NIH Revitalization Act. This Act repealed the department regulation that required the NIH Ethics Advisory Board to approve research involving human reproduction, including IVF. In effect, the new law removed the impediment to federal funding for IVF and other ART research. However, federal funding for IVF research was not forthcoming. NICHD funded plenty of research with animals, but did not fund IVF research on

humans. Because there was no Ethics Advisory Board, de facto, there was not federally funded research in the area of human reproduction, including IVF. Once the impediment of the ethics committee requirement was removed, then NICHD could approve federally funded embryo research. In early 2001, the NIH was once again called upon to implement national policy. As described above, on 9 August 2001, President George W. Bush announced his administration's policy concerning the use of federal funds for embryonic stem cell research. Bush put NIH in charge of implementation, and asked NIH to create a registry of stem cell lines that satisfy scientific, legal, and ethical criteria.

A third agency within the US DHHS that has jurisdiction over ART policy design, especially with respect to Artificial Insemination (AI), is the Food and Drug Administration, which tests and monitors drugs and devices. The principal role of the FDA in the ART policy domain has been and continues to be the safety and efficacy of the techniques, and the health and safety of the client.

What are the characteristics of actor beliefs?

Professional associations like ASRM and ACOG have advocated minimal government regulations and greater access to the technologies for individuals seeking treatment for infertility. They have lobbied for broader insurance coverage and a registry. These groups are portrayed in a positive light. These professional associations are much more interested in guaranteeing an individual's right to procreate than in protecting the embryo. ACOG, for example, believes women should be informed about the safety and efficacy of infertility treatment. ACOG has also been working with RESOLVE to lower financial barriers to treatment by broadening insurance coverage.

Advocacy groups like RESOLVE provide information and support for people experiencing infertility or reproductive disorders. One of their main goals has been to pass state laws that mandate that managed-care organizations – HMOs – operating within a state provide coverage for the treatment of infertility, thus making the technology much more accessible to the average person. For these groups, the issue is equity and fairness. RESOLVE believes that it is unfair that insurance companies pay for women who are fertile to have babies but are unwilling to pay for women who are infertile to attempt to have babies.

Other groups place a much higher value on protecting the embryo. This is the main, and perhaps only, priority of fetal-rights groups. These groups, and the members of Congress who speak for them, have supported a ban on fetal and stem cell research over the years, and have called for a complete ban on human cloning. John O'Connor, the Archbishop of New York, believes that a child created from somatic cell nuclear transfer would technically have no parents. His concern is that

cloned children will be treated as goods rather than people. A belief in the sanctity of human life and the potential for life influenced President George W. Bush's policy regarding stem cell research. In his 9 August 2001 televised speech to the nation, Bush emphasized the rights of the embryo:

> Research on embryonic stem cells raises profound ethical questions, because extracting the stem cell destroys the embryo, and thus destroys its potential for life. Like a snowflake, each of these embryos is unique, with the unique genetic potential of an individual human being.
>
> (Office of the Press Secretary 2001a, 2001b)

A more complete picture of the Bush administration's position is evident in Secretary Tommy Thompson's 2001 testimony before Congress when he defended the president's balancing act that protected the sanctity of life while regulated research could go forward in the private market.

Thompson also stressed his belief in the role of government to advance scientific discoveries. On 9 September 2001, Secretary Thompson, claiming that the President's decision "balanced our nation's deepest respect for life with our highest hopes for alleviating human suffering," told Congress that important work needed to be done in the laboratory. He urged the committee to get beyond speculation and take steps "to do the research and find answer[s]. The role of the federal government should be – and will be – to make sure this basic research takes place." (Thompson 2001b). Secretary Thompson ended his Senate testimony by saying:

> So let's come together and move forward. We must not let this issue deteriorate into a stifling political debate. The only place we're truly going to find answers to all our questions is in the laboratories of America and the world. President Bush has opened the laboratory door. Now, let's get our best and brightest scientists into the lab so they can go to work.
>
> (Thompson 2001b)

Beliefs about protecting the rights of individuals to bear children, protecting the health and safety of human subjects, protecting the embryo, and protecting the sanctity of human life have dominated discourse about ART policy, and have influenced policy design. A belief in the right to be free from economic regulation, a confidence in science to find the cures for diseases, and an attempt to legitimize equity as a bedrock principle of a just society have all had an influence on the content of policy design for ART. Other factors that help explain the form and content of policy in the area of assisted reproduction are institutional, for example, the US Constitution, the structure of government with respect to the separation

of powers and federalism, and the rules that structure decision-making. In the following section, we examine how institutional characteristics influenced ART policy design.

How have institutions and arenas influenced policy design?

Institutional rules on a number of levels influenced ART policy designs. Constitutionally, procreation has been defined as a zone of privacy and autonomy related to procreation, the marital relationship, and contraception, a negative liberty that provides freedom from government intrusion. According to Immaculada de Melo-Martin:

> The right to procreate ... is implicitly grounded in both individual liberty and the integrity of the family unit, and is regarded as a "fundamental right," one that is essential to the notion of liberty and justice.... The series of cases from *Skinner* to *Roe* suggest that a right to reproduce exists. But such a right appears to be negative, i.e., as a right to be free from unwarranted governmental interference.... The right ... denotes freedom of choice relating to whether or when to procreate.
>
> (de Melo-Martin 1998: 63–4)

The practice of infertility treatment has enjoyed protection from political scrutiny partly because of these constitutional protections. Of course, the doctor–patient relationship itself enjoys significant privacy protections as well. Research also enjoys some constitutional protection under the free speech clause of the First Amendment. While scientific researchers have a "fundamental right" to freedom of inquiry, this fundamental right implies no limitation on the authority of the state to regulate the manner in which the research is conducted. Nor does this fundamental right imply an entitlement to federal funding of the research.

In addition to these manifestations of "limited" government, the Constitution defines a government of multiple political institutions – multiple arenas where policy-making may occur. Moreover, federalism gives states autonomy to regulate ART, especially in the area of health and safety as well as a traditional jurisdiction over licensure. State discretion over policy-making in general has increased over decades of devolution and increasing state policy-making capacity and activity. Federalism allowed, and in fact preserved, the historical dominance of state – rather than national – governments in the licensing and regulation of medical practice. States continue to provide this function, and the politics of ART have developed as a fairly routine rather than disrupting extension of the policy processes involving all medical practice in the states. That is, ART politics at the state level have fit within and been structured by the mature health-care policy domains already functioning in the states. ART practi-

tioners in the states have benefitted from the autonomy afforded medical practice generally. Nationally, policy-makers have not disturbed this arrangement by seeking to regulate the practice of infertility treatment, and therefore the ARTs used for that purpose.

It would be difficult to know confidently why national actors have not changed this arrangement. However, one can speculate that national policy-makers see risks in asserting national government power into what has traditionally been a state function. The groups that benefit most from state authority over medical practice – the practitioners and their organizations – have proven to be formidable opponents in national political debates about health-care issues. Many legislative attempts to regulate the health-care sector have been defeated by these groups, and national policy-makers know that facing opposition from these groups makes the policy process brutal and the chance of success low. Other issues that present political risks, including abortion and the right and privacy to bear or beget children, hover nearby.

Federalism allows an alternative to national regulation, and historical circumstances and political expediency have produced it. The characteristics of American state governments, and particularly their characteristics when the health-care policy domains in their states developed, have shaped ART policies as they relate to practice. For most states, the autonomy, self-regulation of practice, and freedom from economic regulation that medical practitioners enjoy is the result of a political bargain with state governments developed in the 1920s and 1930s. Actually, in many states the bargain is older, but medical practitioners consciously fought nationally to preserve their privileges during the period before the Second World War. Groups representing medical professionals continued to fight to preserve their autonomy in the face of national regulation through the 1990s. They won many of these battles, and national policy-makers with experience know this. Moreover, in the area of assisted reproductive technology, federal laws have protected states from federal pre-emption.

Of course, on the research side, the national government is involved. Congress, through its power of the purse, has traditionally been the "patron" of basic research, especially in the life sciences. As the lead author of this chapter (Goggin 1986: 45) has pointed out, the principal donors, however, are not only Congress, but "its agents, the executive branch agencies and bureaus, industry, and the university" who in areas such as biotechnology have become venture capitalists. As investors, each donor has a stake in the outcome of scientific research, and therefore can legitimately make a claim to control the course of scientific research and the clinical applications of that research.

What type of policy-designing behavior prevails?

In the case of fetal tissue research, embryonic stem cell research, and human cloning, the United States government has designed restrictive policies with respect to federal funding. In the area of the *science* or *research* that might lead to the development of assisted reproductive technologies, or therapies for treatment of disease, all governmental institutions have been actively engaged in policy-making. In the case of controversial research in this area of human reproduction, policy-designing behavior is characterized by ideological polarization, where the use of messages and persuasion rather than compromise is the norm.

On the other hand, when it comes to the *practice* of treating infertility, national policy-makers have taken a "hands off" approach, and have been relatively permissive, deferring to state legislatures and the courts. Thus, policy designing for artificial insemination, in vitro fertilization, and surrogacy in the United States has taken place in state capitols, and has been influenced by the characteristics of the health-care policy domain in the states. Infertility treatment has been treated like other medical practices. Over the years, the medical professionals have developed a relationship with state governments that has been characterized by considerable professional autonomy and self-regulation for a century. ART policy-designing behavior in the states is structured by these historical relationships that pre-date the development of ART themselves. Evidence from the over-200 laws that have passed state legislatures over the past thirty years indicates that in the case of AI, IVF, and surrogacy, policy-designing behavior is characterized by bargaining and compromise, and thus is a case of pluralistic bargaining.

What is it in the US external environment that matters?

One factor that accounts for ART policy design in the United States is a faith in science and technology – and especially biomedical innovations – to solve the nation's health problems. The public has entered into a contract with the scientific community that if scientists are given freedom to inquire without outside interference, then scientists will make discoveries that are in the public interest, and private corporations will bring these discoveries to the market for the benefit of society. This view has contributed to the unique ART design choices that characterize this case. Public opinion has been positive toward assisted reproductive technology in general, and toward IVF in particular.

Other changes in the external environment, especially announcements of scientific "breakthroughs" in professional journals like *Science, Nature, and Fertility and Sterility* and in the popular press have affected ART policy design in the United States. Examples abound, but three of the most prominent examples are the announcement that the first mammal was

cloned in Edinburgh, Scotland; the announcement that a Chicago scientist planned to clone himself; and ACT's announcement in late 2001 that it had successfully cloned a human. All three of these announcements precipitated immediate reaction by the US government to ban human reproductive cloning.

Conclusion

Compared to many other countries in Europe and North America that are featured in this book, the United States government has done little to restrict access to ART or limit the autonomy of researchers and practitioners. Governing in the US has been left to professionals and the market. Indeed, government regulation has been minimal, and therefore few policy designs have emerged from the nation's capitol. The exceptions are fetal tissue research and human cloning.

The past thirty years have been characterized by national talk but little action. Most ART policy design has been at the subnational level of government. There are many reasons for this: ART has been linked to the controversial issue of abortion and consequently national politicians have passed the buck to state legislatures; ART is in a "zone of privacy" that guarantees both the infertile person and his or her doctor freedom from government intervention; First Amendment rights guarantee researchers' ability to pursue knowledge; professional self-regulation protects the ability of practitioners to practice medicine; and separation of powers and federalism as well as a political environment marked by devolution fragment power, making it hard to reach consensus.

Notes

1 This was the 1973 US Supreme Court decision to protect the right of a woman to have an abortion.
2 With the exception of the state of New Jersey, marital status, sexual orientation, and age are no barrier to ART.
3 According to a report by insure.com, the estimates for the costs of treatment per cycle for infertility range as follows: (1) $8,000 to $10,000 for IVF; (2) $8,000 to $13,000 for GIFT; (3) $10,000 to $13,000 for ZIFT; and (4) $2,500 for ICSI (intracytoplasmic sperm injection). See http://www.insure.com/health/infertility3.html, accessed 17 January 2002.
4 It should be noted that the Employment Retirement Income and Security Act of 1974 (ERISA) exempts companies that self-insure from state regulation.

6 ART in Spain

Technocratic inheritance and modernist aspirations

Julien Dubouchet and Ulrich Klöti

Introduction

Despite a strong Catholic tradition and a relatively low level of economic and technological advancement in the 1970s,[1] Spain was not only one of the first European countries to pass a law affecting ART,[2] but also produced some of the most liberal legislation on the European continent.[3] This apparent contradiction can be explained as the result of a series of both structural and transitory factors. This chapter sets out to untangle these in order to clarify what contributed to the elaboration of Spain's policy design on ART.

This study begins with the premise that, in Spain, two actors are particularly interested in possible political and legal developments in the field of ART. These are the medical community and Catholic groups. Their respective positions on the subject and their expectations with regard to the content of ART regulations diverge strongly and are, in most cases, impossible to reconcile. Given the fact that the outcome of the political process clearly favoured the views of the medical community, this chapter attempts to illustrate how this actor's views were taken into consideration in the policy process.

Starting from the institutional context of the Spanish political system, we will show that this was the framework in which the proponents of a relatively permissive ART policy were able to take advantage of opportunities, as well as benefit from a transitory situation favourable to their beliefs. Three elements of the Spanish policy design process will be discussed in detail. First, we analyse how the topic of ART came onto the political agenda and how it was framed. Second, we identify how Spain's parliamentary bill on ART was able to garner a clear majority. Finally, we ask whether this process was facilitated by the weakness of the opposition, and why this opposition did not express itself more strongly.

The policy process

The key date in the policy-designing process in Spain was 22 November 1988, when Law 35/1988 on assisted reproduction techniques (*Ley sobre*

Técnicas de Reproducción Asistid: LTRA) was adopted.[4] This law represents the first attempt to regulate this technology, and it constitutes the bulk of the legal framework regulating ART in Spain. Indeed, regulations adopted later are of lesser importance. Since they did not require parliamentary approval, they did not arouse any debate. Moreover, most of them resulted from the implementation of LTRA. Therefore, studying ART policy in Spain essentially means analysing the process that led to Law 35/1988.

The essential process took place in the parliamentary arena. It comprised two distinct and consecutive phases: a phase of evaluation and analysis – a novelty at that time – followed by a phase of legislative activity. The Presiding Council initiated the first phase on 20 November 1984 by creating the Special Parliamentary Committee for the Study of Extracorporal Fertilization, a committee that had the mandate to study the issues chaired by new reproductive techniques. The Committee was composed of one member from each parliamentary group and chaired by the Partido Socialista Obrero Español (PSOE) representative.[5] During the Committee's first meeting in May 1985, the six Members of Parliament (MP) present adopted a work plan and methodology; they selected thirty-six experts to be heard. In parallel, the MPs studied various documents, including reports spontaneously submitted to the Committee. Following hearings by experts, the President of the Committee, Marcelo Palacios, received the mandate to draft a report summarizing discussions within the Committee as well as current scientific knowledge on ART. The Committee examined Palacios' document on 4 February 1986. After two further meetings, the Committee adopted the report, but without the support of the Popular Parliamentary Group (GPP). This first parliamentary phase ended on 10 April 1986 when the so-called 'Palacios report' was approved by Parliament (166 in favour, 11 against, 48 abstentions).

The beginning of the second phase was marked by the submission of the law drafted by the Socialist Parliamentary Group (GPS) to the Presiding Council on 29 April 1987. The proposal was largely based on the recommendations contained in the Committee's report (Official Bulletin of Parliament). Both texts were essentially the work of one author: Marcelo Palacios. During the week after publication, the Chamber of Deputies debated the proposal and accepted it by an overwhelming majority (283 for, 4 against, 3 abstentions). On 22 December 1987, the draft law was submitted to the Committee for Social Affairs and Employment. Proposals for amendments could be submitted until 7 March 1988, and 412 amendments were published on 14 March. Two of these were full texts that were discussed by the Assembly one month later.[6] At this stage, the Special Parliamentary Committee became active: a first working group received the mandate to prepare a report to be used as a basis for discussions within the Committee. After two Committee meetings, a new version of the draft law was adopted and transmitted to the Senate on 18

May. On 20 October, a series of amendments adopted by the Senate was discussed during a plenary session of Parliament and the law was approved.[7]

The policy process of LTRA essentially followed the classical Spanish legislative procedures, but was characterized by two uncustomary features. First, work on the actual draft law started only after the completion of a preliminary study by a special parliamentary Committee. Second, the Committee of the Chamber of Deputies working on the text made use of its full legislative authority (Apariciado 1994: 119–20), allowing it to transmit the draft text directly to the Senate instead of resubmitting it to the lower chamber for a second reading.

The passage of the LTRA constituted only the principal phase of the overall design. Indeed, other primarily administrative decisions on ART were adopted later.[8]

Authoritative decisions[9]

Strictly speaking, the LTRA is the only law that focuses exclusively on ART. All other decisions are either hierarchically inferior to laws, or contain only certain clauses relevant to the subject. The LTRA was indeed conceived as a legal framework in the sense that it includes a certain number of clauses explicitly delegating to the government the task of passing laws and determining the details of the application of the LTRA.

Decisions resulting from the LTRA are Royal Decrees prepared by the government, and do not need parliamentary approval. Three decrees have been adopted so far: (1) the compulsory protocols of studies involving donors and ART clients, as well as the creation of a national gamete register (RD 412/1996);[10] (2) the technical and functional requirements for official recognition of the centres in which these techniques can be practised (RD 413/1996); and finally (3) the creation of a national committee for assisted human reproduction (RD 415/1997).

The only two decisions that played a part in the design, without, however, specifically addressing assisted reproduction, are the Royal Decree on services offered by the health system and the organic law reforming the Penal Code. The first simply includes diagnosis and treatment of infertility in the list of health services covered by social security. The second introduces sanctions for certain techniques involving genetic manipulation and for procedures that can be considered as surrogacy.[11]

The designing process for the most part occurred at the national level. In the complex semi-federal Spanish system (Aparicio 1994: 136–48), autonomous communities often play an important role (Martínez Cuadrado 1996). However, their part in defining ART regulation has been almost negligible. They are either the direct result of the delegation of competencies as set out by the national design,[12] or they have only very indirect influence on assisted reproduction.[13]

The purpose of decrees lies in detailing the practical application of a law. Since the LTRA covers the subject of ART in a comprehensive manner, it seems difficult to modify the design substantially, unless the law itself is challenged by a new text, or is repealed or revised. The framework established by the LTRA has thus remained unchanged since the law was adopted; it has simply been detailed by new measures. These can be of a restrictive nature, such as RD 412/1996, which limits the age of donors to thirty-five years for women and fifty for men. In general, however, these specifications are consistent with the spirit of the law of 1988.

Description of the design

Spain has given itself relatively permissive legislation in the field of ART. The design's openness can be partially explained by the lawmakers' aims. Article 1 of the LTRA lists the four following objectives:

1 To regulate assisted reproductive technologies;
2 To provide an efficient response to the problem of sterility;
3 To prevent and treat genetic or hereditary illnesses;
4 To authorize research on gametes.

These objectives are primarily of a medical nature (Fábriga and Cristóbal 1999: 87) and there is, for instance, no reference to embryos and the protection due to them. Thus, they give a clear idea of the law's underlying scientific framework. The statement on the law's objectives confirms this impression by providing details on both the aims and the spirit that prevailed during the law's conception.[14] ART is usually presented in a very positive manner, and is the bearer of expectations and hopes. The doubts and fears that ART might stir, although deemed legitimate, are often regarded as being irrational. One of the law's goals is to ensure progress and the expansion of scientific research, which must in no way be hindered unless this is justified by reasonable and objective criteria and in order to prevent conflict with human rights or the dignity of the human being. The overriding concern with filling an existing legal void – a source of uncertainty – while promoting scientific research is recurrent throughout the text of the law. It can therefore be summed up as 'offering a framework without constraints'.

This concern is evident in the Law's choice of instruments. Nine out of ten mentioned in the LTRA are regulations. Most frequently, their purpose is to provide a framework for the use of ART. Indeed, the design attempts to determine under what circumstances the various techniques may be used – that is, for whom, by whom, for what, and how? The list of prohibitions is short, whereas the list of formal restrictions is long. For example, the LTRA determines that ART is to be practised only in authorized centres and by specialists, that it is available to any adult woman in

good physical and mental health, and that the only objective of egg cell fertilization may be human procreation. The design's various other instruments follow the same regulatory logic since they deal mainly with information/counselling/consent and with reporting/documentation: a technique is authorized on the condition that its practice is recorded, and as long as the concerned parties are fully informed and have given their formal consent. On questions regarding licensing, inspections/control or penalties/fines, the LTRA usually refers to the existing health law in which ART is considered as one medical practice among others.

Along the same lines, the medical community and the patients are the Spanish design's major target groups. The focus on these two categories is consistent with the regulatory spirit of the design, which sees the connection between doctor and patient as the predominant relationship involved in the use of ART techniques. Similarly, the medical centres themselves are often responsible for putting regulations into effect. With the exception of some data registered with the competent authorities and some reports submitted to *ad hoc* institutions such as the Gamete Register or the National Committee for Assisted Reproduction, the design does not foresee direct involvement by public authorities in day-to-day medical practice.

Autonomy

Due to its comprehensive nature, the LTRA covers a large spectrum of techniques and regulates an important number of related questions (Benítez Ortuzar 1997: 276). Although some authors consider the law to be extremely detailed (Vidal Martínez 1998: 65), the text leaves considerable autonomy to the medical community. Medical teams have substantial freedom of choice among the so-called basic techniques, since artificial insemination, IVF, ET and GIFT are generally permitted. The only conditions for these techniques to be practised are patients' informed consent and the setting up of a medical file. As far as other techniques are concerned, the norm is also an absence of forceful restrictions. There are, however, several noteworthy exceptions that are a direct result of the early date of the LTRA's adoption. For example, the cryopreservation of egg cells is completely forbidden due to inadequately developed techniques at that time. In contrast, ICSI is allowed without any restrictions, as the technique was then unknown and is therefore not addressed in the law. Finally, the Spanish design adopts a fairly low profile concerning research and experimentation: the various techniques are clearly identified and the respective degrees of authorization are more finely detailed. In these cases, both extremes are found, ranging from a total prohibition of cloning (including reference to criminal sanctions), to the almost unconditional approval of research on gametes. An intermediate position is illustrated by a series of cumulative conditions ruling the field of pre-embryos, based on whether or not they are viable (Table 6.1).

Table 6.1 Autonomy in Spain

		Autonomy	
Basic techniques			
Insemination (1)		M	2
GIFT/ZIFT (2)		M	2
IVF/ET (3)		M	2
Total 9: 0–1 no or close to no (N), 2–4 low (L), 5–7 medium (M), 8–9 high (H)		*M*	*6*
Related techniques			
Surrogacy (4)		N	0
Donation (5)	sperm: 5a,	M	2
	egg: 5b	M	2
	of embryos/impregnated eggs: 5c	M	2
Cryopreservation (6)	sperm: 6a,	M	2
	egg: 6b	N	0
	of impregnated eggs 6c	M	2
	embryos: 6d	M	2
Pre-implantation diagnostics (7)		M	2
Genetic selection (8)		L	1
Gender selection (9)		L	1
ICSI (10)		ND	3
Max. 36: 0–5 no or close to no (N), 6–17 low (L), 18–29 medium (M), 30–36 high (H)		*M*	*19*
Research/experimental techniques			
Genetic engineering (11)	on gametes/germ cells (11a)	M	2
	on impregnated eggs, embryos (11b)	L	1
Research (12)	on gametes/germ cells (12a)	M	2
	on impregnated eggs, embryos, zygotes (12b)	M	2
Cloning (13)		N	0
Chimera and hybrid building (14)		N	0
Max. 18: 0–2 no or close to no (N), 3–8 low (L), 9–14 medium (M), 15–18 high (H)		*L*	*7*
Total of all three groups of techniques (max. 9): 0–1 no or close to no (N), 2–4 low (L), 5–7 medium (M), 8–9 high (H)		*M*	*6*

Note
L, low; M, medium; N, no; ND, no design; 1 = low; 2 = medium.

All medical centres that comply with the rules laid down in RD 413/1996 and that make a formal request can use these techniques entirely or partially. These conditions are principally focused on equipment and human resources. Therefore there is, at least in theory, no limitation on setting up new authorized centres. In other words, the nature of ART legislation seems to confirm current practices rather than to dictate new behaviour. First, there are relatively few formal prohibitions. Second,

a considerable number of the conditions related to ART are of a scientific nature and are therefore left to the discretion of medical practitioners.

The autonomy granted to the medical community, as experienced by individual practitioners, is probably even greater than our evaluation suggests.[15]

Access

The Spanish design is very open in terms of patients who are eligible for access to ART. Any woman may access any technique as long as it represents an appropriate response to her problem and its use is authorized. The only formal conditions are that she is of legal age, of sound mind, and that she gives her consent. If she is married, the consent of her husband is also a precondition. In other words, to gain access to ART, women need not to be married or be younger than a specified age. They do not even need to be sterile (Vidal Martínez 1998: 79). This stance is very liberal compared with that in other countries (Palacios 1991).

The situation is more complex as far as medical coverage is concerned. In theory, the national health system reimburses most ART treatment (Duriez and Lequet-Slama 1998: 39; Commission of Social Affairs 2000: 11–13), because a decree on health-care services lists diagnosis and treatment of infertility among its 'specialized services'.[16] Since the population as a whole benefits from the national health system, coverage should theoretically be available to all. Nevertheless, several factors combine to limit access to ART. Although all women have access to ART techniques, only those who are sterile or whose husbands are sterile are entitled to reimbursement, since this is based on the treatment of infertility. It also appears that the rapid development of ART techniques hinders their timely evaluation and consideration by the public health administration (*Diarío Médico* 1998). Moreover, medicine prescribed in conjunction with the above treatments is in most cases excluded from coverage (*Diarío Médico* 2001) (Table 6.2).

For practical reasons a large number of patients turn to private clinics, despite a total lack of coverage of their services by the public health system. In fact, the vast majority of centres practising ART are private.[17] This is mainly due to the limited availability in the public sector and the resulting long waiting lists. It is sometimes possible to arrange a certain degree of coverage for treatment within the private sector with private insurance companies, but in most cases only diagnosis-related expenses are covered.

Thus, in theory, the Spanish design offers very high access to ART. In practical terms, however, this only refers to those who are eligible to benefit from this type of treatment. The range of techniques covered by the health system, which is expected to be broad, is in fact limited by the practical difficulties of integrating new techniques into administrative practice. In addition, by limiting reimbursement to sterility treatments,

Table 6.2 Access to ART in Spain

		Access	
Basic techniques			
Insemination (1)	with gametes of the couple (1a)	H	3
	with sperm donation (1b)	H	3
GIFT/ZIFT (2)	with gametes of the couple (2a)	H	3
	with sperm donation (2b)	H	3
IVF/ET (3)	with gametes of the couple (3a)	H	3
	with sperm donation (3b)	H	3
	with egg donation (3c)	H	3
	with embryo donation (3d)	H	3
Max. 24: 0–3 no or close to no (N = 0), 4–11 low (L = 1), 12–19 medium (M = 2), 20–24 high (H = 3)		*H*	*24*
Related techniques			
Surrogacy (4)		N	0
Cryopreservation (6)	sperm (6a)	H	3
	egg (6b)	N	0
	impregnated eggs (6c)	H	3
	embryos (6d)	H	3
Pre-implantation diagnostics (7)		H	3
Genetic selection (8)		H	3
Gender selection (9)		H	3
ICSI (10)		H	3
Max. 27: 0–4 no or close to no (N = 0), 5–13 low (L = 1), 14–22 medium (M = 2), 23–27 high (H = 3)		*H*	*21*
Total of all two groups of techniques (max. 6): 0 no (N), 1–2 low (L), 3–4 medium (M), 5–6 high (H)		*H*	*6*
For Element 1: Weights for total of all two groups of techniques (N = 0), (L = 4), (M = 8), (H = 12)		*H*	*12*
For Element 2: Judgement for financial coverage of ART (0–3)		*M*	*2*
Total of Element 1 and Element 2 (0–15)		*H*	*14*

Note
M, medium; H, high; N, no; 2 = medium; 3 = high.

coverage of other categories of individuals is excluded despite their right to benefit from ART. For these reasons, it is understandable that Spain's level of access is only medium.

Current debate

During the first ten years following the adoption of LTRA, there was almost no discussion on ART. In the late 1990s, however, a renewed debate surrounding the existing legislation surfaced and voices urging a modification of the 1988 Law have risen. Two main demands[18] have

emerged concerning pre-embryos. The first involves finding a solution to the problem of 'extra' pre-embryos which, if frozen for more than five years, should be destroyed in conformity with the present law (*Diarío Médico* 2001b). The second demand aims to enlarge the scope of authorized research. There have been new technological developments (*El País* 2001a) which make the existing rules appear to be obstacles. Some suggest that 'extra' pre-embryos should be made available for scientific research rather than being destroyed (Estrella digital 2000). The request to be able to practise therapeutic cloning, egg cell cryopreservation and stem cell research are at the heart of the demands of the scientific community,[19] which fears losing ground in the context of international scientific research (*El País* 2001b). In April 2001, the parliamentary majority rejected a proposal by the socialists that would have facilitated research in these fields (*El País* 2001c).

In April 2001, the Minister of Health judged that there was not yet a strong enough consensus for a change in the LTRA (*Diarío Médico* 2001c). Only a few months later, however, she seemed to be considering this very process in more concrete terms (*Diarío Médico* 2001d). A number of signs therefore indicate that a change in the Spanish design is on the horizon.

Explanation of the design: the constraints of the political system

We have identified three types of factors to explain the current design. Institutional or structural factors originate in the workings of the Spanish political system; they are relatively stable, and play a role in most policy design. Transitory factors are specific to the period under study, and played a particular role in our case. Finally, contextual elements have a broader scope, either in going beyond a purely national context or in having an impact extending over a longer period.

The Spanish institutional system has undoubtedly influenced the design through the policy process;[20] the actual level of this influence is, however, quite difficult to determine. Attempts to define the Spanish policy process show that there are widely diverging opinions on the matter. To categorize Spain according to one of the classic schemes such as federalist vs unitarian state or strong vs weak state is already quite difficult (Gibbons 1999: 97). While this is largely the result of the recent creation of the political system,[21] the Spanish state is also exposed to a double movement: on the one hand a growing autonomy of its regions; on the other the process of European integration. Both create a need for reform and continuous adaptation (Heywood 1999: 119).

Despite the difficulties connected with classifying the Spanish political system, it is nonetheless possible to identify certain important features of the political process. Most important is the government's theoretical capacity to concentrate power in its own hands. As long as it can rely on a

comfortable majority in Parliament, the government has the means to promote its own positions and to impose the reforms or measures it deems necessary. This does not necessarily mean that the government is likely to adopt extreme positions,[22] but it does encourage a certain style of government. Indeed, political elites play a crucial role in the Spanish political system. They furnish a significant percentage of government and administrative personnel. Because of this predominant position held by political elites, and due to the essential role played by the administration in project definition, the Spanish design process is often characterized by a technocratic approach to social questions.

This concentration of power has two main corollaries. First, there is no institutionalized method of consultation with interest groups. This absence of an established link between society and public authorities can be seen as a reflection of the relatively weak organization of social groups.[23] Second, and this is a consequence of the above, Spanish politics is characterized by limited public debate and a weakly developed civil society. The inevitable conclusion is that politics does not stimulate important discussions within society as a whole.

In summary, 'Despite [. . .] examples of issues arising from concerns and crises in Spanish society, the role of party and political elites in controlling the flow of the main policy issues on to key agendas is paramount' (Gibbons 1999: 107). Groups defending particular interests outside the parliamentary arena must sooner or later establish direct contacts with members of the political elite if they wish to have the possibility of influencing the agenda. It is with these issues in mind that we turn to the initial stages of the ART policy process.

Emergence of the issue

The emergence of the debate on ART within the political sphere in Spain is closely linked to the development of assisted reproductive techniques, and particularly of IVF. The first serious parliamentary debate on this topic took place in September 1984, just two months after the birth of the first Spanish baby conceived in vitro. At the demand of the Basque National Party and the Social-democratic Centre, a special parliamentary committee to evaluate new reproduction techniques was created by the Presiding Council. A proposal by the Popular Group requesting urgent regulation of ART was not followed up since it was submitted only after the creation of the Committee. This sequence of events suggests that the medical community was at least indirectly at the origin of the attention given to ART at the parliamentary level. The question remains as to whether the receptivity shown by the political world to this new theme was simply a reaction to a topic currently in the news or whether an impulse can be attributed more directly to the medical community. It is interesting to note in this context that the same doctor who later achieved the first

IVF in a public institution in July 1985 piqued the interest of the PNV.[24] Taken as a whole, the existence of contacts between the political and medical communities suggests that the birth of the first baby conceived in vitro opened a window at the parliamentary level and that the medical community did not allow it to be closed.[25]

Framing ART as a medical issue

In framing the design goals, Spain included specifically medical objectives, thereby indicating that the viewpoints of the medical doctors were taken into consideration at the legislative level. The medical community managed to place the debate at the level that suited it best. To do so, it needed to obtain direct access to policy formulation, find allies within the political process, and get its arguments accepted.

The Special Parliamentary Committee was the preferred institutional locus for policy framing. One of its roles was to highlight all the details of ART development. Indeed, the first discussions in Parliament regarding ART did not make reference to a particular conception for ART policy, but rather to the need to know more about this new subject. Two other factors worked to the advantage of the medical community: the majority of experts had a medical background,[26] and they were the first to be heard by the Committee.[27] These advantages flow directly from the work plan agreed upon at the first meeting of the Committee by the six Members of Parliament. Thanks to the predominant position of Marcelo Palacios, the medical community was able to ensure that the questions related to ART were formulated only in medical terms. To create this framework, which literally 'trapped' all the other experts, they resorted to the use of various arguments and stratagems.

First, the representatives of the medical community adopted a somewhat 'external' position with regard to the questions at stake. They did not restrict themselves to their role of technical or scientific experts, but also expressed themselves on ethical and even legal issues. The medical community was thus able to offer a comprehensive response to the questions posed.

Second, the representatives of the medical community appeared before the Committee with well-developed projects and precise proposals on regulations to be adopted, thereby demonstrating both a certain level of cohesion within the community and an organizational capability absent among other categories of experts.[28] The best illustration of this coordination was provided by the so-called Barcelona Group made up of six experts from the Catalonian city.[29] Dividing the questions related to IVF and AI into two subgroups, they were able to propose their papers as basic working documents at the very first meeting of the Committee.

Finally, the experts seem also to have been able to anticipate the types of fears that ART never fails to arouse, adopting quite moderate positions

on several points. Rather than systematically demanding as flexible a legislation as possible, which would have coincided with their objective interests, they were prepared to give up some freedoms as long as these did not result in too high a cost for them. Thus, medical experts rejected surrogate motherhood – of little interest both technologically and financially – and accepted limitations on embryonic research (hardly developed at the time). The medical experts were therefore able to give the impression that they were not primarily promoting their own interests, but were acting as truly neutral and independent experts.

Following these developments, the overall framing of the law could not be seriously questioned at any later stage. Within a very short time the parliamentary majority began presenting ART as an opportunity for important advances in science and social medicine. Demands for regulation were based more on the need for doctors to work within a stable legal environment than on the idea of protecting patients as potential victims of these techniques. There was a consensus that ART was opening up new and still unknown perspectives while raising fundamental questions, and that regulation was necessary if ART was not to develop in a legal vacuum. In this situation, a permissive position rapidly emerged as the predominant point of view.

The medical community is also the most important actor of the designing process. The medical community intervened in its capacity as a professional organization, through medical associations, as experts participating in the public debate, and especially as members of committees, or even as Members of Parliament. This last form of involvement justifies the term 'medical community' as an entity, even if the individuals most active on this issue were clearly the specialists involved.

The presence of medical doctors among the Members of Parliament is very important, since the designing process was concentrated on the parliamentary arena. Here again we should point to the presence of one essential individual actor, Marcelo Palacios. In his role as medical doctor, socialist Member of Parliament and President of the Special Parliamentary Committee, he occupied a key role in the design process.

Obtaining socialist support

The medical community would not have succeeded in imposing its views without the support of a parliamentary majority. Given its substantial representation within the various legislative bodies,[30] it was naturally the PSOE whose support had to be gained for the cause.

The years of the first socialist legislative period, often considered as the first years of modern democracy in Spain, were rather favourable to a certain liberalism as far as morality is concerned. This overall attitude was largely embodied by the PSOE in its role as the major opponent of Catholic conservatism during the Franco regime (Díaz 1999). The PSOE

therefore basically supported innovation and change that could be labelled as progressive. Within this rather promising context for the expectations of the medical community, two additional factors worked in favour of ideological convergence.

The first was Spain's admission to the EEC in 1986; this triggered a considerable pressure in favour of reforms. In the context of European integration, the socialist government systematically attempted to give Spain the image of a modern nation. The continuous references by members of the medical community to recommendations by the Council of Europe and to the know-how of and debates within the European Community, as well as the perspective of being one of the first countries to pass legislation in the field of ART, encouraged the PSOE to become involved in this legislative project.

Second, the PSOE was strengthened in its position by the weakness of new social movements in Spain, such as ecologists and feminist groups,[31] and especially their lack of representation within the political arena. With no critics to fear from the left,[32] the socialists willingly embraced the equation of science and progress. This openness to new technologies remains a trait of the socialist left.

The question remains as to why the draft law did not originate within the Ministry of Health, as would have been logical following the classic Spanish political process. In contrast with most other cases, the process of the LTRA does not reveal the slightest involvement by any administrative service[33] and it was the PSOE that officially claimed to be the author of the LTRA.[34]

A closer look at the political situation of the time reveals that ART regulation did not represent a priority for any major political actor.[35] As far as the government was concerned, joining the European Community and economic matters were far more urgent.[36] The Ministry of Health was involved in the preparation of the General Health Law of 1986 (González Rodriguez and González Fernández 1993) and its subsequent application.[37] Even for the PSOE, which was busy with the 1986 electoral campaign and the internal development of a new political programme (Gillespie 1993), the question of ART did not seem to be a priority.

All of this indicates that work on the issue was tacitly delegated to Marcelo Palacios, who not only chaired the Special Parliamentary Committee and prepared its report, but apparently also edited the draft law and defended it before both the Congress and the Committee for Social Policy and Employment, which was responsible for its evaluation. The fact that a single Member of Parliament[38] took responsibility for the dossier is a particularity of the Spanish designing process. It is also important for the design as a whole, since it created a formal link between the medical community and the parliamentary arena.[39]

Absence of opposition

Although the Spanish policy process offers almost no role for actors other than the parliamentary majority, it is nonetheless possible to influence the latter's decisions. A combination of an effective and mobilized opposition and political demonstrations could make it possible to achieve substantial modifications in the contents of the draft law, or, at the very least, a law's implementation could be postponed. In the case of ART, however, nothing of this nature happened.

During an initial period, it appears that the Catholic community was somewhat 'overtaken' by events – despite its fundamental opposition to them on principle. It failed both to adopt a coherent strategy and to raise adequate funds to support its actions. This failure can be explained by several factors. First, the Church faced an overloaded agenda. In 1987, after it had vigorously opposed the liberalization of abortion, it became engaged in a struggle against an education law challenging the principle of religious education. This parallel existence of other challenging issues, as well as the complexity of the issues raised by ART and the resulting difficulty in mobilizing members of the Catholic community, contributed to the relegation of the question into the background. Furthermore, instructions by the Congregation of the Doctrine for Belief, which serves as a basis for the decisions of the Spanish Episcopal Conference, arrived quite late, because the Donum Vitae was only released in March 1987.[40] In the meantime, the Church apparently aligned its position with those experts within the Special Parliamentary Committee who shared similar convictions, particularly the four professors from Pontificia Comillas University in Madrid. As shown above, they had little impact on the outcome of the work of the Committee.[41]

During a second phase, the existing networks – based on a common membership of Catholic Church members and opposition deputies in Opus Dei – between the Catholic community and minority groups in Parliament, notably Alianza Popular, did not operate efficiently. Furthermore, the framing of the policy design favoured its being based on 'civil ethics', but rejected arguments too obviously inspired by religious principles. For these reasons, as well as due to an apparent cleavage within AP,[42] the Catholic Church never really had a voice in the parliamentary arena.

This poor co-ordination among the members of the Catholic community reached its high point when Members of Parliament belonging to the AP proposed an amendment designed to replace the whole bill. This opposing draft law was deemed unacceptable by the Church, which considered it to be too close to the original text written by the socialists.[43] As a result, when this alternative draft law was voted upon in a plenary session on 14 April 1998, only 43 Members of Parliament voted in favour of it, although there were 105 members of AP in Parliament at that time.

Finally, in 1985, the opposition was deprived of an important instrument allowing it to block legislation. Until that time, it had been possible to request a review of an adopted law by the Constitutional Court, and to suspend its implementation by means of this appeal – even after its formal approval by the legislature – until the court had rendered its decision. This mechanism had proven to be particularly effective in the context of the law on abortion. The socialists had been forced to accept a far more restrictive legislation than they had originally intended (Barreiro 1999). This change did not prevent the members of AP from formally opposing the draft law, but, as described above, the effects on the design were negligible.

Even if it is difficult to evaluate what the opposition's impact might have been had it been effective, the ability of the medical community to promote its point of view was certainly further facilitated by the weakness of the opposition. In this sense, it contributes to explaining the design.

Conclusion

At the beginning of this chapter, we identified two main actors who competed during the design's definition phase. Our argument is that one of these two 'teams' clearly won over the other.[44] In order to explain the evident superiority of the medical community, we have suggested the importance of several explanatory factors. One group of these factors is based on fundamental characteristics of the Spanish political system, which led to what almost seems an inevitable outcome. A second group of factors can be characterized as transitory and previously unknown circumstances of the period when the law was designed. Concerning the first group of factors, it is difficult to see how the Catholic community could have had a chance to obtain the passage of legislation reflecting its point of view. Their only real opportunity would have been to prevent any legislation on ART. The medical community, on the other hand, was well organized from the beginning, capable of seizing opportunities, and able to turn to its own advantage both a favourable context and specific transitory circumstances. The favourable context is illustrated by the fact that its demands were compatible with the vision of the parliamentary majority. The particular circumstances were favourable, to a large extent thanks to the unique position of Marcelo Palacios.

Notes

1 'When Spain joined the EC, the deficiency of its R&D activities owed something to the deficiencies in the general situation of Spanish industry' (Alvarez Aledo 1993: 31)
2 First clinical IVF experiments in Spain were carried out in 1982. The first test-tube baby was born on 12 July 1984 at the Dexus Institute in Barcelona.
3 'Basing themselves on the argument that the liberty of individuals must be pro-

tected, Spain and the United Kingdom seem to be the least restrictive countries in terms of access to medically assisted procreation' (Hantrais and Letablier 1996: 34, our translation).

4 The law was adopted on 20 October 1988.

5 In 1984, the following parliamentary groups were represented: Grupo parlamentario Socialista (GPS), Popular (GPP), Minoría Catalana (GPMC), Partido Nacionalista Vasco (GPNV), Centrista (GPC) and Mixto (GPM).

6 The GPNV and the GPP had each prepared an alternative text – a so-called 'total amendment' – to the socialists' bill. Both proposals were rejected by a large majority (DSCD, 1988, III legislatura, nº 101).

7 Shortly after adoption on 24 February 1989, sixty-three representatives of the Partido Popular submitted an objection on the basis of constitutional incompatibility of the LTRA. The decision was not taken for almost eleven years (Tribunal Constitucional, sentencia 116/1999 del 17 de junio 1999), and the court rejected the opposition in almost all aspects (Diego-Lora 2000).

8 These are Royal Decrees 412/1996, 413/1996, 415/1996 and the *ordén* dated 25/03/1996. Certain paragraphs relating to ART are also included in the Organic Law 10/1995 and the Royal Decree 63/1995.

9 Spanish legislation regulates research on the embryo through two different laws. The key distinction to be made here is between pre-embryos (up to fourteen days) and embryos: research on the former is covered by the LTRA. All interventions on the latter are dealt with in the Ley 42/1988, de donación y utilización de embriones y fetos humanos o de sus celúlas, tejidos u órganos. This law should therefore theoretically be taken into consideration in our analysis. However, since it deals with assisted reproduction only marginally, it is not covered in this chapter.

10 The general text is completed by an *ordén* establishing rules for the latter's operation.

11 For detailed descriptions of clauses on penalties linked to ART, see Benítez Ortúzar (1997, 1998).

12 This is the case of the Decreto 58/1999, de 8 de abril, por el que se crea la Comisión Canaria de Reproducción Humana Asistida. The decree specifically mentioned the possibility of creating a Committee on assisted reproduction at the community level (art 12, RD 415/1997).

13 This applies for instance to the Código de familia de Cataluña, ley 9/1998, or to the Ley 3/1997, Gallega de la familia, la infancia y la adolenscencia.

14 González Morán (1998: 117) refers to an enumeration of motives for the reason of clarity.

15 In the light of this interpretation, most objections to the design were addressed by lawyers, ethicists and moral experts or, on a more general level, by the Catholic community.

16 Real Decreto 63/1995 sobre ordenación de prestaciones sanitarias del Sistema Nacional de Salud.

17 There are 155 private and 36 public centres.

18 The Ministry of Health informed of its intention to launch an information campaign on ART (*Diarío Médico* 2000) and the Partido Popular asked for more resources for a more generous reimbursement of diagnosis and treatment of infertility (*Diarío Médico* 2001a).

19 It is also backed by the National Committee on ART whose so far only report calls for more freedom of scientific research (Comisión Nacional de Reproducción Humana Asistida 1998).

20 Heywood (1999: 118) states that: 'the institutional architecture of the Spanish democratic state has played a critical role in shaping the policy process'.

21 'The beginning of the current era of Spanish politics dates from 1982, when

transition was completed and Spanish democracy consolidated' (Gunther *et al.* 1999: 32).

22 For instance, Newton and Donaghy (1997: 6) note that 'Moderation seemed to be the key-note of the Socialist government first elected in October 1982 and re-elected on three subsequent occasions (1986, 1989 and 1993). Rather than radically alter the direction of policy, the socialists under Felipe González tended to build on the reforms of their predecessors'.

23 'Spain's political history has not been characterized by the institutional stability that permits different social groups to create and consolidate independent, autonomous, representative organizations' (Molins and Casademunt 1999: 124).

24 It is also said that Dr José Angel Portuondo would have joined the Committee if he had not died in an accident. The Committee report is partially dedicated to him, stating that he was one of the pioneers of ART (Informe de la comision especial de estudio de la fecundación 'in vitro' y la inseminación artificial humanas 1986: 42).

25 Our definition of the medical community covers the non-medical scientists active in research related to medical techniques, such as biologists, chemists or geneticists.

26 The parliamentary groups chose the following numbers of experts: fourteen for GPP, ten for GPS, five for GPMC and GPC, and four for GPNV and GPM. Since there were some multiple nominations, the number of experts decreased from forty-two to thirty-six. The expert group was made up of thirteen gynaecologists, eleven legal experts, eight philosophers and four biologists.

27 Both gynaecologists and biologists were heard during the first two expert hearings. These were followed by a session presenting medical data, by the hearings of legal experts, and finally by the evidence of ethicists.

28 When the draft law was published, several individuals criticized the fact that other than medical expert reports were not taken into account (*YA* 1987a).

29 Three of them were even from the same institute (Dexeus Institute).

30 In 1982, the PSOE won 202 out of 350 seats in the Congress (lower chamber) and 134 out of 208 seats in the Senate. In 1986, it kept 184 and 124 seats respectively (Apariciado 1994: 225–8).

31 For a feminist point of view on the LTRA, see Varela and Stolcke (1990).

32 The extreme left was fully convinced by the draft law, and of the necessity to leave an important margin of liberty to both scientists and medical practitioners.

33 There was one exception to this: a document prepared by the Ministry of Justice on questions raised by IVF and AI in relation to civil law. It was submitted to the Special Parliamentary Committee (Ministerio de Justicia 1986).

34 The spokesperson of the Ministry of Health (Fernando Segú) even declared that the Ministry was officially not informed about the socialist draft project (*YA* 1987b).

35 This lack of priority attributed to the future LTRA is confirmed by the fact that consultation of the text, which was ready in May, was delayed by several months in favour of more urgent subjects (*YA* 1987b).

36 The unemployment rate was very high (Martín 2000) and relations with the trade unions tense (Astudillo Ruiz 2001). The latter called for a general strike in December 1988.

37 It seems that even the Ministry was hardly interested in this subject for quite some time. It took seven years for first measures delegated to administration in the LTRA to be taken.

38 Marcelo Palacios's motivations can be linked to his pursuit of a career in the

field of bioethics. For example, he founded the International Society on Bioethics (SIBI).

39 Marcelo Palacios's special role consisted both of his personal involvement and of his position as intermediary between two spheres. This latter role is consistent with the system's usual way of working: 'Ministers and leading individuals within the Spanish party system serve as the most important channels and "gatekeepers" for issues into the key agendas' (Gibbons 1999: 107).

40 With the exception of a presentation in Spain of the Donum Vitae at the time when it was promulgated in Rome, the Church took position in public only once, on 23 March 1988. On this occasion, it diffused a document by the *Comisión episcopal para la doctrina de la Fe*. Although there were rumours that the Church would publish a critical position after the law was adopted, a position was never really taken.

41 This was especially the case for Javier Gafo, who never lost his interest in the topic, as some of his recent work shows (Gafo 1998).

42 After a period of instability partially due to the resignation of its founder in 1986, the AP disappeared as a large coalition of right-wing parties after January 1989. It reappeared under the name of Partido Popular (Newton and Donaghy 1997: 200). Right-wing parties still seem to have difficulties when it comes to adopting a coherent position on ART. This is illustrated by the polemic statements exchanged between the Ministries of Health and Science and Technology on the subject of research on stem cells (*El País* 2001d).

43 The editor of the socialist text agrees on this point (Palacios 1990).

44 This can be simplified by saying that the Instituto Dexeus won over the Pontificia Comillas. A good illustration of the Church's resigned attitude can be found in the small amount of attention given to the issue of ART during its last plenary assembly (Conferencia Episcopal 2001).

7 The United Kingdom

Regulation through a national licensing authority

Robert H. Blank

Introduction: ART policy-making in the United Kingdom

The issues surrounding ART came to the forefront relatively early in the United Kingdom in the aftermath of the birth of the world's first IVF baby in Oldham, England, in July 1978. By March 1979, the Medical Research Council had convened the first of many professional and public bodies to confront the policy issues accompanying the emergence of ART. Over the next decade, a variety of private and public committees and commissions were crucial in framing what came to be a groundbreaking authoritative decision that created a national licensing body for ART research and application.

Given the highly centralised political system and the national health care system in the United Kingdom, it might come as no surprise that Britain was the first country to create a statutory body with broad powers to shape and regulate reproductive technologies. What might be surprising, however, is that the regulatory mechanism adopted, a statutory licensing authority, does not appear to have resulted in significant loss of professional autonomy or patient access and at the same time has largely been successful in regulating ART. As will be demonstrated in detail later, both autonomy in terms of ART application and research allowed, and access to prospective patients, are relatively high.

The authoritative decision on ART in the UK, the Human Fertilisation and Embryology Act, passed by Parliament in 1990, is best seen as the culmination of over a decade of often acrimonious debate in Britain that reflects more complex policy dynamics than might be assumed from sole examination of the Act itself. Despite the potential of this strong majoritarian political system to make drastic policy innovations, the UK experience with ART suggests a more open process where corporate interests, particularly those of the medical associations, were clearly in evidence. It also demonstrates how the strategy of the opponents of ART was instrumental in encouraging the medical establishment to accept relatively stringent public controls over their practice as a means of avoiding even more restrictive policies that would prohibit particular ART-related

research and applications. Moreover, it can be argued that the mere knowledge that Parliament had the unfettered power to do so made the medical community more willing to accept regulation instead of risking prohibition.

The designing process: implications for autonomy and access

The designing process that led to the Human Fertilisation and Embryology Authority cannot be understood without reference to the supremacy of Parliament in making policy and the role of the National Health Service in providing access to health care. The United Kingdom is one of only several democracies without a written constitution. The absence of a codified document means, in effect, that Parliament enjoys sovereign authority, with no threat of a challenge by the courts. Parliament, therefore, has the capacity to make or unmake any law. and no body has the right to set aside or override its actions. By virtue of its legislative sovereignty, Parliament functions as the ultimate arbiter of the constitution.

Some critics have described this concentration of power as 'elective dictatorship' (see Heywood 1997: 277), but from the standpoint of the statutory instrument discussed here this framework is crucial and it is doubtful the Licensing Authority would have survived unchallenged under different circumstances. This is largely because while the common law tradition gives the UK courts wide discretion regarding settlement of disputes between parties, the judicial branch has no legal power to contradict acts of Parliament on constitutional grounds such as is the case in the United States and many European countries. The courts have increasingly become involved in medical cases (including those involving ART) when disputes arise, but they do not have broader power to void acts of Parliament such as the licensing of medical procedures. Although this might change in light of the application of the European Convention on Human Rights in the UK and in a growing activism in the courts, there is no evidence of this to date.

Another factor that is important for explaining access and autonomy in ART policy-making is the institutional centralisation of power in the National Health Service, which, according to Dohler (1991: 282), greatly enhanced health policy reforms initiated by the Government in the 1980s. The National Health Service Act of 1946 created the National Health Service (NHS) on 5 July 1948, founded on the principle of collective responsibility of the state for the provision of comprehensive health services on the basis of equal access for all citizens. A central aim of the NHS Act was to provide health care free at the point of service for those in need of the service. The NHS is funded from taxation, thus representing a redistributive policy of significance despite the frequent criticisms for being insufficiently so and under-serving of the least well off (Allsop 1995: 15).

Moreover, the Act nationalised the hospital system and re-organised it on a regional basis. One goal was to guarantee that everyone, wherever they were geographically or socially, would have access to specialist services. Although the NHS has undergone a series of re-structuring over the years, it has remained a highly bureaucratic organisation with a hierarchical structure. The new-style managerialism and managed internal market introduced by the Thatcher government in the 1980s introduced administrative reforms to increase accountability, competition and efficiency, but the Government made no moves to undercut the foundations of the NHS.

Despite the centralised goals of the NHS, it has continued to function within a structure in which the functional autonomy of the medical profession is dominant. Quite apart from the ability to make clinical decisions within very elastic financial limits, the profession is also well represented on the management and decision-making bodies in the NHS (Allsop 1995: 33). Also, because it is the local health authorities that make decisions regarding how to allocate their funds, for what services they will pay and for whom, there is considerable inconsistency geographically.

Although it likely has the legal authority, the NHS has not instituted national regulations to guarantee that allocation decisions are consistent across regions and thus reduce the considerable variation that exists among the authorities. The result is that access to particular specialist services varies: certain services are readily funded in some hospitals and unavailable in others. One survey, for instance, found that couples in Scotland were seven times more likely to obtain in vitro fertilisation than were couples from southwest England (Nettleton 1998: 142). This may be simply one of the costs inherent in any national health system where even limited autonomy is given regional or local administrators to judge how best to serve their patient population. It would not be surprising, however, if reproduction-assisting services were found to be among the most inequitably distributed services, given their high costs and controversial nature. For instance, access to the specialised procedure of pre-implantation diagnosis is limited to only four licensed centres in the UK, with only one clinic allowed to carry out the embryo biopsy part of the procedure.

Reaching the public agenda

Although artificial insemination had been practised in the UK for many decades, the birth of Louise Brown, the world's first IVF baby, raised public awareness of the possibilities for assisted reproduction. Partly driven by the immediacy of this English first and the vast international attention it raised, in March 1979 the UK Medical Research Council convened an Advisory Group to examine the ethical aspects of IVF research. It was specifically mandated to determine ethical grounds for Council consideration of research proposals in this area.

During the same period of time, the Department of Health and Social

Security had concerns that emerging IVF services fuelled by public demands following the birth of Louise Brown should come under public scrutiny. The Advisory Group's report had five recommendations, most notably that IVF should be regarded as a therapeutic procedure and that health departments should establish a confidential register to record each embryo transfer and subsequent pregnancy. It also recommended that the Advisory Group be re-convened at least every five years to reconsider the issues in light of technological advances.

In 1981 the Medical Research Council approved funding for basic research in IVF. In response to technological changes and the rapid expansion of IVF services, in May 1982 the Advisory Group was re-convened. It reviewed research developments since its last report and drew up guidelines for research in human fertilisation and embryology. Although its primary focus was on technical issues, the Group also addressed broader questions, such as whether or not there is an absolute right for a couple to have children and thus have access to technologies to overcome infertility – a claim rejected by the British Council of Churches.

Most action in these early stages then was centred within the medical research community. It was still viewed by the Government as a political 'hot potato' (Gunning and English 1993: 27). Under growing public pressure and highly dramatic speculative stories in the tabloids, however, in July 1982 the Government established a Committee of Inquiry under Dame Mary Warnock with a mandate to:

> Consider recent and potential developments in medicine and science related to human fertilisation and embryology; to consider what policies and safeguards should be applied, including consideration of the social, ethical and legal implications of these developments; and to make recommendations.

The Warnock Committee, composed of a mix of sixteen lay and expert members, sat for two years. During that period it reviewed submissions from 252 organisations, including Royal Colleges of Medicine, health authorities, research councils, religious bodies, medical charities and university departments. It also commissioned detailed written reports from twenty-two experts, heard oral evidence from twenty-one individuals and organisations, and received 695 letters and submissions from members of the public. In its report, the Committee argued it had tried to 'discover the public good in its widest sense', and it distinguished between benefits of the research to individuals and benefits to the pursuit of knowledge.

The Warnock Committee Report

The Report of the Warnock Committee was released in July 1984, and received a very mixed reaction (Report of the Committee 1984). The

Report offered sixty-three recommendations covering all aspects of assisted reproduction. A major recommendation was that a 'new statutory licensing authority be established to regulate both research and those infertility services which we have recommended should be subject to control'. These techniques included donor insemination; IVF; egg and embryo donation; and the storage and freezing of gametes and embryos. Significantly, the Report recommended that there be substantial lay representation, including that of the chairman, on the statutory authority.

Furthermore, the Report recommended that all practitioners offering these services be licensed by the authority, and that there be criminal offences for unauthorised research. As recommended earlier by the Medical Research Council Advisory Group, the Committee called for creation of a central registry to keep data and monitor these areas. Despite disagreement on the Committee over surrogate motherhood, it recommended that legislation be introduced that would render criminal the creation of surrogacy agencies and the actions of professionals who knowingly assist in the establishment of a surrogacy pregnancy. Thus, all surrogacy arrangements would be illegal and thus unenforceable.

Overlapping the life of the Warnock Committee was a study by the Ethics Committee of the Royal College of Obstetricians and Gynaecologists (RCOG) to provide guidance on the practice of IVF for its members. The Ethics Committee supported IVF and embryo replacement, with or without donated ova or sperm, within stable heterosexual marriages. The use of IVF in conjunction with surrogacy, however, was seen as unacceptable. The Committee recommended that a register should be kept of all attempts to produce a pregnancy by the institutions providing treatment. Furthermore, the College should establish a central register of all babies born in the UK as a result of IVF, with a record of their development up to school age.

Also in 1983, a report was produced by a working group established in 1982 for the British Medical Association (BMA) to study ART techniques and issues. The working group accepted IVF as an ethical medical practice, and gave approval to gamete donation where there was a free, informed consent and adequate pre-screening of all the parties. The group agreed that all IVF centres should hold treatment registers and that, further, health departments should collate statistical data centrally. This body also rejected IVF surrogacy, and concluded that storage of gametes and embryos should not exceed one year.

The Warnock Report produced heated debate both inside and outside Parliament, though the Government was in no hurry to act on most of the Committee's recommendations (Gunning and English 1993: 41). The only issue that sparked quick action was surrogate motherhood, which was perceived as urgent and highly controversial because it was reported that American agencies were coming to the UK to recruit clients. With support from all political parties, emergency legislation was passed in the form of

the Surrogacy Arrangements Act of 1985, which banned commercial agencies as well as the advertising of or for surrogacy services.

The Warnock Report was supported by the major medical associations, including the Medical Research Council, the British Medical Association, and the Royal Society, and by the Church of England. In contrast, the Committee's recommendations were roundly condemned by the Roman Catholic Church, the Society for the Protection of the Unborn Child (SPUC), and LIFE for not taking strong enough action against ART.

Although the medical committees that had visited this issue (with the exception of the RCOG, which called for legislation limited to registration of practitioners and licensing of premises) preferred professional self-regulation to government control, they welcomed most of the recommendations contained in the Warnock Report and saw them as highly preferable to the alternatives called for by the opponents. On the other hand, the medical councils' actions to provide a framework for self-regulation could be viewed as pre-emptive strategies designed to avoid any governmental control of ART. Although they failed ultimately to stop government regulatory action, to a large extent their recommendations served as a foundation for a constructive policy-making environment and a reasonably pro-medicine policy product. At the end of 1984, when the Government invited comments on the Report, the MRC welcomed its recommendation for creation of a statutory authority.

Parliamentary action

The first debate on the Report was held in the House of Lords on 31 October 1984, where it met a very hostile reception, with many members calling instead for a moratorium on ART research. The Report faced a similar reaction in the House of Commons, where the Minister of Health noted the polarity of views. On 5 December 1984, a private member's bill, the Unborn Children (Protection) Bill, was introduced by Enoch Powell. This Bill would prohibit all embryo research and allow IVF only for insertion directly to a patient. Moreover, the Secretary of State would have to review and personally authorise its application *in each case*. The Bill had strong support, with a majority of 172 votes at its second reading in February 1985, and it failed enactment solely on technical grounds as it ran out of time at the report stage because of a filibuster by supporters of the Warnock Report.

In light of the acrimonious reception in both the House of Lords and House of Commons and the widespread show of support for the Powell Bill, the RCOG and MRC councils agreed in early 1985 to establish jointly a non-statutory, voluntary licensing authority. This clearly pre-emptive measure was announced at a press conference on 29 March 1985, with appointment of a distinguished chairman and a diverse committee including strong lay membership. The Voluntary Licensing Authority for In

Vitro Fertilisation and Embryology (VLA) quickly produced guidelines designed to defuse the initiatives of Powell and others to shut down the IVF business completely. (For an excellent description of VLA activities during its six-year tenure, see Gunning and English 1993: 47–67.)

In December 1986 a consultation document, titled Legislation on Human Infertility Services and Embryo Research, was published. Some observers saw the document as a delaying action taken on this controversial subject by a government facing a general election. The Government, however, defended this action by arguing that the 'range and complexity of the issues raised . . . and the strength and diversity of opinion make it desirable that there should be a further period for consultation before any legislation is drafted' (Legislation on Human Infertility Services 1986: p. I, p. 4). The Consultation Paper set out and sought views on three options:

1 Establishment of a statutory licensing authority recommended by the Warnock Committee
2 Direct control of certain procedures by the Secretary of State as proposed by Enoch Powell and others
3 Voluntary, professional self-regulation along the lines of the VLA.

By this point in time, there was very little disagreement over the need for some type of regulation of IVF. Those groups opposed to IVF, such as SPUC and the Catholic Church, realised they would not be able to prohibit its practice, and thus they opted for regulation, attempting to get as tight a regulation as they could. Also, professionals working with ART welcomed a regulatory body to protect them against potential claims of unethical behaviour in this politically controversial area. The Government took a position of neutrality during the parliamentary and public debates, and gave the members a free conscience vote on the matter. Of the over 200 replies, including the submission of the VLA, 70 per cent favoured option 1, the statutory authority. The responses were more divided, however, on embryo research and over the question of how much information should be made available to the children produced through the use of donor gametes.

In November 1987, a White Paper entitled 'Human Fertilisation and Embryology: A Framework for Legislation' was released. It expanded the information in the Consultation Paper, and included discussion of the views submitted in response to it. Although the White Paper included detailed material in some areas such as inclusion of newer techniques such as Gamete Intra Fallopian Transfer (GIFT), it left open the more controversial areas for further discussion in Parliament.

Although it was expected that a bill would be introduced into the 1988/89 session, action was delayed until December 1989, when the Human Fertilisation and Embryology Bill was introduced in the House of

Lords. By this time, because of the slow progress towards political action, the VLA was experiencing financial problems, which required an infusion of a £45,000 public contribution in December 1988 to keep it functioning. Further confusing things, in May 1989 the VLA underwent a name change to the Interim Licensing Authority (ILA).

The Human Fertilisation and Embryology Authority

On 7 November 1990, the Human Fertilisation and Embryology Act received Royal Assent. The main provision of this Act was to establish the Human Fertilisation and Embryology Authority (HFEA), mandating it to design a national system to regulate certain practices involved in the treatment of infertility and research on human embryos. The HFEA was required to operate a licensing system for all centres that store gametes or embryos, or that offer treatment that involves the use of donated gametes. A Licensing and Fees Committee was empowered to ensure that no prohibited activities take place, and that no activities for which licences are required are undertaken without said licence. Centres seeking a licence must provide detailed information about staffing, facilities, operating procedures, and charges. Inspection teams visit each site. An inspection fee is charged, but the largest part of the Authority's income is raised through annual fees charged to centres based on the numbers of treatment cycles performed in the year prior to application (current fees are £36 per IVF treatment cycle and £18 per donor insemination treatment cycle). Treatment and storage licences are issued for a maximum of five years, after which re-application is necessary.

The HFEA also maintains a central registry of all covered treatments, all children born as a result of the treatment, and all semen and ova providers. Its other statutory duties include publication of a Code of Practice, guidance to centres on how to carry out licenced activities, and advice to providers and prospective providers and to persons seeking treatment. The object of the Code of Practice goes beyond securing the safety and efficacy of treatment and research practices and extends to areas of practice that raise fundamental ethical and social questions. Special emphasis is placed on the rights of people who are or may be infertile to proper consideration of their request for treatment. The Act contains a legal requirement for a centre to take account of the welfare of the potential child in considering whether to offer treatment. In order to placate those opposed to offering treatment to single women and lesbian couples, one consideration specified is the child's need for a father. Counselling must be offered to all persons seeking licenced treatment.

Licenced centres are expected to comply with the Code in terms of staffing, assessment of providers, information available to patients and providers, welfare of the children, consent, counselling and the use of gametes, unless they can demonstrate good reason for not doing so in a

particular case (Daniels 1992: 5). The Code of Practice has been reviewed on an average of every two years to ensure continued relevance to changing circumstances. The Fifth Edition of the Code of Practice was published in 2001 and is available on the Internet and otherwise widely promulgated to clinics and members of the public.

The HFEA took up full responsibilities on 1 August 1991. Although there was some support for utilising existing ILA members as the base of HFEA membership, this idea was dismissed and a completely new membership was formed. Gunning and English (1993: 111) argue that this move to clean the slate was a reaction to the pro-life lobby's on-going criticism of the ILA and the Government's desire to ensure widespread support for the new Authority, unburdened by past acrimony. For a nine-month transitional period, however, both authorities were in existence, causing concern among centres and the public (see Gunning and English 1993: 111).

The Act also addressed the thorny political issue of what information should be accessible to children of ART. The Authority is required to keep a register, which includes information about donors. When a child reaches the age of eighteen he or she may request information from the Authority as to whether he or she was born as the result of licenced treatment services. On request, the Authority is required to provide non-identifiable information as specified in the regulations.

Finally, the Act went so far as to specify activities that would constitute a criminal offence. Violations included both the practice of authorised procedures by centres that did not have a valid licence, and the practice of those actions that were not authorised for anyone. Among those actions defined as criminal are:

1 bringing about the creation of an embryo or keeping or using an embryo without a licence;
2 placing in a woman a live embryo other than a human embryo or live gametes other than human gametes;
3 keeping an embryo after the appearance of the primitive streak or later than fourteen days after fertilisation;
4 placing a human embryo in an animal;
5 keeping or using an embryo in circumstances prohibited by regulation;
6 replacing a nucleus of a cell of an embryo with a nucleus taken from a cell of any person, embryo or foetus (cloning);
7 storing gametes or using for treatment gametes of a third party without a licence;
8 storing or using gametes in a way prohibited by regulations.

In a separate section, the Act made all surrogacy arrangements unenforceable in law by amending the Surrogacy Arrangements Act of 1985,

although surrogacy is available through licensed clinics in rare instances where a woman is physically unable to carry to term.

Parliamentary action since 1990

Since its passage, the HFEA has been implemented and its powers solidified in the regulation of ART. Parliament has seemed content to defer to the Authority and delegate decision-making power to it, thus avoiding politically sensitive issues. There has been consistent action by Parliament regarding ART since 1991 (see Appendix A to this chapter, Table 7.3), much of which is designed to bring other laws in compliance with the requirements of the HFEA. None of the statutory instruments have challenged or narrowed the authority of HFEA, and several have actually expanded its powers.

In 1991 there was a spate of statutory instruments (SI) relating to HFEA, most of which served to implement various sections of it and put the force of Parliament behind it. Statutory Instrument 1991 (No. 1540), for instance, implemented section 14 regarding storage period for frozen gametes, while 1991 (No. 1588) specifies regulations for the storage of gametes for research and prohibits the exchange of money or benefits for gametes unless explicitly permitted by direction of the Authority. Statutory Instrument 1991 (No. 1400) implements section 16 of HFEA relating to licence applications and fees, as well as section 45 relating to licence committees, licence procedures, and special exemptions from licensing. Likewise, SI 1991 (No. 1889) prescribes the composition of licence committees and procedures to be adopted by them, as well as procedures for HFEA when hearing an appeal against a determination by the licence committee. Statutory Instrument 1991 (No. 480) gave force to the HFEA by amending the Abortion Act of 1967 to bring it in line with section 37 of the Act.

Some instruments have also amended HFEA in light of new scientific evidence or technologies, or because of problems encountered under the original law. Statutory Instrument 1991 (No. 1781) relaxes requirements relating to consent to the storage of gametes and embryos already in storage as of 1 August 1991, while SI 1996 (No. 375) extends the five-year storage limit for embryos under certain circumstances. SI 2000 (No. 188) was passed in response to the growing debate in 2000 over the use of embryos in research. This instrument amends section 2 of HFEA, and gives the Authority the power to issue licences for research involving embryos for purposes of increasing knowledge of development of embryos, increasing knowledge of serious diseases, and enabling such knowledge to be applied in developing treatments for those diseases.

Special actions have been taken by Parliament to protect personal information under HFEA. SI 1993 (No. 746) amended the Access to Health Records Act of 1990: access shall not be given under section 3(2)

to any part of a health record which would disclose information showing that an identifiable individual was or may have been born as a consequence of services under HFEA. Similarly, SI 2000 (No. 419) amended the 1998 Data Protection Act by exempting from section 7 data concerning human fertilisation information. It protects the anonymity of donors, etc., and puts it in line with adoption and parental orders.

Most of the other statutory instruments relating to HFEA over the last decade have attempted to clarify the legal status/custody of the children of ART. This has required the amendment of many other laws to allow for parental orders for gamete donors. Most of this action occurred in 1994 so as to implement section 30 of the HFEA. Statutory Instrument 1994 (No. 2165 and No. 2166), for instance, amended the Family Proceedings Rules of 1991 to bring them in line with section 30, which confers power upon the court to make a parental order with respect to a child in favour of a married couple at least one of whom is the genetic parent of a child born of a surrogate arrangement. Likewise, the Adoption Act of 1976 was amended in England and Wales (SI 1994, No. 2767) and the Adoption (Scotland) Act of 1978 (SI 1994, No. 2804) was also amended. Statutory Instrument 1994 (No. 2981) amended the 1976 Adoption Act by prescribing new forms of entries to be made in reporting births under section 30 of HFEA, while SI 1994 (No. 3151) extended this to Scotland by amending the 1965 Registration Act and providing new birth certificate forms. SI 1994 (No. 2164) amends the Children Order of 1991, and requires that proceedings of parental orders under section 30 commence in magistrate's court. Finally, SI 1994 (No. 230) amends the Legal Aid in Family Proceedings Regulations of 1991 to remunerate proceedings under section 30, and SI 1994 (No. 2768) provides civil legal aid to such proceedings in magistrate's court.

In summary, Parliament continues to defer to the Human Fertilisation and Embryology Authority to make decisions regarding ART policy, and has taken positive steps to amend legislation in other areas that might be in conflict with HFEA. Moreover, Parliament has broadened the power of HFEA to regulate research on embryos, including stem cell research. After a decade, therefore, the bold experiment of regulating ART through a central national licensing authority appears to be on track.

Autonomy and access

In terms of professional autonomy, the general response of practitioners is that, within the licensing framework, autonomy has not been highly constrained in large part because the HFEA is not closed to new applications and is strongly sympathetic to the interests of the research community. As illustrated in Tables 7.1 and 7.2, the range of conventional ART allowed for practice in the UK is quite inclusive. Although some applications of new techniques may be delayed by licensing requirements and the

Authority's assessment process, according to the HFEA the reason is largely one of safety:

> There are a number of new clinical procedures which, while technically possible, have not been proven safe for both the intended child and the mother. Although such treatments may be available abroad, patients should be aware that they may not be of proven value and may be associated with a high risk to themselves or to a potential child.
>
> (HFEA 1999: 7)

There is no evidence that HFEA has practised dictatorial control or that it has significantly restrained either the practice of ART or embryo research. For instance, in February 2002 HFEA approved two applications for research on human embryos to produce stem cell lines (HFEA 2002). The propensity of HFEA to permit a relatively high degree of professional autonomy in both research and clinical application is likely due in part to its composition, which has a heavy representation of research and clinically-oriented members (see Appendix B for a list of the current members of HFEA). The 'liberal' approach taken by HFEA is often the point of condemnation from opponents of ART. Table 7.1 illustrates that few ARTs are severely limited by the statutory licensing approach.

Seventy-five clinics are licensed to carry out IVF and DI, while an additional twenty-nine are licensed for DI only. Appendix C of this chapter (Table 7.4) demonstrates the expansion of ART applications as reflected in a consistent growth in the number of patients treated, treatment cycles, and live births through IVF and related techniques. Between 1990 and 1999 the number of patients treated with IVF increased from 9,964 to over 27,000, while live births rose from 1,443 to 6,450. The total number of babies born under HFEA auspices also passed 50,000 (over half of these in the last three years). Moreover, the range of services offered to patients has continued to expand, with ICSI and other micro-manipulation techniques widely used since 1995. In August 2001, in an effort to reduce the incidence of multiple pregnancies, HFEA announced its decision to reduce the number of embryos to be transferred from three to two.

As demonstrated in Table 7.2, access to ART in the UK is in the medium range. Although HFEA under law has a strong regulatory function and controls where and under what circumstances ART can be practised, a broad range of ART services is available to patients. Also, although HFEA promulgates age and marital status guidelines in the Code of Practice, its main focus is on the best interests of the potential child:

> One of the conditions of a treatment licence is that 'a woman shall not be provided with treatment services unless account has been taken of the welfare of any child who may be born as a result of the

> treatment (including the need of that child for a father), and of any other child who may be affected by the birth'.
>
> (HFEA 2001: 3.1)

While the Code talks in terms of couples seeking treatment, there are specific provisions for single applicants. According to the Code, people seeking licenced treatment should assess their commitment to having and

Table 7.1 Autonomy in the United Kingdom

		Autonomy	
Basic techniques			
Insemination (1)		M	2
GIFT/ZIFT (2)		M	2
IVF/ET (3)		M	2
Total 9: 0–1 no or close to no (N), 2–4 low (L), 5–7 medium (M), 8–9 high (H)		*M*	*6*
Related techniques			
Surrogacy (4)		L	1
Donation (5)	sperm: 5a,	M	2
	egg: 5b	M	2
	of embryos/impregnated eggs: 5c	M	2
Cryopreservation (6)	sperm: 6a,	M	2
	egg: 6b	M	2
	of impregnated eggs 6c	L	1
	embryos: 6d	M	2
Pre-implantation diagnostics (7)		L	1
Genetic selection (8)		L	1
Gender selection (9)		L	1
ICSI (10)		M	2
Max. 36: 0–5 no or close to no (N), 6–17 low (L), 18–29 medium (M), 30–36 high (H)		*M*	*19*
Research/experimental techniques			
Genetic engineering (11)	on gametes/germ cells (11a)	M	2
	on impregnated eggs, embryos (11b)	L	1
Research (12)	on gametes/germ cells (12a)	M	2
	on impregnated eggs, embryos, zygotes (12b)	M	2
Cloning (13)		M	2
Chimera and hybrid building (14)		N	0
Max. 18: 0–2 no or close to no (N), 3–8 low (L), 9–14 medium (M), 15–18 high (H)		*M*	*9*
Total of all three groups of techniques (max. 9): 0–1 no or close to no (N), 2–4 low (L), 5–7 medium (M), 8–9 high (H)		*M*	*6*

Note
L, low; M, medium; N, no; 1 = low; 2 = medium.

Table 7.2 Access to ART in the United Kingdom

		Access	
Basic techniques			
Insemination (1)	with gametes of the couple (1a)	M	2
	with sperm donation (1b)	M	2
GIFT/ZIFT (2)	with gametes of the couple (2a)	M	2
	with sperm donation (2b)	M	2
IVF/ET (3)	with gametes of the couple (3a)	M	2
	with sperm donation (3b)	M	2
	with egg donation (3c)	M	2
	with embryo donation (3d)	M	2
Max. 24: 0–3 no or close to no (N = 0), 4–11 low (L = 1), 12–19 medium (M = 2), 20–24 high (H = 3)		*M*	*16*
R*elated techniques*			
Surrogacy (4)		L	1
Cryopreservation (6)	sperm (6a)	M	2
	egg (6b)	M	2
	impregnated eggs (6c)	M	2
	embryos (6d)	M	2
Pre-implantation diagnostics (7)		L	1
Genetic selection (8)		M	2
Gender selection (9)		L	1
ICSI (10)		M	2
Max. 27: 0–4 no or close to no (N = 0), 5–13 low (L = 1), 14–22 medium (M = 2), 23–27 high (H = 3)		*M*	*15*
Total of all two groups of techniques (max. 6): 0 no (N), 1–2 low (L), 3–4 medium (M), 5–6 high (H)		*M*	*4*
For Element 1: Weights for total of all two groups of techniques (N = 0), (L = 4), (M = 8), (H = 12)		*M*	*8*
For Element 2: Judgement for financial coverage of ART (0–3)			*2*
Total of Element 1 and Element 2 (0–15)			*10*

Note
L, low; M, medium; N, no; 1 = low; 2 = medium.

bringing up a child or children; their ability to provide a stable and supportive environment for any child produced as a result of treatment; their health and age and consequent future ability to look after or provide for a child's needs; and their ability to meet the needs of any child or children who may be born as a result of treatment, including the implications of any possible multiple births.

Despite its responsiveness and record of expansion of approved services, there is concern about the perceived constraints over access inherent in any licensing system, although in most cases these problems of access are more likely a function of the lack of NHS funding rather than

prohibitions set by the HFEA. However, there have been a growing number of reports of individuals going abroad to gain access to innovative techniques or specific applications that are not available in the UK. For example, in February 2001 the NHS fertility clinic in Nottingham reportedly sent a 44-year-old woman to Rome to undergo pre-implantation screening for her IVF-produced embryos, a process prohibited by the HFEA except where there is a family history of specific conditions such as haemophilia (*Daily Mail*, 4 February, p. 18). While her physician argued that the procedure should be offered to older women with heightened risk of producing embryos with chromosomal abnormalities, because of the absolute authority of the HFEA in this arena the only option other than appeal is to leave the UK for treatment. Also, in October 1999 the Glasgow Royal Infirmary received HFEA approval for a bulk import of donated sperm from Denmark because of severe shortages of donors in their area (HFEA 1999).

As noted above, highly specialised applications of ART, such as pre-implantation diagnosis, are limited not only by strict licensing of centres as to under what conditions, if any, they can be carried out, but also by funding constraints imposed by health authorities. For instance, the author is a member of the priority-setting committee at a London area health authority that was asked to decide whether to fund pre-implantation diagnosis to be conducted by one of the four centres in the UK approved by the HFEA to do the procedure. Although approval was granted, funding was provided for up to only five such procedures per year.

Conclusions

In response to the birth of Louise Brown in 1978, the medical associations and government quickly became involved in framing a policy to deal with the emerging issues surrounding ART. After over a decade of public and private reports, voluntary and interim commissions, and parliamentary manoeuvrings, the HFEA was created in 1990. The UK Human Fertilisation and Embryology Act remains the most comprehensive national public law regarding ART, providing a statutory foundation not only for defining acceptable research, but also for direct regulation of clinical practice. Despite growing pains and continued controversy in some areas, the Authority created by this Act continues to function with reasonably strong support as it enters its second decade of existence.

In terms of autonomy and access, the HFEA generally has been willing to consider and approve for licence a wide range of ART applications, has tended to respond quickly to consider approval of new applications, and has seldom acted directly to block professional autonomy or access. However, HFEA approval of a technique is no guarantee of widespread access in the population due either to constraints the HFEA sets regarding

which clinics are licensed to practice and offer the particular procedure, and/or constraints imposed by the NHS in terms of funding coverage or waiting lists. Despite the presence of a comprehensive licensing authority with broad regulatory powers, the most evident limits on access are linked to funding of the services, not the regulatory context.

One country comparison that is especially interesting is that of Canada. Along with the UK, Canada early on had a highly well-publicised national commission on ART. The Baird Commission (1993) arrived at similar findings to the Warnock Committee, but its recommendations were largely rejected while the UK Parliament eventually acted on them to establish the licensing authority. Although this variance could be attributed to the product of the unitary, highly centralised British institutions versus the loose, federal system of Canada, given where they started, the resulting policy gap between the two countries in regulation of ART is striking.

Appendices

Appendix A

Table 7.3 Statutory Instruments for ART

Year	*Number*	*Subject*
1985		Surrogacy arrangements
1986		Family law reform
1990	*c.*37	HFEA
1991	480	Abortion
1991	1400	Implement licensing
1991	1540	Implement storage
1991	1558	Implement storage
1991	1781	Consent storage
1991	1889	Licence committees
1992	*c.*54	Disclosure of information
1993	746	Access to records
1994	230	Legal aid – parental orders
1994	1776	Parental orders
1994	2164	Parental orders
1994	2165/66	Parental orders
1994	2767	Parental orders
1994	2768	Legal aid – parental orders
1994	2804/05	Parental orders
1994	2981	Birth certificate – parental orders
1994	3151	Birth certificate – parental orders
1996	375	Storage of embryos
2000	188	Embryo research
2000	419	Data protection

Appendix B

Membership of the Human Fertilisation and Embryology Authority, 2000

Chairman, Ruth Deech, Principal, St Anne's College, Oxford
Brenda Almond, Professor of Moral and Social Philosophy, University of Hull
Dr Sue Avery, Scientific Director, Bourn Hall Clinic
David Barlow, Professor of Obstetrics and Gynaecology and Clinical Director, Assisted Reproduction Unit, John Radcliffe Maternity Hospital
Peter Braude, Head of Division of Women's and Children's Health, Guy's, King's and St Thomas' School of Medicine
Christine Gosden, Professor of Medical Genetics, Liverpool Women's Hospital
Andrew Grubb, Professor of Medical Law, Cardiff Law School
Henry Leese, Professor of Biology, University of York
Stuart Lewis, Consultant Psychologist, Ulster Hospital and Community Trust
Anne McLaren, Principal Research Associate, Wellcome CRC Institute
Sadia Muhammed, General Practitioner, Priory Medical Group
Sara Nathan, Journalist
Michael James Nazir-Ali, Lord Bishop of Rochester
Sharmila Nebhrajani, BBC News Media
Francoise Shenfield, Clinical Lecturer in Infertility, RMU
Jean Smith, Specialist Social Worker in Adoption
Lis Woods, Commissioner HM Customs and Excise

Appendix C

Table 7.4 Expansion of access to ART

Year of treatment	*Patients*	*Treatment cycles*	*Live births*	*Babies*[a]	*Live birth rate (%)*	*Multiple birth rate (% of live birth rate)*
IVF						
1978–83[b]	–	–	280	342	–	
1984	–	–	327	399	–	
1985	3,717	4,308	364	444	8.6	
1986	4,687	7,043	605	754	8.6	
1987	7,488	8,890	760	1,013	10.1	
1988	7,515	10,489	956	1,345	9.1	
1989	8,790	10,413	1,157	1,552	11.1	25.6
1990	9,964	11,583	1,443	1,899	12.5	25.5
1991–92	15,087	17,017	2,155	3,062	12.7	27.3
1992–93	14,996	19,553	2,546	3,343	13.0	28.1
1993–94	17,124	22,524	3,205	4,206	14.2	27.6
1994–95	20,077	25,878	3,733	4,887	14.4	27.6
1995–96	23,317	30,432	4,620	6,130	15.2	29.4
1996–97	25,563	33,517	5,601	7,292	16.7	27.4
1997–98	26,685	34,638	5,687	7,397	16.4	27.3
1998–99	27,151	35,363	6,450	8,337	18.2	26.8
Totals	212,161	271,648	39,889	52,402		
Micro-manipulation (ICSI, SUZI)						
1991–92	76	80	3	4	3.8	33.3
1992–93	223	244	14	20	5.7	35.7
1993–94	701	798	74	98	9.3	25.7
1994–95	1,460	1,685	265	343	15.7	26.4
1995–96	4,051	4,651	941	1,247	20.2	28.9
1996–97	5,828	6,652	1,438	1,896	21.6	29.1
1997–98	8,254	9,749	1,919	2,491	19.7	27.4
1998–99	9,776	12,109	2,522	3,232	20.8	26.1
Totals	30,369	35,968	7,176	9,331		

Source: HFEA 2002, at www.hfea.gov.uk.

Notes

a The numbers of babies is higher than that of live births as a result of multiple births (twins, triplets, quads).

b Data were not routinely collected before 1985. Data from 1978 to 1984 were extrapolated from MRC Working Party on Children by In Vitro Fertilisation reports.

8 France

Protecting human dignity while encouraging scientific progress

Isabelle Engeli

Introduction

In France, in 2001, a post-menopausal woman gave birth to a child conceived by her brother's sperm and a donor's egg by means of an in vitro fertilisation carried out in the US. This case provoked controversial debates over moral issues, exacerbated by the fact that under the French legislation an assisted reproductive technology (ART) treatment would not have been permitted in this case. In France, a post-menopausal woman is not entitled to ART treatment and the French legislation requires the sperm donor to be anonymous. In the aftermath of this case, the debate over ART re-emerged around questions that had already been discussed and regulated in the late 1980s and the early 1990s: under which conditions can sexual reproduction be supplanted by ART? Who shall be entitled to ART treatment? Which techniques are deemed acceptable?

The current debate aims at revising the existing legal framework, i.e. the two so-called Laws on Bioethics passed in 1994 (Laws 94-653 and 94-654), which are today still in force.[1] These Laws constitute a legislative arsenal covering the use of a wide array of ART techniques. It is a comprehensive and relatively strict framework that goes well beyond the mere regulation of the medical use of ART by also putting severe restrictions on a patient's access to ART.

This chapter analyses the content of French public policies governing ART in France and the designing process that led to the first policy design in 1988, and eventually resulted in the laws on bioethics in 1994. Two main questions guide our analysis: what were the incentives for France to formulate policy designs on ART, and why did France eventually design a comprehensive and strict regulatory framework for ART practices?

In the first section of this chapter we outline the designing process and its final outcome, i.e. the current French policy design on ART. In the second section, we show the importance of technological developments for the agenda-setting process. Then we explain that the first French policy design in the field of ART (1988) emerged from a minimal consen-

sus and why France did not stop at this first design, and highlight the key roles played by public consultation and the 1993 legislative elections during the pre-parliamentary and parliamentary phases of the designing process that led to the Laws on Bioethics. We conclude by offering a short outlook on the possible results of the current debate on revising the laws on bioethics from 1994.[2]

The designing process

The designing process can be divided into three phases, involving three main arenas: (1) the government/public administration (in particular the General Directorate of Health, *Direction générale de la santé*; Stasse 1999: 70); (2) the Parliament and parliamentary committees; and (3) the pre-parliamentary consultation procedure.

The first phase in the designing process began with the development of IVF in the early 1980s. The resulting deliberation led by intellectuals and the scientific community on how to achieve a sound relationship between science and morals polarised the French debate (Mehl 1998: 155–6). The French government's approach was characterised by waiting until the 1983 creation of the National Consultative Ethics Committee for Health and Life Sciences (CCNE). It was not only the first governmental action in the area of ART (Mehl 1999: 248); it also represented an innovation in the field of bioethics, since France was the first country to set up this type of national committee (Governmental Decree 83-123). In addition to creating the Committee, the government requested an expert report on ART (Alnot *et al.* 1986), which was published in 1986 but went unheeded. The second official report, however, authored by the Council of State (Braibant 1988), constituted the first step towards the regulation of ART by the French State (Mehl 1999: 251). At the same time, the so-called Barzach governmental decrees were promulgated in April 1988. These decrees constituted the first French policy design in the field of ART, and concluded the first regulatory phase.

In 1989, the French government and Parliament jointly launched a second ART regulation phase by initiating the pre-parliamentary process. Three reports reintroduced public consultation (Lenoir and Sturlèse 1991; Bioulac 1992; Serusclat 1992). At the same time, the medical community gradually introduced self-regulation of ART practices within its own ranks. Since both public authorities and part of the medical community seemed to favour the idea of legislation, the socialist government's submission of two relatively permissive bills on bioethics to the National Assembly came as no surprise in late March 1992. Once revised, the bills were then transmitted to the upper chamber of Parliament, the Senate. Mainly as a result of the parliamentary elections held in 1993, the legislative process was then halted for a lengthy period of time. The elections brought about a new right-wing parliamentary majority. In early

summer 1993, the new French government decided to re-launch public consultation on the key issues raised by the draft laws on bioethics. The ensuing report (Mattei 1994) emphasised greater restrictions on ART. The Senate examined and considerably amended the draft laws in early 1994. The government then set up a mixed joint commission that was able to reach a compromise that both chambers could accept. In July 1994, le Conseil Constitutionnel, the French constitutional court, ruled that the laws on bioethics were constitutional (94-343-344 DC of 27 July 1994). This second policy design phase ended with the promulgation of the decrees of application as foreseen in the 1994 Laws.

A new designing phase began in 1999 and is currently in process. As planned by article 21 of law 94-654, the law is in the process of being revised. In the meantime, new reports have been issued. The parliamentary revision of the law initially planned for 1999 was delayed but is now under way. A second reading of the bill in the National Assembly took place in January 2002.

The current policy design: a comprehensive but permissive regulation

Now let us review the consequences of the policy design process – that is, the current French policy design in the field of assisted reproduction technology.

Current French policy design on ART is characterised by a moderate level of restriction, and is based mainly on individual articles from the Laws on Bioethics: Law No. 954-653 deals with the respect of the human body, whereas Law No. 954-654 regulates the donation and use of elements and products of the human body, medical assisted procreation, and prenatal diagnosis (29 July 1994). A series of governmental decrees complement these two laws (Decree No. 95-223; 95-558, 95-560; 96-993, 97-613, 97-555, 98-216, 99-925). Lastly, the policy design includes a decree of 7 February 1990 that modifies the nomenclature of legislation within the field of medical biology. The French design regulates a large number of ARTs by the use of six types of instruments: regulation, attribution of authority, licensing, reporting (obligatory annual reports), obligatory informed consent of patients, and penal and administrative sanctions. It also addresses two main target groups of the field. Specifically, it restricts both doctors' autonomy with respect to the practice of ART and patients' access to ART treatment.

Limited medical autonomy

The current French design is moderately restrictive with regard to the medical community's autonomy in practising ART. All basic and related techniques (the latter do not directly result in the creation of an embryo)

are permissible except for surrogate motherhood (see Table 8.1). However, a strict framework accompanies this authorisation to practise, in particular in the case of related techniques. Indeed, gamete and embryo donation are restricted to exceptional cases, and must be anonymous and free of charge. Embryo donation is permitted if one of the spouses dies or if the plan to conceive by means of IVF is renounced. Moreover, pre-implantation diagnosis (PID) is permitted only in exceptional cases that

Table 8.1 Autonomy in France

		Autonomy	
Basic techniques			
Insemination (1)		M	2
GIFT/ZIFT (2)		M	2
IVF/ET (3)		M	2
Total 9: 0–1 no or close to no (N), 2–4 low (L), 5–7 medium (M), 8–9 high (H)		*M*	*6*
Related techniques			
Surrogacy (4)		N	0
Donation (5)	sperm: 5a,	M	2
	egg: 5b	M	2
	of embryos/impregnated eggs: 5c	L	1
Cryopreservation (6)	sperm: 6a,	M	2
	egg: 6b	M	2
	of impregnated eggs 6c	M	2
	embryos: 6d	M	2
Pre-implantation diagnostics (7)		L	1
Genetic selection (8)		L	1
Gender selection (9)		L	1
ICSI (10)		M	2
Max. 36: 0–5 no or close to no (N), 6–17 low (L), 18–29 medium (M), 30–36 high (H)		*M*	*18*
Research/experimental techniques			
Genetic engineering (11)	on gametes/germ cells (11a)	N	0
	on impregnated eggs, embryos (11b)	N	0
Research (12)	on gametes/germ cells (12a)	M	2
	on impregnated eggs, embryos, zygotes (12b)	L	1
Cloning (13)		N	0
Chimera and hybrid building (14)		N	0
Max. 18: 0–2 no or close to no (N), 3–8 low (L), 9–14 medium (M), 15–18 high (H)		*L*	*3*
Total of all three groups of techniques (max. 9): 0–1 no or close to no (N), 2–4 low (L), 5–7 medium (M), 8–9 high (H)		*M*	*5*

Note
L, low; M, medium; N, no; 1 = low; 2 = medium.

may warrant genetic selection (non-selection of embryos that contain genes carrying an illness to be prevented). Both ICSI and GIFT/ZIFT are permitted. Although the law does not refer specifically to these techniques, they are treated as equivalent ART techniques). The only experimental technique allowed is research on embryos if the purpose of the research is medical, and if it does not affect the embryo (direct benefit for the embryo or for the improvement of ART as a field).

Patient access: restricted but free of charge

Patients' level of access to ARTs in France is characterised by limited restrictions resulting from a combination of strict conditions regarding patients' civil status and a high level of coverage by the social security system (see Table 8.2). The group of patients entitled to ART treatment is considerably restricted. First, only living heterosexual couples, either married or having cohabited for at least two years, may receive treatment. Second, interventions must be therapeutically indicated (infertility or risk of transmission of a serious disease). This strict limitation regarding patients' civil status is compensated by the extensive financial coverage of ART offered. Indeed, in the end, the French social security system covers 100 per cent of the costs resulting from ART intervention (Decree of 7 February 1990 modifying the medical biological intervention nomenclature).

This analysis of France's current policy design in the field of ART shows that it allows a wide range of ARTs while maintaining strict oversight. Why did France design a comprehensive and strict regulatory framework for ART practices? In order to answer this question, we first show the influence of the major technological developments in the field of ART.

The development of ART in France: 1978–94

In France, the environmental factor with the greatest influence on the formulation of the policy design was the development of assisted reproduction technology. ART practices as a whole had a certain impact, and their diffusion shaped both the political agenda and the designing process. Specifically, two technological innovations that had a particularly strong impact are worth introducing. First, the invention of in vitro fertilisation (IVF) opened up new scientific horizons, as it had a great impact on the fight against infertility or hypofertility. This new technique opened up new research fields that attracted practitioners, researchers and patients alike. The spread of IVF nonetheless led to strong reactions resulting from the fact that this technique made possible, for the first time, the creation of a human embryo in a tube. Second, the invention of pre-implantation diagnosis (PID) made possible the selection of in vitro embryos for implantation into the female body and re-launched the

Table 8.2 Access to ART in France

		Access	
Basic techniques			
Insemination (1)	with gametes of the couple (1a)	M	2
	with sperm donation (1b)	M	2
GIFT/ZIFT (2)	with gametes of the couple (2a)	M	2
	with sperm donation (2b)	M	2
IVF/ET (3)	with gametes of the couple (3a)	M	2
	with sperm donation (3b)	M	2
	with egg donation (3c)	M	2
	with embryo donation (3d)	M	2
Max. 24: 0–3 no or close to no (N), 4–11 low (L), 12–19 medium (M), 20–24 high (H)		*M*	*16*
Related techniques			
Surrogacy (4)		N	0
Cryopreservation (6)	sperm (6a)	M	2
	egg (6b)	M	2
	impregnated eggs (6c)	M	2
	embryos (6d)	M	2
Pre-implantation diagnostics (7)		M	2
Genetic selection (8)		L	1
Gender selection (9)		L	1
ICSI (10)		M	2
Max. 27: 0–4 no or close to no (N), 5–13 low (L), 14–22 medium (M), 23–27 high (H)		*M*	*14*
Total of all two groups of techniques (max. 6): 0 no (N), 1–2 low (L), 3–4 medium (M), 5–6 high (H)		*M*	*4*
For Element 1: Weights for total of all two groups of techniques (N = 0), (L = 4), (M = 8), (H = 12)		*M*	*8*
For Element 2: Judgement for financial coverage of ART (0–3)			*3*
Total of Element 1 and Element 2 (0–15)			*11*

Note
L, low; M, medium; N, no; 1 = low; 2 = medium.

debate on ART. This technique made it possible to select embryos out of what could be termed 'convenience'. Some observers began to fear that PID would be used for eugenic purposes. Together with the media's coverage of attempts in other countries to clone animals or humans, the invention of PID largely influenced the restrictive turn that the ART debate took, especially in Parliament, as will be shown below.

In short, technological development is one of the factors explaining the evolution of the political agenda on ART. Indeed, individual policy-design phases follow the general evolution of the technological development of ART. Furthermore, the extensive spread of ART practices has

contributed to making the problems related to ART more prominent. This factor, however, does not explain the content of the French design. Indeed, while all countries in which ART is practised have been affected by technological progress, these countries did not all adopt a design similar to the French one, if they adopted one at all. Let us begin with the first French ART policy design.

The first policy design: the decrees of 1988

The first phase of the designing process in the field of ART ended with the formulation of the initial policy design in 1988, which was made up essentially of governmental decrees.[3] The 1988 design was only moderately restrictive in comparison with the current design: its major objective was to institute an authorisation procedure for the practice of ART. It therefore restricted practitioners' autonomy, but did not refer to patients. It nonetheless granted practitioners a high level of autonomy in the sense that no ART technique was forbidden. This minor level of restriction on practitioners' activities and especially ART centres, can be explained by the fact that the 1988 regulatory framework was the result of a minimal consensus among public and private actors on the necessity of regulating ART centres.

The opportunity to pass laws affecting ART led to strong disagreements between actors from the medical and intellectual communities. The stir caused by the Braibant Report (1988), which underlined the necessity to set up a comprehensive law on ART amongst other areas, illustrates this climate. In the meantime, the development of IVF had led to a proliferation of ART centres (more than 120 according to Alnot *et al.* 1986) that differed in three ways: success rate; cost; and indications (medical or out of 'convenience'). Some actors – mainly representatives of the medical community – put pressure on public actors to obtain state intervention aimed at checking the risks of abuse but also at safeguarding their prerogative in the field of ART. In response, the Ministry of Health suggested a limitation of the number of centres by means of a procedure of authorisation. It therefore appears that this procedural regulatory framework was the result of a minimal consensus between public actors and members of the medical community: both opposed legislation, at least in the short term, but shared the goal of containing further proliferation of new ART centres.

The French designing process did not end after this first phase. It entered a second phase, leading to the emergence of the Laws on Bioethics, a much more comprehensive legal framework for ART. The following section shows how the shift towards a legal framework for ART was connected to the absence of a comprehensive regulation covering all ART and observed by all practitioners.

The shift towards the current policy design

In the early 1990s, the French government once again launched a public consultation with the increasingly clear intention of elaborating a comprehensive legal framework for ART. As the 1988 design had been based on a consensus, the government could well have limited itself to keeping it, and improving on it in selected areas. Why then was the 1988 design not maintained, and why did French public actors decide to launch a new designing process?

As described above, the scientific development of ART played a role to a certain extent. It was, however, rather the absence of a set of rules covering all ART practices and followed by all practitioners that gave the government its main incentive to launch the legislative process that would lead to the Laws on Bioethics. First, as shown above, the 1988 policy design restricted doctors and researchers only to a certain extent, since it focused mainly on procedural aspects. In addition, it did not cover research on in vitro embryos, which was being practised in unknown conditions at the time. Moreover, regulations were not consistently abided by, and non-authorised centres continued to practise ART (Lenoir and Sturlèse 1991: 41). Second, self-regulation of the medical community was not comprehensive enough to substitute for the design of 1988 – indeed, it completely omitted certain ART practices. The main techniques regulated by medical self-regulation were AID (artificial insemination by donor) and IVF.[4] Moreover, when such rules did exist, not all members of the medical community observed them. The fact that self-regulation addressed neither all ART nor all practitioners pushed public authorities towards developing a set of rules that would deal with these regulatory gaps. Finally, judges could also have brought forth a form of ART regulation. However, they did not succeed in taking a uniform position regarding the permissibility of post-mortem insemination and fertilisation, a question perceived as being very important at that time.[5]

In conclusion, the absence of a regulation covering all ART practices and observed by all practitioners, further emphasised by scientific development and diffusion of new ART, proved to be the key factor in the shift from a minimal to a comprehensive regulatory framework. It pushed the French government to launch a second phase of policy-design formulation, which eventually resulted in the Laws on Bioethics of 1994. This factor also mobilised or at least enlisted the support of the medical community, Parliament, and interest-group members for a comprehensive legislative framework that would regulate both the autonomy of medical practitioners and researchers in the field of ART, as well as patient access to ART.

The formulation of the current policy design

As described above, the lack of a regulation covering all ART practices and observed by all practitioners contributed to the shift towards a comprehensive regulation of ART and thus to the legislative debate that led to the Laws on Bioethics. How can we explain the policy-designing process? In order to understand the parliamentary process that resulted in the Laws on Bioethics, we must take a close look at the pre-parliamentary phase. This important stage consisted of a broad public consultation of influential actors by the government and Parliament jointly. This public consultation had two major effects: on the one hand it influenced the configuration of influential actors, on the other it facilitated the building of a consensus among them. This consensus already favoured limiting practitioner and researcher autonomy, and would in part be adopted by Parliament. Nevertheless, the change in the parliamentary majority led to a further restriction of medical autonomy. Before presenting the pre-parliamentary and parliamentary stages leading to the current policy, let us turn to the pre-existing framework within which it was formulated.

The framework of the current design's formulation

The current French policy design was formulated within an already existing state-defined regulatory framework. As Rose and Davies (1994) point out, existing policies in the field partly shaped the new policy. In other words, the current French design on ART is not new but is rather a redesign of one that already existed. Indeed, the current design did not emerge in a vacuum. Its initial boundary markers were determined by both the existing design on ART and on abortion, and the French social welfare system. First, the 1988 design shaped the first part of the pre-existing framework. Current regulation on ART does not contradict previous rules, but considerably enlarges their restrictive scope. Indeed, the 1988 design legitimised the practice of ART to at least IVF and AI/AID, and this contributed to preventing the involved actors from reconsidering whether they should be permitted at all. Second, existing laws on abortion (Law 'Veil' of 17 January 1975 on the interruption of pregnancy, Law No. 79-1204, Law No. 82-1172) also constituted a framework for the construction of the current design of legislation on ART, in particular regarding the status given to the human embryo. Indeed, granting the embryo a current legal status would necessarily have led to questioning the decriminalisation of abortion. This was one of the main issues discussed during the debate on the embryo. Finally, patients' level of access to ART was strongly influenced by the French social welfare system. In France, ART had always been considered to be a health-related question, at least by public actors. Indeed, in French law sterility is considered to be an illness. Therefore, the French health-care system in general and the com-

pulsory social welfare system in particular can also be considered as conditions that influenced the process of formulation of the Laws on Bioethics.

Let us begin by introducing France's compulsory social welfare system (*Sécurité sociale*). The system is mostly based on the principle of solidarity, and therefore distributes the anticipated total cost of social risks between all individuals. It is financed in large part by employer and employee contributions. Protection against financial risks linked to illness takes the form of health insurance, one of the branches of the social welfare system.

Only in rare cases are medical treatments fully covered. Nevertheless, sterility is recognised as an illness to be 100 per cent covered, since it can cause suffering that may lead to pathological disorders (Montagut 2000: 4). This full coverage is explained by a previous law that foresaw the full reimbursement of costs resulting from the diagnosis and treatment of sterility (Law 78-730). The French health insurance system thus for the most part explains why ART has a fairly high accessibility rate in France. It is one of the basic conditions that influenced the formulation of the French designing process leading to the Laws on Bioethics. On the one hand, since sterility is considered to be an illness, the health insurance system made it possible for ART-related costs to be reimbursed, regardless of the patients' revenues. On the other hand, it also explains the therapeutic indication of ART and the relatively severe restriction regarding the civil status of patients. Indeed, ART is considered as a remedy for sterility or for the potential transmission of a serious and incurable illness, and not as an alternative means of procreation accessible to all (Mehl 1999: 338–49).

The configuration of influential actors

The current French design has been influenced not only by context variables and technological development. Actors' decisions, structured by institutions, have also to a large extent determined this design. Actors' decisions are characterised by underlying beliefs, which motivate their content. An overview of the actors involved, as well as their beliefs, will allow a better understanding of the issues at stake and interactions between actors during the pre-parliamentary and parliamentary stages.[6] Different types of actors influenced or attempted to influence the current design, and these actors all had specific beliefs about which types and degrees of comprehensiveness of ART legislation were necessary. Three ideal types of beliefs are identified, based on the type of relationship existing between law and science – i.e. the way in which a legal framework should frame the medical practice of ART.

A first ideal type of beliefs or 'belief system' advocated moderate legal intervention. Legislation must regulate the use of ART so as to protect human beings from the potential negative effects of rapidly developing science. However, scientific progress in general and the field of ART in particular are considered as being generally beneficial. The medical

community can be trusted, as can its capacity to make appropriate ethical decisions. Left-wing parties, a large section of the medical community, and the Protestant Church shared this set of beliefs. A second ideal type of beliefs favoured a very restrictive legislation dominated by suspicion towards scientific progress, and underlining the potential for eugenic practices in order to justify its call for a firm regulatory stand on ART. According to this belief system, the state should no longer let practitioners and researchers fix ethical limits in the field of ART, where the fate of man is at stake. Fear of eugenic practices is strong in this belief system which is shared by most moderate right-wing party members, by a small section of the medical community, and by associations defending the family. A last set of beliefs advocated an even more restrictive regulation of ART. It held that legislation should not be a hostage of the dictate of science, and that it should rather follow 'natural' laws, thus preventing procreation outside of sexuality in the context of marriage. Some of the actors who advocate these beliefs are even opposed to IVF and artificial insemination. The Catholic Church and the traditionalist Catholic right are characterised by this belief system.

These three belief systems influenced actors' positions and actions in the process leading to the Laws on Bioethics. Accordingly, three coalitions represented three opposing views. It was the power configurations between actors, structured by institutions, which made it possible for some of these actors to promote their goals in accordance with their beliefs. As we will see, pre-parliamentary public consultation gave the medical community a very important role. Moreover, during the parliamentary phase, another institutional factor – the 1993 legislative elections – gave the new right-wing government and right-wing members of parliament (which now held a majority in the National Assembly) the opportunity to put forward their more restrictive conception of medical autonomy.

The pre-parliamentary phase in the development of the current policy design

Before taking a closer look at the parliamentary formulation phase of the current design, we highlight the key role of the pre-parliamentary phase, consisting mainly of a broad public consultation organised jointly by the government and Parliament. This type of pre-parliamentary stage is not limited to the case of ART. Indeed, the French State has a long tradition of public consultation (Meny 1989: 95). This consultation's main function was to collect the positions of actors judged to be concerned with ART. Public consultation, however, is more than a simple survey of diverse opinions: It organises actors' interactions by offering and/or limiting opportunities for intervention, and thus displays the characteristics of an institutional arena. Points of view about the nature of the relationship between the French State and specifically interest groups (cf. Elgie and

Griggs 2000) diverge. We can nevertheless observe that, in the context of ART, relations between the State and interest groups were characterised by mutual dependence, even though the State set the rules of the game.

Public consultation resulted in four official reports to the Prime Minister (Alnot *et al.* 1986; Braibant 1988; Lenoir and Sturlèse 1991; Mattei 1994), as well as two parliamentary information reports (Bioulac 1992; Serusclat 1992). The consultation had two major effects on the process leading to the current policy design on ART.

First, public consultation largely contributed to the configuration of influential actors within the designing process. Consultation procedures have the effect of institutionalising those actors who are asked to participate in the designing process and of marginalising those who are not (Meny 1989: 96). On the one hand this procedure reduced the influence and even distanced certain actors, for example, representatives of feminist and homosexual groups. On the other hand, public consultation gave other actors traditionally considered to be representative of society, such as major religions and associations defending the family, considerable weight. In addition, public consultation made it possible for actors who were non-traditional but directly concerned with ART to intervene. ART patients were almost exclusively represented by the interest group 'Association Pauline et Adrien'. Most other associations, such as those promoting the widely condemned practice of surrogacy, were excluded from the consultative process. Finally, and above all, public consultation provided the medical community with a large platform. Doctors, biologists and researchers gave evidence, speaking both as representatives of interest groups and as individuals. The lack of a single body representing the medical community (Hassenteufel 1997: 193) enabled actors from various hierarchical levels to participate in the consultation. Specialised ART practitioners thus were recognised as having a status at least level with that of the representatives of the Order of Practitioners and the National Academy of Medicine. The process of public consultation granted the medical community the status of not only medical but also of ethical expertise: actors from within the medical community both explained the development and deontological regulation of ART, and expressed hopes and fears for society with respect to ART. Finally, the National Consultative Ethics Committee achieved the status of a moral authority, a 'voice of ethics'. This was largely due to its role as organiser of a debate among actors who had, for the most part, also participated in the public consultation. Thus, the public consultation's first effect was that of contributing to the identification of influential actors whose opinions had to be taken into account. Some of these actors had the resources to impose their participation and their opinions during the consultation. Doctors and the CCNE mobilised their resources both in terms of expertise and symbolic influence. However, other actors – some of them intellectuals – who were active on the issue of ART were given only a marginal role. Participants in

the public consultation were indeed chosen strategically. On the one hand, practitioners, the CCNE and the main religious groups legitimised the proposals resulting from the various reports. On the other hand, the marginalising of other actors who defended extreme or at least highly divergent positions led to the second major effect of public consultation, namely the development of a broad consensus.

Indeed, public consultation opened the way for a certain consensus among actors entitled to participate in the regulation of ART. It played the role of a policy broker (Sabatier and Jenkins-Smith 1999: 122) by looking for a compromise between actors' different positions. The consensus obtained constituted part of the conceptual basis for the elaboration and modifications of the draft bills on ART, and it therefore had a profound impact on practitioners' level of autonomy. Know-how from within the medical community played an important role in defining a consensus on the level of medical autonomy. On the one hand, the warnings of some doctors about certain ART practices were taken seriously. On the other hand, most medical self-regulation observed by a large number of practitioners was fully adopted by the authorities and included in their reports. In particular, the rules applied in the Centres for Study and Conservation of Human Eggs and Sperm (CECOS) enjoyed a great deal of authority (Neirinck 1996: 71). The CCNE's positions on ART also influenced the formulation of the design. Indeed, the CCNE enjoyed the status of a moral authority, especially with public actors, and overshadowed the positions articulated by the Order of Practitioners and the National Academy of Medicine. Accordingly, actors adopted a large number of proposals based on the opinions issued by the CCNE, for example regarding the status of *potential human being* (Opinion No. 1). However, the CCNE's influence did not go uncontested. Some of its opinions, such as its recommendation to permit post-mortem conception (Opinion No. 40), were not taken into account, as most actors rejected them. Although there was a consensus in favour of restricting medical autonomy, this restriction was overall very moderate. Four main principles for the regulation of ART were suggested: free donation and non-commercial use; consent; donor anonymity; and respect for human dignity. With the exception of surrogate motherhood, all basic and related ART practices were allowed. Except for these leading principles, few detailed conditions were formulated.

In short, public consultation as an institutional arena put actors from within the medical community, including members of the Committee of Ethics, in a privileged position: the institutional weight that they received enabled them to promote their beliefs on ART. Actors from within the medical community were nevertheless divided as to the degree of restriction of medical autonomy to promote. On this issue, public consultation played the role of policy broker, leading the way to a consensus resulting from a compromise between different positions. This compromise

explains why public consultation resulted in a proposal characterised by a relatively flexible regulation of medical practices.

The current policy design's parliamentary formulation phase

Public consultation yielded a consensus both on the medical community's degree of autonomy and on the level of patients' access to ART. The then socialist Government to a great extent adopted this consensus in the draft laws that it elaborated, which were rather permissive in comparison with the final design.[7] Moreover, it was silent on the fate of excess in vitro embryos. This silence would have given doctors and researchers a large de facto margin of autonomy with regard to ART practice. However, the level of medical autonomy foreseen by these initial bills was modified by a more restrictive set of rules on ART practice during the parliamentary phase of the designing process. The main factor that modified the consensus was a further institutional factor: the legislative elections of 1993. After these elections, the changed parliamentary majority offered a window of opportunity for right-wing actors to impose their more restrictive views on medical autonomy during the parliamentary phase of the designing process of the Laws on Bioethics.

The parliamentary controversy on in vitro embryos

The initial draft laws on bioethics were modified first and foremost with respect to doctors' and researchers' degree of autonomy. Actors within the parliamentary arena clashed in particular on certain controversial techniques related to in vitro embryos: research on embryos, PID, donation, and destruction of excess embryos.[8]

Parliamentary actors held strongly diverging beliefs on the destiny of in vitro embryos. Left-wing actors, including the 1992 government and the National Assembly's special Commission (1992), advocated a flexible regulation of medical practice on in vitro embryos, which would have allowed research on embryos and PID. Right-wing actors opposed this position and promoted a more extensive protection of in vitro embryos in order to avoid the potential risk of eugenic practices. Two approaches on how to protect the embryo are identified: right-wing members of Parliament and of the National Assembly's Special Commission (1994) shared a moderate approach that favoured allowing PID within strict regulatory control, as well as experiment-based research, whereas right-wing senators and the Senate Commissions promoted a more restrictive view rejecting both PID and research on embryos. Finally, the traditionalist Catholic right-wing fully rejected these two coalitions of beliefs. In contrast, they favoured an extremely restrictive position on ART in which the embryo was considered to be a living human being entitled to the protection of a full human being. The embryo's vulnerability and its incapability of consenting were

perceived as arguments against the authorisation of research and embryonic selection by means of PID.

At the time of the first reading in the National Assembly, a left-wing majority was in place. Left-wing actors therefore had elbow room to impose their beliefs about ART. However, the legislative elections of 1993 changed this political configuration.

A framework resulting from a compromise between right-wing party actors

The 1993 legislative elections, which took place when the draft laws were in their first reading in the Senate, gave the current design its final touch. The left-wing parties, which had held a relative majority since 1988 in the National Assembly, lost a great number of seats to their right-wing opponents – 478 out of 577 seats henceforth were occupied by right-wing parties, compared to the previous 276. A right-wing majority was already in place in the Senate.

This change in the parliamentary majority consolidated the right's power in Parliament, and led to a right-wing government. This shift explains the move towards a far more restrictive regulation of ART and consequently of medical autonomy within the debate on ART. Fears of unlimited medical power and the risks of eugenic practices dominated the ART debate as of the first reading in the Senate. Without restricting the provisions that permit but strictly regulate AI and IVF, the Senate and the new rightist government introduced new restrictions and bans on certain ART practices, especially those with an impact on in vitro embryos. During the bill's second reading, the now right-wing dominated National Assembly relaxed the new restrictions only slightly, and did not question the validity of the fears of eugenic abuse. Left-wing and traditional Catholic right-wing actors were not strong enough as a coalition to counter moderate right-wing actors; some joined the right wing, but abstained from the final vote on the compromise that was reached.

The current policy design, and in particular its clauses concerning the in vitro embryo, are therefore the result of a moderate-right compromise. For instance, the majority of the senators accepted the idea of authorising PID, while members of the National Assembly accepted stricter conditions. Similarly, while senators agreed to the destruction of excess embryos created before the promulgation of the laws, National Assembly members accepted temporarily leaving open the fate of embryos created after the law's promulgation (Mehl 1999: 283).

Conclusions

France's policy design in the field of assisted reproductive technology consists mainly of the Laws on Bioethics of 1994. It permits many forms of ART, but strictly regulates doctors' autonomy in practising ART and

patients' access to ART. What were the incentives for France to formulate policy designs on ART, and why did France eventually design a comprehensive and strict regulatory framework for ART practices? Let us briefly summarise our argument.

We have shown that the first French design (1988) in the field of ART was relatively permissive in terms of granting practitioners and researchers autonomy, since it was the result of a minimum consensus among public and private actors. However, the design process did not end with this first phase. The absence of a comprehensive regulatory framework covering all ART practices and observed by all practitioners, and technological development, pushed public actors, highly encouraged by part of the medical community, to launch a long designing process that led to the Laws on Bioethics.

The process was institutionally structured, partly by public consultation during the pre-parliamentary phase and partly by the legislative elections on 1993. The public consultation largely shaped the configuration of influential actors. In addition, public consultation took the role of a policy broker in seeking to arrive at a consensus among the actors consulted. The consensus was elaborated first and foremost under the leadership of the medical community. This consensus was rather open-ended, and did not prevent members of Parliament from leading a controversial debate on the fate of in vitro embryos. Analysis of parliamentary debates shows us that discord with respect to issues related to in vitro embryos persisted both among the members of each chamber and between the two chambers. In the end, it was an institutional factor – the changed legislative majority and resulting change in the configuration of political forces – that gave right-wing actors the opportunity to promote a stronger limitation of medical autonomy, by negotiating a compromise.

A new designing cycle began in 1999 with the launching of a new public consultation in view of a revision of the Laws of 1994. The French government introduced a draft law on the issue of bioethics to the National Assembly in June 2001 (No. 3166). The lower chamber discussed this bill in a first reading in January 2002. As of October 2003, it is currently awaiting its second reading in the Senate. The revised draft Law on Bioethics includes three major innovations requested by many actors: (1) an explicit prohibition of reproductive cloning; (2) the permission for strictly regulated research on embryos; and (3) the creation of an independent agency on procreation, embryology and human genetics similar to the British Human Fertilisation and Embryology Authority. According to a government communiqué, this agency would have sizeable power and resources, and would be responsible for the regulatory oversight of its areas of competence, including research. The French design may become more flexible in terms of the degree of autonomy it grants doctors and researchers. This would enlarge the medical community's scope of allowed practices, but would not alter the strict oversight of ART

practice. As for the categories of patients who have access to ART, the possibility of other patient groups being included is limited, even though the authorisation of post-mortem fertilisation seems possible. Indeed, a wide consensus still favours free access, but access restricted to heterosexual couples. We must however exercise predictions with caution. A 1993 scenario might repeat itself, and the change in parliamentary majority resulting from the right-wing victory in the June 2002 parliamentary elections may lead to a more restrictive approach to assisted reproductive technology in the future draft law.

Notes

1 The law 94-548 (01.07.1994) is the third so-called law on bioethics.
2 Our thanks go to all the experts who responded to our questionnaire and the experts who agreed to an interview, namely Simone Bateman, Pierre Jouannet, François Laborie, Catherine Labrusse-Riou, Danielle Moyse, Chantal Ramogida and Eva Weil. The interviews were conducted in collaboration with Frédéric Varone and Nathalie Schiffino of the University of Louvain, who we would like to thank for their precious collaboration.
3 Decrees 88-327 and 88-328. This regulation was completed by the Circulars No. 193 of 28 April 1988 on Medically Assisted Procreation and No. 194 of 21 July 1988 on Medically Assisted Procreation, as well as the Byelaw of 20 September 1988 defining the index of needs with regard to medically assisted procreation activities. The 1988 design was to be completed by article 13 of Law 91-1406 regulating health-related aspects of sperm donation and limiting the time period for which centres were granted the authorisation to practise ART.
4 For the ethical rules of the CECOS (Centres for Study and Conservation of Human Eggs and Sperm), see David (1991). For the other rules, see GEFF (1991); CECOS (1991); Collège National des Gynécologues et Obstétriciens français (1991).
5 Decision of the High Court of Créteil of 1 August 1984 ordering the restitution of sperm samples to the widow; Decision of the High Court of Toulouse of 26 March 1991 forbidding the restitution of sperm samples; Decision of the Court of Appeal of Toulouse of 18 April 1994 ordering the destruction of in vitro embryos.
6 A questionnaire using the 'reputational approach' allowed us to identify fifty-four influential actors.
7 It should be noted that the draft laws focused on the more general area of the human dimensions of bioethics. They covered the donation and use of the human body's elements and products (Law 94-654), prenatal diagnosis on in vivo embryos (Law 94-654), and respect of the human body (Law 94-653). These draft laws were authored by the Ministry of Justice (Law 94-653) and the Ministry of Health (Law 94-654).
8 Another controversy focused on the question of donor anonymity.

9 The Netherlands

Conflict and consensus on ART policy

Arco Timmermans

Introduction

In May 1983, the first Dutch baby resulting from in vitro fertilisation was born in the Dijkzigt Academic Hospital, Rotterdam. Since then, in vitro fertilisation has proliferated in the country, from some 400 treatments in 1985 to over 13,000 attempts in 2000 (Kremer 2001). Other techniques for assisted human reproduction have also become part of medical practice, and research activities have unfolded rapidly. The demand for medical intervention in human reproduction increases every year. International developments in biomedical research have yielded possibilities of genetic screening and manipulation with significant effects on the quality of human life. These activities in practice and research take place in the specialised centres of general and academic hospitals, and they are funded mostly with public money.

The Netherlands is often said to have relatively permissive policies on morality issues such as abortion, euthanasia, homosexuality and drugs, but this seems to be less the case with assisted reproductive technologies. For Dutch policy-makers, assisted reproductive technology is a major problem. Many of the technologies that exist or are developed involve scientific uncertainties. Medical professionals have divergent views on the effects of these technologies, and they differ also as to the degree to which uncertainties are considered relevant. Definitions of human life, of health risks, and even of what constitutes a 'success' in fertilisation treatments, vary. Controversies among medical scientists and practitioners also relate to diverging value judgements. Value judgements on issues of human reproduction may differ among medical professionals, and they certainly differ between political parties, interest groups and social groups affected by decisions made on these issues. As in most other Western countries, the use and development of technologies for assisted human reproduction reached the political agenda in the mid-1980s, and from then on, multiple attempts at making policies have been made. Also similar to most other Western countries is the traditional self-regulatory power of the medical profession. For medical associations, the question was how much their autonomy would be affected by government policies.

In this chapter, I analyse and explain Dutch policy on ART. How has the Dutch government responded to national and international developments in reproductive medicine? How broad is the scope of policy – which technologies are included? How much autonomy is left for the medical profession? What is the degree of access for those in demand of these technologies? How can public policy on assisted reproductive technologies be explained? What actors have been policy entrepreneurs? Were initiatives taken by members of the medical community claiming permissive regulation and research money? Or by patient or user organisations, or other social groups concerned with access to the technologies? Or perhaps political actors worried about the rise of medical experimenting? And how have the institutional arenas for policy-making channelled the interaction between experts, politicians and other actors? What has been the nature of 'boundary work' between politics and expertise in policy-making? These are the questions to be addressed in this chapter. Here I present policy design, and then move on to its explanation.

ART policy 1985–2002

Assisted reproductive technology appeared on the political agenda in the mid-1980s. Since the birth of the first IVF baby in 1983, the number of hospitals providing in vitro fertilisation treatments has increased, and initiatives for setting up private IVF centres have been made. These activities were possible because, in this field, the autonomy of medical professionals was large. Moreover, an information asymmetry on the properties and effects of IVF techniques existed between medical specialists and public actors such as the Ministry of Health and the Health Inspectorate. Medical centres claimed that in vitro fertilisation was a successful solution for the problem of infertility, and that the emerging technologies were promising. For this reason, a crucial source of expertise for the government was the Health Council (Gezondheidsraad), a prominent advisory body in which a special committee was formed to consider ART practices such as in vitro fertilisation. The Health Council has influenced the definition and image of assisted reproductive technologies in policy-making since the mid-1980s.

The 1980s: primacy of planning and control

In the course of the 1980s, a provisional package of policies was adopted. Coalition governments avoided the political hazards of considering all aspects of the emerging technologies. The focus was on planning and control of centres using and developing medical technologies for practice, not on social or legal aspects of the technologies, and least of all on research issues. The government delegated to the Ministry of Health the task of designing a temporary but compulsory licensing system for IVF,

based on a report by the Health Council, the main advisory body of the government in this field. Under this, a licence would be required for all medical procedures involved in in vitro fertilisation treatments, from hormonal stimulation to embryo transfer. In addition, arrangements for subsidisation were created, and intended to be temporary.

All these provisional policies were refined and made more definitive at the end of the 1980s. While the scope of public and political debate was expanding to issues such as surrogacy, genetic screening, donor anonymity and other legal questions, policy decisions remained limited to conditions for licensing in vitro fertilisation, and preventing commercialisation. In July 1989, the most comprehensive political decision, the Planning Decree In Vitro Fertilisation (Planningsbesluit in vitro fertilisatie[1]), was published. It was presented by the responsible ministers of Health and Education (both Christian Democrat) as a more coherent and updated version of the existing regulation, mentioning the required – and permitted – capacity of 4,500 IVF treatments per year, for which eleven hospitals would be licensed, a new condition being that they must demonstrate that at least 10 per cent of the IVF treatments resulted in a pregnancy. The government displayed confidence in the social acceptance of in vitro fertilisation and in the capacity of medical centres to self-regulate within the boundaries of the licensing system and the targets mentioned. However, the Planning Decree also contained an explicit prohibition of egg cell donation, and this triggered political revolt. In November 1989, the government amended the Planning Decree by removing the prohibition of egg cell donation, but emphasised that commercial trade in egg cells or donation of egg cells to surrogate mothers was strictly prohibited.[2] The existing arrangement for subsidisation (allocation of subsidies by the Health Insurance Council but no incorporation into the Health Insurance Fund) was considered to be '1990s-proof', although the main argument for this was political risk avoidance.

The 1990s: opening a political Pandora's Box

Beyond the Planning Decree In Vitro Fertilisation of 1989, 'newer' issues related to research on embryos and family and juvenile law surrounding the emerging technologies were given more attention. In the early 1990s political commitments were made to initiate legislation, but the enforcement of these commitments turned out to be a weak point. Several bills were prepared, informed by expert reports published by the Health Council, which was scrutinising not only medical but also ethical aspects of ART. The bills dealt with fertilisation techniques, sperm donor anonymity, medical experiments with embryos, and the prohibition of commercial mediation for surrogacy. In the mid-1990s, the legislative projects on ART were critically reviewed by a new government coalition, for the first time since 1945 excluding the previously powerful Christian Democrats.

In March 1995, the new government announced an entirely new bill on embryo research, more comprehensive but also less restrictive than intended by the previous government.[3] For the first time, research on embryos used not only for reproductive purposes became a serious point of political consideration.

However, regulation ensued not only from within the public arenas; the medical associations were also active in producing self-regulation of techniques related to in vitro fertilisation. On 1 May 1996, the Dutch Association of Obstetricians and Gynaecologists (NVOG) and the Association of Clinical Embryologists (VKE) put a moratorium on MESA and TESE (NVOG 1996). They reported that these techniques involved too many medical uncertainties, and would not be used. This was in line with a forthcoming report on ICSI by the Health Council. In 1998 the Association of Obstetricians and Gynaecologists specified the indications for IVF treatments; the proportion of clients applying for IVF treatment on grounds other than blocked fallopian tubes was increasing rapidly.[4] Also in 1998, the Association presented internal guidelines for surrogacy, in particular the containment of demand and supply of egg cells.[5] This self-regulation was meant to prevent uncontrolled practices, but it also demonstrates that the medical profession still had considerable autonomy.

The government had confidence in this self-regulation, and concluded that the regulatory frame needed updating. Other sources for policy adaptation were the ensuing reports of the Health Council on ICSI and on the Planning Decree. An update of the Planning Decree In Vitro Fertilisation, formally a renewed decree, was published on 1 April 1998.[6] By 1996 the number of IVF treatments had increased to 11,000, and demand was still increasing. The most significant change in regulation was that surrogate motherhood was permitted under the conditions given by the NVOG. On 27 April 1998, a change was made in the arrangement for subsidisation of IVF by the Health Insurance Council.[7] The subsidisation rules were relaxed in the sense that, from then on, all licensed IVF centres (not only hospitals mentioned in the Hospital Provisions Act) could be subsidised. To date, there has still been no decision on incorporating IVF into the Health Insurance Fund Council, though in effect all clients eligible for IVF treatment get their expenses covered for maximum three IVF attempts (per case of assisted pregnancy). Furthermore, on 26 May 1998 a Royal Decree was published prohibiting gender selection, the only exception being a medical indication that gender selection would prevent a gender-related genetic disease in the child.[8]

Policy beyond 2000: regulating embryo research

The government in office between 1998 and 2002 produced a number of decrees that mostly codified medical practice or contained incremental changes, but the more ambitious legislative projects were still underway at

the turn of the century. In June 2000, single women or lesbian couples were no longer excluded automatically from medical treatment, and in December 2000 the Planning Decree In Vitro Fertilisation was amended to allow a limited number of medical academic centres to do research on MESA.[9] The moratorium on practising this technique, however, was maintained.

The most significant piece of legislation was on embryo research. An earlier attempt in the mid-1990s to regulate embryo research had foundered, but in June 2002 the Embryo Act obtained final approval in Parliament. With this Embryo Act, which took force on 1 September 2002, the scope of legislation on assisted reproductive technologies increased significantly.[10] It now includes rules on property and control of gametes and embryos, and on the conditions for consent from adults providing these gametes or embryos, on embryo research for purposes of pregnancy or for other purposes, on use of fetal tissue and on the prohibition of gender selection on non-medical grounds, and it also states that a central commission should monitor the implementation of the Act, supervise medical centres doing embryo research, and report to the Minister of Health annually. Importantly, the Embryo Act prohibits the creation of embryos specifically for research, except in cases where the research is intended to increase knowledge on infertility, or on assisted reproductive technologies, genetic diseases or transplantations. Prohibited practices include in vitro development of embryos beyond fourteen days, cloning, genetic manipulation, hybrid and chimera building, and implantation of human embryos in animals or animal embryos in humans. The prohibition on creating embryos specifically for research is, however, meant to be temporary; the Act states explicitly that the government will propose a decision to drop the prohibition within five years. For this decision, the government is supposed to consult both legislative chambers.

Analysis of present policy: scope, autonomy and access

The ART policy in place in early 2002 has a much broader scope than during the 1980s and 1990s. This may seem the logical consequence of ongoing developments in ART, but it is by no means true that policy-makers always keep track of technological developments. In fact, as we have seen, it is only recently that the scope of public policy decisions has increased. Below I consider the renewed Planning Decree on In Vitro Fertilisation (1998, amended in 2000) and the Embryo Act (2002), which together provide a comprehensive (but not always consistent) set of policy goals and instruments specifying target groups and those responsible for policy implementation.

Policy goals, instruments, target groups and implementers

The goals mentioned in the Planning Decree of 1998 and the Embryo Act of 2002 vary, but are not inconsistent: warranting high quality and efficiency of in vitro fertilisation practices, and safeguarding human dignity. The first is orientated to the containment of in vitro fertilisation practices which in themselves are socially and politically accepted; the second is concerned with setting the boundaries for what is and what is not acceptable. This is reflected in the sets of instruments used. The Planning Decree contains a refined regime for licensing, including quality standards and monitoring and reporting requirements. The more substantive regulation in the Decree is adopted in part from the Dutch Association of Obstetricians and Gynaecologists. The Embryo Act specifies procedures for monitoring embryo research (the central commission is given competence to approve research protocols which are obligatory for centres conducting embryo research), rights of those providing gametes and embryos for research, and, importantly, regulation containing explicit prohibition of certain kinds of embryo research and experimentation. In the Embryo Act, target populations are embryo research centres and adults providing gametes or embryos. The most explicit implementer mentioned in the Embryo Act is the central commission to which the task of monitoring research is delegated.

Given these goals and instruments, what is the degree of autonomy allowed to medical professionals? And how much access do clients have to ART?

Autonomy

The renewed Planning Decree on In Vitro Fertilisation and the Embryo Act contain procedural and substantive constraints on the autonomy of the medical scientific community, applying both to practitioners and researchers. A first note on these constraints, however, is that they are in part self-imposed; as we saw, the Dutch Association of Obstetricians and Gynaecologists engaged in self-regulation when in vitro fertilisation became more generally in demand. This self-regulation, however, was oriented mostly towards techniques involving major scientific uncertainties and aimed at preventing 'excessive medical practices' *à la* Brave New World.

The scope of autonomy of the medical community in terms of the specific technologies it is permitted to use in practice or to do research on is limited mostly – and only recently – by the formal prohibitions in the Embryo Act. Limits on practising, or on research, imposed voluntarily by self-regulation do not as such constrain autonomy. Some of the self-regulatory constraints were subsequently incorporated into the Planning Decree and, as public policy, do reduce the degree of autonomy.

Examples are the moratorium on the use of MESA and TESE in IVF treatments, and the list of indications for IVF treatment compiled by the NVOG – though this list has expanded, so practitioners hardly consider this a serious constraint and they enjoy considerable autonomy in treating a clientele much more diverse than the married heterosexual couples for which the technology was initially made accessible.

Autonomy is delimited also by procedural conditions qualifying or specifying how ART can be put into practice or be studied. Both the Planning Decree and the Embryo Act limit medical autonomy in this respect through licensing, monitoring and reporting, as well as a number of strict limitations and prohibitions (including penalties). This procedural and substantive regulation also has a selective effect within the medical community, as practice and research are permitted only for professionals within licensed centres. Commercial activities in this field have always been strongly constrained. Regarding respect to research on new techniques, the recent Embryo Act has limited medical autonomy considerably. As a result, the overall level of autonomy of medical professionals is medium. Table 9.1 specifies autonomy for different types of techniques.

Access

When the first regulation for in vitro fertilisation was made, the working rules with respect to access were that only married heterosexual couples should be served. The medical community, however, has used its autonomy to expand its clientele. In practice, there is variation in the conditions used by medical centres for allowing access; some are more permissive with respect to marital status, sexual orientation and age (treatments of women above forty) than others. For the use of specific techniques, the Planning Decree contains guidelines – as, for example, the rule that a surrogate mother should first have given birth to at least one healthy child herself. The different rules included in the Decree and in the Embryo Act restrict access to specific techniques either directly (most obviously with respect to embryo research and experimenting) or indirectly (as, for example, with rules on donor information or on surrogacy, which may deter clients on the supply or demand sides from applying for a treatment). Overall, these rules yield a medium level of access. Note that this pertains to individual clients seeking access to reproductive technologies and not to commercial organisations, which increasingly seek access to reproductive technologies and their results, but for which conditions are much tighter – if access is allowed at all.

However, regulation of techniques is not the only relevant factor determining the level of access. Access to ART also has a price. This point has relevance particularly to in vitro fertilisation techniques used in medical practice. Medical centres have been subsidised for limited numbers of in vitro fertilisation treatments by the Health Insurance Council since 1986.

Table 9.1 Autonomy in the Netherlands

		Autonomy	
Basic techniques			
Insemination (1)		2	M
GIFT/ZIFT (2)		2	M
IVF/ET (3)		2	M
Total 9: 0–1 no or close to no (N), 2–4 low (L), 5–7 medium (M), 8–9 high (H)		*6*	*M*
Related techniques			
Surrogacy (4)		2	M
Donation (5)	sperm: 5a,	2	M
	egg: 5b	2	M
	of embryos/impregnated eggs: 5c	2	M
Cryopreservation (6)	sperm: 6a	2	M
	egg: 6b	2	M
	of impregnated eggs 6c	2	M
	embryos: 6d	2	M
Pre-implantation diagnostics (7)		2	M
Genetic selection (8)		1	L
ICSI (10)		1	L
Max. 36: 0–5 no or close to no (N), 6–17 low (L), 18–29 medium (M), 30–36 high (H)		*20*	*M*
Research/experimental techniques			
Genetic engineering (11)	on gametes/germ cells (11a)	1	L
	on impregnated eggs, embryos (11b)	1	L
Research (12)	on gametes/germ cells (12a)	2	M
	on impregnated eggs, embryos, zygotes (12b)	2	M
Cloning (13)		1	L
Chimera and hybrid building (14)		0	N
Max. 18: 0–2 no or close to no (N), 3–8 low (L), 9–14 medium (M), 15–18 high (H)		*7*	*L*
Total of all three groups of techniques (max. 9): 0–1 no or close to no (N), 2–4 low (L), 5–7 medium (M), 8–9 high (H)		*5*	*M*

Note
L, low; M, medium; N, no; 1 = low; 2 = medium.

Though IVF is still excluded from the standard programme covered by the Health Insurance Fund (the public arrangement for health insurance for lower income groups, including about 60 per cent of the population), clients eligible for treatment (determined in part by doctors) are usually subsidised. Private insurance organisations have followed this line, although they usually have stricter conditions for reimbursement, and insurance packages are more expensive.[11] For treatments abroad (waiting

Table 9.2 Access to ART in the Netherlands

		Access	
Basic techniques			
Insemination (1)	with gametes of the couple (1a)	2	M
	with sperm donation (1b)	2	M
GIFT/ZIFT (2)	with gametes of the couple (2a)	2	M
	with sperm donation (2b)	2	M
IVF/ET (3)	with gametes of the couple (3a)	2	M
	with sperm donation (3b)	2	M
	with egg donation (3c)	2	M
	with embryo donation (3d)	2	M
Max. 24: 0–3 no or close to no (N = 0), 4–11 low (L = 1), 12–19 medium (M = 2), 20–24 high (H = 3)		*16*	*M*
Related techniques			
Surrogacy (4)		2	M
Cryopreservation (6)	sperm (6a)	2	M
	egg (6b)	2	M
	impregnated eggs (6c)	2	M
	embryos (6d)	2	M
Pre-implantation diagnostics (7)		2	M
Genetic selection (8)		1	L
Gender selection (9)		1	L
ICSI (10)		1	L
Max. 27: 0–4 no or close to no (N = 0), 5–13 low (L = 1), 14–22 medium (M = 2), 23–27 high (H = 3)		*15*	*M*
Total of all two groups of techniques (max. 6): 0 no (N), 1–2 low (L), 3–4 medium (M), 5–6 high (H)		*4*	*M*
For Element 1: Weights for total of all two groups of techniques (N = 0), (L = 4), (M = 8), (H = 12)		*8*	*M*
For Element 2: Judgement for financial coverage of ART (0–3)		*2*	
Total of Element 1 and Element 2 (0–15)		*10*	

Note
L, low; M, medium; N, no; 1 = low; 2 = medium.

lists or restrictions in the use of techniques encourage clients to this), it is even quite difficult to get expenses covered. As a result, the medium level of access to ART used in medical practice is determined in part by financial conditions.

Table 9.2 shows the degree of user access. Note that, with respect to access, some variation exists between medical centres for treatments such as IVF, depending on the access rules these centres have developed within their sphere of autonomy.

Test tubes and 'polder politics': understanding policy design

Dutch policy today is located at a medium position on the dimensions of autonomy and access. Clients travel abroad rather than into the country. This situation contrasts with the relatively liberal regime in this country concerning other morality issues such as abortion and euthanasia. Though capacity problems also play a part, the more restrictive conditions for access are important. The anticipation of legislation specifying conditions for abolishing sperm donor anonymity, for example, has led to a drastic decrease in supply within one year.[12] This legislation was still under parliamentary scrutiny in early 2003 but is expected to be adopted.

How can this policy profile be explained? What are the positions on these issues taken by political actors, associations of doctors, patients and other interested organisations with stakes in policy decisions? Why have some actors been more successful than others in promoting their preferences as to the extent and direction of government intervention? How have the institutional arrangements for policy-making in this field influenced the policy process? In this section I deal with these questions. For the answers, I consider the relevant actors and their beliefs with respect to the issues, and the arenas in which images of ART were created and where policy decisions were made.

'Institutional genetics' and the pain of consensus building

The Netherlands is a centralised consensus democracy (Lijphart 1999; Timmermans 2001). Institutional arrangements for policy-making are based on the general principles of power sharing and proportional representation. The legislature contains multiple political parties, and governments are always coalitions. Within these coalitions, policy negotiations are multidimensional – the positions of parties vis-à-vis each other vary across different fields of policy. In the legislative and executive arenas parties need to build and sustain a majority, but this is difficult to achieve for questions of morality such as abortion, euthanasia and assisted human reproduction, on which the religious cleavage is still salient. Even within parties, divisions on these issues appear difficult to reconcile.

Another feature of Dutch consensus democracy is that within the health policy subsystem, interests are represented in specific semi-public bodies dealing with medical, ethical or financial aspects of health policy. It is a specific form of the Dutch 'polder politics'. In most Western countries, health care involves both public and private elements, such as in financing and policy implementation and monitoring (Freeman 2000: 1–9), but health *policy-making* is less often a mixture. The semi-public bodies existing in the Dutch health policy subsystem have distinct functions. The Public Health Insurance Council (Ziekenfondsraad), for

example, has regulatory power on matters such as public health insurance coverage. The Health Council (Gezondheidsraad) has strong expert authority in advising the central government. This compartmentalisation goes with tight jurisdiction, rules of access and decision-making that make the health policy subsystem relatively closed for new social groups with stakes in ART policy, such as patient groups and women's associations. Moreover, arrangements giving bodies with direct stakeholders and experts a fixed role at early stages in the policy process may influence problem definition and the image of policy solutions (including the possibility that no policy is actually needed). Particularly when issues are controversial, policy-makers are receptive to expert judgments that can help depoliticise these issues.

Agenda setting and policy images

Within this context, how have issues of ART reached the political agenda? Government intervention in this field of medical care has been debated since the mid-1980s, mostly by a selective group of actors, and attempts to prevent policy decisions have been multiplied. Policy-making is not linear, and agenda setting is a continuous process. It reflects the way in which medical discoveries and emerging practices are depicted by actors with divergent beliefs on these matters.

Over time, many controversies have been argued – mostly unknown to the broader public – over the framing of the problem and the image of ART. In the 1980s, the prevailing problem definition focused on infertility, which was seen first of all as a medical problem for which the new technologies were promising. It was not only the medical community that held this view; it was also the position advocated by the client interest organisation, the Dutch Association for In Vitro Fertilisation, established in 1985 (in 1995 renamed Freya, after the goddess of fertility). Initially the emerging technologies were 'in search of a public' (Kirejczyk 1996: 88), but once in use they were believed to need state planning and control. The initiative for this was taken in the legislature, but the substance of the policy was influenced strongly by experts, represented by the medical associations who influenced policy-making, and by the most prominent advisory body of the government in this field, the Health Council. Experiences with abortion policy, which had given rise to political controversy in the 1970s and 1980s, induced political actors to avoid public debate and circumvent clear policy choices by considering mainly procedural aspects.[13]

In the early 1990s, the image of planning and control policy was declining as medical practice and research appeared to be contained less effectively than expected. Activities in medical centres on the non-regulated issues of embryo research were initiated. Further, the interests of children born after medical intervention became more prominent among doctors,

social groups and politicians. This increased the quest for control – that is, for substantive regulation – but parties in the legislature were still ambiguous about how to do this. Internal party divisions continued to exist, and this strengthened the reluctance among parties to mobilise the broader public, whose interest in this field and the concerns about the future developments were increasing (Kirejczyk 1999: 896; Van der Bruggen 1999: 16–17). In the second half of the 1990s, international developments in research and debates in arenas such as the European Parliament and the European Commission were becoming more important to the construction of the national political agenda.

Actors, stakes and arenas

Agenda setting and policy image construction happened in arenas to which only a limited set of actors had direct access. In the Dutch case, political and interested party representation is strongly organised according to formal and functional rules; that is, rules specifying access, competencies and resource allocation not only for actors responsible for political decision-making, but also for stakeholders in the field. These rules limit the number of actors to political parties, health policy specialists from government departments, associations of medical professionals, and organisations representing clients of reproductive technologies and the legal interests of children.[14] Other actors that could be expected to have stakes in policy decisions either remained relatively aloof or were not successful in influencing the image of the medical technologies and the content of subsequent decisions. The medical and pharmaceutical industry, for example, does not appear to have put decision-makers under constant pressure with respect to these technologies. Its interests, whenever visible, were represented more indirectly through medical professionals in practice and research. Catholic and Protestant church organisations were also not very active either in lobbying or in expressing a clear opinion on these matters. The main carriers for their views were the religious parties in the legislature. A Pro Life Platform criticised what was called an 'instrumental use' of embryos, but it operated at the margin of decision-making (Schroër 2001: 64). The feminist movement continuously challenged the dominant image of reproductive technologies as a 'solution' to the alleged 'problem' of infertility, but its view did not receive much political support (Kirejczyk 1996: 295–8). Finally, there has not been much national judicial involvement in this specific field. The most significant case was a District Court decision in 1994 which allowed a medical centre without a licence to initiate in vitro fertilisation treatments. This decision, however, was followed promptly by an emergency law that effectively tightened the regulatory regime.

Parties and political arenas

The first group of actors thus consisted of the political parties in the two legislative chambers and those participating in the government coalitions. Though the legislature, particularly the Lower House (Tweede Kamer) contains multiple parties (usually more than ten), the most relevant are those participating in the government. The major parties are the Christian Democrats (CDA), who are pro-human life and opposed to permissive policies, particularly on embryo research, and the Social Democrats (PvdA), the Liberals (VVD) and the Liberal Democrats (D66), which are all secular parties emphasising individual self-determination, but with varying views on how liberal ART policy should be. The Christian Democrats took a dominant position in three successive two-party coalitions in office between 1982 and 1994 (CDA-VVD 1982–86, CDA-VVD 1986–89, CDA-PvdA 1989–94). Under these three coalitions, any policy beyond the generally accepted techniques of in vitro fertilisation was politically unfeasible due to a value conflict between the coalition partners. Legislative majority building excluding one coalition party (which, typically, would be the CDA) was also unfeasible because coalition discipline is tight (Timmermans 2003). Even when policy proposals such as draft decrees or bills have reached the formal executive or legislative arena, informal working rules within a coalition are important for the process of decision-making. Often the 'consensus' reached within the coalition was more apparent than real, rendering this concept empty in terms of substantive policy decisions.

In 1994 a coalition government comprising the three secular parties was formed, and took a second term in office from 1998 until April 2002. The policy beliefs of the three secular parties on ART (as on other morality policy issues) were becoming more pronounced, but also less divergent than in previous governments. This was a crucial condition for rendering policy proposals more viable.

Medical professionals and arenas of expertise

Political actors and arenas may be vital in order to make political decisions, but the content of these decisions may originate from elsewhere. Medical professionals are prominent in representing the supply side of ART. Specialised bodies containing spokespersons from the medical profession and from health insurance organisations are important because they not only give expert advice but also have policy-making and implementing competencies.

The Dutch Association of Obstetricians and Gynaecologists (NVOG) is the main organisation containing spokespersons from the community of medical practitioners and researchers dealing with ART. The dominant belief within the NVOG on ART is that scientific discoveries and the

application of results of these discoveries make a fundamental contribution to the quality of human life, and as such should be promoted. As in the other countries in this volume, the medical community has a tradition of autonomy, but this does not mean that the NVOG advocates a policy of 'anything goes'. The association has established self-regulation, which commits members to treatment protocols and conditions for research, though medical centres have discretion in deciding who to accept for treatment. Media and public attention for this variation from centre to centre is increasing.[15]

Two important loci of expertise on the supply side of ART are the Health Council (Gezondheidsraad) and the Public Health Insurance Council (Ziekenfondsraad). The Health Council is the most prominent advisory body of the government in the field of health policy. It was created in 1901, at a time when public health issues were becoming the concern of the central government and the need for expert advice began to be felt (Rigter 1992). Today the Health Council deals with almost any subject related to public health, and its institutional position is embedded formally in the Health Act of 1956. The Council contains spokespersons from the medical community as well as experts on ethical and legal issues, and is supposed to make recommendations on a scientific basis and to be independent from particularistic interests. The Health Council is usually requested by the Minister of Health to give advice on a particular medical problem or technique, but it can also take the initiative to consider a medical issue. It produced as many as thirteen different reports on ART between 1984 and 2000, most of which were upon ministerial request.

The Health Insurance Council (Ziekenfondsraad) has a narrower scope, dealing with financial arrangements for public health insurance, and in particular with the composition of the Health Insurance Fund, the package of health expenses coverage for those with a compulsory health insurance (based on the Health Insurance Act). The Health Insurance Fund is a public financial arrangement for lower income groups that includes what is 'essential health care', but a debated issue is whether or not in vitro fertilisation is part of this. In the Health Insurance Council, medical professionals, health fund organisations, employers, trade unions and independent members are represented. It has not only an advisory function but also delegated powers to allocate subsidies, such as for research, and both are relevant regarding access to ART, in particular in vitro fertilisation. Formally, both the Health Council and the Health Insurance Council are not policy-making arenas, but their recommendations are important for the image of ART and, in this indirect way, for policy content. The beliefs within the Health Council with respect to ART reflect the prominence of medical professionals within this body; scientific advances and improvement of the quality of human life have driven most of the recommendations. The central belief underlying the input of the Health Insurance Council to policy-making seems to be equal access to

services, though it has refrained from clear policy advocacy – decisions on incorporation of in vitro fertilisation into the health insurance fund were left to political actors.

These advisory bodies to the government, with a fixed position for the organised medical profession, are key institutions in the health policy subsystem. As such, the supply side for ART within the health policy subsystem is extremely important for the definition of problems, the image of ART and, subsequently, for the contents of policy design.

Clients of ART in search of arenas

The most significant organised actors on the demand side for assisted reproductive technologies are the Dutch Association for In Vitro Fertilisation (Nederlandse Vereniging voor Reageerbuisbevruchting, NVRB), in 1995 renamed Freya (after the god of fertility), and the Association for Juvenile and Family Law (Verening voor Familie- en Jeugdrecht, VFJ). The goals of these two organisations differ, but they are not contradictory. Freya intends to represent the interests of all those with fertility problems, defines infertility as a medical and not as a 'luxury' problem, and promotes enlarged access to infertility treatments. It does not, however, promote an unconditional use of the technologies in practice, and acknowledges that medical and social limits exist.[16] The VFJ, the Association for Juvenile and Family Law, represents the legal interests of children born following artificial insemination by donor or in vitro fertilisation, as well as the interests of egg and sperm donors. It is not opposed to use of ART as such, but seeks to expand legal guarantees and rights. Freya in particular was consulted, on an *ad hoc* basis, by the Health Council, but it did not engage in active lobbying in the political arenas.[17]

Other organisations and social groups have also tried to influence agenda setting and policy images, but for these actors access to the policy subsystem and to the broader political arenas has been rather limited. Generally, the representation of clients is much less institutionalised within the policy subsystem than is the participation of medical professionals. Client organisations that were able to have a say in policy design did this in *ad hoc* consultations, not as players with a fixed position in the arenas of the health policy subsystem, and even less as active lobbyists in the political arenas.

Designing policy: interaction between politics and expertise

In the Dutch political system arenas the accommodation of value conflict is imperative, and this puts emphasis on appeasement rather than on setting clear priorities and making policy innovations. Morality issues such as ART are discussed during government formation, when coalition parties use this informal setting to make substantive or, more often,

procedural agreements that are usually vague enough to avoid any party seeing its values threatened.

The other important institutional feature is that the health policy subsystem contains institutionalised bodies in which medical, ethical and financial issues are dealt with. The presence of arenas in a position between politics and the community of medical professionals is extremely important for transforming difficult problems into substantive policy alternatives. The Health Council in particular has influenced the image of ART, through its fixed position and its expert authority. The many occasions on which the Health Council considered assisted reproduction were used by successive coalition governments for depoliticisation. In assessing the impact of Health Council reports dealing with in vitro fertilisation, Schroër (2001) found that the most significant recommendations were adopted in policies. In 1986, when the Health Council released its first main report on in vitro fertilisation, the definition of the problem (infertility is a medical problem for which a medical solution is becoming available) was largely adopted when the government set out to formulate procedural regulation, and the incremental policy changes made since then have often been based on Health Council reports. At the end of the 1990s, the Health Council gave systematic consideration to embryo research, and advised the government to curtail embryo research, but permit the creation of embryos specifically for research (Gezondheidsraad 1997a, 1997b, 1999). These recommendations were also taken into account, but they were less decisive for the contents of the new bill than in earlier cases of regulation. The government, supported by a parliamentary majority, did not adopt the proposal to permit the creation of embryos for research, but instead formulated a number of strict medical conditions. The Embryo Act that was approved in the autumn of 2002 resulted more from policy designing within the political arenas than had previous policy decisions. This is interesting, because issues of embryo research involve the deepest ethical dilemmas.

Nonetheless, the emerging pattern suggests a dynamic in the relationship between politics and expertise – between political decision-makers and medical experts. In this dynamic, value divergence leads to political stalemate and to a de facto delegation of policy designing away from political arenas to bodies of expertise – provided that there is a 'sense of urgency' for political actors to engage in policy-making in this field at all.[18] Moreover, the risks that are involved in sharing political responsibility for policy (whatever the locus of initial design) induce political actors to make procedural rather than substantive regulation. This type of delegation of designing policy contents and the focus on procedures becomes less salient when values are more convergent and political consensus is possible to reach, or already exists. Under these conditions, coalition politics is more conducive to policy contents.

In the Dutch case this dynamic has an institutional foundation: the rules of policy-making in the Dutch health policy subsystem require con-

sultation of the Health Council, whatever the degree of conflict. Thus, political controversy, or the deliberate attempts to suppress it in Dutch politics of accommodation, induced the government to rely heavily on expert knowledge from the Health Council and use this knowledge for policy designs that themselves were mostly procedural. The community of medical practitioners was expected to fill this in through self-regulation. This knowledge may itself have contributed to political consensus building, but political parties have their normative limits as to what they can and want to learn in the policy process. Values and beliefs on which political parties base their identities are usually quite inelastic and uncompromising (Sabatier 1999a). For this reason, the possibility of reaching political consensus (and a legislative majority) on issues in this field depends largely on which political actors are directly involved in consensus building. In the Dutch case, this set of actors is fixed for four years: it is the government coalition, in which the informal rules of the game leave little space for unilateral action by individual parties.[19] The shift in government in 1994 marked the actual beginning of policy-making on embryo research issues. In this process the Health Council continued to be important, but the emergence of agreement within the coalition – and by implication the broadened basis of parliamentary support – reduced the need to follow the recommendations of the Health Council. Expert authority was less necessary for depoliticisation of the issue.

Conclusion: conflict, consensus and the politics of expertise

Value dissent and uncertainty lead to high transaction costs of policy-making on ART. The choice made explicitly or implicitly by political actors in the Netherlands to avert the problems surrounding regulation of medical practice, and in particular embryo research, has been politically rational. Klein (1993: 204) argues that conceding medical autonomy is a sensible political strategy for diffusing blame, and Johnson (1993: 151) points at the undermining effects of destabilising professional jurisdiction for the legitimacy of official action. This explains the focus on procedural government regulation and the alleged confidence in self-regulation within the medical community. It also explains the incremental nature of policy-making over time in the Dutch case.

The institutional setting is important in that the fixed position of the Health Council facilitated (or even implied) the transfer of issues from the political arenas to the Health Council as a subsystem arena. This channelled the risk-avoidance strategies of coalition parties. In this institutionalised relationship, scientific expertise provides the concepts and images of the technologies that policy-makers use to depoliticise and accommodate divergent values. The decomposition of problems in which different technologies and aspects of these technologies are dealt with separately is a result of this relationship.

These features of Dutch consensus democracy in the field of health policy suggest that the 'boundary work' between medical scientific expertise came close to the technocratic model, at least until the late 1990s.[20] In this model, scientific expertise prevails over politics. That is, experts may not have formal decision-making power, but in effect they shape and control problem definitions and images of technologies (Hoppe 2002: 39–43). In this way, they also feed policy design. This is a form of depoliticisation that serves politicians well. The technocratic model of boundary work results from a choice made by politicians, and does not always mean that experts aggressively try to gain control of the policy process. The relationship thus involves mutual gains, because the autonomy of the medical community is not constrained by substantive policy interventions, and policy-makers can resort to codifying medical practices and avoid hard policy choices. Hence the emphasis on planning and control in policy decisions until the mid-1990s. This managerial orientation in policy-making may be a more general phenomenon, but the technocratic model of boundary work relates also to another point that is specific to ART: it is a new policy field full of scientific uncertainties, ethical dilemmas and political risks.

One final point to be made in relation to policy-making and the nature of boundary work is that a structural asymmetry exists in representation of interested parties. The organised medical profession has a fixed position, as in the Health Council, and is more directly involved than client organisations, who are mostly consulted on an *ad hoc* basis. Social groups such as feminists with concerns about the technologies – supportive or critical – have still less access to policy arenas in the system or the policy subsystem. Freeman (2000: 112–15) observes that client participation is a general weakness in health policy-making. This may sustain the technocratic model, in that lay knowledge and the voice of users have a weak basis of representation. In assessing recent public debates on cloning, the Institute of Technology Assessment signals a 'privatisation of life ethics' in which moral intuitions are banned from the public debate (Swierstra 2000: 138). This tendency contrasts with the recent political consensus formation and legislative activity on embryo research, in which substantive choices were made. This last development may suggest that boundary work in policy-making on ART is moving in a direction where politics and expertise are more in dialogue. The democratic challenges in this possible change however remain the ones that are almost intrinsic to the Dutch politics of accommodation: how to channel the social demand for user and citizen participation in the policy process.

Notes

1 Staatscourant, 31 July 1989.
2 Wijziging Planningsbesluit in vitro fertilisatie (Staatscourant, 29 May 1990).

3 Intrekking Wijziging van de Wet inzake medische experimenten i.v.m. regels inzake handelingen met menselijke embryo's en geslachtscellen (Handelingen Tweede Kamer 1994–95: 23016, no. 7); Notitie regelgeving inzake enige handelingen en wetenschappelijk onderzoek met embryo's en foetussen (Handelingen Tweede Kamer 1994–95, 16 March 1995).
4 Richtlijn Indicaties voor IVF (NVOG 1998a).
5 Richtlijn Hoogtechnologisch draagmoederschap (NVOG 1998b).
6 Planningsbesluit in vitro fertilisatie (Staatscourant 1998, no. 95).
7 Wijziging regeling subsidiëring Ziekenfondsraad in vitro fertilisatie (Staatscourant 1998, no. 84).
8 Besluit verbod geslachtskeuze niet-medische redenen (Staatscourant 26 May 1998).
9 Wijziging Planningsbesluit in vitro fertilisatie (Staatscourant 14 December 2000).
10 Also in March 2002, the government submitted a bill on xenotransplantation, containing a general prohibition. The government however left open the possibility that the responsible minister may redefine xenotransplantation, which then could affect (limit) the scope of the prohibition.
11 Moreover, Freya, the clients' association for assisted reproduction, reports that switches from the public health insurance fund to a private insurance program are sometimes not allowed in case a client undergoes IVF treatment. For information on Freya's mission and activities, see the organisation's website at www.freya.nl.
12 *De Volkskrant*, 16 March 2002.
13 The Abortion Act was approved in 1981 and took force in 1984. For an account of abortion policy-making in the Netherlands, see Outshoorn (1986).
14 This limited set of relevant actors has appeared from interviews in which the reputation was used, and from re-analysis of secundary information sources, in particular Kirejczyk (1996) and Schroër (2001).
15 See, for example, *NRC Handelsblad*, 30 March 2002.
16 Information obtained from the Freya website.
17 Interview with Jelle van Lenthe, president of Freya.
18 As pointed out earlier in this chapter, ART was first placed on the policy-making agenda in the mid-1980s and kept re-appearing in the 1990s.
19 Unless the government resigns before the end of its Constitutional term in office.
20 On the concept of boundary work and the forms it may take, see Jasanoff (1990) and Wittrock (1991).

10 Germany

ART policies as embryo protection

Christine Rothmayr and Celina Ramjoué

Introduction: from embryo protection to stem cell research[1]

The core piece of German legislation on assisted reproductive technology (ART) is the Embryo Protection Act (Embryonenschutzgesetz, EschG), adopted in 1990. In order to protect the embryo, the EschG declares different types and uses of ART to be criminal and thereby formulates very restrictive policies with respect to applying ART and conducting research in the field. The EschG is narrowly focused on embryo protection, and does not comprehensively address ART. Up to now, attempts to adopt a comprehensive act on ART on the federal level have failed to materialise.

The most recent Parliamentary decision, the Stem Cell Act (Stammzellengesetz, StZG) adopted in 2002, addresses embryonic stem cell research. Deriving stem cells from embryos within Germany is prohibited by the EschG. The Stem Cell Act stipulates the conditions under which stem cell lines might be imported from abroad, and the conditions research projects using imported stem cell lines must meet. The StZG therefore renders stem cell research in Germany possible. How has it come about that a country prohibits deriving stem cells from embryos for research purposes on its own territory, but at the same time aims to render research on embryonic stem cells possible by importing stem cell lines from abroad?

The following analysis aims at explaining how it came about that ART was framed almost exclusively in terms of embryo protection on the national level, why no comprehensive federal act on ART has ever been adopted, and why the policies overall turned out to be very restrictive. Furthermore, we will analyse how a compromise was found that on the one hand kept to the very strict doctrine of embryo protection, but at the same time opened up the possibility for German researchers to participate in the international competition with respect to research on embryonic stem cells.

A very restrictive design

Overall, the policy design aims at protecting the embryo (EschG), respecting and protecting human dignity and the right to live, while granting the

freedom for research (StZG §1). In order to do so, the authoritative decisions strongly restrict the autonomy of the medical profession and clearly limit access in terms of marital status and sexual orientation.

The core authoritative decision of German policy design is the Embryo Protection Act of 1990. In terms of instruments, the EschG almost exclusively governs ART by declaring certain techniques and practices to be criminal offences. By doing so, it fully prohibits egg donation, embryo donation and pre-implantation diagnostics, and declares the transfer of more than three embryos to a woman within a cycle to be a punishable offence (§1(3) EschG). It prohibits the creation of an embryo for any other purpose than transferring it to the woman from whom the egg comes in order to induce a pregnancy. Any research on embryos and totipotent cells is declared a criminal offence. Finally, it states that only a doctor is allowed to practise ART and that there is no obligation for a doctor to participate in applying ART. Because the law takes the form of criminal provisions, potentially anyone (not just the doctors) is the target group of the Embryo Protection Act. The Act on Adoption Arrangements, which was amended in 1989 in order to prohibit commercial surrogacy, also has criminal provisions and potentially addresses any person.

The Stem Cell Act generally prohibits the import of stem cells, and then formulates under which conditions a research project might still use imported stem cells. The examination regarding whether a project meets the conditions is performed by a newly created Central Ethics Commission for Stem Cell Research (Zentrale Ethik-Kommission für Stammzellenforschung). Violations of the Act can be punished with imprisonment or fines. Thus, in contrast to the Embryo Protection Act, the Stem Cell Act uses a mix of instruments.

Owing to their legally binding character, the *Guidelines on Assisted Reproduction* of the German Medical Chamber, last updated in 1998, are also part of the policy design. The binding medical guidelines repeat some of the prohibitions formulated in the EschG, but they add further limitations. Through a combination of quality standards, information and counselling requirements, reporting and documentation duties, and various regulations on how and when to practise what type of technique, they further limit the autonomy of individual doctors (see Table 10.1).

Overall, the picture regarding access is twofold (see Table 10.2). The design clearly limits access in terms of marital status and sexual orientation, but grants relatively broad insurance coverage for married couples.

In terms of marital status and sexual orientation the eligibility is clearly limited to married and, on a case-by-case basis, to stable unmarried couples. The EschG does not answer family law questions. As a consequence of this omission, medical self-regulation tries to avoid creating situations of legal uncertainty, and therefore discourages the use of donor sperm and limits the access of non-married couples to a case-by-case basis.

Insurance coverage for married couples, however, is broad in terms of

Table 10.1 Autonomy in Germany

		Autonomy	
Basic techniques			
Insemination (1)		L	1
GIFT/ZIFT (2)		L	1
IVF/ET (3)		L	1
Total 9: 0–1 no or close to no (N), 2–4 low (L), 5–7 medium (M), 8–9 high (H)		*L*	*3*
Related techniques			
Surrogacy (4)		N	0
Donation (5)	sperm: 5a	L	1
	egg: 5b	N	0
	of embryos/impregnated eggs: 5c	N	0
Cryopreservation (6)	sperm: 6a,	L	1
	egg: 6b	L	1
	of impregnated eggs 6c	L	1
	embryos: 6d	L	1
Pre-implantation diagnostics (7)		N	0
Genetic selection (8)		N	0
Gender selection (9)		L	1
ICSI (10)		L	1
Max. 36: 0–5 no or close to no (N), 6–17 low (L), 18–29 medium (M), 30–36 high (H)		*L*	*7*
Research/experimental techniques			
Genetic engineering (11)	on gametes/germ cells (11a)	L	1
	on impregnated eggs, embryos (11b)	N	0
Research (12)	on gametes/germ cells (12a)	L	1
	on impregnated eggs, embryos, zygotes (12b)	N	0
Cloning (13)		N	0
Chimera and hybrid building (14)		N	0
Max. 18: 0–2 no or close to no (N), 3–8 low (L), 9–14 medium (M), 15–18 high (H)		*N*	*2*
Total of all three groups of techniques (max. 9): 0–1 no or close to no (N), 2–4 low (L), 5–7 medium (M), 8–9 high (H)		*L*	*2*

Note
L, low; N, no; 1 = low.

techniques and number of cycles covered. Unmarried couples, if granted access, have no right to insurance coverage. Since 1990, insurance coverage for ART has been regulated by the Social Code (Sozialgesetzbuch). The detailed terms of insurance coverage are specified by the National Committee of Physicians and Sickness Funds (Bundesausschuss der Ärzte und Krankenkassen). Coverage by the statutory health insurance funds could be seen as a logical consequence of the EschG justifying the use of

Table 10.2 Access to ART in Germany

		Access	
Basic techniques			
Insemination (1)	with gametes of the couple (1a)	M	2
	with sperm donation (1b)	M	2
GIFT/ZIFT (2)	with gametes of the couple (2a)	M	2
	with sperm donation (2b)	M	2
IVF/ET (3)	with gametes of the couple (3a)	M	2
	with sperm donation (3b)	M	2
	with egg donation (3c)	N	0
	with embryo donation (3d)	N	0
Max. 24: 0–3 no or close to no (N = 0), 4–11 low (L = 1), 12–19 medium (M = 2), 20–24 high (H = 3)		*M*	*12*
Related techniques			
Surrogacy (4)		N	0
Cryopreservation (6)	sperm (6a)	H	3
	egg (6b)	N	0
	impregnated eggs (6c)[a]	M	2
	embryos (6d)	N	0
Pre-implantation diagnostics (7)		N	0
Genetic selection (8)		N	0
Gender selection (9)		M	2
ICSI (10)		M	2
Max. 27: 0–4 no or close to no (N = 0), 5–13 low (L = 1), 14–22 medium (M = 2), 23–27 high (H = 3)		*L*	*9*
Total of all two groups of techniques (max. 6): 0 no (N), 1–2 low (L), 3–4 medium (M), 5–6 high (H)		*M*	*3*
For Element 1: Weights for total of all two groups of techniques (N = 0), (L = 4), (M = 8), (H = 12)		*M*	*8*
For Element 2: Judgement for financial coverage of ART (0–3)			*2*
Total of Element 1 and Element 2 (0–15)			*10*

Note
L, low; M, medium; H, high; N, no; 1 = low; 2 = medium; 3 = high.

ART: given that the broad majority of Germans are covered by mandatory health insurance funds, excluding insemination and IVF from coverage would mean excluding the vast majority of the Germans from using these techniques. However, courts have always acknowledged coverage of IVF and insemination without donor, and paved the way for the respective changes of the Social Code (Laufs 1992: 62).[2]

The main implementers of the policies just described are the Länder Medical Chambers, the Sickness Funds and the Ministry of Public Health. As a criminal law, the EschG does not explicitly mention any implementers. The Stem Cell Act is implemented by an administrative unit of

the Ministry of Public Health and a newly instituted Central Ethics Commission for Stem Cell Research. The main implementers of medical guidelines are the Medical Chambers themselves. The Länder are indirectly involved in implementing the design. They are in charge of approving the professional code of the Länder Medical Chambers declaring professional guidelines on ART, elaborated by the Federal Medical Chamber, as binding.

The two sequences of the designing process: a brief overview

The use of the IVF technique in Germany from 1981 onwards (Orland 1999) and the development of biotechnology in general (see for example Benda Report 1985) pushed the issue onto the political agenda in the mid-1980s. The medical profession was the first actor to issue a binding decision. Professional law has regulated ART in Germany since 1985. Such a binding self-regulation was facilitated by the way the medical profession is organised. The Länder Medical Chambers self-regulate their profession with the Medical Professional Code, which has to be approved by the Länder authorities and which constitutes binding law for the profession. The Federal Medical Chamber elaborates the model for this Professional Code. In 1985 the German Federal Medical Chamber elaborated guidelines on how to practise IVF and ET, which the Länder Medical Chambers integrated into their Medical Professional Code. The *Guidelines on Assisted Reproduction*, first issued in 1985, were subsequently updated in 1988, 1991 and 1998 in order to take into account technological progress and new legislation.

At the same time as the medical profession adopted their guidelines, the first concrete recommendations regarding what legal measures should be designed were elaborated by a joint expert group of the Federal Ministry of Justice and the Federal Ministry of Research and Technology, the Benda Commission (Benda Report 1985: 1, 49–51). Its recommendations, published in 1985, strongly built upon existing self-regulation and, in comparison to the bill introduced to Parliament and the finally adopted EschG, its recommendations were considerably less restrictive and also broader, not only focusing on embryo protection. The majority of the commission held, in particular, that some forms of embryo research might be acceptable.

This report led to a first proposition from the Ministry of Justice for discussing the adoption of an Embryo Protection Act in 1986 (Bundesminister der Justiz 1986). This clearly led towards the later adopted Embryo Protection Act by proposing that certain practices and techniques be declared criminal acts. To adopt restrictions as criminal measures was in the power of the federal government (GG Art. 74 (1)), while adoption of a comprehensive federal law on ART would have implied a change of the basic law, which needs a two-thirds majority in both chambers.

Compared to the later adopted Act, the design of this working draft was significantly less restrictive with respect to several techniques and to research. Notably, it did not contain prohibitions of egg and embryo donation, or using IVF for surrogate mothers, and it did not prohibit a transfer post mortem. Furthermore, it did not fully prohibit embryo research. The government sent this draft for informal consultation with the parliamentary groups of the German Bundestag, the other Federal ministries, the Länder, and different interest groups and organisations (Eser *et al.* 1990: 39).

While the government had been elaborating a first draft for the EschG, the Länder had not been inactive. Given that the Länder are important players in health care provision and the supervision of the medical profession, they engaged early in the debate on ART. Several Länder started to elaborate propositions for state laws from 1985 onwards, namely Bavaria and Rhineland-Palatine, where the Christian Democrats were in power. However, these bills were never adopted (Abschlussbericht Bund-Länder-Arbeitsgruppe 1988). At the same time, the Länder became active in the Bundesrat. On the initiative of Baden-Württemberg and Bavaria, and after being discussed in various committees, the Bundesrat decided that the Länder, together with the Bund, needed to elaborate a comprehensive concept for legislation in the field (BR-Drs. 210/86). This decision led to the institution of a common working group of the Federal government and the states (Bund-Länder Arbeitsgruppe).

The report of the common Working Group (Abschlussbericht Bund-Länder-Arbeitsgruppe 1988) recommended legislating comprehensively on ART through a combination of federal criminal law and laws on the Länder level. In addition to the government draft from 1986, the report recommended prohibiting egg and embryo donation, insemination and transfer post mortem, limiting the number of eggs to be fertilised for ET, regulating the possibilities for cryopreservation, the selection of the sperm donor, documentation duties regarding the donor, and access rights to this information for the child. With respect to research, the report proposed not only prohibiting the production of embryos for research purposes, but also research on 'left-over' embryos as well as any pre-implantation diagnostics on totipotent cells. Given that it was not yet possible to regulate all these questions in one federal law, they proposed a federal law combined with a model law for the Länder.

Shortly after the publication of the Bund-Länder Working Group's report the Ministry of Justice elaborated a second proposition for an Embryo Protection Act (Bundesminister der Justiz 1988), which turned out to be more restrictive, and certainly intervened more in the autonomy of the doctors and researchers, than that recommended by the Benda Commission and designed in the first discussion proposition. The government informed both chambers about the ongoing work in February 1988 (BT-Drs. 11/1856 und BR-Drs. 58/88), but did not yet introduce it into

Parliament. Its content, however, corresponded to the bill introduced to Parliament in 1989.

Following the parliamentary debate the governmental bill was altered slightly, based on some smaller changes proposed by the Bundesrat and retained by the preparing commission of the Bundestag, the Committee of Legal Affairs. Given its clear majority in the Bundestag, the governmental coalition passed the bill with no difficulties against the votes of the opposition, whose propositions and motions did not win a majority. The Social Democrats had introduced a counter-proposition in the form of two motions; one to change the Basic Law, and the other proposing to adopt a comprehensive law (BT-Drs. 11/5709 and 11/5719). Furthermore they had introduced two propositions for changing the governmental bill, asking for prohibition of sperm donation and gender selection (BT-Drs. 11/8191 and 11/8192). The Greens had introduced a proposal for a resolution on ART proposing to prohibit basically all ART, in particular IVF (BT-Drs. 11/8179).

In short, the governmental bill, with its narrow focus on embryo protection, prevailed against propositions for more comprehensive federal legislation. It also limited more permissive propositions, particularly in terms of embryo research, and restrictive ones as proposed by the parliamentary opposition. Finally, a comparison of the first government proposition for a law with the finally introduced bill reveals that the governmental draft was rather restrictive from the beginning, but became even more so over time. It was only in 1994 that German Basic Law was effectively amended to include ART as one of the domains in which the federal government has the prerogative to legislate. A comprehensive federal law on ART, however, has not yet been adopted.

ART once again became a controversial debated issue at the end of the 1990s, because existing legislation did not cover some of the new techniques and some of the political actors were not satisfied with the existing design. The new debate focused in particular on stem cell research and pre-implantation diagnostics. So far this new round of political debate has led to one new Act, the Stem Cell Act, which was adopted in 2002.

Different actors contributed to pushing ART onto the political agenda again. The Ministry of Public Health took the initiative to propose a revision of the EschG that would also address the newer issues of pre-implantation diagnostics, and organised a conference in Spring 2000 to discuss the issue. For different reasons, the project of comprehensively revising the existing EschG was abandoned. The Green Minister of Public Health who had launched the revision had to step down in January 2001. Furthermore, the Chancellor had a more liberal vision of how to regulate ART than that promoted by the Green coalition partner. Finally, the Bundestag itself put the issue on the political agenda again by instituting an Inquiry Commission on Law and Ethics in Modern Medicine (Enquetekommission Recht und Ethik der modernen Medizin, Plenarprotokoll 14/96, 24 March 2000) in March 2000.

Because of international competition and the pressure imposed by different interested parties, in particular research interests, the political debate focused first on stem cell research. Based on the Inquiry Commission's report on stem cell research, different propositions on how to regulate the issue were introduced to Parliament and sponsored by groups of representatives cutting across party lines (BT-Drs. 14/8101, 14/8102, 14/8103). One motion called for a complete ban, a second wanted to admit import under strict conditions, and the third motion also wanted to allow import of stem cells while stipulating that if existing stem cell lines were not sufficient, the Bundestag would change the EschG in order to allow the use of stem cells derived in Germany. Interestingly the three propositions were supported by coalitions crossing party lines by including important leaders from different parties. Leaders from the Social Democrats, the Christian Democrats and the Greens sponsored the first motion. The Social Democrats and also some leaders from the Christian Democrats supported the second motion. The third motion was sponsored by the Liberals, and also included members of the Christian Democrats. Given the divisions within the major political parties, the Bundestag decided to allow for a free vote. The proposition to allow for importing stem cell lines under strict conditions won after two rounds of voting (Plenarprotokoll 14/214: 21239-61). Although the stem cell research question is regulated for the time being, the question of whether to allow preimplantation diagnostics has not yet been addressed by legislation or by a revision of the existing law.

Framing ART policies in terms of embryo protection

The framing of ART policies in terms of embryo protection is the first factor that we consider for the final, restrictive design. The German Constitutional Court is a potentially influential actor offering a venue to the opposition to counteract decisions of the governmental majority (Landfried 1994). In 1975 the Federal Constitutional Court declared the abortion law to be unconstitutional, and stated that the constitutional protection of human dignity (Art. 1 GG) and the right to life (Recht auf Leben, Art. 2 GG) applies to the embryo after implantation (Wilde 2001: 183–5). The State accordingly recognised the obligation to protect the embryo. This jurisprudence on the protection of the embryo strongly contributed to framing ART in terms of embryo protection. The importance of jurisprudence was reinforced by the fact that the opponents of the decriminalisation and liberalisation of abortion in 1975, the Christian Democrats, were now in government. Overall, the debate regarding the EschG must be interpreted as judicialised politics.

The framing of ART as a constitutional question of embryo protection attributed an important position to the Department of Justice, which took the lead in elaborating the EschG. It also gave a strong position to legal

experts during the whole debate. From a constitutional point of view, the question was whether the same protection that applied to the embryo after implantation also applies to the embryo in vitro. The legal opinion that dominated the debate was that the human dignity clause of the Basic Law applied to the embryo from the moment of fertilisation of an ovum (Kuhlmann 2001: 78–9), and the finally adopted EschG effectively extended protection to the embryo in vitro. This prevailing interpretation of constitutional protection of human dignity and human life contributed, together with other factors, to the adoption of a very restrictive act.

Not surprisingly, the constitutional debate was also a very important point of reference in the recent stem cell research debate. Even though the Stem Cell Act allows for embryonic stem cell research with imported stem cell lines, the interpretation that the human dignity clause and right to live clause of the Basic Law also apply to the embryo in vitro, underlying the EschG, continued to be raised as an issue in the debate.

The actor constellation

The EschG was elaborated and adopted under a coalition government of Christian Democrats (CDU/CSU) and Liberals (FDP). The governmental coalition controlled a majority in both chambers during the whole designing process, except in the Bundesrat in 1990 (Sturm 2001: 169), where the opposition had an absolute majority. Despite its clear majority, the governmental coalition took several years to elaborate the Embryo Protection Bill and introduce it to Parliament. The government sent two drafts for informal consultation among interested groups and parties before presenting the bill to Parliament. By doing so it encouraged a public debate (Hampel *et al.* 1998: 71), which was considered necessary because ART was a novel issue and also because the opinions among political parties and interest groups on how to legislate on ART were divided and reached from total prohibition to fairly permissive policies based on the self-regulation of the physicians. Opinions within the political parties and also within the coalition were not unanimous either. During the pre-parliamentary phase, the opposition from the left together with other interest groups, namely the churches, successfully mobilised the public and thereby contributed to making the governmental proposition more restrictive. Furthermore, the analysis of the position of the different parties and interest groups clearly shows that, with the exception of the organisations representing medical and research interests, all relevant actors advocated restrictive to very restrictive policies.

Party preferences and the mobilisation of the left

The government parties promoted restrictive policies, but did not want to prohibit these new techniques fully. The government aimed at protecting

the values of the constitution, in particular the human dignity and the well being of the child (BT-Drs. 11/1856 and 11/5460). The government coalition advocated a strong protection of the embryo, and thereby continued the policy of the Christian Democrats towards abortion. In comparison to the abortion debate, the government was now facing an opposition from the left promoting even more restrictive policies, yet on the ground of different beliefs.

The Social Democrat and Green opposition promoted even more restrictive solutions than the government coalition of Christian Democrats and Liberals. The Greens perceived IVF as an instrument to control the reproductive behaviour of women, and argued that IVF was not a therapy but a doubtful experimental technique that not only included considerable health risks for the women but also promoted eugenic thinking. They proposed a total prohibition of IVF and any type of embryo research, and considered the EschG to be insufficient to prevent the dangers and misuse of ART (BT-Drs. 11/8179).

Compared to the Greens the position of the Social Democrats was less radical, but they still asked for more restrictions than the government proposed. For them ART included the possibility of helping childless couples but also implied different dangers, namely those of dividing sexuality and procreation and thereby depersonalising sexuality, and of the danger of eugenic uses, which violate human dignity. In order to protect human dignity, the Social Democrats wanted to set tight limits to ART and prevent abuse through criminal sanctions. They proposed a combination of different instruments, such as information and documentation duties and licensing, as well as full prohibition. In addition to the prohibitions included in the EschG, they promoted total prohibition of cryopreservation of embryos, gender selection and the use of donor sperm (BT-Drs. 11/5710, 11/8191 and 11/8192).

The position of the left was motivated by different factors: a very important one was certainly the experience of World War II and the importance of anti-fascism in the self-understanding of the left. ART was understood as opening the door for eugenic uses, which needed to be counter-acted by total prohibition or at least prohibition of any selection mechanism. The critical attitude of the left was also based on sceptical attitudes towards research and science in general, due to the role that the medical profession had played during World War II. Finally, feminist arguments and policy beliefs with respect to population policy and the relations between the First and Third Worlds played a strong role among the Greens.

During the pre-parliamentary phase the opposition, or more precisely the 'New Left', successfully influenced government propositions by mobilising the public during the debate that emerged in the second half of the 1980s. The 1980s in Germany were characterised by strong social movements, in particular environmental and feminist movements, but also

anti-nuclear and peace movements, motivated by a strong distrust of political and scientific elites (Hampel *et al.* 1998: 71). The Green and feminist critics started to mobilise against ART from 1985 onwards (Betta 1995: 115), by organising a convention about 'Women against Genetic Engineering and Reproduction Medicine'. A second convention about biomedicine followed in 1988. Early on the feminist and Green critics thereby linked reproductive medicine and biotechnology in general. Furthermore, there were also other extra-parliamentary actors that advocated restrictive policies, such as the Churches. The German Bishop's Conference and the Protestant Church established a common working group. They based their policy position on the belief that the embryo is a human being right from the moment of fertilisation and has a right to be protected. Both Churches were against using IVF, and wanted, if IVF should be allowed at all, strict measures to be taken (Evangelische Kirche Deutschlands und Deutsche Bischofskonferenz 1989).

The mobilisation of public opinion by the left played a role in making the government proposition more restrictive. Another explanation focusing on party politics also needs to be considered. From 1983 onwards the Greens were also represented in the Bundestag, with 5.6 per cent of the votes and 27 out of 498, in 1983 enlarging their representation to 42 seats out of 497 (8.3 per cent of the votes) in 1987, mostly at the expense of the Social Democrats (Jefferey 1999: 109–12). From a party political point of view, the policies advocated by the New Left might have been relevant for the Social Democrats. The newly emerged competition for votes between the two leftist parties made it more difficult for the minority within the party to advocate more permissive policies in order to make their voice heard, and may also have contributed to the Social Democrats' advocacy of very restrictive policies. Thus Christian Democrats were facing an opposition asking for more restrictions in a field, the 'protection of unborn life', where they traditionally had occupied a more conservative position than the left. This actor constellation made it difficult for research and medical interests to form a coalition with one of the two big parties in order successfully to influence the final result, even though they participated in several commissions and consultation procedures in the pre-parliamentary stage.

Medical and research interests: advocating self-regulation and moderate restrictions

From the researchers' point of view, the German Research Council (Deutsche Forschungsgemeinschaft) and also the Max-Planck-Gesellschaft defended the freedom of science (Freiheit der Wissenschaft) written in the constitution, and strongly criticised the first proposition for an EschG from 1986. They clearly voiced the opinion that self-regulation was sufficient and that any federal law must not prevent scientific development in

the field. Embryo research up to the fourteenth day should be permitted under certain conditions, and even the production of embryos should not be fully prohibited, but permitted if necessary, because the advancement of medicine can be expected to prevent the production of any surplus embryos in the future (Deutsche Forschungsgemeinschaft 1987). Under pressure of public opinion, the German Research Council and the Max-Planck-Gesellschaft declared a moratorium on embryo research in 1988 (Betta 1995: 102).

With regard to embryo research, the Federal Medical Chamber elaborated guidelines that were, from a strictly legal point of view, not part of the professional code (Eser *et al.* 1990: 70). It declared cloning, chimera and hybrid building to be inadmissible, and also that embryos must not be created solely for research purposes. At the same time they allowed research under certain conditions up to the fourteenth day of development, under the condition that the Ethics Committee of the Medical Chamber of the Land or the university approves the project.

In contrast to the guidelines on embryo research, the guidelines on ART adopted for the first time in 1985 through amending the Professional Code were binding professional law. Violations of the professional code could be pursued in court. The self-regulation of ART specifies the professional prerequisites, medical indications and information duties of doctors, and at the same time states who should have access and which techniques should be practised. The self-regulation specifically rejects surrogacy and suggests limiting IVF to married couples while using the gametes of the couple. Cryopreservation of embryos is accepted under certain conditions, and the revised self-regulation from 1988 adds that the creation of embryos solely for research purposes is inadmissible.

If we now compare the propositions of the Benda Commission, the first draft for the EschG, the governmental bill and the EschG with the policies advocated by the associations and organisations representing research interests and the medical profession, we may formulate two conclusions: (1) the propositions of the Benda Commission came closest to the preferences of the medical community and the research interests, and (2) the DFG and the Federal Medical Chamber did not succeed in realising their policy preferences – the finally adopted EschG turned out to be considerably more restrictive than they had wished.

The Länder and the Bundesrat: promoting a comprehensive law

Federalism played a role in different ways. The way German federalism works was relevant for the non-competition between the Länder and the national self-regulation of the physicians. There was bottom-up pressure by the Länder to adopt policies, and they also influenced the governmental proposition into a more restrictive direction. However, they did not

succeed in realising their policy goals because of the strategy chosen by the government to adopt a criminal law focusing on embryo protection, and the diverging positions among the Länder.

The Länder did elaborate and discuss propositions on how to regulate the issue of ART at the Länder level, but none of them effectively adopted legislation. The Länder are important players in the health-care sector, because they implement policies and also possess legislative powers. While the federal level formulates the largest part of the legal framework, the Public Health Offices at the Länder level play an important role in promoting and providing health care (including hospital sector), and supervising and organising the medical profession and the local and regional health insurance funds (Wassener 2002). Accordingly, the issue of ART very directly concerned them. Principally it would have been possible for the Länder to adopt their own laws. As long as the Basic Law does not attribute legislative power in a specific matter to the federal level, and that was not the case before 1994, the Länder have the right to take measures. German federalism, however, corresponds rather to the idea of a 'unitary federal state': cooperation between Länder and Bund and cooperation between Länder has the goal of establishing equal legal, economic and general living conditions nationwide (Benz 1999: 136). Competition between the Länder is therefore discouraged, and the Länder did not act unilaterally on the issue of ART.

One venue of cooperation between the federal and Länder level in policy formulation is the institution of common working groups, where the Länder and the federal government try to elaborate a common solution. This was the case in the field of ART. The report of the common Working Group (Bund-Länder Arbeitsgruppe) clearly proposed more restrictions than the first governmental draft from 1986, and it also favoured a more comprehensive legislation. The Working Group proposed either the adoption of a more comprehensive law on the federal level (also addressing problems of kinship and sperm donation, for example), which would have needed a change in the Basic Law in order to attribute the respective power to the federal level, or the combined adoption of federal and Länder legislation using the existing competencies at the federal level, in particular criminal law. The finally adopted EschG met, in terms of restrictiveness, the propositions of the Working Group, but the Länder were not successful in realising their policy goal of a more comprehensive regulation.

The power of vetoing governmental bills depends on the type of bill, whether it is a *Zustimmungsgesetz*, which needs the consent of the Bundesrat, or an *Einspruchsgesetz*, where the Bundestag can override the Bundesrat during the mediation procedure. Because the Upper Chamber represents the Länder governments, different parties or coalition of parties might hold the majority in both chambers. The Bundesrat can therefore also provide a 'power-base' for the opposition that might lead to

gridlock (Sturm 2001: 167). Even though the opposition had a majority in the Bundesrat in 1990,[3] this was not the case during the elaboration of the EschG. In fact, the Bundesrat accepted the EschG as adopted by the Bundestag, and did not call upon a mediation committee (Vermittlungsausschuss). This might have to do with the fact that the Bundesrat could not formally veto the EschG, because it did not need its consent. There are several indications, however, that the Länder accepted the EschG because there were considerable differences among them. Overall, the Bundesrat would have preferred a more comprehensive regulation of ART. The Länder did not, however, agree upon specific details, and therefore supported the government proposition.

In 1994, four years after the adoption of the EschG, the German constitution was effectively changed to give the federal level priority in legislating on ART. There were obviously differences in policy preferences among the Länder with respect to specific questions. These differences, together with the opposition in the Bundestag asking for even more restrictions, seem to have reduced the chance of changing the constitution considerably at this point in time, as a change in the Basic Law requires a qualified two-thirds majority in both chambers. The substantial ART polices first had to be decided, and the issue to be off the political agenda, in order to open up the possibility of winning sufficient support to change the constitution.

The stem cell debate: new government, new policies?

The EschG had established a strong protection of the embryo from its very early stages, including any totipotent cell. The derivation of stem cells in Germany would have demanded a change of the existing legal framework, yet the question of whether stem cell lines could and should be imported from abroad had not been addressed by the policy design so far.

The broad consensus in favour of setting strong limits to research in order to protect the embryo based on different beliefs also persisted in the stem cell debate. The change in government, in particular the active role Chancellor Schröder took in promoting freedom of research, together with the fact that the issue of stem cell research divided opinions within parties, allowed the research interests to prevent a full de facto prohibition of embryonic stem cell research in Germany and to be fully excluded from international competition. The proponents of generally more permissive policies with respect to embryo research did not, however, succeed in changing the existing policy design, but the existing legal gap was closed in favour of their point of view.

The actor constellation was clearly different from that observed during the design process for the EschG, and the strategies adopted and the institutional rules evoked also differ considerably. In contrast to the EschG, the Stem Cell Act was not introduced by the government but was initiated

by the Bundestag based on the report of the Inquiry Commission on Law and Ethics in Modern Medicine. An inquiry commission has the mission of preparing legislation on complex issues by assessing the current state of the art in terms of factual knowledge, but also with respect to opinions about possible solutions, and of formulating possible measures that might be considered for state intervention. The motion for instituting the commission was supported by fractions of the government parties, the SPD and the Bündnis 90/Grüne, as well as by the major opposition party fractions, the CDU/CSU and the FDP (Plenarprotokoll 14/96, 24 March 2000). The reasons for instituting the Commission were twofold. First, given the fast developments in biotechnology and medicine and the basic ethical questions these developments raised (Enquete-Kommission 2001), the parties wanted to initiate deliberation on whether the existing legislation adequately protected human dignity and health while still opening up possibilities for future medical progress. Second, because the issue did not divide parliament along party lines and parties themselves were divided over possible solutions, taking the initiative had advantages. The institution of the Commission allowed the search for a broad compromise and also the possibility of counter-acting the policy preferences of the Chancellor, who was in favour of more permissive research policies.

The Inquiry Commission presented its intermediary report on stem cell research, only one of the issues it dealt with, in November 2001 (BT-Drs. 14/7546). This intermediary report reveals a consensus on how to interpret the legal framework as defined by the EschG. The commission explained that the current law does not prohibit the import of pluripotent stem cells for research purposes. In contrast, harvesting stem cells, or any other research activity that would lead to the destruction of the embryo or any totipotent cell, was prohibited by the EschG. However, opinions were divided on what measures to take in order to close this legal gap or address the issue of harvesting stem cells in Germany by changing the EschG. The majority of the members voted for prohibiting the import of stem cells, and the Commission presented two alternatives for regulating the stem cell research question: (1) either prohibiting the import of pluripotent cells, or (2) admitting it under tight measures of control (BT-Drs. 14/7546).

The Chancellor was clearly in favour of liberalisation of the existing restrictive policies (*Die Woche* 20 December 2000; *FAZ* 3 May 2001), and tried to mobilise the 'modernisation part' within his own party. He clearly supported the policy preferences of the research organisations, the DFG, who had in fact launched a priority program on stem cell research in 2000, but suspended its decision to fund embryonic stem cell research until after the Bundestag decision. In contrast to the EschG, the international competition, as well as decisions made by other countries, seemed to have strengthened the position of the research interests in connection with stem cell research. Furthermore, the decision of the Chancel-

lor to concentrate on stem cell research instead of supporting a total revision as initiated by the former Green Minister of Health further emphasised the freedom of research issue. Shortly after the institution of the Inquiry Commission, which must be understood as a venue or instrument for the Parliament to strengthen its position in the debate, Chancellor Schröder created a National Ethics Commission, which also addressed the issue of stem cell research. The National Ethics Commission must be considered as an expert arena whose composition was decided by the Chancellor's office (Kanzleramt). A majority of the National Ethics Commission was in favour of a temporary import of the stem cells. The National Ethics Commission announced its position only shortly after the publication of the intermediary report in November 2001 (Nationaler Ethikrat 2001).

Parliament did not, however, follow the Chancellor's view, but struck a compromise between the actors wanting to prohibit the import of stem cell lines and the promoters of more permissive research policies in general by not revising the existing protection of the embryo but allowing the import of stem cell lines that met certain conditions. While the stem cell question is now regulated, other controversial issues, such as preimplantation diagnostics, are still on the political agenda.

Conclusion

The core of German policy design is the EschG. We have explained its very restrictive policies as the outcome of the combination of a government advocating restrictive policies and an opposition proposing even more restrictive policies. Furthermore, the analysis of the preferences of interest groups revealed, that with the exception of medical and research interests, all relevant actors advocated restrictive to very restrictive policies. This has to do with the experience of World War II, which rendered all political actors particularly attentive to the pernicious potential of eugenic uses of the new technology and the constitutionalisation of the debate based on the existing jurisprudence with respect to the protection of the embryo. In addition, the strong extra-parliamentary social movements seemed to have formed a relevant broader context for the successful mobilisation of the left against ART in the second half of the 1980s.

The division of power between the federal and the state levels may explain the fragmentary character of the EschG. The adoption of a comprehensive federal law on ART was postponed because the necessary two-thirds majority seemed impossible to reach because of diverging views in both chambers. The necessary change in the Basic Law was realised four years later. However, a comprehensive law has never been adopted, and attempts to initiate a revision in this direction have failed so far. Because of its narrow focus on embryo protection, the EschG does not cover other aspects of ART – in particular the question of access. Insurance coverage has been legitimised and extended through court decisions, but might

also be explained by the organisation of the German health-care system. Finally, because of its limited focus, self-regulation still plays a considerable role and is also relevant to the question of access.

While international competition in medical research does not seem to have played a role for the EschG, it has been more significant for the stem cell debate. The majority of the Bundesrat did not re-design the existing very restrictive policies with respect to embryo protection, but used a gap in the existing legislation to allow stem cell research by importing stem cell lines from abroad. The most recent decision, the Stem Cell Act, therefore continues the very restrictive policies adopted in the early 1990s, but at the same time allows German researchers to participate in the international research competition. Given that opinions within parties were divided, the change in government and the active role of Chancellor Schröder in promoting freedom of research have allowed the research interests to prevent a full de facto prohibition of embryonic stem cell research.

Notes

1 Besides documentary analysis the case used the reputational approach in order to identify the relevant actors: List: 75, Experts: 12, Nominations: 229, Threshold: 2, Result: 33.
2 The health care reform project under discussion in 2003 is likely to abolish insurance coverage for IVF in the near future.
3 In 1990, according to Sturm (2001: 170), the opposition had a majority. Sturm indicates, however, that elections are spread over the whole year, and changes in the federal government occur at different times. The opposition had a majority for most of the year, but whether that was the case at that moment is unclear.

11 Switzerland

Policy design and direct democracy

Christine Rothmayr and Uwe Serdült

Introduction[1]

Assisted reproductive technology (ART) became a political issue in Switzerland during the first half of the 1980s. The beginning of in vitro fertilisation (IVF) practice in Switzerland in the 1980s[2] led to a public debate on ART, and the adoption of public policies. Public policies were first adopted on the sub-national level by some of the Swiss states. However, due to a popular initiative the policy designing process shifted to the federal level. Since 1 January 2001, policy design for ART in Switzerland has been almost exclusively defined by federal law. The design is rather restrictive. It limits strongly the autonomy of the medical practitioner, restricts access to ART in terms of both sexual orientation and marital status, and makes it dependent on the financial capacities of the patient.

The policy-making process that led to these restrictive policies on the federal level involved two popular initiatives proposing amendments or changes to the constitution with respect to ART and, accordingly, Swiss citizens were called to vote twice on ART policies. We may therefore pose the question of whether the very restrictive design is the result of strategic use of the instruments of direct democracy. As we will argue, direct democracy in fact offered important venues for influencing agenda building and the framing of the ART issue in the early agenda-building phase. The instrument of the popular initiative was equally useful to proponents of very restrictive policies in order to influence policy formulation in the pre-parliamentary and parliamentary stages of adopting federal law. While direct democracy is a necessary institutional factor in explaining the resulting design, it is not sufficient in itself. The following analysis reveals that a majority of the political parties were promoting rather restrictive policies on the grounds of various beliefs, bridging the right–left divide and allowing for a broad coalition of right- and left-wing forces for restrictive policies in Parliament. Proponents of total prohibition of basic techniques, such as in vitro fertilisation and insemination by donor, did not, however, realise their policy goals. Medical associations, with the support

of some of the political parties, were able to counteract the activity of proponents of very restrictive policies through lobbying and by influencing cantonal policy designs early on by presenting cases to the Swiss Federal Supreme Court.

Overview of the policy-making process

The policy-making process began at the cantonal level. Ten out of twenty-six cantons adopted cantonal laws and regulations,[3] but the measures adopted by the cantons were later replaced by federal policies. On the federal level, parliamentary motions and requests for deliberation were first deposited in 1984, and included cantonal demands to take action. The shift from cantonal to federal level was substantiated by a popular initiative, entitled 'Against the abuse of biotechnology and assisted reproductive technology' (the *Beobachter* initiative). If an initiative is filed with more than the 100,000 required signatures and meets other formal and legal requirements, the Federal Council (executive) is obliged to present it to Parliament and, finally, to the people. Government and Parliament can not only recommend the acceptance or rejection of an initiative, but can also propose a counter-proposal that addresses the issue of the initiative. The counter-proposal can take the form of a constitutional article (direct counter-proposal) or a federal law (indirect counter-proposal). If the counter-proposal lives up to the principal intention of the initiative committee, it is quite likely that the committee will withdraw the initiative and the popular vote will only turn on the counter-proposal, in the case of a direct counter-proposal.[4] This was in fact the case for this first popular initiative on ART and biotechnology. The Federal Council proposed a direct counter-proposal, in the form of a constitutional article on ART and biotechnology, to Parliament. As a result of the decisions taken by Parliament, the initiative was retracted and, in 1992, the Swiss citizens accepted the counter-proposal in the subsequent popular vote.

On the ground of this constitutional article on ART and biotechnology, a federal law and two ordinances were designed during the 1990s (FmedG: SR: 814.90; VNEK: SR 814.903; FMedV: SR 814.902.2). The design of the law was influenced by a second popular initiative, sponsored by opponents of the 1992 constitutional amendment (Initiative für menschenwürdige Fortpflanzung). It aimed at reversing the constitutional amendment of 1992 by fully prohibiting IVF and insemination by donor. This time, the Federal Council did not make a direct counter-proposal but proposed a federal law on the grounds of the existing constitutional article as an indirect counter-proposal. In December 1998, after a very conflictual debate, Parliament adopted the federal law on ART.

The policy-making process continues to evolve. As a result of technological progress and because the policies so far only incompletely address the question of embryo research, by the end of May 2002 the federal

government had sent a proposal for a law on embryo research into the pre-parliamentary consultation procedure. By the end of 2002, the embryo research bill had not yet been introduced to Parliament.

The resulting design: low autonomy, limited access

The Swiss design aims at securing the well being of the child in general, protecting human dignity, the personality and the family, and also preventing the abuse of ART. These goals correspond to the restrictive Swiss policy design. Federal policies strongly limit the autonomy of the medical community by prohibiting a number of techniques and defining in detail under what conditions and how doctors are allowed to practise ART. Access to ART is equally limited, as only heterosexual couples (and for certain techniques only married couples) are admitted and that access depends on the financial ability of the patients to cover the respective costs of treatment. The main target groups are medical practitioners, private and public health-care providers alike. In accordance with the Swiss type of 'implementation-federalism' (Linder and Vatter 2001), the main implementers are the cantons. Their leeway is very limited, as the federal law and the ordinances predefine the details of implementation.[5]

Low autonomy

A number of techniques, such as egg and embryo donation, pre-implantation diagnostics, cryopreservation of embryos,[6] surrogate motherhood, genetic engineering on gametes, germ cells and embryos, cloning, and chimera and hybrid building are fully prohibited. For the techniques that are not fully prohibited, the policies define in detail under what conditions and how doctors are allowed to practise them: The design prescribes medical indications and defines how certain techniques have to be practised, for example by limiting the number of embryos to be transferred. With the exception of insemination with the sperm of the partner, all techniques require a licence. The licensing system defines the training requirements and asks for the proof of the necessary equipment and training. It also includes inspections and controls, and defines reporting duties.

Existing legal measures on ART only partially address the question of embryo research. Questions such as whether research on 'left-over' embryos should be permitted and under what conditions, and which type of embryo research is acceptable, have not been clearly addressed by federal law. The governmental proposition for an Embryo Research Act is still in the pre-parliamentary stage. The proposed law would allow for research on left-over embryos, including stem-cell research under certain conditions (EDI 2002).

Furthermore, the design limits the autonomy of practitioners by taking

into account the rights of the child, i.e. by guaranteeing the right of people to know their genetic origins, and by formulating information and counselling duties towards the patients that need to be respected. Finally, anyone who violates the provisions of the law may be punished by means of fines or imprisonment. As a result of this combination of instruments, the autonomy of medical practitioners is low (see Table 11.1).

Table 11.1 Autonomy in Switzerland

		Autonomy	
Basic techniques			
Insemination (1)		L	1
GIFT/ZIFT (2)		L	1
IVF/ET (3)		L	1
Total 9: 0–1 no or close to no (N), 2–4 low (L), 5–7 medium (M), 8–9 high (H)		*L*	*3*
Related techniques			
Surrogacy (4)		N	0
Donation (5)	sperm: 5a,	L	1
	egg: 5b	N	0
	of embryos /impregnated eggs: 5c	N	0
Cryopreservation (6)	sperm: 6a,	L	1
	egg: 6b	L	1
	of impregnated eggs 6c	L	1
	embryos: 6d	N	0
Pre-implantation diagnostics (7)		N	0
Genetic selection (8)		M	2
Gender selection (9)		M	2
ICSI (10)		ND	3
Max. 36: 0–5 no or close to no (N), 6–17 low (L), 18–29 medium (M), 30–36 high (H)		*L*	*11*
Research/experimental techniques			
Genetic engineering (11)	on gametes/germ cells (11a)	N	0
	on impregnated eggs, embryos (11b)	N	0
Research (12)	on gametes/germ cells (12a)	L[a]	1[a]
	on impregnated eggs, embryos, zygotes (12b)	L[a]	1[a]
Cloning (13)		N	0
Chimera and hybrid building (14)		N	0
Max. 18: 0–2 no or close to no (N), 3–8 low (L), 9–14 medium (M), 15–18 high (H)		*N*	*2*
Total of all three groups of techniques (max. 9): 0–1 no or close to no (N), 2–4 low (L), 5–7 medium (M), 8–9 high (H)		*L*	*2*

Notes
L, low; M, medium; N, no; ND, no design; 1 = low; 2 = medium; 3 = high.
a legal measures under elaboration by the end of 2002.

Limited access

While limited autonomy accords well with the goal to protect from abuse, the goal of protecting the family – in the traditional sense – has clear implications for access. Access is limited to married and stable heterosexual couples. In the case of sperm donation, the couple must be married. Single women and homosexual couples have no access to ART techniques in Switzerland. In addition, several related techniques are not accessible at all because they are fully prohibited (see Table 11.2).

Health insurance is compulsory in Switzerland, and the main providers of health insurance plans are private mutual insurance institutions and

Table 11.2 Access to ART in Switzerland

		Access	
Basic techniques			
Insemination (1)	with gametes of the couple (1a)	M	2
	with sperm donation (1b)	L	1
GIFT/ZIFT (2)	with gametes of the couple (2a)	M	2
	with sperm donation (2b)	L	1
IVF/ET (3)	with gametes of the couple (3a)	M	2
	with sperm donation (3b)	L	1
	with egg donation (3c)	N	0
	with embryo donation (3d)	N	0
Max. 24: 0–3 no or close to no (N = 0), 4–11 low (L = 1), 12–19 medium (M = 2), 20–24 high (H = 3)		*L*	*9*
Related techniques			
Surrogacy (4)		N	0
Cryopreservation (6)	sperm (6a)	H	3
	egg (6b)	N	0
	impregnated eggs (6c)	M	2
	embryos (6d)	N	0
Pre-implantation diagnostics (7)		N	0
Genetic selection (8)		M	2
Gender selection (9)		M	2
ICSI (10)		M	2
Max. 27: 0–4 no or close to no (N = 0), 5–13 low (L = 1), 14–22 medium (M = 2), 23–27 high (H = 3)		*L*	*11*
Total of all two groups of techniques (max. 6): 0 no (N), 1–2 low (L), 3–4 medium (M), 5–6 high (H)		*L*	*2*
For Element 1: Weights for total of all two groups of techniques (N = 0), (L = 4), (M = 8), (H = 12)		*L*	4
For Element 2: Judgement for financial coverage of ART (0–3)			*1*
Total of Element 1 and Element 2 (0–15)			*5*

Notes
L, low; M, medium; H, high; N, no; 1 = low; 2 = medium; 3 = high.

health insurance funds that are highly regulated. Health insurance is financed by member contributions, and is subsidised for people on a low income. A commission linked to the Federal Office of Social Security decides which treatments are to be covered by the mandatory health insurance. This is also the case for ART (Leistungen Krankenkasse 23 March 1973, 28 August 1986, 1 April 1994; Verordnung Leistungen Krankenkasse 1 January 1997 and 1 January 2001). The medical costs of IVF/ET and GIFT/ZIFT have to be assumed by the patients themselves, although coverage by the mandatory health insurance is available for insemination. Accordingly, access to ART depends on the financial capability of the patients. Given the exclusion of certain patient groups and the fact that very few techniques are covered by mandatory health insurance, access to ART is rather low.

The starting point: policy convergence on the cantonal level

The policy-making process started out at the cantonal level due to Swiss federalism. The Swiss health-care system is decentralised and is characterised by a mixture of public and private health-care providers. The cantons play a major role in formulating and implementing health policies (Schenkel and Serdült 2002: 473); they are important health-care providers, are in charge of cantonal and regional hospitals, and are notably in charge of university hospitals. University and cantonal hospitals were among the first adopters of the new IVF technique. As important players in health-care policies, as well as being providers directly confronted, early on, with the questions provoked by the new techniques, some of the cantons did not want to wait for federal legislation to emerge as this can take considerable time to be adopted. The cantons chose rather to adopt their own laws and regulations.

The design of cantonal laws and regulations varied strongly. Three cantons, Glarus (1988), St Gallen (1988) and Basel-City (1991), prohibited almost all available ART, including full prohibition of IVF and gamete donation. The cantonal laws of St Gallen and Basel-City were challenged in the Swiss Federal Supreme Court, which at the time, in the case of an abstract review of a cantonal law, was the court of first and final appeal. While the Court's power of constitutional nullification is restricted with respect to federal acts (Auer *et al.* 2000), its jurisdiction includes the power to nullify cantonal laws.

The Court ruled on the first case, the canton of St Gallen in 1989 (BGE 115 Ia 234, 15 March 1989), before the federal government published its message concerning the *Beobachter* initiative and before the parliamentary debate took place. The Court ruled that general prohibitions of certain techniques in cantonal laws were unconstitutional and questioned the practice of the anonymity of donors (BGE 115 Ia 244).

The impact of this ruling was as follows. The canton of St Gallen passed

a much more permissive law on ART in 1992. At the same time, the ruling influenced the policy-making process and the design of policies in cantons not directly involved in the court case. It also had implications for the restrictive policy of the canton of Glarus, and stopped the policy-formulation process in at least three cantons that were intending to adopt similarly restrictive laws. The ruling did not, however, interrupt the policy-making process in Basel-City. In 1993, the Swiss Federal Supreme Court nullified the largest part of this cantonal Act and confirmed its earlier jurisprudence.

The Court's decision led to policy convergence at the cantonal level by ruling out extremely restrictive solutions. It thereby clearly influenced the starting conditions for the debate on the federal level. The arguments of the Federal Supreme Court found a strong resonance with the actors on the federal level. In particular, the opponents of total prohibition referred to the Court's opinion that general prohibition violates the right to personal freedom. Furthermore, its jurisprudence strongly contributed to adopting the right of people to know their ancestors (Rothmayr 2001).

Explaining the restrictive federal design: the constitutional article

A popular initiative defines the direction for future legislation

The *Beobachter* is a well-known consumer protection magazine of the German-speaking part of Switzerland, which not only addresses consumer issues in the strict sense but also raises problems and issues in Swiss society and politics in general from a critical angle. In reaction to developments in biotechnology and ART in the human field, the magazine started a popular initiative entitled 'Against the abuse of biotechnology and assisted reproductive technology' in order to put the issue onto the federal agenda and to force the Federal Government to take action.

The *Beobachter* initiative framed the issue in terms of 'protection against abuse', and thereby reflected the committee's concerns with technological progress and its impact on society. The text of the initiative was based on the following beliefs. The proponents of the initiative clearly located a relevant danger of abuse of ART. They argued that the techniques, in particular IVF, opened up the possibility of 'human breeding', including the dangers of eugenic uses, which violate human dignity and integrity. Furthermore, the rights and well being of the child must be taken into consideration. It is not only the danger of abuse in terms of genetic engineering, but also the right of children to know their genetic origins and to grow up with parents who are able to take care of their upbringing and well being that require regulation. Federal intervention is also necessary because science (but also human behaviour in general) is not mainly driven by ethical considerations, but by pressure from international

competition and financial interests. Without clear prohibition, therefore, what is technically possible will also be done (*Beobachter* 1985–92). For these reasons, ART was not primarily seen as a health-care issue but rather as a question of respecting the law of persons (Schutz der Persönlichkeit). It is therefore also not surprising that the Federal Office of Justice, which traditionally addresses questions of respecting the law of persons, had the lead in the decision-making process, and not the Office of Public Health. The manner in which the initiative framed the issue turned out to be very influential throughout the designing process. The constitutional amendment that was finally adopted retakes crucial parts of the initiative in terms of goals and prohibitions.

The debate in parliament: policy preferences and the mechanism of the popular initiative

The Federal Council formulated a direct counter-proposal. Based on the report of the expert commission, the Federal Council preferred a constitutional article combining the human and non-human sector with respect to ART and biotechnology. Furthermore, given the strong conflicts involved, the Federal Council also wanted to gain time and let the public debate 'cool down' a bit before adopting concrete prohibition of certain techniques. The government therefore proposed a constitutional article which, in contrast to the initiative, did not propose any concrete prohibition. The input to the parliamentary stage was therefore twofold: the initiative that suggested some specific regulations in order to prevent the abuse of ART and biotechnology in the human sector, and the counter-proposal of the Federal Council that simply proposed an article defining goals and the obligation to pass legislation on certain issues.

Parliament comprehensively re-designed the proposition of the Federal Council by re-integrating and re-phrasing some of the key elements of the initiative, and expanding the list of prohibitions and conditions. One might wonder why the governmental parties did not support the proposition of their government. This can be explained by the Swiss political system, which is a hybrid system that combines features of presidential and of parliamentary systems (see, for example, Klöti 2001). The Federal Assembly elects the Federal Council, the collegiate council that forms the executive of the national government, and the seven members are elected individually for a fixed term of four years according to an informal convention on party composition that has persisted since 1959.[7] Parliament can only express no confidence in a member of the Federal Council by choosing not to re-elect her or him, but in practice has never done so. If a proposal of the Federal Council is defeated either in Parliament or by popular vote, this has no consequences in terms of the resignation of the Federal Council or for the next re-election (Kriesi 1995: 200–4). Accordingly, there are no consequences if the governmental

parties do not support the counter-proposal of the government in Parliament. Furthermore, the Swiss system differs significantly from the classical parliamentary system, as there is no strict party discipline. Members of the governmental parties are therefore 'free' to follow their own policy preferences.

The fact that Parliament returned to substantive clauses, by reconsidering and expanding the ones proposed by the initiative, was on the one hand influenced by the mechanism of the popular initiative, and on the other hand grounded in the distribution and weight of certain policy preferences in Parliament.

Public discussions and laws adopted in some of the cantons pointed towards public opinion in favour of clear restrictions. In addition, the *Beobachter* was a well-known consumer protection magazine with considerable mobilisation power and media presence. Anticipating the preferences of the voters and taking into account the mobilising potential of the interests behind the initiative, Parliament refused to adopt the solution of the Federal Council and decided to include and expand the goals and prohibitions proposed by the initiative. Parliament was clearly concerned that if it stuck with the counter-proposal of the Federal Council, citizens would prefer the initiative to the counter-proposal. However, the initiative entailed different problems in the way it was formulated. A more substantial constitutional section would make withdrawal of the initiative likely, and by including specific prohibitions and conditions it took up the broadly existing wish to specify some questions on the constitutional level without specifying future legislation in great detail. Even the Federal Council subsequently argued that such an article should be preferred to its own proposition (Amtliches Bulletin SR 1990: 486).

A second explanation for the success of the initiative and the re-designing of the Federal Council's proposition in Parliament is the distribution of policy preferences among political parties and the weight of these parties in the decision-making process.

The first group of actors (PP1) advocated minimal or no state intervention at all. This first group based its policy preferences mainly on the belief that it is not the task of the government to decide the ethical questions involved in ART and thereby interfere with the personal freedom of the couple concerned. Furthermore, proponents of this group believed that self-regulation by the medical profession is best suited to handle the medical questions involved in these new techniques, and thereby showed confidence in the self-regulating capacity of the research community.

The second group (PP2) wanted the state to set clear limits to the practice of ART, but without totally prohibiting basic techniques such as IVF and gamete donation. In their view ART entailed dangers of abuse, for example in terms of eugenics, violating human dignity, and integrity. At the same time, they believed that the right of reproduction is part of the right to personal freedom. While no one has a right to have a child by

means of ART, total prohibition of certain techniques would intervene with the personal freedom of every couple in an unacceptable way.

The third group (PP3) aimed at strong state intervention by fully prohibiting IVF and gamete donation, or at least IVF. Two different sets of beliefs underlie this preference: Christian-religious beliefs, and a sceptical attitude towards technical progress and science in general. Opponents of IVF with religious–ethical motivation believed that human life must be protected from its very beginning, i.e. from the penetration of a sperm into the ovum, or at the very least with the unification of the nuclei. Only the total prohibition of IVF would guarantee that no life would be destroyed. In addition, they believed that IVF instrumentalises human life and puts Man in charge of certain decisions that should be left to nature.

The position in favour of prohibiting all use of IVF was also based on a critical attitude towards technical progress, a strong scepticism towards science combined sometimes with feminist concerns. From this point of view, IVF is not principally an instrument to help couples to have children, but rather a technique developed by scientists in order to provide access to the beginning of life and opportunities to experiment on embryos. IVF gives scientists enormous power, and abuse of this power cannot be prevented, given that the history of technical progress clearly shows that science is not driven by ethical considerations. In addition, from a feminist perspective it was argued that IVF degrades women to an object for egg retrieval and that women need to be protected from the power of doctors who are imposing their own interests on them. Furthermore, opponents believed that ART would enhance traditional role models by implying that women can only find their real fulfilment in motherhood.

Only a very small minority in Parliament, mainly from the Liberal Party, argued that the state should not intervene at all (PP1). The Radical Party, and also a number of members from the Social Democrats, the Christian Democrats and the People's Party – all four represented in government and having together a large majority in Parliament – wanted certain restrictions (PP2), but without total prohibition of basic techniques.[8] Opinions within the Social Democrats, the Christian Democrats and the People's Party, however, were divided, and total prohibition was also supported or considered by members of these three parties (PP3). Furthermore, some small centre and left parties, such as the Protestant Party, the Greens and Feminists, supported total prohibition. In short, the vast majority wanted to set clear limits to ART, and there was considerable support for total prohibition from both sides of the political spectrum, the left and the right, although based on different beliefs (Amtliches Bulletin SR 1990: 477–93; 1991: 250–457; 615; NR 1991: 556–67; 588–636; 1288; 1408).

In order to build a viable majority, a design needed to be found that satisfied the concerns of those members of Parliament, in particular of the

governmental parties who were considering total prohibition, should the constitutional article turn out to be too permissive. Such a majority would not only serve to pass a constitutional article that did not include total prohibitions of IVF and gamete donation, but it would also allow for broad support by the political elite in order to enhance the chances of the counter-proposal being accepted in the popular vote. The distribution of policy preferences and the need to build a viable majority supporting the counter-proposal influenced parliamentary debate in a restrictive direction. Parliament decided to adopt the main goal of the initiative, of protecting against abuse of biotechnology and ART, and in addition, compared to the text of the initiative, expanded the list of specific conditions and prohibitions contained in the constitutional article. Parliament's choices led in fact to the retraction of the initiative, and resulted in the acceptance of the counter-proposal with a majority of 73.8 per cent for to 26.2 per cent against in the popular vote of 17 May 1992.

The second designing phase on the federal level: explaining the Federal Act on ART

The influence of a second popular initiative

As a reaction to the new constitutional article, those interests that considered the adopted frame to be too permissive launched a second popular initiative. This aimed at reversing the constitutional article, and asked for total prohibition of IVF and gamete donation in the federal constitution. As a result of this second initiative, the debate on whether fully to prohibit these techniques continued during the designing process for the federal law. The proponents of the second initiative opposed the broad majority, who had supported the constitutional article. Among the supporters of the constitutional article, however, opinions were divided with respect to how restrictive the future law should be. The main conflicts concerned the prohibition of egg donation and pre-implantation diagnostics. The Radical Party strongly advocated permitting pre-implantation diagnostics and egg donation, while parts of the Christian Democrats, the Social Democrats and the People's Party wanted these techniques to be prohibited. Small parties from the left and the right supported the latter. Instead of the typical centre-right or centre-left coalition (Kriesi 2001), the decision-making process was therefore dominated by a rather unusual left–centre–right coalition excluding the Radical Party. This actor constellation largely corresponds to the one described above for the constitutional amendment. It gave a majority in Parliament supporting the prohibition of egg donation and pre-implantation diagnostics. An attempt to reverse the proposed prohibition on egg donation and pre-implantation diagnostics during the parliamentary debate failed. However, the strong position of the Radical Party in the upper chamber, the Council of

States, combined with the fact that opinion in the other parties was divided, led to a more liberal position of the Council of States. With a tiny majority, the Council of States rejected the prohibition of egg donation and pre-implantation diagnostics. The National Council accepted the prohibitions proposed by the Federal Council, presuming that by not adopting these prohibitions it would risk strengthening support for the initiative. During the reconciliation procedure between the two chambers, the Council of States gave in to the more restrictive solution of the National Council. This is probably due to the fragile majority that led to a more liberal solution in the Council of States.

In contrast to the constitutional amendment, however, the law was mainly designed during the pre-parliamentary stage, and was then, after a long and very controversial debate, adopted in Parliament with no major changes. The result of the pre-parliamentary stage corresponds, therefore, in large part to the law that was finally adopted by Parliament by the end of 1998.

The law could not take force before the popular initiative was voted on, as it was meant to be an indirect counter-proposal to the initiative. The vote took place in March 2000, and the initiative was clearly defeated by a majority of 71.9 per cent of the voters.

The importance of the pre-parliamentary stage

The instruments chosen for the law resulted, first, from the direction spelled out by the constitutional article. The constitutional article already used prohibition and regulation to address ART, and the law clearly continued in the same direction. The choice of the combination of the other instruments certainly corresponds to the overall goal of protection from abuse and, given the goal of the protection of the family, it is not surprising that access has been limited to stable heterosexual or married couples in the case of sperm donation. The federal law continues, therefore, the framing of ART as initiated by the *Beobachter* initiative.

At the same time, the design adopts instruments already used on the cantonal level or discussed in other medical contexts. The question of informed consent has been discussed in other medical contexts as well, but this was the first time that a federal law would prescribe informed consent. Licensing systems had been used before by some of the cantons for private clinics wanting to practise ART (Geneva and Vaud). We could, accordingly, say that the choice of these instruments reproduces existing patterns of instrument choice.

Policies adopted by other countries were also taken into consideration. There are references at least to the following countries: Germany, Sweden, the Netherlands, Great Britain, Austria, Denmark, France, Norway and Italy. Reports of the Council of Europe and other documents elaborated on the supra-national level were also taken into account. The

policies adopted by other countries mainly served to position the designing solutions discussed in Switzerland within the European and international context. Among the different countries listed, it seems that the German Embryo Protection Law and discussion, and also the French design and discussion, played a prominent role. The final design clearly leans more towards the restrictive German policies than towards the more permissive French ones. Media analysis and opinion polls indicate a considerable cultural difference between the German-speaking part of Switzerland and the French- and Italian-speaking parts: Swiss-Germans were clearly more critical regarding ART and biotechnology (Bonfadelli *et al.* 1998: 154; Bonfadelli *et al.* 2001; Maeder 1992). In addition, both popular initiatives were launched in the German-speaking part of Switzerland. It is, however, not possible accurately to evaluate and compare the possible influence of the policies adopted by other countries, or the relevance of discussions and reports on the international, the European or EU level on the Swiss design, compared to other influential factors.

In the pre-parliamentary stage, two elements were particularly controversial: prohibition of egg donation and of pre-implantation diagnostics. The constitutional amendment did not define whether these two techniques should be prohibited or not. The preferences of the members of the Federal Council and the solutions advocated by their Departments differed. The Department of Justice, headed by a Christian-Democrat and having the lead in elaborating the law, proposed to prohibit both techniques, after internal debate, while the Department of Home Affairs, headed by a Social Democrat and in charge of science and research questions, wanted to allow, under certain conditions, pre-implantation diagnostics and egg donation. The Federal Council as a whole decided to follow the version elaborated by the Department of Justice, and sent the respective draft for a law into the pre-parliamentary consultation procedure.

The feedback from the pre-parliamentary consultation procedure includes the whole spectrum of possible opinions (Zusammenstellung der Vernehmlassungen Humandmedizingesetz 1996). Despite the fact that prohibition of egg donation and pre-implantation diagnostics was criticised, the Federal Council kept to the content of its proposal and sent it to Parliament, while at the same time recommending rejection of the popular initiative.

It might be argued that the Federal Council probably followed the beliefs of a majority of its members and supported the view of the Department of Justice. We have, however, no information about the decision-making process within the Federal Council, and their decision might also be interpreted as a set of strategic choices: with the prohibition of egg donation and pre-implantation diagnostics, those actors who would support the initiative in case the law would turn out to be too permissive could be expected to vote for the law. In addition, the forces advocating

no further prohibition were not very strong. Formulating a more restrictive solution would not risk the initiation of a referendum against the law – another instrument of direct democracy in Switzerland.

Laws and decrees of the Federal Assembly can be challenged through an optional referendum, which requires 50,000 signatures of citizens. The referendum has to be understood as an intervention, or the possibility of a veto, at the end of the policy formulation and decision-making process (Kriesi 1995: 88). Its importance lies not only in the acceptance or rejection of the result of the decision-making process, but in its latent impacts on the policy formulation process as a whole (see Linder 1994: 118; Papadopoulos 2001). The outcome of a referendum is always uncertain, and the success rate in popular ballots (at 60 per cent) is fairly high (Linder 1994: 100). Therefore, political actors try to negotiate a compromise that satisfies the interests that have the potential to initiate and win a referendum.[9]

The Radicals were effectively threatening the use of a referendum; however, neither they nor any other party or interest group initiated one. The chances of success were considered to be too small, given that the other governmental parties would support the law and that support for such a referendum among the interest groups was also limited.

Finally, the pre-parliamentary stage was also important for the question of embryo research. The Federal Act on ART does not address the question of embryo research, because the task of formulating legal measures with respect to embryo research was attributed to another legislative project under the lead of the Department for Home Affairs, in particular the Federal Office for Education and Science. This instituted an expert group commission on human-subject research. In its first report, the majority of this expert commission on human-subject research recommended allowing some embryo research under specific conditions, as well as pre-implantation diagnostics to a certain extent. A minority, however, did not share this point of view, and proposed to prohibit both. The Department of Justice then produced a legal opinion on the implications of the constitutional amendment on whether to prohibit these two techniques or not. The conclusion was that the constitution did not predefine prohibition of both techniques, but that the constitutional article on ART and biotechnology overall pointed in the direction of prohibiting research on left-over embryos (Bundesamt für Justiz 1995).

Overall, it seems that the division of labour between the administrative units and their diverging interests postponed decisions on embryo research. Given the political discussion regarding ART, it was likely that strong limits would be set to any type of invasive embryo research. By attributing the task to another legislative project under the lead of the administrative department in charge of research questions, the option was kept open to adopt less limiting policies later on. The governmental proposition for a federal act on embryo and stem cell research, which was still in the pre-parliamentary stage at the end of 2002, does in fact propose

to allow for research on left-over embryos, including stem cell research under certain conditions.

Interest groups' participation in federal policy-making: the limited influence of medical associations

Beginning in 1981, the Swiss Academy of Medical Sciences (SAMW) issued standards for self-regulating the practice of ART in Switzerland (SAMW 1981, 1985 and 1990). Comparison with the constitutional amendment reveals strong parallels. We can thus ask whether the parallels reflect the influence of the SAMW on the design of the constitutional amendment, in the sense that the influence of organisations and associations from the medical sector prevented a design that fully prohibited IVF and gamete donation.

The guidelines represent a certain consensus within the medical community on limiting the application of ART. They were effectively respected in practice, and many clinics even limited their offers more than required, for example by only offering ART with the gametes of the couple concerned. In other words, the policy preferences of the medical community at the stage of designing the constitutional amendment were not that fundamentally different from those of the majority of other political actors. All this certainly contributed to the SAMW standards becoming an important point of orientation. The influence of the standards was certainly not just based on the medical community's authority as experts in the field. Different representatives of the SAMW and the medical community were actively involved in the pre-parliamentary and parliamentary stages. They were part of the expert commission, and were strongly represented as experts in the hearings held by the preparing commissions of the Council of States and the National Council (Kommissionsprotokolle NR/SR 1990/91), in which the *Beobachter* initiative also strongly participated, whereas the proponents of very restrictive solutions were present to a lesser extent. Only one of the interest groups, who later sponsored the second initiative, the 'Gesellschaft für Bioethik', was invited to one of hearings in the preparing commissions. Feminist interest groups, furthermore, were divided about whether to fully prohibit all techniques or not. In contrast to the abortion issue, their influence on the ART issue therefore remained limited (Moroni 1994). Finally, representatives of medical interests had successfully challenged total prohibitions on the cantonal level by calling upon the Swiss Federal Supreme Court.

The picture for designing the federal law is rather different. Medical associations were against prohibiting egg donation and pre-implantation diagnostics. They also did not wish that the civil identity of the donor would be revealed to a child conceived by sperm donation. However, they did not succeed in realising their preferences, and this may have been for various reasons.

First of all, according to the results of the reputational approach and the documentary analysis, the policy designing process was an open one, giving access to interest groups strongly voicing other policy preferences. Various interest groups with a feminist and ecological background had a critical approach to biotechnology and reproduction technologies. In addition, several organisations with a religious conservative background participated, and finally organisations representing the disabled also did not share the views of organisations and associations from the medical profession.

Second, organisations of the medical profession did not enjoy privileged access to participating in the policy-making process. This might also have to do with the fact, that the Department of Justice had the lead in formulating the law.

Third, they did not succeed at re-framing the issue of ART into a question of offering medical help for childless couples. It seems that the framing of the *Beobachter* initiative, but also the approach chosen by the second initiative, continued to dominate the political discussion.

Fourth, the patients were not well organised or very visible. Patient organisations participated only marginally in the policy-making process (at one hearing of a preparing commission), and therefore hardly supported the medical profession in its quest for allowing egg donation and pre-implantation diagnostics.

The picture is therefore twofold: on the one hand, interest groups and associations representing the medical profession certainly contributed to preventing total prohibitions of basic techniques; on the other hand, the final policy design only partly corresponds to their preferences by prohibiting more techniques than postulated by the medical experts, revealing a limited influence.

Conclusions

By the mid-1980s, ART had become a salient political issue in Switzerland. The policy designing process was characterised by a shift from self-regulation by the medical community and various legal measures adopted on the sub-national level to rather detailed policies on the federal level. These federal policies strongly limit the autonomy of the medical community, and clearly restrict access to ART.

Our analysis has revealed that the popular initiative was an important venue to influence the designing process for interests wanting to set clear limits, as well as for interests wanting to prohibit almost all ART. The instrument of direct democracy allowed the issue to be definitely established; the framing in terms of 'protection against abuse' defined how ART was approached for the rest of the policy designing process. Furthermore, proponents of total prohibition of basic techniques like IVF and insemination by donor successfully influenced the resulting design in a

direction strongly limiting the autonomy of the medical community by launching a second initiative.

However, the influence by means of the popular initiative can only be understood when taking into account the rather conservative position of a relevant number of parliamentary actors and interest groups. The framing resonated well with the majority of the political actors. There was considerable support for rather restrictive policies from both sides of the political spectrum, including three out of the four governing parties represented in Parliament – the People's party, the Christian Democrats and the Social Democrats. In addition, various interest groups having a critical approach to reproduction technologies and biotechnology voiced their preferences for restrictive policies. Furthermore, in order to explain the design it is important to take into account how proponents of more permissive policies sought to influence the designing process. The medical community, by participating as experts in the pre-parliamentary stages of design, successfully contributed to preventing total prohibition of basic techniques, while having to accept more restrictions to research and practice than was their goal. Proponents of more liberal policies also presented cases of cantonal policies to the Swiss Federal Supreme Court, whose jurisprudence in turn strengthened the position of the actors opposing total prohibitions of basic techniques.

Finally, the ongoing discussion on embryo research and stem cell research indicates how technological progress, the pressure from the research community and the adoption of policies in the surrounding countries influences the Swiss political agenda. By the beginning of 2002 a new designing cycle had already started, and the gap with respect to regulating embryo research in the existing legislation, which we interpreted as being the result of strategic interaction between different federal departments, might soon be closed through a federal law likely to permit certain types of research on left-over embryos.

Notes

1 The case study is based on documentary analysis, reputational approach (total number of questionnaires sent out to experts: 16; number of responses from experts: 7; number of nominations: 147; threshold = 1; result: 34 actors), as well as more than 50 personal and telephone interviews conducted to a large extent for a former project (see Rothmayr 1999).
2 The first IVF baby was born in 1985 in Locarno; according to the Expertenkommision Humangenetik und Reproduktionsmedizin, there were four public hospitals and two private clinics practising IVF in the mid-1980s.
3 Argovia, Basel-City, Basel-Country, Geneva, Glarus, Neuchâtel, Obwalden, St Gallen, Ticino and Vaud.
4 Otherwise the people have the opportunity to decide on the initiative as well as the counter-proposal. It is also possible to vote in favour of both proposals.
5 The Federal Data Protection Commission, the Federal Office of Civil Law Affairs and the Federal Office of Statistics are also involved in implementation.

6 The cryopreservation of impregnated eggs is permitted.
7 This also takes into account national languages.
8 Distribution of seats for the governmental parties 1987/1991/1995 in the National Council (200) and the Council of States (46): Radicals (FDP): 51/44/45 and 14/18/17; Christian Democrats (CVP) 42/36/34 and 19/16/16; Social Democrats (SPS) 41/41/54 and 5/3/5; the People's Party (SVP) 25/25/25 and 4/4/5.
9 Research has shown that the chance of acceptance or rejection in the popular vote is related to whether the National Council is divided over an issue or not (Sciarini 1998: 628–9).

12 Legislation for protection

Why Norway designed restrictive policies in the field of ART

Ivar Bleiklie

Introduction[1]

The Norwegian history of policy design in the field of assisted reproductive technology (ART) presents us with a paradox. Norway is a small parliamentary democracy with a strong unitary state and a large public sector, where practically all medical research and service provision takes place within the public sector. Medical services are furthermore funded by the universal national welfare system. As a Scandinavian welfare state, Norway is counted among the most advanced, activist and universal ones in the world, including social security arrangements that cover a wide range of needs as well as an extensive public service apparatus providing free (or near free) social and health services for the entire population (Esping-Andersen 1990; Eitrheim and Kuhnle 2000). Another important feature of the Norwegian welfare state is the strong influence of the medical profession over the development and management of the public health-care system (Erichsen 1996). Finally, since 1978 Norway has had a pro-choice legislation on abortion and finds itself among the liberal European countries where the state has left the choice to the women concerned. I therefore find it reasonable to assume that these characteristics would have had certain effects on policy design in the field of ART, such as providing the medical profession with considerable autonomy in practising ART and promoting medical research in the field. I would also assume that these characteristics, together with the liberal legislation on the closely related abortion issue, would favour expansive policies designed to ease access to medical services such as ART. Why, then, do we find an almost diametrically opposite policy design? In comparative terms Norway has been an early legislator and a strict regulator, limiting professional autonomy and the range of services available to the public quite severely in a comparative perspective.

In order better to understand this paradox, I shall address three questions:

1 Why is the autonomy enjoyed by physicians in this field low?
2 Why is access to ART treatment low?

3 Why does the Norwegian policy design appear to contradict basic features of the Norwegian welfare state and the preferences of the medical profession?

In this chapter I shall first describe the policy design and re-design as it manifests itself in the major authoritative decisions. Then I shall present the policy process; the changes that have taken place over time, the central issues and the policy movements up to the present time. Finally I shall discuss possible explanations for the pattern that has been observed in terms of influential actors, actor beliefs and interests involved in the process, the institutional conditions under which the actors participate, the designing process itself, and the more general context in which the process takes place.

Policy design

Assisted reproductive technology policies in Norway have been laid down in a national legislative process punctuated by two major parliamentary decisions: the enactment of Law no. 68 of 12 June 1987, on artificial reproduction (hereafter the 1987 Law), and Law no. 56 of 5 August 1994, on medical application of biotechnology (hereafter the 1994 Law). The 1994 Law replaced the 1987 Law, and was revised in 2000.

Legislative activity followed a process that started in the wake of the controversy in the United States over experiments with recombinant DNA (rDNA) in the early 1970s. If we look at the policy preferences expressed by major actors, the dominant perspectives and preferences have varied over time. In the 1970s, before the actual policy design process began, the topic of risk dominated the policy debates. The scientific and economic possibilities offered by biotechnology, including ART, gained considerable attention and support in the early 1980s – i.e. in the early phase of the policy design process. Since the late 1980s the ethical and moral aspects of ART have been emphasized and have remained at the forefront of the policy debate. However, as we shall see, during the process leading up to the 1987 legislation major policy design characteristics were established that have remained stable until the present time.

Goals, instruments, target groups and implementers

The policy goals are formally laid down by the 1994 Law in the form of an objects clause that states:

> The object of this Law is to ensure that the medical application of biotechnology is undertaken in the best interest of the people in a society where there is room for everyone. This is to take place in concordance with principles of respect for human dignity, human rights

> and personal integrity and without discrimination on the basis of hereditary dispositions, based upon ethical norms grounded in our western cultural heritage.
>
> (Law on Medical Application of Biotechnology, §1–1)

The objects clause provides a broad normative frame of reference for the law that gives it the character of a regulatory framework. It does not regulate specific ART, but broad categories of technologies related to 'insemination' and 'pregnancy outside the body' and relevant research. The policy scope, therefore, is wide in the sense that the law is consciously designed to cover existing and future technologies. The regulation of specific technologies that fall under the law is left to administrative bodies.

Although the policy domain has developed and changed over time, certain characteristics have remained relatively stable. In terms of policy instruments, public policies have primarily dealt with legislation. Legislation and discussions about its use have dominated the political scene, with one exception; the decision to boost biotechnological research in the 1980s. By defining broad categories of ART the legislation formally confers considerable discretion to the Ministry of Health[2] and related bodies, in implementing and interpreting how the law applies to specific techniques. The law does include a number of policy instruments in addition to regulation, such as licensing of institutions allowed to practise ART, reporting from health institutions practising ART, information and counselling of patients, and penalties for violating the law. The implementers of ART policies are thus national health authorities and physicians within hospitals that are approved to apply ART. The counties administered the hospitals until the end of 2001, when the national health authorities took over the responsibility. The major target group is made up of the physicians who decide which patients are eligible to receive treatment by means of ART, and which particular techniques they may apply. The law furthermore explicitly mentions health institutions, patients and donors as target groups. The patients are primarily represented by the Association for the Involuntary Childless (AIC).

Low autonomy and low access

The limited types of techniques that are permitted, and the central administrative control regarding the use of ART, strongly circumscribe the autonomy of medical practitioners (Table 12.1).

Autonomy is low with regard to all basic techniques, and for related and experimental techniques the range of policy variation is limited to low autonomy or full prohibition, the latter being more frequent than the former. What is left for physicians to decide is when to apply ART within the confines of the law, and the right to select donors of sperm cells. The law additionally states that sperm donors' identity shall be kept secret, and

Table 12.1 Autonomy in Norway (1994 law)

		Autonomy	
Basic techniques			
Insemination (1)		L	1
GIFT/ZIFT (2)		L	1
IVF/ET (3)		L	1
Total 9: 0–1 no or close to no (N), 2–4 low (L), 5–7 medium (M), 8–9 high (H)		*L*	*3*
Related techniques			
Surrogacy (4)		N	0
Donation (5)	sperm: 5a,	L	1
	egg: 5b	N	0
	of embryos/impregnated eggs: 5c	N	0
Cryopreservation (6)	sperm: 6a,	L	1
	egg: 6b	N	0
	of impregnated eggs 6c	L	1
	embryos: 6d	N	0
Pre-implantation diagnostics (7)		L	1
Genetic selection (8)		N	0
Gender selection (9)		L	1
ICSI (10)		L	1
Max. 36: 0–5 no or close to no (N), 6–17 low (L), 18–29 medium (M), 30–36 high (H)		*L*	*6*
Research/experimental techniques			
Genetic engineering (11)	on gametes/germ cells (11a)	L	1
	on impregnated eggs, embryos (11b)	N	0
Research (12)	on gametes/germ cells (12a)	L	1
	on impregnated eggs, embryos, zygotes (12b)	N	0
Cloning (13)		N	0
Chimera and hybrid building (14)		N	0
Max. 18: 0–2 no or close to no (N), 3–8 low (L), 9–14 medium (M), 15–18 high (H)		*N*	*2*
Total of all three groups of techniques (max. 9): 0–1 no or close to no (N), 2–4 low (L), 5–7 medium (M), 8–9 high (H)		*L*	*2*

Notes
L, low; N, no; 1 = low; 0 = no.

that donors shall not be informed of the identity of the child or children. However, the law defines a number of conditions for using ART that makes for low autonomy, such as limitation of eligible patients, and limitation of the right to perform ART whereby a general licence to perform ART is given by the Ministry of Health to institutions for a two year period in addition to a specific permission granted by the Ministry in each individual case (Table 12.2).

Table 12.2 Access to ART in Norway (1994 law)

		Access	
Basic techniques			
Insemination (1)	with gametes of the couple (1a)	L	1
	with sperm donation (1b)	L	1
GIFT/ZIFT (2)	with gametes of the couple (2a)	L	1
	with sperm donation (2b)	L	1
IVF/ET (3)	with gametes of the couple (3a)	L	1
	with sperm donation (3b)	L	1
	with egg donation (3c)	N	0
	with embryo donation (3d)	N	0
Max. 24: 0–3 no or close to no (N = 0), 4–11 low (L = 1), 12–19 medium (M = 2), 20–24 high (H = 3)		*L*	*1*
Related techniques			
Surrogacy (4)		N	0
Cryopreservation (6)	sperm (6a)	L	1
	egg (6b)	N	0
	impregnated eggs (6c)	L	1
	embryos (6d)	N	0
Pre-implantation diagnostics (7)		L	1
Genetic selection (8)		N	0
Gender selection (9)		L	1
ICSI (10)		L	1
Max. 27: 0–4 no or close to no (N = 0), 5–13 low (L = 1), 14–22 medium (M = 2), 23–27 high (H = 3)		*L*	*1*
Total of all two groups of techniques (max. 6): 0 no (N), 1–2 low (L), 3–4 medium (M), 5–6 high (H)		*L*	*2*
For Element 1: Weights for total of all two groups of techniques (N = 0), (L = 4), (M = 8), (H = 12)		*L*	*4*
For Element 2: Judgement for financial coverage of ART (0–3)		*N*	*0*
Total of Element 1 and Element 2 (0–15)			*4*

Notes
L, low; N, no; 1 = low; 0 = no.

As opposed to other kinds of medical treatment, where the patient's medical condition defines access to medical services, access is limited by a provision stating that nobody has a right to receive treatment by ART. Furthermore, only married heterosexual couples or couples living in stable 'marriage-like' cohabitation are eligible for treatment depending on medical and psychosocial assessment. Access is further limited by the condition that only the couple's own gametes, with certain exceptions, may be used for conception outside the body. Within Norway's system of universal welfare and an almost entirely public health-care system, access to most health services is eased by the general insurance coverage of publicly

approved medical services. There are, however, certain exceptions. Cosmetic surgery, for instance, is not covered if it is not reconstructive surgery because of accidents or deformity. As a rule, ART treatment was covered by the national insurance system until the end of 2001. Access until then may therefore be characterized as medium. However, as from 1 January 2002 couples had to pay the full cost of IVF and access was considerably reduced, bringing Norway into the low access category.

The policy process 1976–2000

In order to understand and explain this design we have to take into account the previous debates and policy options that were advocated and discussed in the late 1970s and early 1980s.

Policy debates in this period focused on risk and economic opportunities. Both topics were framed in a pragmatic, instrumental perspective where estimates of beneficial versus dangerous consequences were weighed against one another. During the 1980s a major policy shift moved policy debates towards ethical and moral issues. This also represented a change of perspective from a pragmatic focus on consequences to a focus on the relationship between policy and ethical values. In this debate the protection of unborn life was pitted against the value of social justice in terms of equitable access to social and medical services.

Throughout the period the main line of contention has been between 'technology optimists' and 'technology pessimists'. Thus technology optimists, who prefer a permissive policy design, dominated in the early 1980s, whereas the pessimists, who pursue a restrictive design, have had the upper hand since the first law was debated in the late 1980s. This shift took place when the ART issue became linked with the abortion issue. The opponents of the 'pro-choice' legislation that was introduced in 1978, first and foremost the Christian Democrats, in principle never accepted the legislation, and from their perspective the defence of the 'unborn life' must go on. The emerging ART issue provided an opportunity to demonstrate this. The linking of the issues had deep implications for the discussion and actor constellations involved in the issue. In the 1990s there was a slight move in a more liberal direction, as the 1994 Law is a bit less restrictive than the 1987 Law. An overall assessment of ART policy design based on our evidence indicates that Norway has tended to be a strong performer in the area of legislation and a weak performer in the areas of research and service provision.

The 1987 legislation

By the late 1980s modern bio- and gene technology had become established research topics at all Norwegian universities, and an increasing number of private businesses were entering this area (Brekke 1995). Thus

an activity had emerged that might become the object of public regulation and initiatives. From the late 1980s the field of biotechnology was defined in legal terms, and a formal division was established between human and non-human application of biotechnology.[3] Politicians increasingly felt that the possibilities being opened up in the field of reproductive technologies called for them to deal with the issue in order to bring the field under some kind of political control. One event that contributed to this sentiment was the birth of the first test-tube baby in Norway in 1984. In 1985, the Parliamentary Committee of Health and Social Affairs therefore asked the Government to present a proposal for the legal regulation of artificial insemination, prenatal diagnostics, in vitro fertilization and so forth (Stidende 1984–85: 3714).

The initiative resulted in the legislation that was approved by Parliament in 1987: the law on artificial reproduction, said to be the world's first national legislation on IVF or so-called 'test-tube fertilization'. It dealt with artificial insemination and fertilization outside the human body, and it was proposed by a minority Labour government that took office after a centre-right minority coalition of Conservatives, Christian Democrats and the Centre Party had broken down the previous year. As the outcome illustrates, it represents a view on the role of political authorities that is far more restrictive than the pragmatic view the Ministry expressed a few years before. Its main points were as follows:

1 Only institutions approved by the Ministry of Social Affairs may undertake artificial insemination
2 Storage of sperm can only take place at a number of specified institutions
3 Deep-freezing of unfertilized eggs is prohibited
4 Deep-freezing of fertilized eggs may only be used for implantation in the woman from which they originate and may be stored for a maximum of twelve months
5 Research on fertilized eggs is prohibited
6 Only married couples where both parties have provided written consent may be offered treatment
7 Nobody has a right to demand treatment
8 Decisions on treatment are to be made by a physician, based on medical and psychosocial evaluation of the couple
9 Artificial insemination with donor sperm may only take place when the husband is infertile or carries a dangerous disease
10 The donor is anonymous, and may not himself receive information about the identity of the couple or the child
11 In vitro fertilization can only take place if the woman is infertile
12 IVF-treatment may only be undertaken with the couple's own egg and sperm cells, and fertilized eggs may only be transferred back to the female from whom they originate

13 Donation of fertilized and unfertilized eggs is prohibited
14 In vitro fertilization for diagnostic reasons or for research purposes is not permitted.

The Centre Party and the Christian Democrats voted against the law because they considered it to be too liberal. Thus, the technology was questioned from an ethical point of view because it was linked with an existing ethical and political struggle over abortion. During its debate on the 1987 Law (on artificial reproduction), Parliament requested that the government present a report to Parliament on ethical guidelines for research and development of biotechnology and gene technology. The request led to the establishment of two committees.

The Biotechnology Committee (Bioteknologiutvalget) had already been established in June 1987. It focused on the non-human application of biotechnology, and although it raised general ethical problems it dealt mainly with questions of risk and the need for public regulation. Its work led to the 1993 Law on the Production and Application of Genetically Modified Organisms.

The Ethics Committee (Etikkutvalget) was appointed in April 1988. It focused on human applications as its mandate was to clarify the concept of bio- and gene technology in a human setting and consisted of the following tasks: clarifying the practical possibilities of medical application in the immediate and foreseeable future; and ethical aspects related to R&D and the needs for public ethical and legal control and management. In addition it was asked to clarify commonly held ethical principles in Norwegian society that may form the basis for ethical guidelines, as well as existing and new ethical, economic and administrative instruments for management, control of the technology, and the development of administrative competence in the area. Finally, the Committee was supposed to monitor the work of similar bodies in Norway, the Nordic countries, the EC and within the OECD.

The report from the Committee (NOU 1991: 6) was released in November 1990. Few of the Committee's recommendations were unanimous, and there was dissent both in more permissive and in more restrictive directions. The report covered a wide range of issues, but focused mainly on areas of application – in particular, assisted reproduction, prenatal diagnostics and fetal research. Other areas, such as gene therapy and cross-breeding, were treated more superficially because their application was assumed to lie too far into the future.

The Law on Medical Application of Biotechnology 1994

Based on the above-mentioned report to Parliament, a new law was approved in 1994. It represented a move in a slightly more permissive direction compared to the previous law. Although the Labour Govern-

ment had proposed a rather extensive liberalization of the 1987 Law, allowing for egg donation under special circumstances, the use of donor sperm in combination with IVF, and limited research on embryos, the three proposals were all turned down in Parliament.

Nevertheless, the resulting law represented a careful step in a more permissive direction. Maximum storage time for deep-frozen fertilized eggs was expanded to three years (from twelve months in the 1987 Law), indications for IVF treatment were expanded to include male and unexplainable infertility (as opposed to female infertility only in the 1987 Law), and pre-implantation diagnostics was allowed in 'special instances of serious disease where no treatment is available' (Ot.prp. 37 1993–94: 61).

The main critique of the government proposal came from the Christian Democrats and the Centre Party together with the Socialist Left Party. This alliance between parties that represented opposite extremes in the abortion controversy combined two different critiques, a criticism based on traditional and Christian values (Christian Democrats, Centre Party) and an apparently more modern 'green scepticism' (Socialist Left Party) (Hviid Nielsen 1994).

The Biotechnology Board

The Biotechnology Board was established in 1991, and is an independent body that until 1997 consisted of twenty-three members, one each from six different ministries[4] and nine organizations,[5] and eight members appointed on the basis of expert knowledge (among them two theologians, one professor of science and three professors of medicine), in addition to the Chair, who was a professor of medicine. The task of the Board is to '...consider questions of a principal and general nature concerning biotechnological activity' and '...contribute with information to the public on questions regarding biotechnology' (Ot.prp. 8, 1992–93, p. 92). The Board was given an advisory role to the Central Government (Ministry of Health and Social Affairs). Its composition reflected the character of the discussion that has tended to be considered a confrontation between medical and Christian values. However, because of a critical evaluation by the Directorate of Public Management (Statskonsult), the Board has undergone some major changes in recent years (Statskonsult 1997). The Directorate recommended strengthening the independent status of the Board, and wanted a clearer focus on principal issues with less attention to detailed regulation. The composition of the Board was subsequently changed. The number of representatives has been cut to nineteen, leaving out the former ministerial representatives and increasing the number of expert members to ten. In addition, these latter members represent a broader range of expertise than in the previous Board, including lawyers, philosophers and social scientists. The new Board was appointed while the Christian Democratic Party was in office

(1997–2000), in a minority coalition with the Liberals and the Centre Party, and critical voices have maintained that the changes in composition benefited the views of the leading Government Party at the time. However, in 2000 the Social Democratic Government that was in power between March 2000 and October 2001 again made considerable changes in the composition of the Board.

Revision of the 1994 Law

The Law on Medical Application of Biotechnology was revised in December 2000. As part of the revision, the Biotechnology Board undertook an evaluation of the Law in 1999 (Bioteknologinemnda 1999). Most of the recommendations from the Board were not unanimous, but in general the majority recommendations pointed in a restrictive direction. While the Board recommended lifting the ban on deep-freeze storage of non-fertilized eggs, a majority wanted to prohibit such deep-freeze storage. A majority also wanted to abolish donor anonymity, a proposal that would spell an end to sperm donation according to the Norwegian Medical Association, who took a clear stand against the proposal. The use of micro-injection techniques combined with IVF – a technique not considered in the 1994 Law – was rejected by the majority of the Board because of the risk of transferring genetic infertility to the next generation, but mainly because it wanted to define a limit for the ongoing expansion of available techniques. Regarding other considerations, the Board's recommendations were in agreement with the 1994 Law.

The fact that the Labour Party was back in government from March 2000 might lead to the expectation of a more liberal proposition from the Government. Judged by media coverage (cf. note 1), it might be expected that the question of expanding the availability of IVF to include single women as well as the question of donor anonymity would be 'hot topics' in the discussion regarding the revision of the law. However, as already indicated, this did not happen. A broad majority supported by all major political parties except the populist right-wing Progress Party presented the proposal that was adopted in December 2000 (Ot.prp.93 1998–99). The 2000 revision made two changes. First, the law was made more precise. Whereas the 1994 Law applied to 'medical application of biotechnology on humans', the 2000 revision stated that the law does not apply to research that has no consequences for participants in terms of treatment, diagnosing or information that can be traced back to particular individuals; however, it also applies to 'ambulatory genetic services in Norway'.[6] Second, the revision laid down particular conditions for when and how ambulatory (i.e. outreach) genetic services can be applied. Thus, the revision did not entail any significant changes in the legislation with regard to autonomy and access in the context of ART. However, changes in the funding rules removed ART from the list of treatments eligible for

public insurance coverage from 2002, thereby making the design more restrictive.

Explaining policy design

The Norwegian policy goal has apparently been stable, straightforward and simple – to establish public control over ART based on a set of shared values. The shared element is the idea that some kind of balance has to be struck between what is medically possible and what is ethically justifiable. However, if one moves beyond this general aim there has been a clear disagreement and variation over time as to how this balance should be struck. The central issue turns on the extent to which ethical concerns ought to limit the freedom to pursue medical research objectives and treatment opportunities. In trying to explain why Norway ended up with such a restrictive policy design as it did, I shall focus on the policy context of the design process, the actors and beliefs that were engaged in the process, the institutional conditions under which the actors operated, and characteristics of the policy design process itself.

Policy context

The context or external environmental setting is made up of scientific discoveries and 'breakthroughs' that triggered the issue of ART in the first place. Two additional contextual factors are of importance to the development of the Norwegian case: the abortion controversy, and the high degree of 'stateness' of the system. The policy context affected the process in a number of different ways.

A number of events in research and biotechnology were important when the issue came onto the public and political agenda. The rDNA controversy in the 1970s launched the bio- and gene technology debate, and with it the ART issue, into the public arena, primarily as an issue to be discussed by experts. Second, the experiments with IVF from 1980 onwards, and the ensuing birth of the first 'test-tube' baby, made ART a political issue in its own right.

Although the economic potential of biotechnology in general was an important topic in the policy debate in the early 1980s, little attention was paid to the economic potential of biomedical research.[7] In a fully publicly funded system, both medical practice and research depend on public funds and the political willingness to provide such funding. Research therefore normally has no direct economic impact on medical practice.

The abortion issue contributed to the way in which the ART issue was defined and the importance that it gained politically. The way in which this contextual factor entered the policy process is better understood when we take a closer look at the actors and their choices below.

The biotechnology issue in general and the ART issue in particular

demonstrate characteristics that are very similar to the alcohol and drug abuse issues in Norway. These include the absence of clearly defined and organized producer interests, and weakly organized consumer interests.

In order to understand how the ART issue became linked with the abortion issue and why a restrictive control regime reminiscent of the alcohol and drug control regimes was adopted, we must look at the peculiar circumstances and actor constellation that characterized Norwegian parliamentary politics when the major decisions on ART policies were made.

With regard to public opinion, I have so far not come across poll data on the ART issue, but among politicians we interviewed the perception was that the population in general was divided on the issue, just as the politicians were.

Actor choices and beliefs

The ART policy field in Norway has been dominated by a limited set of actors consisting of political parties, government agencies and the medical community: the Christian Democratic and Labour Parties, the Ministry of Health and its subunit the National Board of Health, the medical research community (in particular at the University of Trondheim) and, early in the process, the Norwegian Research Council. In addition, one patient group, the Association of the Involuntary Childless, and the national Norwegian Church played a part to some extent, but our respondents disagree regarding how significant their participation has been. Our data indicate that the Christian Democrats rather than the Church have been influential in gaining support for the restrictive policies they both seek to promote. Two sets of data support this conclusion.

In addition to the interview data, I have used two measures of actor influence in the policy process. According to the reputational data there have been seven particularly influential actors in the design of ART policy: The Biotechnology Board, The National Board of Health, The Ministry of Health and Social Affairs, The Christian Democrats, The Labour Party, Researchers at Trondheim University Hospital, and The Association of the Involuntary Childless (AIC).[8]

If we look at mass media activity our data corroborate this impression (cf. note 1), with the caveat that mass media activity reflects in particular political activity leading up to decisions and the actors who actively try to affect public opinion at this stage of the process. Thus in particular actors belonging to the civil service may be expected to have a less prominent role here than in the other arenas. In the media arena, political parties and their representatives dominated. The medical and research community played a significant but less prominent role, whereas the Church and the AIC were barely visible. However, the AIC has frequently teamed up with physicians who have represented AIC interests.[9] Restrictive views were

more frequently expressed (37 per cent) than neutral (35 per cent) or permissive views (28 per cent). It is also worth noting that the views expressed by members of the medical community tended to be cautiously balanced rather than permissive with regard to ART. It is also important to note that the Norwegian Medical Association, representing the medical community as such, did not take a clear stand in the debate, with the exception of its struggle to preserve donor anonymity.

The actors have been grouped around two major positions as indicated above. The actual policies have been shaped by the conflict between two contending clusters of beliefs, one 'technology optimist', and the other 'technology pessimist'. These beliefs are arguably nourished by a traditional Norwegian conflict pattern where 'establishment interests' are lined up against a 'counter movement' of rurally based parties and urban radicals (Rokkan 1967). The technology optimists are made up by parts of the medical community, the Labour Party, parts of the Progress Party (populist right wing) and most of the Conservative Party. They take a liberal stand on regulation issues, and prefer to introduce legislation after or in step with the technological development in the field. Their position is based on two major beliefs: first, a belief in science, the ability of the scientific community to regulate itself and the possibilities it offers with regard to improved medical treatment services; and second, a belief in the rights of consumers or patients to have their expressed concerns regarding procreation satisfied as easily and equitably as possible. Religious groups, the Socialist Left Party, the Centre Party, Christian Democrats and parts of the Conservative Party make up the technology pessimists. They are more restrictive with regard to regulation issues, and prefer to introduce legislation that pre-empts technological development. The pessimists share a belief in the potential dangers of scientific activity if democratic institutions do not control it. They may, nevertheless, be grouped in two different camps. One camp justifies its position in religious terms, and its scepticism against science is accompanied by the 'pro-life' belief in the rights of and the need to protect the unborn life. To this camp it is self-evident that the politics of designing an ART policy is part of the same struggle as they fought over the abortion issue. The second camp justifies its position in terms of 'green values', a general scepticism against the 'technicalization' of man and society, and the fear of a eugenic 'selective society' where the technological capability to produce individuals with desirable qualities determines life and death questions. Within this camp one finds many supporters of a pro-choice abortion policy.

Whereas the optimist view is based on research – and welfare arguments, the pessimist position is based on religious and ethical arguments. There seems to be a general agreement among respondents and others that in a comparative perspective, the balance between the two views has tilted rather strongly towards the restrictive and technology pessimistic side. The economic growth issue that surfaced in the early 1980s seems to

be conspicuously absent from the story as related by the respondents. However, it is important to note two additional characteristics: first, the broad support for concentrating on regulation policies; and second, the broad coalition behind the modest modification of the legislation in 2000. Although there was disagreement among political actors as to how the balance should be struck between freedom of medical research and development on the one hand and ethical concerns on the other, they were united in their view that the field should be regulated because the ethical implications of medical research makes medical self-regulation insufficient. In spite of the fact that most actors expect policies to move in a less restrictive direction in the longer term, one may speculate whether the initial concentration on regulation policies has given the pessimists the upper hand in the debate to such an extent that the ideological foundation for any serious challenge to present policies until now has been effectively undermined. This interpretation is also corroborated by the conservative position of the Biotechnology Board, with its broad representational basis in connection with the 2000 revision of the 1994 Law. We may conclude that this was not an issue where interests and resources were clearly defined. Except for the AIC, this was an issue that, for the major political actors, was defined in terms of values rather than interests.

Yet, as pointed out previously, it was far from evident that the technology pessimists would influence the decisive parliamentary votes on legislation so strongly. Neither the preceding policy debates nor the political strength of the actors representing the two contending parties spoke in favour of the final policy design. If we look at the parliamentary situation and the position of the political parties on the issue, a more permissive policy design might have been expected. The two biggest parties in Parliament when the decisions were made in 1987 and 1994 were Labour and the Conservatives, which together held an absolute majority.[10] The Progress Party also leaned in a permissive direction. The remaining minority consisted of restrictive parties, the Christian Democrats, the Centre Party and the Left Socialists.[11] I shall return to this question in connection with the design process.

Institutional conditions

Although actor choices obviously matter to outcomes of policy processes, actors normally devise their strategies and make their choices in a highly institutionalized environment where behaviour is influenced by rules and norms that partly represent constraints, partly determine the actors' perceptions of appropriateness, and partly constitute habitual ways of going about their tasks.

If we focus on the decisive parliamentary process, one important rule shapes Norwegian parliamentary politics (particularly under minority governments) in a way that constrains the options of the major actors.

Parliamentary elections are held at regular four-year intervals. The Prime Minister does not have the discretionary power to dismiss Parliament and hold new elections, in contrast to a number of other European countries. The political parties and the government therefore have to live with whatever parliamentary situation the regular elections bring and make the most of the situation. This puts greater pressure on the parties to reach compromises and pursue courses of action that make them attainable, whether through anticipated reactions, log-rolling (a system of vote trading) or other means.

The role played by the medical community in defining issues before the legislative phase stands in clear contrast to its apparent passive acceptance of the policy that was actually designed, and this needs to be explained. The readiness of the medical community to accept a policy that severely restricts the autonomy of experts in connection with ART-related research and medical practice does not necessarily reflect a weak medical profession. The initiatives of the experts themselves to regulate the field seem to corroborate an observation made in comparative studies of the medical profession (Erichsen 1996). In Norway there is historically a very close relationship between the medical profession and the state, and the profession has been ready to accept public regulation in return for control over the administrative bodies that are responsible for that regulation. Furthermore, it seems that research in this field has been concentrated mainly in one university. This suggests that this research may have had a rather narrow base of support within the medical community. Our respondents supported this, and several of them pointed out that the medical community was divided on the issue of ART. These institutional conditions may explain why the medical community through the Norwegian Medical Association did not take a very clear stand and does not seem to have been perceived to be an influential actor. In the one case where it did take a clear stand – on the issue of donor anonymity – its view did in fact prevail.

The role and position of the medical community aptly illustrate a more general stable characteristic of the field. All actors find themselves in a setting dominated by the state and where there are few serious independent economic or producer interests. It is taken for granted, even by the medical profession itself, that self-regulation does not suffice and state regulation is necessary.

When considering the redefinition of the issue in the late 1980s, it is important to keep in mind that it coincided with the shift from an arena dominated by experts and bureaucrats to one dominated by politicians and legislative activity. The movement of an issue from one institutionalized arena to another brings it together with a new set of actors that may define the problem and its solutions in new and unexpected ways. This often makes policy outcomes hard to predict in early stages of the process, as has been pointed out by scholars of policy processes (March and Olsen

1976). However, it is also important to bear in mind that the goal of regulating ART remained stable throughout the process, as did the definition of the problem. This, and the fact that the actors seemed to share a belief in the importance of seeking common ground in spite of apparently diverging beliefs about the ART issue itself, made it easier to reach compromises that carried the parliamentary vote.

The design process

If we consider the policy arenas engaged in the development of ART policy over time, the process turned on an issue that came onto the political agenda because of progress in medical research. Although the rather small group of actors that formulated policy proposals during the early 1980s has been expanded and involves more actors today, their inclusion has been part of a process whereby the issue has become institutionalized and defined in terms of well-established conflict patterns and participants. However, it is important to note the extent to which the policy field with its various arenas was completely dominated by actors that control (e.g. political parties) or belonged to central government institutions. Thus, measured in terms of the criteria of membership, integration, resources and power, the constellation of actors involved still resembles, in Rhodes and Marsh's (1992) terms, a 'policy community' rather than an 'issue network'.

If we return to the situation in Parliament, we pointed out that a majority apparently supported a permissive policy. However, in the legislative processes in both 1987 and 1994 the general policy of the two Labour minority governments was to seek support for their proposals by forging shifting majority coalitions with either the Christian Democrats and the Centre Party to its political right or with the Socialists to its political left. The Labour party sought, with certain exceptions, to avoid the appearance of seeking the support of the Conservatives in order to get policies adopted, and they even more fervently sought to avoid the Progress Party.[12] In both cases, the proposals were rather restrictive and Parliament voted in favour of the proposal. However, both in 1987 and in 1994 a minority of Christian Democrats and Centre Party representatives wanted an even more restrictive law and voted against the proposal nevertheless. In the former case this was a successful strategy and the opposition was defeated. In the latter case the Socialist Left Party joined the opposition, as did the Conservatives, and Labour's proposals for a more permissive law were defeated.

I suggest therefore that the major explanation of these outcomes is the nature of parliamentary politics given the constellation of parties in Parliament. First of all, intra-party conflict and insecurity affected party strategies. Labour and most other parties were far from agreement on the issue, and the majority parties were not sure what support they could

count on in the end. It is not an unlikely proposition that the sum of the personal views of MPs would add up to a more restrictive policy than the official positions of the major parties might indicate. This was also an issue where MPs faced less party pressure and enjoyed more freedom to vote according to their conscience than usual. The issue became a question of individual moral conviction rather than one of party discipline. The difference between the permissive view expressed by Conservatives in the 1980s and the fact that they sided with the restrictive parties during the 1994 vote in Parliament may illustrate how uncertainty and internal conflict affected party behaviour. This gave Labour a good reason to act with care and seek a compromise that would gain broad support. Labour acted strategically in order to gain support for its proposals in connection with all three authoritative decisions, but in 1994 in particular their strategy failed.

A second factor that might have added to the restrictive tendency is that Labour anticipated the reactions of the parties they depended on in 1987, and proposed a restrictive law in order to appear as a moderate conciliator between optimists and pessimists. By proposing a relatively restrictive legislation they wanted to show their willingness to compromise with the pessimists. However restrictive their proposal, they knew that the Conservatives had no alternative but to support them, since the Labour proposal was the most permissive they could hope for anyway.

Third, log-rolling, a process whereby parties trade votes to secure favourable action on projects of interest to one another, may have contributed to an outcome that favoured the 'pessimist' position. Apart from one example, we have not come across evidence as to whether this is a characteristic of ART politics or if it has influenced policy design.[13]

Furthermore, the parliamentary process is likely to reflect and be affected by the general political climate that informs parliamentary politics. In spite of the insecurity and divisions that existed within many parties and among physicians, the general political climate on the issue in Norway was restrictive. There was a general agreement among all actors that ART should be regulated by the state. There were no influential actors who represented radically permissive positions, and not even the Norwegian Medical Association argued that self-regulation was satisfactory.

The observations regarding intra-party conflict, anticipated reactions and log-rolling, together with the generally restrictive climate, meant that although important principles were at stake the issue was framed as a question of personal values and convictions rather than political ones. The parties were thus able to live with defeat and accept the decisions they opposed.

This account demonstrates how parliamentary politics and the strategic choices made by the actors on the parliamentary arena contribute to explaining the policy design. However, in order fully to understand the

choices that were made, we need to take into consideration the institutional conditions under which these choices were made. Thus both the way in which the election regime affects minority governments and coalition politics, and the statist nature of the field are important in order to understand the outcome.

Conclusion

The development of the policy design process illustrates how interaction between particular actor constellations and institutional conditions may produce unexpected yet dynamically stable outcomes.

The shift from the research and committee phase to a phase dominated by parliamentary politics entailed a gradual opening up of the field. The politicization of the field and its framing as an ethical issue were two aspects of the same process, as was the link with the abortion issue.

The process that started out in an arena dominated by medical expertise subsequently opened up to a wider set of experts and policy-makers who became responsible for the legislation and regulation of medical practices. The shift unleashed a constellation of political forces that combined a generally restrictive attitude towards ART based on ethical considerations, technological pessimism and a belief in state regulation.

This paved the way for a restrictive policy design with little autonomy for physicians and low access for patients. Thus Norway became an early legislator and a strict regulator. Once the actual design process had taken hold it solidified into a piecemeal and gradual process, typical of Norwegian politics (Bleiklie 2000; Olsen 1983), where the important arenas, the main actor groups and beliefs change slowly and gradually.

Notes

1 The analysis is based on: (1) twenty-two interviews with central actors in the policy process. The interviews were performed by Ole Brekke, the Norwegian Centre for Research in Organization and Management; (2) a survey of four major Norwegian newspapers, *Aftenposten* 1984–99, *Dagens Næringsliv* 1988–99, *Bergens Tidende* 1992–99, *Dagbladet* 1996–99, and the national news agency *NTB* 1985–99, with the search based on cues '*Artificial reproduction*', '*test tube*' and '*cloning*'; (3) a questionnaire to five experts about reputed influence in the field; (4) policy documents. The two Masters theses by Brekke (1995) and Høviskeland (1995) were useful in understanding the ART policy field and its issues.

2 The Ministry responsible for Health has been significantly reorganized during the period covered by this study. Until 1 January 2002, when the Ministry of Health was established as a separate unit, health and social issues belonged to the same ministry.

3 The 1993 Law on production and application of genetically modified organisms (non-human application) comprises the non-human application of biotechnology that was previously covered by the 1987 Law.

4 Environmental Affairs, Health and Social Affairs, Agriculture, Fishery, Industry, and Municipal Affairs.

5 The Trade Union Association (LO), Employers' Association (NHO), Farmers' Association, Small Farmers' Association, Fishermen's Association, Consumer Commission, National Association for Environmental Conservation, National Association of the Handicapped, and the Cooperative Committee of the Research Councils.
6 The prohibition against genetic selection and gender selection remains unchanged.
7 However, other areas of biotechnological research, such as fish farming, received considerable attention.
8 Fifteen experts were asked to nominate influential actors. Five experts returned the questionnaire, and the seven actors identified were those nominated by three or more experts.
9 One example is when doctors write newspaper articles 'commissioned' by or in collaboration with the AIC.
10 Together they constituted 77 per cent and 58 per cent of the representatives when the votes were taken in 1987 and 1994. Counting the Progress Party as technology optimists increases the majority to 78 per cent and 64 per cent respectively (Central Bureau of Statistics 2001: Tables 6 and 12).
11 The three restrictive parties thus constituted only 22 per cent and 35 per cent of the representatives in 1987 and 1994 (Central Bureau of Statistics 2001: Tables 6 and 12).
12 Labour has avoided a coalition with the Conservatives, as the two parties present themselves as major government alternatives and the two parties have a mutual need to appear as opponents. The right-wing populist Progress Party has been considered unacceptable as a partner by all other parties because of its unpredictability and anti-immigration policy.
13 One of the respondents gave the following example: in 1987 the Christian Democrats and Conservatives made a deal whereby the Conservatives traded support for a ban against research on fertilized eggs against support from the Christian Democrats for granting private institutions the right to offer IVF.

13 Comparing policy design across countries

What accounts for variation in ART policy?

Christine Rothmayr, Frédéric Varone, Uwe Serdült, Arco Timmermans and Ivar Bleiklie

Introduction

The purpose of our common research project is to establish a knowledge base for understanding current policy debates such as the discussion on embryonic stem cell research and cloning. Another purpose is to understand design and re-design in the ART policy domain, and to contribute to theory development in the field of policy design in advanced industrial democracies. On the basis of the common framework presented in Chapter 1, and by using the same data collection instruments, the authors of the individual country chapters have explained the policy designing process and the resulting design in function of actors' behaviour, established institutions and the broader context. The following comparison has two purposes: to provide a general synthesis of the national case studies, and to provide an explanation for the variation in the policy designing process (intermediary variable) and the policy output (dependent variable). How do institutional rules, actors' strategies and constellations' together with the broader context, influence the designing process and the resulting policy design? Which variables account for the variation in policy content found across the eleven countries studied?

By continuing with our inductive comparative case study research strategy (see Chapter 1), the following analysis first compares the resulting policy designs in terms of the autonomy and the access granted and thereby classifies the countries studied into three broad categories of permissive, intermediate or restrictive policy design. The three sections following the classification of the design reconstruct the empirical patterns found regarding actors' constellations, institutions and the context variables by discussing to what extent these variables influenced the designing process and the resulting design. To round up the discussion of possible explanatory variables, the conclusions summarise the findings, assess the analytical framework applied, and outline perspectives for future research.

Dependent variable: policy output

Within the project we classified the policy designs (as determined at April 2002) on the basis of a detailed coding according to how strongly they intervene in the autonomy of the main target group, the physicians and researchers, and on how strongly they limit access for beneficiaries (such as patients) in terms of civil status, sexual orientation and financing (see Chapter 1 and Appendix). Self-regulation entered into our coding only if it was legally binding on the basis of a legal delegation to the stakeholders.

The results of the case studies allowed us to map countries along the two dimensions defined by the concepts of autonomy and access that we chose for characterising the policy content of ART. Values on the scales for autonomy and access should be taken as 'soft' measures. The detailed country studies show that the story is more complex than a dot on an *x* and a *y*-axis. The procedures to establish them were, however, the same in all the country studies, and the coding of access and autonomy followed by the mapping shown in Figure 13.1 was of help in developing a transparent way of categorising and comparing the eleven countries in relation to one another on a progressive–restrictive scale. For the overall comparison we have decided to not take into account the financial dimension of access, in order to reduce the complexity of comparison.

As we can observe in Figure 13.1, autonomy and access are quite closely related. There is a tendency for countries that allow more autonomy in the ART field to restrict access to ART to a lesser degree, and vice versa. This allows us to divide the combined degree of autonomy and access into three categories: restrictive, intermediate or permissive policies.

Not all the cases with low autonomy score low on the access dimension as well, and not all the countries that fall into the intermediate category have medium access. There are in fact two exceptions, Germany and Spain. For the proposed categorisation we have decided to give more weight to the autonomy dimension, because it concerns the main target group of the policy design – the physicians and researchers (see Table 13.1).

Restrictive countries such as Germany, Norway and Switzerland aim at protecting patients and society at large from the potential negative effects and assumed dangers of the new techniques. In these countries many techniques are prohibited, and whatever is allowed is strictly regulated. They limit the use of and access to ART considerably, and prohibit several techniques – namely egg donation, pre-implantation diagnostics and embryo donation – and define strict conditions and rules for special licensing, reporting and controls for what is allowed. Furthermore, they strongly protect the embryo, to the extent that IVF is regulated in such a way as to exclude the production of left-over embryos. Embryo research is fully or almost prohibited. The question of embryonic stem cell research is not yet regulated in all three countries: in Germany and Norway the use

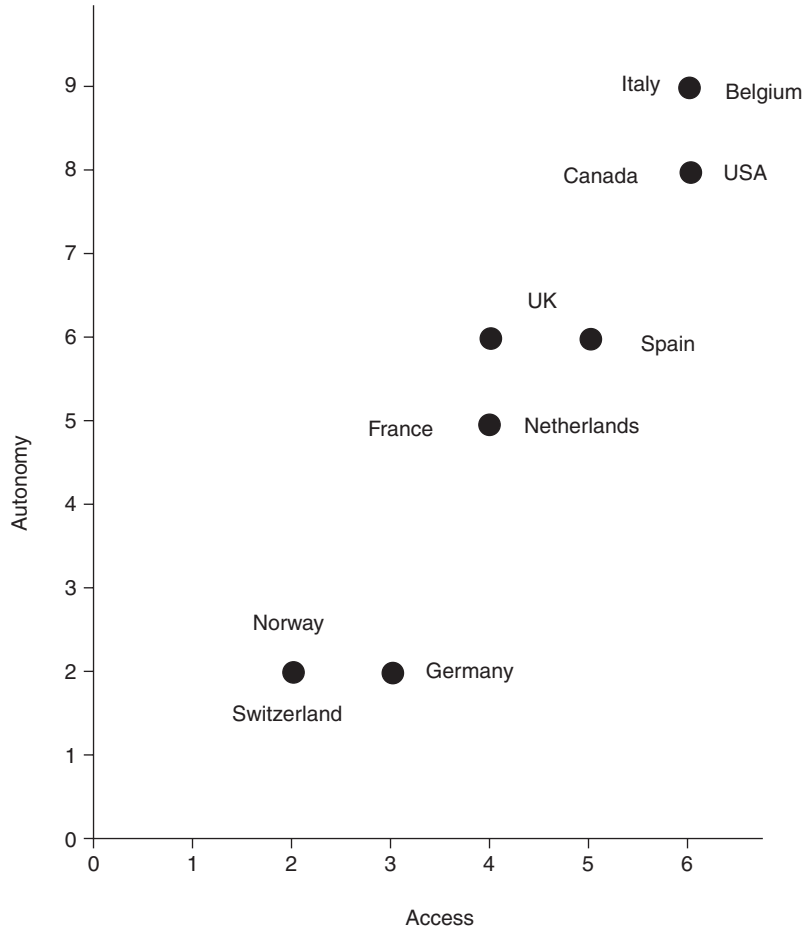

Figure 13.1 Country mapping along autonomy and access scales*.

Notes
* Leaving out the financial component, thus reducing the maximum for access to 12.
Autonomy: 0–1 no or close to no (N), 2–4 low (L), 5–7 medium (M), 8–9 high (H); *access*: 0 no (N), 1–2 low (L), 3–4 medium (M), 5–6 high (H).

of fertilised eggs for deriving stem cells for research purposes is prohibited; in Germany the importation of stem cell lines is permitted; in Switzerland a legislative proposal allowing for using left-over embryos for stem cell research is under elaboration. Human cloning and chimera and hybrid building are prohibited in all three countries. For the techniques allowed, access is limited to stable heterosexual couples. For some techniques involving gamete donation, access is limited to married couples (Switzerland).

Table 13.1 Categorisation of countries along a permissive–restrictive scale

Policy output	*Countries*
Permissive	Belgium, Canada, Italy,[a] USA
Intermediate	France, the Netherlands, the United Kingdom, Spain
Restrictive	Germany, Norway, Switzerland

Note
a Classification is based on regulation of the private medical sector in Italy.

Four countries – France, the Netherlands, the United Kingdom and Spain – can be found in the intermediate category of restrictiveness or permissiveness of their policy design. The policy content of these countries is characterised through permitting a wide range of techniques, including pre-implantation diagnostics, egg and embryo donation, while controlling and monitoring closely their use and imposing conditions of application and access. In France access is limited to stable couples, in the Netherlands and Britain single persons or same-sex couples have access on a case-by-case basis, while Spain in principle does not restrict access. Surrogacy is generally prohibited or declared invalid in these countries, with the exception of the Netherlands, where it is allowed on the condition that it is not commercial. While reproductive cloning and hybrid and chimera building are prohibited, embryo research and therapeutic cloning are not prohibited. The UK and Spain, however, are less restrictive than France or the Netherlands when it comes to research issues. The overall goal of the design in these four countries is to provide efficient, high quality and safe treatment, and to take the well being of the child into consideration. In terms of instruments, licensing, monitoring, reporting and setting quality standards are important, and are combined with some regulatory conditions and a very limited number of prohibitions.

In countries with permissive policies, i.e. Belgium, Canada, Italy (private sector) and the USA (federal level), with a few exceptions almost everything is permitted providing some procedural rules are respected. In Canada and the USA, there is no comprehensive design on the federal level; the existing design is limited to research-related policy issues, in particular the question of public funding of research. Canada also includes the question of sperm banks. In Italy (most) public policies are very limited in scope and only concern the public health-care sector, while in Belgium the design is purely procedural (authorisation for practising). As a result of the limited scope of public policies in these four countries, a very broad range of techniques may be practised. Research is restricted insofar as reproductive cloning is prohibited in Italy and in some states in the USA, and is discouraged by a voluntary moratorium in Canada. Cloning is not prohibited in Belgium, where in spring 2003 a proposition for a bill to prohibit reproductive human cloning was debated in

parliament. As a result of the limited scope, governance of ART is mainly left to private regulation, i.e. the self-regulation of physicians and health-care providers. The goals seem to vary in this group, and include providing treatment opportunities and to assuring the quality and safety of treatment. Because governance is largely private, market forces play an important role in the ART field.

Having presented the variation in our dependent variable and having classified the policy design of the eleven countries into three categories of permissive, intermediate and restrictive policy design, the following section turns to the first set of variables mentioned in our analytical framework: actor's beliefs and constellation.

Actors' beliefs and constellation

In this section we consider the hypothesis that actors' beliefs and interests within a certain constellation of political actors transform either directly into a permissive, intermediate or restrictive policy design in the field of ART, or indirectly by influencing the nature of the designing process.

By using documentary analysis, expert interviews, surveys among policy experts (reputational approach) or a combination of these techniques, we have established a set of potentially influential actors for the policy design process in each country. These actors form an actor constellation which can be divided into groups of actors such as governmental parties or governments (eventually forming a governmental coalition), opposition parties, public administration, associations of the medical profession (including clinics), and other interested organisations such as patient groups, feminist, gay and pro-life movements, and religious groups. In federalist countries, we have also taken into account sub-national actors' beliefs and interests. In order to reconstruct each country's actor constellation during the designing process, we have focused on the most resourceful actors and their respective beliefs and interests. Important resources for political actors in a designing process include political office, organisational power, money and access to decision-makers, as well as access to the media and the public, which can all be cumulative or complementary and can range from low through medium to high.

Actors' beliefs: no divide along the left–right line, and fragmentation within actors

Regarding beliefs, we have found that actors favouring permissive policy designs in the field of ART usually think that scientific and medical progress are beneficial for humankind and that medical treatment should be made available as soon as scientific criteria indicate it is advisable. State intervention should be kept at a minimum. In general, the actors believe that the medical community and researchers know best, and regulation

should be left to professional organisations. Actors promoting intermediate policy designs agree to protect human beings from the potentially negative effects of rapidly developing science; however, scientific progress in general, and in the field of ART in particular, is considered to be beneficial. Modest state intervention is reasonable. Supporters of restrictive policy design for ART are critical towards scientific progress and estimate the negative effects and risks to be higher than the potential benefits. The state is thus called to intervene strongly and restrict practitioners' and researchers' autonomy.

The analysis of actors' beliefs revealed three important characteristics of the belief structure in the field of ART. First, there is no clear pattern across our countries with respect to the left–right dimension. Political parties and interest groups from the left of the political spectrum have advocated both very restrictive policies and intermediate policies. The beliefs of political parties and interest groups from the centre or the right of the political spectrum range from very restrictive to permissive beliefs. Thus, parties with the same ideological background advocate policies with very different degrees of restrictiveness. The hypothesis of partisan influence on policy choices – according to Manfred Schmidt (1996) a 'valuable tool for comparative studies of policy choices' – turns out to be less useful for the field of ART.

The second characteristic is the fragmentation of beliefs within influential actor groups. Beliefs turned out to be either rather homogeneous or fragmented within these groups. In several countries, within 'catch all' parties but also within the medical and research community, beliefs are fragmented.

Interestingly, promoters of strong state intervention seem to share policy preferences on the ground of different beliefs, the third important characteristic. What Nielsen *et al.* (2002: 179–80) have shown for biotechnology in general on the basis of Eurobarometer data – that resistance to biotechnology is divided in two camps, a traditionalist or 'blue' segment and a modernist or 'green' segment – seems to hold for ART in some countries as well. Strong state intervention is demanded by conservative and religious groups, and by parties that claim that life begins at conception and procreation outside marriage is unnatural (see Nielsen 2002: 193). 'Green' or modernist resistance is based on the dangers and risks involved and the potential negative effects on certain groups, namely women and the disabled.

In order to explain variation in the resulting design and the designing process, we take into account variation in the dominant beliefs among political parties, the medical community and other interest groups. With respect to other interest groups, we also suppose that variation in whether they participate as influential actors or not is relevant for understanding the designing process.

Besides beliefs, actors' interests are taken into account. Regarding

interests, we simply denote whether a political actor is a) in favour or b) against a policy proposal potentially resulting in a permissive, intermediate or restrictive policy design, or c) against regulating ART (on the national level) at all, thus resulting in no policy design. We assume that ART policy design also depends on the congruence of beliefs and interests among resourceful actors. A congruent actor constellation should result in a designing process coming to a substantial output and policy design – be it permissive, intermediate or restrictive – depending on the prevailing beliefs within that actor constellation. In cases where beliefs and interests among the most resourceful political actor categories are not congruent, we expect the designing process to come to a halt or to be postponed so that no substantial policy design comes into effect, thus being permissive by default.

Countries with an interrupted design process

According to our understanding, whenever beliefs and interests among the most influential political actors are not congruent, we ought to expect difficulties for the acceptance of substantial policy designs on ART. The policy design process can come to a halt, or be disrupted or postponed, resulting in no design or in a design with very limited scope – as is the case in Belgium, Canada, Italy and the USA (see Table 13.2). Other variables, such as the fragmentation of beliefs and the non-mobilisation of civil society actors, play a role as well in creating deadlocks and interrupting designing processes.

In Belgium, for example, the beliefs of the most significant actors, both within the governmental coalition and also among physicians and researchers, were fragmented. Furthermore, the governing parties had a strong interest in not endangering the governmental coalition. Bad

Table 13.2 Dominant beliefs and congruence of beliefs and interests for countries with interrupted designing process

Country	*Government/ opposition*	*Medical community*	*Other interest groups*	*Congruence of beliefs and interests*	*Resulting design*
Belgium	fragmented/ fragmented	fragmented	no participation	no	permissive
Italy	fragmented/ fragmented	fragmented	no participation	no	permissive
Canada	fragmented/ fragmented	permissive	fragmented	no	permissive
The USA	fragmented/ fragmented	permissive	fragmented	no	permissive

experiences with previous debates on abortion, resulting in a collapse of the governing coalition, were still remembered. Also, as another impediment, doctors and sub-national units preferred to preserve their autonomy in health matters. In addition, other interest groups (such as patients, feminist groups and religious interest groups), were not resourceful enough, beliefs among them were fragmented, and they were therefore largely absent from the designing process. The fragmented beliefs and the non-congruence of interests and beliefs within the governmental coalition, combined with the lack of pressure from civil society, resulted in a deadlock and a purely procedural and insubstantial policy design.

In Italy, the actor constellation appeared very similar. A strong fragmentation between and within the parties of the governing centre–left coalition, and even among doctors, combined with on the one hand a restrictive church, and on the other hand a lack of pressure from other interest groups, eventually led to preferences for no design at all and deadlock in parliament. Thus ministerial circulars and ordinances covering specific ART issues for the National Health Service, but not for the private sector, make up the policy design.

In Canada and the USA, we encounter an actor constellation that has some features in common with that in Italy and Belgium, but also observe some differences. In Canada brokerage practices explained the lack of interest of the governing party in taking a clear stand on ART, because of upcoming elections, and prevailed over the beliefs of governmental actors (Health Canada) for moderate federal intervention. Physicians and researchers had no interest in federal legislation at all, and nor did the provinces. At the same time, beliefs among other interest groups were fragmented, and even though women's groups and anti-abortion groups participated in the designing process, public mobilisation regarding the ART issue remained modest. In the case of Canada, we could argue that electoral politics, and fragmentation of beliefs among interest groups and within the governmental party, allowed physicians and researchers to realise their goal of no federal intervention.

In the USA, there was a strong opposition from within the Republican Party. It was easier for the Republicans not to start an 'abortion-like' discussion, to avoid the issue, and to leave legislation to the states that have, together with the medical community and clinics, little interest in federal regulation of health-related matters. In contrast to Canada, Italy and Belgium, however, the debates on ART on the federal level mainly focused on research issues; attempts to regulate ART comprehensively on the federal level, as discussed in the other three countries, were never under scrutiny.

We can thus conclude that permissive policy designs in the field of ART are not in any of the four cases (Belgium, Canada, Italy, the USA) the result of beliefs among the influential actors pointing towards permissive

policy designs. The permissive policy designs are the result of actor constellations with strongly fragmented and polarised beliefs that in turn had an influence on the designing process. Institutional factors, namely federal division of powers, and circumstantial factors such as coalition stability and electoral politics (upcoming elections) contributed to avoiding or postponing the federal regulation of ART.

Countries with an uninterrupted design process

In France, Germany, the Netherlands, Spain, Switzerland and the United Kingdom the majorities in parliament have been able to pass considerable pieces of legislation on ART because either the governing party did not face a lot of opposition (as in the case of Spain) or it was in line with or able to find a compromise with the most important interest organisations. Governmental coalitions were not an issue or (as in the case of the Netherlands, where coalition politics considerably delayed legislation) the beliefs of the members of the coalition were not too far apart (see Table 13.3). In the case of the federal countries within this group, federated governments or the medical community were not against intervention at the federal level.

As an exception to the assumption that non-congruence of interests and beliefs stop the decision-making process or lead to postponing the decision, we can observe that in Norway – where a more permissive policy

Table 13.3 Dominant beliefs among actors in countries with uninterrupted designing process

Country	*Government/ opposition*	*Medical community*	*Other interest groups*	*Congruence of interests and beliefs*	*Resulting design*
The Netherlands	medium/ medium	medium	medium	yes	medium
Spain	medium/ medium	medium	no participation	yes	medium
France	medium/ medium	medium	medium	yes	medium
The UK	medium/ medium	permissive	medium	yes	medium
Germany	restrictive/ restrictive	medium	restrictive	yes	restrictive
Switzerland	restrictive/ restrictive	medium	restrictive	yes	restrictive
Norway	medium/ restrictive	medium	no participation	no	restrictive

design should have resulted, looking at the beliefs of the most influential political actors – because of party politics and an interest in not endangering the minority government, a substantial policy output was possible. This was mainly due to a minority Social Democratic Government compromising voluntarily with the beliefs of more conservative parties pointing towards a restrictive policy design on ART. This compromise was facilitated by the mobilisation of 'blue' (mainly the 'pro-life' belief in the rights of and need to protect the unborn life) and 'green' (i.e. a general scepticism against the 'technicalisation' of man and society and the fear of a eugenic 'selective society') resistance, nurtured by traditional cleavages and the linkage of abortion and ART issues in Norway.

So what accounts for the differences in the resulting design among these seven countries? For the cases with an uninterrupted designing process, we can observe (with the exception of Norway) a strong relation between the prevailing beliefs among the most influential political actors and the resulting policy design.

In France, the Netherlands, Spain and the United Kingdom, the beliefs of the governmental parties were consistent with interests in passing legislation on ART resulting in a policy design labelled as intermediate, regulating ART with only a few restrictive elements, in principle granting relatively open access. The majority in parliament was strong enough to pass ART legislation and transform its beliefs on ART into a corresponding policy design. There was either no relevant participation from interest groups promoting restrictive policies (Spain), or intermediate beliefs dominated among the relevant interest groups (France, the Netherlands, the UK). It is, however, noteworthy that the British medical community had to accept more restrictions than they promoted, while there seems to be a strong congruence between beliefs of the medical community and the resulting design in Spain, France and the Netherlands. In Spain and the Netherlands, physicians and researchers were able to realise their goals because of a relatively moderate position of the decision-takers and the absence of relevant restrictive pressure by other interest groups.

In Germany and Switzerland, the prevailing technology-sceptical and conservative beliefs within the actor constellation translated well into restrictive policy designs. In Germany, the beliefs of governmental and opposition parties alike tended towards restrictive policy designs for ART. Christian Democrats are strongly rooted in conservative Catholic beliefs (especially on the sub-national level), whereas the opposition of Greens and Social Democrats voiced strong beliefs against biomedical progress and pushed for even more restrictive policy designs. Such was also the case in Switzerland, where a coalition of conservative and technology-sceptical actors led to the adoption of a restrictive policy design. No important actors promoted permissive designs, although some were in favour of a more moderate state intervention – namely the medical community and the Liberals. Despite early rather restrictive self-regulation

by the medical community, in Germany and Switzerland medical doctors were not able to get an intermediate design through, but had to accept the less restrictive of the restrictive designs under discussion because of a combination of traditional, blue and modernist green and left resistance. This was also present in Norway, the third restrictive case in our sample.

In short, among the countries with an uninterrupted designing process, variation in beliefs among influential political parties and other interest groups seems largely to explain the variation in the resulting design.

Institutions: the impact of system and sub-system arenas

By taking the 'institutions matter' hypothesis seriously, the following section discusses to what extent variation in institutions accounts for variation in the policy designing process and the resulting policy output. Chapter 1 introduced the concept of the policy arena as a locus where authoritative decisions on ART policy are taken. Therefore, we proposed taking into account both the political system at large and the policy domain-specific arenas. With respect to the system level, various authors have argued that the type of democracy does not determine policy choices, and that the effects of institutions depend upon the game the policy actors play and the characteristics of the policy domain concerned (Scharpf 1997; Schmidt 2002: 160; Weaver and Rockman 1993).

The results of our empirical analysis support this line of argument. Classification of countries according to constitutional features, type of democracy or political system has revealed no clear pattern with respect to policy output.

There is no convergence in the content of ART policies adopted by traditional 'consensus democracies' (Lijphart 1999). While Belgium adopted very permissive policies, the Netherlands established an intermediate regulation and Switzerland designed restrictive policies. The same applies to typically 'majoritarian democracies': Canada formulated a permissive policy design, while the UK follows an intermediate policy. It is, nevertheless, noteworthy that none of the countries classified by Lijphart (1999: 246) as majoritarian along the 'executive-party dimension' of democracy adopted restrictive ART policy.

In the same vein, federalist versus unitary state structure does not explain by itself the variation in policy design across countries. For each category of the ART policy design we identified empirically both federalist and unitary countries – for example, among the permissive countries Canada versus Italy, among the intermediate regulators Spain versus France, and among the restrictive countries Germany versus Norway. This result is not surprising. Recent more detailed studies looking at policy outcomes in socio-economic fields, where we would be more likely to expect a direct link between institutional designs and policies than in the value-loaded issues of assisted reproduction, did not find any clear link between federalism and policy performance (Castles 2000; Keman 2000).

Finally, countries with parliamentary regimes (e.g. Canada, Italy and Belgium) and presidential systems (e.g. the USA) have both adopted a permissive ART policy. It is also quite obvious that parliamentary systems with multiparty coalitions – as a specific subgroup of parliamentary regimes – do not share the same type of policy design, as for example the different choices of Belgium (permissive), the Netherlands (medium) and Germany (restrictive) reveal.

Taking into account policy-making arenas at two levels of analysis – i.e. combining system level arenas such as legislatures, executives and courts with subsystem level arenas with more or less institutionalised arenas relevant to designing ART policy (for example in the health field) – allows for a more adequate analysis of the impact of institutional features on the policy designing process and, in combination with actor and context variables, an explanation of the resulting policy outputs. Table 13.4 presents the eleven countries cited here according to two institutional features. The first is the number of arenas, where we have distinguished between countries where policy design is undertaken within few arenas (mainly parliamentary at national level) or many arenas (involving both several arenas and multiple levels such as federal/national, regional and/or local). The second feature is the dominant nature of rules, explained in Chapter 1, classed as being relatively lax (winning principle) or tight (power-sharing principle) (Lijphart 1999; Timmermans 2001). The relative tightness of the prevailing rules is related to the decentralisation of arenas – i.e. the extent to which they are structured to accommodate the interests of diverse social and political minorities, and correspondingly limit the freedom of decision-makers representing the majority to impose their will. The relationship between state and society is organised differently in typical consensus or negotiation democracies (e.g. countries with more arenas and tighter rules). In these countries corporatist structures frequently exist, and in the field of health these take the form of institutionalised but relatively exclusive arenas with specific policy-making competencies. The less rigid nature of rules in majoritarian countries with fewer arenas is in part a matter of different state–government relationships: interest representation is more open and *ad hoc*.

Institution characteristics at the national level do not seem to explain much per se, but do so when in interaction with actors in the policy design process.

The literature quoted here seems to assume that the number of arenas in a political system follows from the nature of the rules. The tightness of rules and the number of arenas are considered to be two indicators of the same underlying dimension expressed by the distinction between consensus and majoritarian democracies. However, as we know from previous studies of specific policy sectors, there is considerable variation with regard to the number of arenas and the tightness of rules within countries, and thus within the same type of democracy. The two indicators may

therefore in principle vary independently of one another, and in the further analysis we allow for this possibility. This means that the number of arenas engaged in a given policy domain may depend on the actions of particular actors or actor constellations in that domain. It also means that the tightness of the rules may vary in a policy domain depending on the extent to which it is dominated by tightly-knit policy communities or more open policy networks. Thus Table 13.4, presents four different combinations in a cross-classification of the two dimensions.

The first thing one notices is that countries with the same type of policy design along the permissive–restrictive dimension do not fall neatly into common categories. However, there are some patterns that are worth noting. First, restrictive policy designs have all occurred under conditions of tight rules and in situations characterised by few (Norway) as well as many arenas (Germany, Switzerland). Second, in domains where arenas are few and the rules are lax we find three (Spain, the UK, France) of four intermediate design countries, leaving the Netherlands as one intermediate design case characterised by tight rules and many arenas. Third, permissive policy designs have been produced under three kinds of conditions, characterised by multiple arenas and lax rules (Canada, the USA), multiple arenas and tight rules (Belgium), and few arenas and tight rules (Italy). These observations suggest that different policy designs may to some extent be understood as products of different combinations of the policy arenas engaged and institutional rules. However, there is no one-to-one relationship between the type of policy design and the circumstances. We have also observed that similar policy designs may be the product of different circumstances, which suggests that there are different trajectories that may lead to the same or similar outcomes.

The following discussion shows that countries with uninterrupted policy-making process share features with respect to the number of policy

Table 13.4 Variation of policy arenas (in brackets: type of policy design adopted)

	Number of arenas	
Nature of rules	*Few*	*Many*
Lax/winning	The UK (I) Spain (I) France (I)	USA (P) Canada (P)
Tight/power sharing	Italy (P) Norway (R)	Belgium (P) The Netherlands (I) Switzerland (R) Germany (R)

Sources: adapted from Lijphart 1999; Timmermans 2001.

Note
P, permissive; R, restrictive; I, intermediate.

arenas and the nature of rules, and that countries with interrupted designing processes also have some institutional features in common. In order to identify and understand these similarities, we will now discuss the designing processes in countries with few and many policy arenas. For each group of countries, we will analyse the relative influence of lax versus tight rules for policy-making. Both institutional dimensions, arena and rules, may in fact have different effects on the strategies of actors, and thereby on the final policy design.

In his famous 'veto player' theory, Tsebelis (1995, 1999) presents the hypothesis that an increase in the number of institutional veto players reduces the likelihood of policy change. The presence of many different institutional sites for veto offers protagonists of the status quo multiple opportunities to prevent decisions entailing a change away from the status quo – for example, no state intervention at all, regulation with very limited scope or only of procedural nature. This leads to the prediction that in centralised countries with few arenas considerable policy change occurs (as already shown), whereas in countries with multiple institutional loci for veto, policy stability and eventually non-decision is greater.

In contrast to this first interpretation of policy arenas as loci for vetoing policy propositions, Baumgartner and Jones (1993: 35) argue that the existence of many 'institutional venues' in a country also yields opportunities for 'policy entrepreneurs'. Referring to a number of case studies of policy-making in different fields, they say that federalism, separation of powers and jurisdictional overlaps are opportunities for change as much as they are inhibitors of change (1993: 240). Baumgartner and Jones emphasise the role of policy entrepreneurs, who are seen to use the different venues for policy-making strategically. In short, as the number of policy arenas increases, the potential of opportunities for policy entrepreneurs also increases. In this approach, a decentralised system is not necessarily slower or less successful in producing policy than a centralised system with few policy arenas.

Many arenas: interrupted and delayed process

Veto players seemed to have played an important role in countries with an interrupted designing process and a resulting permissive design of ART. In Canada and the United States, both federal countries with single party governments, the impact of the territorial distribution of policy-making powers seems to have been large. Health policy-making competencies are firmly in the hands of the provinces and states. In all Canadian provinces medical practices are the domain of medical colleges, controlled by the medical profession. Very few guidelines relevant to ART have been developed. The provinces avoid confrontation with physicians and researchers, knowing that they can always blame the federal government for failing to adopt (criminal law) legislation. Likewise, the federal authorities can argue that

the absence of provincial cooperation delays the adoption of a comprehensive ART policy. In the same way, in the USA the principle of 'limited government' long implied a low level of federal interference, until issues of embryo research and cloning appeared on the national agenda. On these issues, the federal government, with the president as a key policy initiator, has recently constrained the autonomy of the research community. The proposed ban on human cloning has not passed the Senate, and whether future attempts will succeed is an open question. However, the applicability of the veto player argument should not be overrated. It needs to be added that Canada stands out in contrast to the US case because here the federal government was not stopped by the actions of veto players, but made a conscious decision to refrain from using the major effective policy design instrument at its disposal and opted not to use criminal law legislation. Furthermore, the federal US policy agenda was different from the other cases in our study because it focused primarily on research and funding of research.

In Belgium, a young federal state with a multi-party coalition government, the most important reasons for the absence of substantive decisions on ART policy seem to have been the frequent political deadlocks within the central government (e.g. the Social Democrats as gate-keeper and veto players), the capacity of physicians to self-regulate themselves and, to a lesser extent, the non-cooperative nature of relationships between the subnational governments on health policy. However, although Belgium is a federal state like the USA and Canada, where many arenas are engaged, it also has tight rules with its tradition of power sharing. Rather than built-in veto points, we suggest that it is a failure to produce the consensus on which power-sharing rests that accounts for non-decisions on ART in Belgium.

Thus, the group of countries with many policy arenas show a very similar picture: policy-making tends to be more protracted. In these cases, the presence of many policy arenas has contributed to interrupted and delayed designing processes. Furthermore, the content of the policy design is limited, resulting in permissive policies. This pattern emerges not only from Chapters 4 and 5, on Canada and the USA, but also from the study of Belgium (Chapter 2). However, in the latter case one needs to consider the way in which tight rules combined with many arenas in order to explain the design. Thus if we look at the outcome of these design processes, the empirical evidence seems to support the theoretical expectation of Tsebelis. However, if we focus on how these outcomes were produced, we find only partial support for his veto player argument – the US case makes a good fit, Canada fits to some extent, and the Belgian case is better understood as a failure to produce consensus under the tight rules of institutionalised power sharing.

The designing process in the Netherlands is different from that observed for the other countries with many arenas. The rules of accommo-

dation in the Dutch coalition system slowed down legislative progress considerably, but did not lead to a complete halt. ART policy problems were difficult to settle, and policy initiatives were either withdrawn or failed to obtain a legislative majority. The tight nature of regulation was relevant for finally adopting legislation, and the fact that beliefs among the most relevant actors were not fragmented and overall indicated an intermediate policy design, facilitated power-sharing.

Few arenas: interrupted and delayed process

The Italian case stands out as one where, in spite of the relatively few arenas engaged, there has been failure to produce an ART policy at all. The design process has been largely concentrated on the 'navette' of legislative proposals between the lower house and the Senate, a process that has prevented decisions from being taken. The strong opposition of the Catholic Church and its representatives in political parties, as well as the fragmented beliefs among the medical communities, explains (as in Belgium) the predominance of non-decisions during the designing process.

Few arenas: uninterrupted and rapid design process

In the United Kingdom, France and Spain, ART issues have been dealt with in centralised arenas, and controlled by the national government without a serious threat of veto from pressure groups. In Spain and the United Kingdom, a single party majority made government control possible. Bicameralism exists in these two countries, but only the lower chamber appeared to be important in ART policy-making. In the French parliamentary arenas, majority building depended more on rules of coalition governance, and this prolonged policy-making. Furthermore, a committee of members of the Assemblée Nationale and the Senate considered ART issues. Although it varies across the three countries, none of them have tight rules.

A general pattern also emerging from the analysis of these early regulators is that beneficiaries of the ART policy, in the form of patients, were not much involved in policy-making. In France and the United Kingdom consultations took place in arenas without pre-fixed rules, and this was more favourable to well-organised groups – in particular the physicians, who are the primary target group of ART policy. In Spain, the technocratic orientation of the Socialist Party gave experts considerable leeway in policy development.

The designing process in Norway reveals features different from the ones described for the other three countries with a small number of arenas. Legislation on ART was adopted very early by a minority government. The 'Storting' was in effect a unicameral legislature, which partly

explains a quick decision-making process. Another part of the explanation is the fact that the necessity of comprehensive state regulation operated as an institutionalised norm that was taken for granted by all involved actors, the medical profession included. The resulting policy design is considerably more restrictive than the regulation adopted in the United Kingdom, France and Spain. The difference in policy output results from a combination of institutional factors and the comparably more restrictive policy preferences of some of the influential actors. The power-sharing devices (i.e. tighter rules) of the Norwegian democracy induced the minority government to take into account the more restrictive beliefs of the opposition.

Many arenas: uninterrupted process and restrictive policy design

The policy designing processes in Germany and Switzerland rather support the idea of many venues yielding opportunities for 'policy entrepreneurs' (Baumgartner and Jones 1993: 35). In Germany (an early regulator) and Switzerland, where the rules of the game within arenas are the tightest, national coordination has been strong for different institutional reasons: Germany has a unitary federalism, and Switzerland's federalism is combined with direct democracy.

German federalism corresponds rather to the idea of a 'unitary federal state', because cooperation between Länder and Bund and cooperation between Länder aims to establish equal legal, economic and general living conditions nationwide (Benz 1999: 136). Competition between the Länder is therefore discouraged. Given the competencies of the Länder in the health-care field, they built bottom-up pressure to adopt federal policies through the Bundesrat but also through a common working group of the Länder and the Bund. This lack of competition finds its parallel in how the physicians approached the issue of ART: binding early self-regulation, elaborated on the national level but adopted on the Länder level through the professional codes, set the same standards and limits nationwide before legislation was adopted. Furthermore, governmental initiatives led to the institution of various expert commissions, and in the case of stem cell research the Bundestag created a special enquiry commission in order to set out policy formulation.

In Switzerland, actors used different institutional venues to promote their policy preferences. Proponents of very restrictive policies mobilised the possibility of influencing federal policies through cantonal policies. They were hoping that horizontal coordination, whereby several cantons could adopt very restrictive policies, would place pressure on the federal level and lead to the adoption of very restrictive national policies. Opponents of total prohibition, however, used the power of the Federal Supreme Court (i.e. a top-down intervention) successfully to challenge the building of bottom-up pressure. At the same time, policy entrepreneurs used the

instrument of popular initiative to shift the power of policy-making to the federal level and to influence the designing process through revising the Constitution. Federal policy-making on ART has been a game of initiatives and anticipation of possible referendums in different arenas. Furthermore, existing inter-cantonal coordination and cooperation, as well as the smallness of the country, also contributed to all actors wanting to avoid differing unilateral action on the state level.

Thus, Germany and Switzerland seem to be cases providing empirical support for the argument of Baumgartner and Jones (1993), that multiple policy arenas provide policy opportunities. If these two countries are a good illustration of the 'arenas as opportunities' argument, it is nevertheless worth mentioning that beliefs among the most resourceful actors were rather homogeneous and promoted strong state intervention through restrictive policies.

The limited sample of cases and the co-variation of institutional features with actor and context variables do not allow us to draw any general conclusions about veto players and arenas as opportunity structures. Several countries support the veto player idea, but our analysis also indicates that taking into account arenas at different levels reveals how actors use different venues as opportunities for promoting state intervention.

The broader context and emulation among countries

Our analytical framework supposes that the external environment is significant for 'new' policies and the re-designing of existing policies through influencing the actors' behaviour and constellation. We also assume that the development of knowledge and research, and specific events such as mediatised court cases or medical scandals triggered by technological developments, might influence agenda setting. Furthermore, other relevant competing or related political issues and existing policies on the national level (the legacy of the past, such as abortion policies) and also policies on the international level and emulation among countries might be useful variables to understand variation in designing processes and policy content. Finally, we speculate that variation in public opinion on ART might help to understand variation in policy content across countries.

Problem pressure: variation in practice and research?

The case studies imply that there is a link between agenda-setting and scientific breakthroughs with respect to the invention and the adoption of IVF and the progress in stem cell research. The amount of time it took to reach a decision, and whether policies were designed at all, however, was influenced by the actor constellation and the institutions as demonstrated above. The recent announcements regarding cloning humans have certainly reinforced already ongoing debates.

Even though breakthroughs and new knowledge spread fast within the international scientific community, there have been considerable differences with respect to ART practice and research from the mid-1980s onwards, due partly to self-regulation by the physicians and probably also to differences in the health-care system (i.e. the role and importance of private vs public health care). Does this mean that the problem pressure[1] might explain differences in policy design across countries? Or can we assume that countries with a fast-growing ART market and who were leaders in research in this field adopted less restrictive policies?

Comparable data on the ART 'market', with respect to research and applications, are not readily available, and where they are available we are often confronted with estimates, the lack of longitudinal data, and figures that date from after the adoption of main legislation. Despite the missing data, we can draw two interesting conclusions from our case material.

Some countries (e.g. Germany, Switzerland and Norway) did prohibit, through legislation, techniques that were actually not practised in these countries at the time of their prohibition. ART seems to be a policy domain where national policies do not just address what is actually practised on their soil, but also techniques and research practised elsewhere or imaginable one day (i.e. still experimental). From this angle, variation in medical and research practice, i.e. variation in the problems to be addressed, seems not to explain variation in policy content. At the same time there are the 'innovator countries', namely the UK, Belgium and the USA, where we have some indication that in fact international research competition and economic incentives seem to have played a role in actors' strategies (physicians) and the nature of intervention of the state by favouring a framing of the issue in terms of research policy and market regulation.

Competing issues and the legacy of the past

Besides the agenda-setting effects of mediatised scientific breakthroughs and other events in the realm of biomedicine and biotechnology, competing policy issues had an impact on the place and salience of the ART issue in the governmental agenda.

In Belgium, the competing policy issue of euthanasia contributed to postponing decision-making processes, because the government did not want to deal with two delicate ethical issues at the same time. In Spain, in the second half of the 1980s, democratic transition and European integration were much more salient issues, and contributed to a lack of public mobilisation and, through that, to an expert-centred designing process.

In terms of other policy issues, the cases refer most often to abortion and the legacy of past experiences (see, for example, Rose and Davies 1993) made during decriminalisation debates. In Belgium, the Netherlands and France, experiences influenced actors' strategies: in Belgium,

avoiding a similar institutional crisis to that experienced during the decriminalisation debate contributed to the fact that ART was not substantively regulated. In the Netherlands, past experience contributed to the avoidance of public debate and circumventing clear policy choices. In France, actors avoided defining the status of the embryo in order not to question existing abortion law. A similar pattern can be observed in Italy, where some of the left parties fought against restrictive policies endangering liberalised abortion laws. In the USA, the abortion issue increased the controversy over issues related to embryo research and cloning, and mobilised the anti-abortion interest groups. This development was similar in Norway, where the linkage of ART to the abortion issue strengthened the influence of actors promoting restrictive policies. Finally, in Germany the preceding court decisions on the abortion issue contributed to the constitutionalisation of the debate and the strong focus on the status of the embryo in the policy design.[2] In sum, experiences gained during the debates leading to decriminalising abortion policies mattered for actors' strategies.

Weak international harmonisation and limited lesson-drawing

With respect to the supranational level, there has been little pressure from the European Union and international organisations for unifying policies in the field of ART. The European Commission and the European Parliament have – as mentioned in Chapter 1 – contributed to the debate on regulating ART through reports, opinions and resolutions, but so far, according to the case studies, have not had a decisive influence on policy-making at the national level. The same is valid for the conventions of the Council of Europe that are of relevance for the ART sector, the Convention on Human Rights and Biomedicine dating from 1997,[3] amended in 1998 by the Additional Protocol on the Prohibition of Cloning Human Beings.

On the ground of the existing information, these protocols and the discussions within the EU seem not to have significantly influenced the policy-designing processes on the national level in the field of ART so far. This is not very surprising, given that by 1997 several countries had already adopted their own policies and prohibited human reproductive cloning.

The diffusion of policies and policy learning across countries have equally had no clear-cut impact on the choices made (see Bennet and Howlett 1992; Hall 1993; May 1992; Rose 1991, 1993; Schneider and Ingram 1988). The majority of the countries examined how the issue of ART had already been regulated in other countries, yet there are no clear indications that countries have adopted policies already been proven useful elsewhere. 'Technology optimists', however, have used what has been not prohibited abroad as an argument against strong state intervention with respect to research and embryonic stem cell research in particular.

In sum, and before turning to the last of our context variables, lesson-drawing and supra-national activities have so far been of rather of limited relevance for understanding the designing of ART policies on the national level.

Public opinion: variation in attitudes across countries?

None of the case studies cited here mention shifts in public opinion over time as an explanatory factor for the policy-making process. One might, however, wonder whether the variation in policy design mirrors the variation in public opinion – that is, in countries with more restrictive policies the public is more critical towards ART, but attitudes are less restrictive in countries with more permissive policies. Considerable research has already been done regarding media coverage and individual attitudes towards biotechnology and technology in general over the last three decades (Bauer and Gaskell 2002; Durant *et al.* 1998; Gaskell and Bauer 2001). Unfortunately, for ART there are no comparable longitudinal data on individual attitudes available. The Eurobarometer,[4] of which some questions have also been used in the USA, introduced questions about biotechnology in 1996, by which time the majority of the European countries that finally adopted policies had already made the main decisions (Germany, Spain, Norway, the UK, France) or a first important step had been adopted (Switzerland). In addition, whether ART was framed as a (bio)technology issue or treated as a health issue varies across countries, and indicates the limits of using questions on biotechnology in general for the ART debate. Nevertheless, it is worth comparing the restrictiveness of the design with the data on attitudes towards biotechnology in order to see whether there is a common pattern or not, yet without assuming any specific causal relation.

Midden *et al.* (2002) have classified attitudes per country on the basis of the 1996 Eurobarometer survey by looking at the extent to which individuals believe that the further development and use of six biotechnology applications (xenotransplants, food production, lab animals, crop plants, medicine and genetic testing) should be encouraged (Midden *et al.* 2002: 207). Table 13.5 cross-tabulates the five categories of encouragement defined by Midden *et al.* (2002) with the restrictiveness of policy design for ART.

There is a tendency for countries with more negative attitudes towards the encouragement of biotechnology applications to have more restrictive designs and vice versa. The most negative and most positive countries, Austria and Portugal respectively, were however not included in our sample, and the USA and Canada were not part of the comparison performed by Midden *et al.* (2002). These findings therefore need to be interpreted with prudence.

Overall, if we look at the broader context, variations in problem pressure, international harmonisation and lesson-drawing are not very helpful

Table 13.5 Mean encouragement scores for six biotechnology applications (only for European countries included in our sample)

Policy design	*Mean encouragement scores*				
	(1) Most positive	*(2)*	*(3)*	*(4)*	*(5) Most negative*
Permissive		Italy	Belgium		
Intermediate		Spain	France, the UK, the Netherlands		
Restrictive				Germany, Norway, Switzerland	

Source: Midden *et al.* 2002: 208, based on Eurobarometer survey of 1996.

in understanding variations in the designing process and the resulting policies as determined by April 2002. The legacy of the past and competing issues are useful for explaining actors' strategies and the variation in the designing process. Finally, the data available on public opinion imply a covariation of public attitudes with the degree of restrictiveness or permissiveness of the design. Given that the available data are not ART-specific and mirror the situation only from 1996 onwards, more far-reaching conclusions are not possible.

Conclusion – the designing process and policy design

The limited number of cases and the restriction to western industrialised nations limit the conclusions and generalisation of the findings; however, the comparison reveals some noteworthy results about the link between the designing process and the resulting design, and general assumptions about the influence of institutions, actor configurations and strategies.

The comparison revealed, first, that permissive policy designs in the field of ART are in none of the four permissive cases (Belgium, Canada, Italy, the USA) the result of beliefs among the most influential actors pointing towards permissive policy designs. Permissive policy designs are the result of actor constellations with strongly fragmented and polarised beliefs. Institutional factors, namely federal division of powers, and circumstantial factors such as coalition stability and electoral politics (upcoming elections) contributed to the avoidance or postponement of federal regulation of ART. Among the countries with an uninterrupted designing process, variation in beliefs among influential political parties and other interest groups, the mobilisation or non-mobilisation of non-medical interest groups seems largely to explain variation in the resulting design. The combination of strong 'blue' and 'green' (Nielsen *et al.* 2002) resistance among influential actors seems to be particularly favourable for restrictive policies in the field of ART.

When the above observations are combined with the institutional analysis at domain level, taking into account the number of arenas and the nature of rules, the following patterns are revealed. First, permissive policy designs might be the outcome of policy processes shaped by three different combinations of actor beliefs and institutional conditions. In countries with polarised beliefs among important actors and lax decisional rules (Canada, the USA), actors successfully used veto points provided by a comparably high number of arenas. In countries with polarised beliefs and tight decision rules (Belgium, Italy), failure to establish consensus combined with medical self-regulation to produce permissive designs. Countries with few arenas and lax decision rules (France, Spain, the UK), and where dominant actors advocate an intermediate design, tended to adopt moderate ART policies through an expert-centred process. However, the Netherlands, with many arenas and tight rules, also produced an intermediate design. It is important to note in this context that had this study been concluded one year earlier, before the last legislation of 2002, Dutch policy design might have come closer to being permissive. In terms of an interrupted and delayed policy process this would have brought the Netherlands closer to Belgium, a country with which it has historically shared a number of institutional characteristics. In countries with a combination of 'blue' and 'green' resistance and tight decision rules (Germany, Switzerland), a large number of arenas provided opportunities and access points for policy entrepreneurs and led to restrictive policies. However the same combination of resistance and tight rules could also form the basis for restrictive policies in a country with few arenas (Norway) through consensus building in parliament.

If we look at the broader context, variations in problem pressure, international harmonisation and lesson-drawing were of limited importance to the designing process on the national level. However, the legacy of the past (namely of the liberalisation of abortion debates) influenced, through actors' behaviour, the designing process, and competing issues on the agenda contributed in some countries to delaying or postponing decisions. To what extent variation in attitudes of the population towards ART translated into variation in the final policy design remains unknown, given the data at our disposal.

To conclude this summary of the findings, we can group the countries into four ideal type designing processes.

The first type of designing process can be labelled as *designing by non-decision*. Belgium, Canada, Italy and the USA belong to this type. Until quite recently this was also the case for the Netherlands. They share a non-congruence of interests and beliefs, combined with strong fragmentation of beliefs. Our findings suggest that non-decisions, given the beliefs and interests, may ensue under at least two different circumstances observed in our study, that make it difficult either for winners to impose their will or for power-sharing systems to establish viable compromises. This results in disrupted designing processes and no design, or a 'minimal' design.

The designing processes of the second group, France, Spain and the UK, might best be described as *designing by experts*. These countries have several features in common: congruence of interests and beliefs among the important actors, a favoured and uninterrupted designing process, and a substantial design output according to the dominant beliefs of the most resourceful actors. Therefore, few arenas seem to favour a 'closed' designing process where research and medical interest are successful in realising their policy goals, resulting in moderate state intervention.

The designing process of Switzerland and Germany, as a third ideal type, can be labelled as *designing by mobilisation and consultation*. Congruence of beliefs and interests among the most influential actors, a majority of actors favouring restrictive policies, and tight decision rules permitted different actors to use the opportunity of multiple arenas to create pressure to adopt policies corresponding to their restrictive beliefs.

Design by party politics characterises the designing process in Norway as the last ideal type. Although beliefs appear to be incongruent when looking at the actors in the policy process, tight decision rules and few arenas formed the institutional conditions for rapid policy design and restrictive policies. Furthermore, compromises in parliament were promoted by a shared normative conception about comprehensive state responsibility and generally restrictive policy preferences among major political actors.

Outlook – political science and biomedicine

Given the number of cases and potentially influential variables posited by the analytical framework, the comparison could not investigate all the elements in depth. Furthermore, it is important to take into consideration the fluidity of the policy process and the fact that our study provides a snapshot of such processes with a focus on design at a particular point in time. Our categorisation of policies and design processes may therefore well change. There are several links between variables that are worth further investigation – in particular the role of expertise, the role of physicians and researchers and of their self-regulation and mobilisation, not only on the national and supra-national levels but also on the local level in form of bioethical committees. Interestingly, early restrictive self-regulation cannot counteract state intervention (Rothmayr 2003). In contrast to studies already undertaken, we feel that the sole focus on medical and research actors misses some interesting variation in mobilisation and access among other interest groups, such as, for example, feminist interest groups. Furthermore, the influence of the health-care system should be investigated in more detail, in particular with respect to the financial aspects of access, which seem to vary according to the type of health-care system. There are some interesting anomalies, such as Norway, with a

national health-care system, not covering any ART treatment, and American patients successfully influencing state governments to force private and non-mandatory insurance providers to include ART treatment in the standard packages. The impact of existing arenas and actor constellations in health-care systems also seems to depend on the framing of the ART issue. The question of framing seems even more pressing given the most recent issues discussed – stem cell research and cloning. At different points in time related issues might be framed differently, as public health issues, as research problems or as questions of technological progress and society (Bleiklie 2003; Braun and Abels 2003; Rothmayr and Varone 2002).

With respect to the comparison of our dependent variables, future research should take into account not only the policy output, but also the implementation and outcomes of ART policies for different target groups. This would imply a critical assessment of the definition of 'design' used in our case studies, which measured the strength of state intervention on the national level and did not take into account any private regulation or any policies on the sub-national level, for example adopted by the federated entities.

Taking into account a larger number of countries, and including other cultural contexts, will allow the drawing of more general conclusions. The combination and comparison with other biotechnology policy fields would also reveal to what extent the findings are typical for the new field of biomedicine and biopolitics.

In Chapter 1 we argued that even though we are dealing with a new and emerging policy field with some particular characteristics, such as a high rate of scientific innovation and touching upon fundamental ethical questions about human life, the application of existing assumptions from the field of policy design might contribute to explaining and understanding current policy choices. The case studies and the comparison have demonstrated that existing concepts can be successfully applied to ART policy-making. Despite the 'bioethical institutionalisation' taking place on the national and supra-national levels (Salter 2003), existing decision arenas and established networks, namely in the health-care field, have been dealing with the ART issue. Maybe the strong basic values involved, the fragmentation of beliefs and the fact that the issue does not necessarily divide along the usual cleavages makes the field particularly at risk for stalemate and interrupted policy-making processes. High media attention, newsworthy scandals and announcements of breakthroughs might, through permanent defining and re-defining of ART issues, reinforce this tendency.

By the spring of 2003, in the majority of the countries in our sample old policies had been re-designed and new policies decided. While our analysis mainly focused on 'first generation' ART policy, the second and third generation are underway and in some countries have already been

decided. Biomedicine is evolving with great speed, and the need to develop new policies, 'a second generation' of policies, to deal with the challenges this development creates means that this will continue to be a dynamic and exciting policy field. The ongoing phase of re-design will allow assessment of whether the new dominant research issue, namely stem cell research, and the growing international competition and pressure in this field will lead to convergence in policy design or whether policies continue to differ considerably. A stronger harmonisation seems likely, yet so far there are no indications of a radical and fast overall trend of convergence in ART policy design. We have argued that a full understanding of ART policies calls for the application of a number of different approaches and may therefore draw on a number of theories. Eclectic approaches similar to the one we have used is one way to go. However, our understanding of the field, as well as the disciplinary discussion, may also be enhanced by research that tests one particular assumption based on a specific theory. First and foremost, it is important that political scientists do not miss this second opportunity to catch up with this evolving and intellectually challenging field of policy studies.

Notes

1 'Problem pressure' refers to the activity that policies seek to affect; in our case, medical services and research in the field of ART. The idea is that policies are reactive and try to solve problems as they arrive. Consequently, one would expect comprehensive policy design in countries with a high level of research activity and developed services, and less in countries with little activity in the field.

2 Legal reform of criminal code of 1974, introducing a periodic model and rendering abortion not punishable during the first three months of pregnancy, declared unconstitutional by the German Constitutional Court in 1975; the law complying with the ruling declared abortion punishable under the exception of four indications, medical, eugenic, rape or incest, or social (Kamenitsa 2001).

3 By the time this manuscript was completed, in spring 2003, of the countries in our sample France, Italy, Switzerland, the Netherlands and Norway had signed, but only Spain had ratified.

4 The 'Eurobarometer' is the name for the regular public opinion surveys conducted on the behalf of the European Commission at least twice a year in all member states of the EU. Since the early 1970s they have provided regular monitoring of social and political attitudes among the European public. Since the Eurobarometer is sponsored by the EU, the US is not usually included in the survey, but from time to time there is collaboration and some questions asked in the Eurobarometer for EU countries are used in parallel surveys in the US.

Appendix: instructions for measuring autonomy and access

Measuring autonomy

In order to measure the degree of autonomy we applied the categorisation as displayed in Table A.1, comprising three categories: high, medium and low autonomy. These three categories only apply to techniques for *which there is a design*; otherwise the category *'no design'* is attributed.

In order to standardise comparison, we not only defined categories but

Table A.1 Categorisation of autonomy by technique

Category	*Variables/instruments*
High (3 points)	General permission, authorization for the application of the technique for accredited doctors/hospitals;
Medium (2 points)	A. ensuring quality/security through a combination of at least 3 out of the following instruments: licensing, inspections/controls, quality standards, reporting /documentation, information/counselling/consent with respect to patients; however no specific restrictions when and how the technique might be applied; B. or: punctual restriction, but not combined with more than two out of the above mentioned instruments (see A);
Low (1 point)	A. in addition to a combination of at least 3 out of the above mentioned instruments (medium A), specific restrictions to be observed for the application of the technique through regulations, which intervene into the concrete medical practice; might or might not be combined with penalties/fines for not respecting them. B. or: general prohibitions with limited exceptions
No (0 points)	General prohibition of the technique
No design (3 points)	if there is no design at all for the respective technique

Note
The following instruments do not enter into the distinction of categories for autonomy: subsidies, rights, contracts, attribution of authority.

also used a fixed list of techniques (see Tables in case studies). For every technique on the list we evaluated, on the grounds of all the instruments applying to the specific technique, in which category of autonomy it fell. The techniques were grouped into three sections: (1) the basic techniques, which contain the techniques of 'fertilisation': insemination, GIFT/ZIFT and IVF; (2) the related techniques, which are used in combination with the basic techniques and by themselves are not capable of inducing a pregnancy; and (3) research and highly experimental techniques.

Measuring access

a) Element 1: civil status/sexual orientation

We gave weight to the fact that certain techniques are prohibited and therefore access to these techniques is impossible. For each basic and related technique we attributed the following scores in the access table:

0 = full prohibition
1 = only married couples
2 = stable heterosexual couples
3 = civil status or sexual orientation do not matter

Access should be assessed as follows:

1st step: enter 0 for prohibited techniques
2nd step: enter 1, 2 or 3 for each of the allowed techniques, depending on to what degree civil status matters for access.

b) Element 2: financial coverage

For the second element we tried to make a general evaluation and attribute values ranging from 0 to 3. For values 1 to 3, we assumed that these rules apply under the condition of a given medical indication for applying ART:

0 = patients pay themselves or can only pay by buying (additional) insurance coverage
1 = only a limited spectrum of the allowed techniques/laboratory works are covered by a national health system or a mandatory insurance plan.
2 = the major part of the allowed techniques/laboratory works/medication are covered by a national health system or a mandatory insurance plan.
3 = national health system or mandatory health insurance takes over expenses for all allowed techniques.

Combining elements 1 and 2

Access is a combination of the score for civil status and the score for the degree of financial coverage of ART. We simply added the two elements according to the formula below. Note that we gave as much weight to the first element (CIVIL) as we needed in order to get a hierarchical indicator.

$$\text{ACCESS}\begin{bmatrix}0\\15\end{bmatrix} = \text{CIVIL}\begin{bmatrix}0\\4\\8\\12\end{bmatrix} + \text{FINANCE}\begin{bmatrix}0\\1\\2\\3\end{bmatrix}$$

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