
Regulating Biomedicine in Belgium and France: Neighboring Countries, Diverging Policies

Nathalie Schiffino (Catholic University of Mons,
Belgium)
and
Frédéric Varone (University of Geneva,
Switzerland)

1. Introduction

The invention of the technique of in-vitro fertilization (IVF) in the late 1970s and its routinization in the mid-1980s created the basis for new medical techniques, such as intracytoplasmic sperm injection (ICSI), pre-implantation diagnostics, genetic screening and engineering, as well as new fields for biomedical research, such as research on embryos and stem cells, as well as therapeutic and reproductive cloning. The development of these new assisted reproductive technologies (ART) and subsequent biomedical research offers the hope of great benefits, such as the cure of degenerative diseases. However, these innovations have also given rise to grave concerns over their potential negative effects, such as the return of eugenics in the form of embryo selection techniques. In the face of these controversial perspectives, ART and biomedical research have been, since the late-1970s, widely discussed in the media and have become a salient issue on the political agenda (Durant et al. 1998;

Gaskell and Bauer 2001; Bauer and Gaskell 2002). Furthermore, a number of advanced industrialized democracies have passed national legislation in response to these debates (for a comparative overview of these “biopolicies”, see Bleiklie et al. 2004).

Our contribution - as political scientists - to the ongoing debates over the regulation of biotechnology consists in examining “how” and “why” governments pursue particular courses of action or inaction (Heidenheimer et al. 1990) in the fields of ART and biomedicine. Hence, we aim primarily to provide a broader empirical knowledge base on how public policies are designed and chosen in two particular European countries, Belgium and France. Despite the considerable amount of political activity and the public attention surrounding these biotechnology issues, there is still a deficit in terms of political science research on this topic (Rothmayr and Varone 2002). This seems particularly evident if we compare what has been undertaken in the growing fields of bioethics, biolaw, and bioeconomics to the still missing – or at least underdeveloped – political science research in “biopolitics”.

At a first glance, one might expect France and Belgium to formulate and implement similar ART policies (see for example Bennett 1998 and Seeliger 1996 on the theory and methodology of “policy convergence”). Several factors could be listed in support of this assertion. First, the French and Belgian publics partly share similar opinions on ART and on biotechnologies in general. The Eurobarometer 58.0 study, for example, revealed that France and Belgium had a similar degree of relative optimism towards biotechnologies from 1991 to 2002 (53% for Belgium and 56% for France in 1991, up to 40% in Belgium and 39% in France in 2002). Both countries obviously supported - in the same proportion - genetic tests,

the cloning of human cells and xeno-transplantation, more than they supported genetically modified organisms and food (in 2002, at least 50% support for genetic tests compared to at least 50% opposition to GM food).

Secondly, Belgium and France are neighboring countries and have several cultural traits in common. This geographical proximity and shared cultural values could facilitate lesson-drawing and policy transfer processes (Rose 1991; Dolowitz and Marsh 1996). Emulation between Belgium and France could, for example, occur if policy-makers in one country were dissatisfied with their ART policies, shared the values of their neighboring state and had knowledge of this state's policies. As an illustration of such a process, Belgian Parliamentarians sometimes mention French decisions or other foreign countries in support of their own bills¹.

Finally, as investigated in the scientific literature for other countries (see for instance Hoberg 1991 for an analysis of the American influence on Canadian environmental regulation), one could assume that the size of the country affects the policy-making process. The presumption is that larger countries are more likely to influence small states than vice-versa, especially when geographically adjacent to one another. As a matter of fact, Belgium settled a licensing procedure for ART centers (1999) ten years after France (1988). The same time lag

¹ See for example « *proposal for a bill aiming at insuring the transparency of centers practicing artificial insemination and in vitro fertilization* », by H. Hanquet (ex-PSC) dated 24 March 1988 (Sénat, Doc. Parl., 147/1, SE 1988: p. 2, 4-5); « *proposal for a bill on certain aspects of bio-ethics* » submitted twice, in June 1992 et 1995, in Parliament by Ph. Monfils (PRL) (Chambre, Doc. Parl., 413/1, 1991-1992, 18 June 1992; Chambre, Doc. Parl., 1/37, S.E. 1995, 29 June 1995: p. 4, 6).

applies to the creation of a National Bioethics Committees in France (1983) and Belgium (1995).

However, a detailed analysis of the ART policies adopted in Belgium and France, and an overview of other bioethical issues (e.g., the partial decriminalization of abortion and euthanasia), show that this common sense presumption of similarity is somewhat misleading: convergence of public opinion, geographical proximity, cultural proximity and differences in size are not sufficient conditions for convergent public policies.

In the fields of ART and biomedical research, Belgian and French policies strongly differ in terms of their substantive content. We provide two sets of explanations for this variation (based on the theoretical considerations proposed by Varone et al. 2006). The first is actor-driven. The main target-groups (Schneider and Ingram 1993) of the ART policies, i.e. the physicians and the researchers, and the final beneficiaries of these “biopolicies”, i.e. patients and political parties (Schmidt 1996), behave in different ways, leading to different policy content. The second set of explanations focuses on institutions. The features of the political systems (e.g., centralization versus federalism) and the influence of “contextual” variables on the internal decision-making process (e.g., the attitude towards international - and especially European - pressure) also help to explain the policy differences. In general terms, the Belgian consensus-style of democracy is based on decision-making processes that vary sharply from the French majoritarian system (Lijphart 1999). In the case of ART policies, non-decisions and professional self-regulation resulted in a very liberal policy in Belgium, while we observed more interventionist policies in France.

Our analysis proceeds in three steps. We begin, first, by describing the development of ART regulation in Belgium and then, secondly, reconstruct the ART policy

designing-process in France. In each case, we highlight key elements of the substantive policy content. Thirdly, we undertake a systematic comparison of the decision-making process and constitutive elements (e.g. objectives, instruments, implementation arrangements, target-groups and final beneficiaries) of ART policies in Belgium and France, bringing to light certain obvious similarities and significant differences. We then highlight five factors that contribute to explaining the divergence: the actor networks within the policy sector, the game of political parties within specific governments, the role of administrative agencies in unitary versus federal states, the reaction towards international pressure and, the political sequencing of bioethical issues other than ART. This first empirical analysis of the ART policies adopted in France and Belgium leads us to suggest seven research hypotheses to explain further the “biopolicies” adopted in other countries and biotechnological sectors.

2. Belgium: the experience of physicians’ self-regulation

2.1. State of the ART in Belgium

Belgium has been active in every stage of the development and commercialization of ART (Belgian College of Physicians 2002). The extent of the application of ART in Belgium indicates that it is a leading country in the ART domain, both in terms of artificial insemination (AI) as well as in vitro fertilization (IVF).

Since the 1960s, Professor Schoysman has been developing artificial insemination at the Vrije Universiteit Brussels (VUB). In 1988, there were some twenty centers responding to between 500 and 1000 demands for AI a year (CEDIF 1988). Each center owned its own sperm bank. In 1983, the first Belgian “test tube baby” was born after IVF was performed at the Katholieke Universiteit Leuven

(KUL) and then at the Saint Pierre Hospital in Brussels. From 1990 to 1996, the number of IVF cycles grew from 2685 to 3488. Moreover, the team of P. Devroey and A.C. Van Steirteghem at the VUB were the first to implement the technique of Intra-Cytoplasmic Sperm Injection (ICSI), reporting the first successful birth using this technique in 1992. Today, ICSI is a well-known procedure that is applied worldwide.

Until 1999, ART centers developed without licensing. According to a national report (BelRAP 1995-1996), 35 centers were active in 1996, with 24 in Flanders, six in Brussels and five in Wallonia, giving Belgium the highest density of ART centers in the world for quite some time. Despite the introduction of new regulations in 1999, the country still faces an oversupply. If we consider that the global average is one center per 700,000 inhabitants, Belgium has 21 official centers (or one center per 500,000 inhabitants) offering a variety of types of ART programs. Thus, there is strong economic competition between the most efficient, i.e. University, centers.

Since the end of the 1990s, stem cell research has been a very promising area of biomedicine, originating from the use of ART treatments (e.g. supernumerary embryos). Such research can be carried out on embryonic cells or adult cells. The therapeutic benefits lie in the potential ability to treat serious diseases such as Parkinson's or replacing tissue damaged by injuries. It is, however, difficult to precisely delineate scientific stem cell research in Belgium. Research remains confidential until results are officially released in scientific journals. This phenomenon is partly linked to the mostly financial impact of the publication of results. However, research on human embryonic stem cells seems poorly developed. Research on animal embryonic stem cells is more widespread in both Wallonia and Flanders (Antwerp University, KUL, VUB),

but this primarily focuses on fundamental research, such as creating transgenic mice. Therapeutic research mainly applies to research on adult stem cells (Université de Liège, Université catholique de Louvain -UCL).

2.2. Policy process

We have identified four historical stages in the design of ART policy in Belgium. During each of the four main phases in the policy design, a specific issue dominated the debates within particular decision arenas.

The first phase ran from the 1960s until the 1980s; this was the period of artificial insemination in which the development of the technology was limited by the physicians themselves. While Belgium was forging its leading role in developing new techniques, no legal decisions were taken to clarify them. At that time, the National Council of the Medical Order adopted one single regulation. In 1975, this Council introduced Article 88 into its Medical Code of Conduct. At that time, it stipulated that AI with a donor (AID) should be limited to married couples, who must give their written and informed consent while the sperm donor remained anonymous. Since then, the anonymity of the sperm donor remains the rule in practice² but is no longer explicitly stipulated in the Code.

² During the 1999-2003 legislature, (the Verhofstadt I government), this was publicly restated by the federal minister for Consumption Protection, Public health and the Environment. On the contrary, the current government (Verhofstadt II, formed after the federal legislative elections of May 18th 2003) *could* revoke this attitude because the government declaration stipulates that: “Parliament will be invited to distinguish between sperm donors who wish to maintain anonymity and donors who do not object to possibly being identified later on following a request of the parties concerned” (*A Creative Belgium of Solidarity. Breathing space for the country (Leefbare wijken in leefbare steden)*, 15 July 2003, p. 59.).

Moreover, after revisions of the Code, the condition of marriage is also no longer mentioned; Article 88 no longer refers (as it did in 1975) to “the woman and her husband” but rather to “people and couples” who need assisted reproductive care.

In its current version, Article 88 of the Code also focuses on the well-being of the future child (his/her family balance linked to social and legal conditions), the responsibilities of the physicians, and the importance of the ethics committees at the hospital level. The Code insists on the persons giving their “enlightened, conscious and deliberate” consent. Consent must be written in cases where the person requires the donation of gametes.

The second phase of policy design encompassed the period from 1982 to 1987. In 1982, a bill was introduced in the Parliament of the French Community, one of the sub-national entities within the Belgian federal system, for the purposes of regulating several aspects of artificial insemination. The proposal considered regulations for sperm donation and sperm conservation (e.g. licensing of sperm banks; forbidding of commercialization), AI practices (written, free and enlightened consent of the stable or married couple; donor anonymity) and finally, the legal status of paternity of a child born by AI. This proposal stated that the husband - or the cohabitant - of the inseminated woman was the legal father of the child if he had given his consent for an artificial insemination by donor (AID). But the French Community, as a sub-national entity, had no formal power to modify the Civil Code, which was *de jure* necessary for regulating the paternity order. Thus, the bill was never adopted.

Meanwhile, in 1987, the paternity order was officially protected by a revision of the Civil Code. A federal law was enacted on the 24th of February 1987 with the aim of modifying Article 318 § 4 of the Civil Code.

Since then, the husband who gives his consent (for an AID) cannot contest the paternity of the child (of his wife). We find that this regulation by the public authorities is a consequence of the attempt to regulate ART at the French Community level in 1982.

The third phase (running from the beginning of the 1980s to the end of the 1990s) was characterized by the creation of the National Consultative Committee for Bioethics. Since May 1984, the idea of creating such a Committee has been discussed at the federal level. After quite a complicated but consensual debate between all the political entities involved (i.e. at the federal level as well as at the level of the French, Flemish and German Communities), the law that institutionalized the National Committee for Bioethics was adopted on the 6th of March 1995. The Committee issued notices and disseminated information on the problems triggered by scientific research and by its applications in biology, medicine and health. Since its creation, the Committee has published several notices on ART in general³.

During this third phase, it is interesting to note that, apart from this institutional design, several substantial ART regulations were also proposed in Parliament. Three rather 'restrictive' bills on a mandatory licensing and reporting system for ART centers that practice AI, IVF and embryo transfer were proposed in February 1987, April 1987 and

³ See among others Notice No. 2 of 7 July 1997 on the Convention on Human Rights and Biomedicine; Notice No. 3 of 17 November 1997 on the choice of sex as well as notice No. 22 of 19 May 2003 regarding the choice of sex for no medical reason; Notice No. 6 of 8 June 1998 regarding the ethical bases for the optimisation of offering and functioning of the ART centres; Notice No. 10 of 14 June 1999 regarding reproductive human cloning; Notice No. 18 of 16 September 2002 regarding research on *in vitro* embryos; Notice No. 19 of 14 October 2002 regarding the destination of frozen embryos.

March 1988. Three rather 'permissive' bills were proposed in June 1992, June 1995 and February 1997, which aimed at regulating general aspects of ART, in particular, AI, IVF, surrogate mothers, genetic screening and testing and research on supernumerary embryos. However, none of these bills were accepted, thus highlighting a non-decision process within the parliamentary arena.

The fourth phase began at the end of the 1990s and is continues to the present. During this period the policy agenda has focused on the official licensing of ART centers and, predominantly, on research on *in vitro* embryos.

In 1999, the political parties, in accordance with the leading ART centers, set up a procedural regulation process. The medical sector's official justification was to guarantee the quality of ART care. An unofficial - but powerful - argument was the economic competition between the centers and their growing numbers, especially in Flanders. The decision-making process led to the four decrees on the 15th of February 1999. These decrees introduced a licensing system, thus limiting the oversupply situation in the ART field, and created a Physicians' College aimed at globally supervising the quality of care within the ART centers.

Furthermore, on the 4th of June 2003, the Minister of Social Affairs adopted a legal decision guaranteeing the reimbursement of IVF/ICSI under specific conditions (mainly the number of implanted eggs, in order to limit the occurrence of 'multiple pregnancies'). Since the 1st of July 2003, Belgian patients are thus guaranteed to receive full financial coverage by Social Security, for medical as well as laboratory acts. The only condition for entitlement to such coverage deals with the number of transferred embryos, which is linked to the age of the patient.

This specific design process in Belgium, characterized by general procedural rules and Social

Security reimbursement, has led to an open system of ART care. Indeed, the autonomy of practitioners is only limited by the licensing procedure, which does not hamper any technique or activity (for instance, pre-implantation diagnosis). Safeguards are put in place by the doctors themselves *via* the local ethics committees at the hospital level, the National Committee for Bioethics, the Code of Medical Conduct and the rules decided by the medical team within each ART center. The system is also open to all patients, whatever their marital status, sexual orientation or economic resources. As we have just described, no law restricts the access of stable heterosexual couples to treatment. This means that single and homosexual patients are also entitled to treatment. And since 2003, the cost of ART treatment no longer curbs the potential parents' desire to have a child through ART. All licensed ART centers get a fixed price for laboratory work (1182 € per cycle).

The same openness prevails for research on *in vitro* embryos. Two European initiatives have contributed to a debate on *in vitro* embryo research in Belgium. Firstly, on the 4th of April 1997, the Council of Europe issued the Convention on Human Rights and Biomedicine (with its Article 18 forbidding the creation of embryos for research purposes). The Convention was amended with an additional protocol on the prohibition of the cloning of human beings in January 1998. Secondly, European Directive 98/44/CEE (of the 6th of July 1998), based on the legal protection of biotechnological inventions, excludes the human body and processes of human cloning from patents and human embryos from use 'for industrial or commercial purposes' (Articles 5 and 6).

European initiatives were part of the debate about ART in Belgium. Among the Senate, the Commission of Social Affairs released a report on Article 18 of the Convention on Human Rights and Biomedicine. Between

1997 and 2001, there was intense parliamentary activity about research on *in vitro* embryos and even cloning. A dozen bills were proposed both at the Senate and at the Chamber of Representatives.

On the 8th of February 2001, a Senate select committee on bioethical matters was established. The discussions triggered within this Committee led to the Parliamentary process of adopting a federal law. The law of 11th of May 2003 regarding research on *in vitro* embryos authorized the procuring of embryonic stem cells from supernumerary embryos (up to 14 days of development). It also allowed for the creation of human embryos for research purposes (i.e. therapeutic cloning under specific conditions). It explicitly forbade reproductive cloning. Finally, it proposed the creation of a Federal Commission for scientific and medical research on embryos *in vitro*. Apart from this law, no other regulation has been adopted (meaning that Belgium has no regulation on ART in general nor has it signed the Biomedicine Convention).

2.3. Explanation of the Belgian policy design

The description of the policy process highlights the main characteristics of the Belgian policy related to ART and research on *in vitro* embryos: mainly non-decisions in the Parliamentary arena (except for one specific ART issue, i.e. embryo research), the Executive's intervention to set up a licensing procedure, and significant self-regulation by physicians and researchers. Several factors explain this peculiar situation, which gives the ART medical community considerable autonomy.

In Belgium, practitioners belong to different sociological families (catholic or secular). In the health field, each sociological family possesses its own mutual insurance institution and hospitals. Thus, each ART center

belongs to a hospital within a sociological pillar. The philosophical or religious values of the pillar influence the practices of the center, *via* the local ethics committee and other mechanisms. Hence, physicians and researchers do not all share the same values and interests. This structure is not conflictual but consensual. It is an illustration of institutional pluralism. The different ART centers agree to let the other centers practice ART following their own Code of Conduct, provided that they benefit from the same freedom (according to the “tit for tat” strategy, as described by Axelrod 1984).

Moreover, they decide on concerted action, with the aim of limiting all public intervention. The self-regulation of their practices, at the decentralized level of all ART centers that display great bioethical pluralism, is politically acknowledged as a credible alternative to a public debate that would seek to harmonize ART practices in Belgium.

This corporate management of ART has never been challenged by the actors that are external to the sector. Indeed, the absence of mobilization of the final beneficiaries (the patients) constituted a favorable context for the absence of any policy until 1999, as well as for a procedural-style of political regulation (the procedure takes the form of official recognition of the ART centers and reimbursement of expenses for the patients) and, finally, for the legal consecration of the liberty of biomedical research (law of the 11 May 2003 on *in vitro* embryo research).

Infertility still belongs to the private rather than to the public domain: the issue of infertility is still taboo. Belgium has hardly experienced any formal organization on the part of the final policy beneficiaries (i.e. patients) that could exert pressure on politicians, be audited by Parliament, or be interviewed by the media, for instance. On the other hand, neither feminists nor gay rights associations consider the ART issue their priority

(homosexual couples are free to receive ART treatment in Belgium). Thus, ART in Belgium can be characterized as a “policy without public” (May 1991). Recently, public opinion has become more sensitive to the issue of stem cells and cloning, but is largely in favor of biomedicine in general.

Thus, the interest of the practitioners to have their sector regulated is limited, and this for three reasons. Firstly, they hold a leading global position in the ART field and wish to retain this position, especially following the rapid evolution of techniques. Secondly, their fragmentation hampers self-regulation of the whole sector. However, they do agree on the licensing procedure that protects the ART market (shares of the different hospitals and clinics). Thirdly, attitudes are changing rapidly within certain catholic institutions. For example, the doctors and researchers of the Catholic University of Louvain (UCL) declared themselves, in October 2002 (i.e. before the adoption of the law of 2003), in favor of embryo research and, if necessary, of the creation of embryos for research. This initiative, which triggered major opposition from the Catholic Church, illustrates the willingness of the medical sector to self-regulate and to pursue a liberal policy.

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 well-established medical practices. The politicians adopt authoritative decisions *a posteriori*: they grant licenses to well-established medical practices rather than anticipating or dramatically modifying them.

Facing a medical community that can regulate its practices and is extensively supported by the final beneficiaries, the political actors have not felt it necessary to intervene strongly in terms of regulating ART and research on *in vitro* embryos. This is in sharp contrast, for

instance, with what happens in another biotechnology sector: the GMO sector. Regarding the GMO issue, political actors are confronted with a pro-active mobilization of civil society that exerts pressure on a loose network of target groups (the firms and the universities promoting GMO; for a more detailed comparison, see Varone and Schiffino 2004).

In Belgium, political actors have been so reluctant to regulate biomedicine that it has carried a political risk for them. Indeed, Social Christian parties played a key role in the government coalitions from 1945 to 1999. While they were central decision makers, they obviously avoided putting bioethical matters on the political agenda, mainly for two reasons. The first reason was to hamper internal divisions of the Social Christian parties between conservative and more liberal members⁴. The second reason was to preserve the government coalitions that united Catholics and seculars (socialist and liberal parties) since World War II. Following the institutional crisis over the abortion law in 1990, the Social Christian parties strategically avoided debate and decisions on bioethical issues (it is mentioned in government agreements). This explains the high number of non-decisions (bills proposed but never enacted) during the design process before 1999.

In 1999, for the first time in fifty-four years, a new government coalition (Verhofstadt I), composed of the Socialists, the Liberals and the Greens, came to power, thus excluding the Social Christian parties. In recent years, one fact has therefore been significant: the secular coalition has modified the public agenda on bioethical issues. For

⁴ These parties were the « Parti social-chrétien » (today called « Centre Démocrate Humaniste ») in the French-speaking part of the country and the « Christelijke Volkspartij » (today « Christen-Democratisch en Vlaams ») in the Dutch-speaking region.

example, the process of decriminalizing euthanasia came to an end (law of 28 May 2002), homosexual marriage was allowed (law of 13 February 2003), embryo research was regulated within a liberal framework (law of 11 May 2003), and the adoption of children by homosexuals was allowed (law adopted by the Parliament in April 2006). The government formed in 2003 by the Socialists and the Liberals (Verhofstadt II) has also planned to open the debate on surrogate mothers and the anonymity of sperm donors.

The sequence of the appearance of bioethical issues on the political agenda is an additional explanatory factor that needs to be taken into account. Two phenomena must be considered here: the legacy of other bioethical issues (especially the abortion crisis) and the competition between bioethical issues on the political agenda. Apart from the fact that abortions, like ART, concern embryo status, the abortion policy has influenced the policies of other bioethical issues in relation to the way decision-makers have dealt with it. The debates on the decriminalization of abortion in Belgium led to major political crises. The King refused to sign the law and had to abdicate for one day. The point we have made about Social Christian parties indicates that, since then, political mechanisms have been established to avoid new crises on bioethical matters.

The regulation of euthanasia also had an influence on the ART agenda and, more specifically, on the embryo research agenda. Euthanasia and other bioethical issues (homosexual marriage, for instance) were all discussed in the same main policy arena: the Senate. Until the euthanasia discussion came to an end, the embryo research debate was clearly sidelined. As previously mentioned, the secular coalition (in power since 1999) has managed several ethical issues at the same time. But decisions need

to be placed in a sequential order, from a purely practical point of view of tackling the issues.

The relatively recent federalization of Belgium is another explanatory factor. Belgian ART policy mainly belongs to the ideal-type of functional federations (Watts 1999, Braun 2000). In a functional federation, competencies are attributed along the functions of policy formulation and policy implementation. While formulation is normally the responsibility of the federal government, policy implementation usually belongs to sub-federal governments.

The federal and the federated government levels share responsibilities in the health care sector. The 1980 reform of the Belgian state delegated some policy powers to the three communities (French, Dutch and German speaking communities). The communities shifted some of these policy responsibilities to the three regions (Brussels, Wallonia and Flanders) in 1993 due to budget deficits.

As far as ART is concerned, this gradual federalization process has clearly delayed fundamental policy-making. As described above, the failure of the first substantial bill on artificial insemination in 1982 was due to a conflict of competencies between federal and federated entities. Today, the multi-level governance structure still causes a complex division of policy responsibilities. Theoretically, federated entities can develop a policy within and outside hospitals. *De facto*, the federal level has a predominant role by deciding on the number of ART centers, as well as by editing the rules. The regions deliver licenses to the ART centers, but the federal state controls the quality of care as a result of the recent Physicians' College. This example of vertical fragmentation explains the lack of control of the various levels of power. In any case, the different governments do not consult one another as to how to act: unlike other health sub-sectors, there are

no inter-Ministerial conferences on ART (for an international comparison of the influence of federalism on ART policies in various countries, see Rothmayr et al. 2003).

Therefore, the limited presence of administrative actors at the core of the policy network is an important point to be highlighted. The tasks of conception, implementation and control of the policy are *de facto* largely delegated to organs that are predominantly composed of physicians (mainly the National Bioethics Committee, the Physicians' College, the Federal Commission for the Medical and Scientific Research on *in vitro* Embryos). Given the centrality of the medical context in the entire design process, it is hardly surprising that the policy design is open. It is left to the discretion of each ART center how to self-regulate its practices and, consequently, to exploit (or not) the legal possibilities of research and therapies according to the law of the 11 May 2003.

Finally, ART is weakly regulated on the European and international scene. At the heart of the European Union, little sovereignty is relegated in terms of public health. The initiatives that have been taken at the international level concern less ART in general than research on embryos and the development of cloning, which happen to be the fields in which Belgium has set up legislation. But adhering to the Council of Europe texts on biomedicine is a matter of each state's discretion.

One of the motives of the political decision-makers to legislate in the field of stem cell research is the desire to sign and ratify the Convention on Biomedicine and Human Rights, without however limiting the autonomy of the medical and scientific communities. To explicitly adhere to the Convention, while at the same time expressing reservations about article 18 of the Convention, Belgium

must refer to a national law that delimits a different framework than that of the Convention, which became possible with the law of 11 May 2003.

With respect to ART, the legislative power has not intervened. In the field of *in vitro* embryo research, it intervened to promote a liberal law. As it stands, at the heart of the European Union, only two countries have adopted the explicit position of authorizing research on supernumerary stem cells and creating embryos with research aims: Belgium and Great Britain. The legislative framework in Belgium (in the way in which it has been defined, viz. privileging the autonomy of scientists) also clarifies the Belgian position in obtaining financing for research projects, at the heart of the 6th framework-program of the European Union, for instance (see COM (2003) 390 final).

3. France: the experience of state intervention

3.1. State of the ART in France

France is often considered to be an active European country in the field of ART (Charles and Claeys 2001). It has been practicing AI for a long time and the second European “test tube baby”, born in 1982, was French. A hundred ART centers, distributed in the different French Regions, are licensed. The statistical data that can be collected mainly comes from two sources. Firstly, the National Commission of Medicine and Biology of Reproduction and Prenatal Diagnosis (CNMBRDP) is in charge of the monitoring of licensed ART centers. It receives and synthesizes all the activity reports that each licensed center is obliged to submit annually. Secondly, the association FIVNAT, that brings together most of these centers on a

voluntary basis, collects the data relating to patients who use ART techniques.

The number of ART-based births is growing. This steady growth is explained by a combination of various factors: the increasing mastery of the skills in the centers, which are now able to improve their results significantly; access to the ICSI technique, which significantly improves the success rate in certain cases of male infertility; a greater selection of patients who begin ART procedures; and, finally, a positive effect in terms of the efficiency of ovarian stimulation treatments.

We do note, however, a significant drop in the number of transferred embryos, which results from a growing awareness of the risks that multiple pregnancies represent for the mother and the children. The drawbacks and handicaps linked to premature births, the risk of miscarriages or adopting embryonic reduction, which is always painful and dangerous, have indeed led to a drop in the number of transferred embryos. This approach is also occurring in other countries, such as Belgium, where the reimbursement of treatments by social security is implemented on condition that the procedure respects a predetermined number of transferable embryos, taking into account the woman's age.

3.2. Policy process

The policy process has gone through four phases. The first phase started at the beginning of the 1970s and went on until the 1980s, corresponding to a phase of technical development in a framework of self-regulation by doctors. During this first phase, medical practices were broadly developed. In terms of artificial insemination by donor (IAD), centers set up sperm banks. At Bicêtre

hospital, Dr Georges David created the first Centre for the Study and the Conservation of Eggs and Sperm (CECOS) in 1973. In 1982, the entire team of CECOS France created a Federation of all CECOS centers with the aim of bringing together their research results and improving the techniques used, initiating research targeted on fertility, representing themselves at the institutional level, and helping the centers in their everyday practice through specialist commissions. With respect to IVF, the first “test-tube baby” was born in 1982. Some medical teams were more particularly involved in top-notch developments, particularly those at the Necker hospital (Paris) and the Bécélère hospital (Clamart).

To sustain those practices, local ethics committees were created on the initiative of the doctors themselves who were working at university hospitals, sometimes with specialists from other disciplines. These committees began to study the protocols of the therapeutic trials with the aim of giving an informed opinion on the ethical quality of the research methods and suggesting, if needed, lines of conduct for a greater respect of the patient. They also evaluated more targeted issues of everyday practice (Bateman 1998: 13-14). During the first phase, these committees remained consultative. The CECOS centers established a code of conduct, which inspired measures that were later adopted in the bioethics laws of 1994 (see below).

The second phase, from 1983 to 1988, was marked by the creation of a National Committee for Bioethics (CCNE)⁵, which was not only in charge of ART issues, but also had to deal with the more general ethical issues triggered by scientific progress in biology, medicine and health. Nevertheless, since its first notices dating back to

⁵ Decree n°83-132 of 23 February 1983 creating a National Committee for Bioethics related to Life Sciences and Health.

1984, it has been engaged with ART issues (beginning with Notice No. 3 of 23 October 1984 « on ethical problems related to ART »)⁶.

In 1983, this institutional design, decided by presidential decree, corresponded to a first public regulation. Meanwhile, the composition and the functioning of the CCNE (the technical section, a working group that calls upon external specialists), as well as the creation of local committees by the doctors, show that, during this second phase, ART regulation was broadly left in the hands of experts. The issues, such as prenatal diagnosis, gametes donation, etc., were quite specific and different from ordinary medical practice, and thus needed to be formulated by doctors and researchers. These experts even hold key positions at the heart of deliberation organs: the president of CCNE was a doctor (Jean Bernard).

The third phase, from 1988 to 1994, was characterized by the development of a specific ART regulation: it is an “in-between” intervention by the public authorities. In 1988, they decided upon procedural rules by adopting the two so-called « Barzach decrees » (The decrees were under the responsibility of Michèle Barzach, the minister in charge of Health and the Family)⁷. These two decrees were essentially procedural because they

⁶ The Committee has delivered more than eighty notices among which approximately one third focus on ART issues such as prenatal diagnosis (see for instance Notice No. 5 of 13 May 1985) and pre-implantation diagnosis (see Notice No. 19 of 18 July 1990 and Notice No. 72 of 4 July 2002), research on embryos (a.o. Notice No. 8 of 15 December 1986), gametes donation (for example Notice No. 20 of 18 July 1990), cloning (Notice No. 54 of 22 April 1997), ICSI (Notice No. 75 of 12 December 2002 for the ethical aspects) and so forth.

⁷ (1) Decree no 88-327 of 8 April 1998 on the activities of medically assisted procreation; (2) Decree no 88-328 of 8 April 1988 on the creation of the national Commission of medicine and reproductive biology.

stipulated the measures that the ART centers had to follow to be able to practice treatment (specialization of the doctors, infrastructure, authorization, etc.). They created an *ad hoc* organ: the national Commission of medicine and reproductive biology⁸. The decrees left a great deal of autonomy to the physicians because they did not establish a list of medical practices that were authorized or prohibited.

In 1988, the so-called Huriet law of 20 December 1988 was also passed. The local ethics committees were replaced by “consultative committees on the protection of individuals who are involved in biomedical research”. These committees, being consultative organs, became compulsory since their approval was required before the onset of any research protocol.

In the fourth phase, from 1994 to the present, a substantive regulation regarding ART and embryo research (there is no clear-cut distinction between these two areas in the French legislation) has reformed the previous regulation. Three « bioethics laws »⁹ were adopted, including one (No. 94-654) directly related to ART. After 1994, the legal framework was further elaborated with a series of decrees (95-223, 95-558, 95-560, 96-993, 97-613, 97-555, 98-216, 99-925).

Between 1988 and 1994, doctors and patients’ associations exerted pressure so that political decision-

⁸ At a first glance, the name already shows that this Commission has a more specific mission than the Committee for Bioethics. It is not only an advisory body. It is an implementer of the Huriet Decrees, delivering or withdrawing the agreement to ART centres.

⁹ (1) Law n°94-548 of 1 July 1994 on the treatment of nominative data with the aim of research in the field of health, (2) law no 94-653 of 29 July 1994 on the respect of the human body and (3) law no 94-654 of 29 July 1994 on the donation and the use of elements and products of the human body, on medical assistance and on procreation and prenatal diagnosis.

makers would legislate on ART, in terms of the costs and medical decisions on treatments, such as the woman's age, and thus also preventing the proliferation of centers and their diverse practices.

Thus law no 94-654 explicitly defined ART (art. 8) as encompassing artificial insemination, in vitro fertilization, embryonic transfer or any other technique aiming at procreation. It limits access to treatment to patients forming a heterosexual couple that has been married or cohabiting for at least two years. As far as medical practices are concerned, the law included a list of prohibitions, for example the creation of embryos or their marketing. It also required that sperm donors had to remain anonymous and already had to have children of their own. Moreover, regarding the autonomy of the doctors, the law adopted the authorization measures described in the Barzach decrees and further broadened them, notably by setting the conditions for prenatal diagnosis. It thus constituted a more restrictive framework compared to previous regulations.

Social security covered treatments to patients meeting the criteria defined by the law. In this respect, French regulation could also be viewed as restrictive, if not on the basis of an economic factor, then certainly with respect to sociological factors. Indeed, it linked up the possibility of treatment with strict conditions of marital status (the stability of the couple and heterosexuality) as imposed by law.

The fourth phase has now come to a standstill since the revision procedure of the Bioethics Laws has a five-year delay. The legal framework foresaw reviewing the legal conditions within five years and currently remains underway.

3.3. *Explanation of the French policy design*

From the description of the policy process, it is obvious that the policy design is rather interventionist in France. The medical and scientific community was given significant freedom until the 1980s. But the government decided as far back as 1983 to create an expert apparatus to counsel the political decision-makers on ethical issues. Fifteen years ago, it also fixed all procedures for the functioning of ART centers. Finally, at the beginning of the 1990s, it adopted laws that delineate more than a bare framework for ART practices. The French Bioethics Laws of 1994 explicitly define who is entitled to ART treatment and under which conditions.

Several explanations for the interventionist ART policy in France can be provided. A major factor is the nature of the majoritarian political system. The semi-presidential system of France sometimes enables a single party to entirely dominate policy-making; at other times it requires cohabitation; and yet at other times it possesses some of the attributes of a power separation system. The ART policy design offers an illustration of this complex style of regulation, where “policy entrepreneurs” (Kingdon 1984; Baumgartner and Jones 1993) play a key role.

In the area of ART, the crucial years were those leading up to the adoption of the bioethics laws in 1994. The first bills on ART were introduced in the *Assemblée nationale* in 1992 by a Socialist government that was well positioned to obtain a swift enactment. Designed by a Socialist government and a presidency comprising several bio-optimists, these bills were rather permissive, legitimizing several aspects of ART research. However, the Socialist Party was not unified in this permissive preference and therefore the bills provoked significant legislative debates. Following these debates and public consultations, the *ad hoc* commission mandated by the *Assemblée*

nationale to study the bills proposed some restrictive amendments.

The decisive move toward restrictions on ART research, however, came in 1993, when legislative elections brought a right wing majority to the assembly. Unlike members of the Socialist Party, supporters of the Right in France have a more unified view that embryos deserve protection; they oppose any change in the current sacred status accorded to embryos by the country's abortion law (17 January 1975). After the 1993 elections, parliamentary debates shifted towards the importance of protecting embryos in a manner consistent with the law on abortion. This perspective justified imposing restrictions on research that results in the destruction or alteration of embryos, which became an essential element of the 1994 laws on bioethics.

When the five-year delay in revising the bioethics laws was over (in 1999), Lionel Jospin's socialists formed the government in coalition with the Green Party. Indeed, President Chirac was forced to abandon several of his policy responsibilities to Jospin's Socialist government, because his party did not control a majority of seats in the *Assemblée nationale*. Jospin's socialists themselves did not have sufficient seats in the legislative assembly to govern alone and therefore had to allow the formation of a coalition government with the Green Party. In terms of policy design, this cohabitation implied that French political parties were variously capable of translating their preferences in public policy.

Including several bio-optimists, Jospin's government sought to increase the permissiveness of the 1994 laws on bioethics, notably in terms of measures on embryo research. The proposed amendments prompted a long and cumbersome debate in the *Assemblée nationale*. Unable to secure the adoption of the bill before the 2002

elections, the Socialist party was forced to abandon control over the revisions of the laws on bioethics to a strong rightist government. Indeed, in the spring of 2002, Jacques Chirac was re-elected president of the Republic. A few weeks later, his conservative political party, the “Union pour un mouvement populaire” (UMP), won a majority of seats at the *Assemblée nationale*, earning Chirac the possibility to appoint a government (Raffarin I). Under these circumstances, Chirac and his political party had considerable control over policy-making, which mainly explains why the amendments proposed in the new bill were more restrictive than previous measures. Thus, the transfer of embryos after the death of the father was prohibited because “it sets serious problems of principle”. The principle of research on supernumerary embryos was also forbidden, save very strict exceptions; although the current law authorizes research if it has therapeutic aims. The creation of embryos was prohibited with no exceptions because of a presumed abuse towards therapeutic cloning.

This interventionism of political decision-makers is strongly linked to the centralized administrative structure. French civil servants are grouped in a Health Agency that can facilitate a coherent and efficient policy. For example, the Director of the Health Agency can ask for advice from the Committee for Bioethics¹⁰.

The intervention of the public authorities is reinforced by the existence and the assertiveness of groups within civil society and particularly of the patients’ associations (e.g. “Association Pauline & Adrien”). The coverage of ART treatments under the country’s health insurance system has been guaranteed for a long time. In the bioethics laws, infertility is officially considered an

¹⁰ See for instance Notice No. 74 of 12 December 2002 on umbilical cord blood banks with the aim of research use.

illness to be cured. In this context, ART belongs to a public domain where the issue is still considered to be private. Patients' associations have participated in the public debate by being heard in the Parliamentary select committees. They have addressed the political decision-makers in the hope of a better understanding of the issue, but did not oppose the majority position in Parliament.

Moreover, in the years leading to the adoption of the bioethics laws in 1994, most citizens trusted the network of scientists and physicians that were making most ART decisions. As indicated in several public opinion polls, civil society did not question the competencies of physicians nor of researchers in regulating their field (on this topic, see in particular Montpetit et al. 2005).

Strictly viewed from a policy network perspective, the restrictions included in the 1994 laws may therefore appear to be surprising. And interestingly enough, the network of scientists and physicians did not resist those restrictions. The right wing government of 1993 was in a strong position to act on its concerns relating to the protection of embryos. The capacity of this government to act unilaterally encouraged cooperation among network actors. Scharpf (1994) has indeed shown that under the "shadow of hierarchy", actor cooperation increases. Fearing unilateral action by a party in a position of authority, actors actively seek to attain a consensus, even if this entails a compromise with regard to their preferences. It is therefore in view of appeasing the concerns of a government in power that the network of ART scientists and physicians accepted restrictions on embryo research. The cooperation not only prevented unilateral action, it protected fertility clinics from intrusive government interventions. This is akin to the self-regulation that the ART centers have defined since the 1970s.

An interventionist regulation was facilitated by the absence of international constraints in the field of biomedicine. Indeed, it was up to the national decision-makers to choose what would be allowed or forbidden. Therefore, political decision-makers decided upon the public regulation of ART by taking into account the scientific expertise that was provided by the ethics committees and the practitioners, and by paying attention to public opinion, but with room for maneuver in the face of international pressure.

It should be underlined that the bioethics laws of 1994 preceded the adoption of UNESCO's declaration on the human genome as well as the Convention on Human Rights and Biomedicine, which were both proclaimed in 1997. The pressure to regulate was 'bottom-up' rather than externally imposed. This was also highlighted by the official impulse given by President Chirac to stimulate a concerted ban on reproductive cloning at the European and even at the international level (see, for example, his speech at the 20th anniversary of the National Bioethics Committee). Moreover, the Council of Europe's Convention on Human Rights and Biomedicine is, legally speaking, the most constraining kind of international agreement for national governments: an international declaration creates a moral obligation, whereas a convention creates legally-binding obligations, which are, however, rarely enforced by an international authority. It is interesting to note that the country's bioethics laws conform to the dispositions of the Convention, including embryo research concerns.

4. Comparison: similar problems but diverging solutions

The guiding research question of this article is how and why France and Belgium have formulated and

implemented different ART policies. We are thus interested in the ART policy design of each country. Policy design can be understood as set of five attributes or constitutive elements that traditionally distinguish a given policy from another policy (according to Knoepfel et al. 2001): (1) policy goals, as intended consequences (e.g. protect human dignity); (2) policy instruments, as the means proposed to achieve the desired ends (e.g. licensing of ART centers); (3) implementers, i.e. the public and private actors in charge of taking measures to implement the policy instruments (e.g. ministry of health, committee of physicians); (4) target groups, as the persons and groups whose behavior a policy intends to influence (e.g. physicians and researchers); and (5) the final beneficiaries who experience the end effects of a specific public policy (e.g. patients, embryos). Finally, we could also identify the “policy rationales” underlying the political regulation of biotechnologies, as the expressed justifications for the choice of goals, instruments, implementer and target groups. According to Schneider and Ingram (1997), these policy rationales provide the logical links between all the constitutive elements of the policy design. They might be assessed as the practical “logic of action” on which the state intervention is based.

4.1. Policy content: similar instruments but different goals and implementing actors

The data presented in Table 1 result from an analysis of content of the main authoritative decisions taken by the public authorities, i.e. the main public regulations including sanctions for the actors they target. The operational coding of the variables and the details of such analysis have been developed in previous publications (see in particular Bleiklie et al. 2004). The column headings of Table 1 correspond to the analytical concepts of policy

analysis presented above. Thus, the content of ART and embryo research policy is analyzed in terms of its goals, implementers, instruments, target groups and final beneficiaries.

As we can see, there are similarities regarding the instruments of ART policies. In Belgium and France, decision-makers have chosen licensing procedures, reporting by ART centers, sanctions and subsidies for patients. Target groups are also the same in both countries (mainly physicians). Differences arise when we compare the goals, implementers and final beneficiaries of the ART policies. Regarding ART in general, the policy goals are similar because they tend to help individuals with infertility problems, but they differ over embryo research. Indeed, while the Belgian policy aims at promoting scientific progress by authorizing embryo research and creation, French policy focuses on the protection of embryos by forbidding experiments on embryo as well as embryo creation for research purposes. Moreover, if implementers share similarities (Health Ministers, experts), they differ regarding the strategy of coordination and centralization. Finally there is a sharp contrast with regard to the final beneficiaries. The civil status of ART patients is much more varied in Belgium than in France. Furthermore, in terms of embryo research, the definition of the final beneficiaries is strikingly different in Belgium compared to France.

Table 1: Policy content in Belgium and in France

	ART		Embryo Research
Authoritative Decisions	Belgium Royal Decrees of 15 February 1999 regarding planning, norms and qualitative evaluation of ART centers		B Law of 11 May 2003 on <i>in vitro</i> embryo research
	France Law no. 94-654 of July 29, 1994 (under revision)- Public Health Code		F Law no. 94-654 of July 29, 1994 (under revision)- Public Health Code
Public Policy (PP) Goals	B and F ART purpose is to remedy infertility. Its purpose can also be to avoid particularly severe illnesses in children		B Promote scientific research
			F Protect embryo
Implementers of the PP	B and F Minister of Public Health Experts bodies	B Regions	B and F Minister of Public Health Experts bodies
Instruments of the PP	B and F Licensing Sanctions Subsidies for patients Reporting		B Licensing Reporting Sanctions
			F Ban

Table 1, continued

	ART	Embryo Research
Target groups of the PP	B and F Hospitals/ART centers Physicians/Researchers patients	B and F Hospitals/ART centers, Universities
Final Beneficiaries of the PP	B Couples and singles; Homo and hetero sexual	B Patients (to be cured by the therapeutic application of stem cells research)
	F Stable and heterosexual couples	F embryos

4.2. Policy process: similar framing but different policy-making

Regarding the designing-process, the problem framing is similar in both countries. As a matter of fact, the sequence of policy issues is largely comparable (see Table 2): we find phases corresponding to largely similar stages of problem-definition and agenda-setting (Cobb and Elder 1972. Schön and Rein 1994), but what diverges is the decision-making process itself. Firstly, there is an important time lag between decisions adopted in France and decisions made in Belgium. In other words, moments in which decisions are taken vary from one country to the other. For instance, a National Committee for Bioethics was created in France a decade earlier than in Belgium. Secondly, the policy-making process, especially in the Parliamentary arena, is characterized by several decisions in France *versus* a majority of non-decisions (Bachrach and Baratz 1963) in Belgium. Thirdly, the main arena for

formulating ART policy is the Executive in Belgium versus the Parliament in France.

Table 2: Policy process in Belgium and in France

<i>Problem framing according to technology and medical practices development</i>	Policy adopted in France	Policy adopted in Belgium
Artificial Insemination	CECOS (1973)	Code of deontology (1975) Civil Code (1987)
In Vitro Fertilization (including ICSI and related techniques)	Bioethics Committee (1983) Licensing (1988) Bioethics laws (1994)	Bioethics Committee (1995) Licensing (1999)
Research on embryos, on stem cells and therapeutic cloning	Pending revision of Bioethics laws	Embryos Law (2003)

4.3. Explaining divergences in ART policies

In a nutshell, Table 3 summarizes the main variables that have been discussed in-depth in the two national case studies and that contribute to explaining why the ART policies adopted in Belgium and France are different. As a matter of fact, both actors' interests and resources (e.g., role of target groups, implementers and political decision-makers) and institutional factors (e.g.,

national decision-making rules, international arena and bioethical agenda) influence the final policy design.

Table 3: Explanatory variables of diverging ART policies in Belgium and France

	France Interventionist ART policy	Belgium Liberal ART policy
Self-regulation by Physicians	Initial self regulation at sector level as basis for public intervention	Permanent self regulation at hospital (ART center) level as substitute of public intervention
Demands of Patients	Mobilization and traditional family model (e.g., split between ART patients and feminists/gay lobbies)	No mobilization neither of ART patients nor of feminists/gay lobbies
Partisan choice of Political Parties	Left parties (permissive policy) versus right parties (restrictive policy)	Secular parties (permissive policy) versus Christian- democrats parties (restrictive policy)
Resources of the Administration	Centralized and coordinated	Decentralized and uncoordinated
Expertise and advices of Bioethics Committees	Republican tradition: one recommendation with minority reports	Pluralistic tradition: one recommendation with several diverging reports

Government type	Majoritarian. “One party: one decision”: political color alternation	Consensual. Coalitions with “One ideological trend”
Unitary/Federal State	Planning and impulse	Endorsement of existing practices
International pressure	Pro-active attitude in congruence with the European Biomedecine Convention and pressure against cloning at the UNO	Reactive attitude towards Art. 18 of the European Biomedecine Convention and pressure favoring stem cells research at the UNO
International pressure	Pro-active attitude in congruence with the European Biomedecine Convention and pressure against cloning at the UNO	Reactive attitude towards Art. 18 of the European Biomedecine Convention and pressure favoring stem cells research at the UNO
Bioethical agenda-setting		
Abortion	Decriminalization (17 January 1975)	Decriminalization (3 April 1990)
Euthanasia	Criminalized (17 January 1975) (see mobilization in support of a mother’s quadriplegic in September 2003)	Decriminalization (28 May 2002)
Homosexual marriage	Contract (PACS) (15 November 1999)	Civil status (13 February 2003)

Now, following this very first empirical evidence, we might suggest – inductively - several research hypotheses to explain why “biopolicies” converge and/or

diverge across both countries (e.g. Belgium versus France) and/or policy fields (e.g. assisted reproductive technologies versus genetically modified organisms in the agro-food sectors).

5. Conclusions: Explaining “biopolicies” across countries and sectors

Three rough categories of variables are potentially useful in addressing the differences and similarities of “biopolicies” across several countries and sectors: “policy networks”, “country pattern” and “internationalization” (see Varone et al., forthcoming). These categories of variables are strongly related to the three traditional comparative approaches to the study of politics and policies, which Levi-Faur (2004) refers to as the “Policy Sector Approach” (Freeman 1986; Marsh and Rhodes 1992 and all “policy networks” scholars), the National Patterns Approach (Richardson 1982, Vogel 1986 and all “comparative politics” scholars) and the “International Regime Approach” (Krasner 1983 and Keohane 1984). Thus, in order to guide further empirical studies on various “biopolicies” (regulating ART, GMOs, etc.), and on the basis of our own empirical research on ART policies adopted in France and Belgium, we suggest seven hypotheses about the policy effects of policy networks (hypotheses 1 and 2), party politics (hypothesis 3), institutional features at the national level (hypotheses 4 and 5) and international rules (hypothesis 7):

- Hypothesis 1: If a policy sector is organized around a “policy community” dominated by the target groups, the policy will grant a high degree of autonomy to the target groups, perhaps even supporting a self-regulatory arrangement. In short, policy communities, understood as closed networks of civil society and state actors who share

similar beliefs, should encourage the adoption of permissive biotechnology policies. A corollary of this hypothesis is that when a policy community makes the initial policy choices, the permissive trajectory should be sticky. Major departures from this trajectory should be difficult to accomplish, especially if the initial choice supports self-regulation.

- Hypothesis 2: Where “issue networks” characterize a sector, groups opposed to or concerned by potential negative effects of biotechnology can be successful at establishing an alternative understanding of biotechnology to that of target groups, and thus policies will turn out to be more restrictive. Of course, issue networks alone are insufficient to explain the adoption of restrictive biotechnology policies, but their openness greatly encourages activities of social mobilization and free decisive state actors from the influence of a limited number of powerful target groups. Naturally, issue networks also encourage the adoption of restrictive policies, even in the absence of a successful mobilization by social movement organizations, when the state agency that exercises prime responsibilities in the sector has restrictive policy preferences (see hypothesis 5 below).

- Hypothesis 3: If, in the case of ART, a Christian and/or neo-conservative party is in power and controls the cabinet position in charge of biotechnology, or, in the case of GMO, an environmental party, then the content of the policy will be more restrictive. Conversely, if the governmental power is in the hands of secular and/or progressive parties (for the case of ART), or parties less responsive to environmental issues (for the case of GMO) then the content of the adopted policy will be more favorable to the interests of the target groups.

- Hypothesis 4: If groups opposed to biotechnologies are involved in various policy-making

arenas, and if those arenas can coordinate their policy-making activities, biotechnology policy decisions should be restrictive towards target groups. Conversely, if target groups can confine policy-making to a single site of power, or if coordination between the various policy-making arenas is weak enough to encourage regulatory competition, then the content of the policy should be more permissive.

- Hypothesis 5: If the administrative department that takes responsibility for biotechnological issues tends to represent the interests of the target groups (for example, the departments of agriculture, economy and research for GMOs and public health for ART and biomedicine), then the content of the policy will be permissive. Conversely, if the administrative agency handling the topic is more likely to represent the interests of groups opposing or concerned about biotechnology (for example, the department of environment in the GMO area), the content of the public policy will be more restrictive towards target groups.

- Hypothesis 6: If groups opposed to biotechnology and/or their representatives within the political and administrative spheres instrumentalize European policies or other international rules, then the content of the policy will be more restrictive for the target groups. We should note that the phenomenon of the instrumentalization of the international context could take various concrete forms (e.g., Knill and Lehmkuhl 2002). As a corollary of our hypothesis, we suggest that if the target groups and/or their political and administrative representatives are the ones who use international rules successfully then the content of the domestic policy will reflect their interests more closely.

- Hypothesis 7: If the target groups and/or their political and administrative supporters are able to

demonstrate the effectiveness of permissive solutions adopted in other countries, as well as the pernicious effects of a more restrictive national laws, then the content of the policy will more likely take into consideration their interests, in particular their economic interests. Conversely, if the groups concerned or opposed to biotechnology and/or their political and administrative supporters make credible a more restrictive public intervention by presenting a similar policy, which has been adopted in other countries, and that is economically and politically viable, then the target groups will find their activities more restricted by the content of the resulting public policy.

Of course, a systematic comparison of the policy design adopted by several countries in various biotechnological sectors is required to test empirically the plausibility of the suggested research hypotheses.

Beyond the analysis of the policy design per se, one also has to scrutinize the policy implementation as well as the induced policy outcomes and impacts. For example, the divergence of the ART regulatory framework observed in Belgium and France opens a common space between these neighboring countries, where ART practices can freely develop. Similar public opinions regarding ART, a shared language, geographical proximity and the relationship of influence between small and big states favor a game of actors beyond the regulatory frameworks and the countries' boundaries. The differences in regulating ART in Belgium and in France have thus specific consequences. The mobility of French patients and their opportunities to receive an ART treatment that meets their demands in the neighboring country strengthens the differences in regulations. It is a kind of "win-win" relationship between France and Belgium. On the one hand, France keeps restrictive bioethical laws and does not hamper minority

patients (singles, homosexuals) in their efforts to have a child. On the other hand, Belgium has a significant pool of patients from France and favors the majority of its patients since Belgian patients benefit from reimbursement by Social Security for ART treatment (French patients receiving ART treatment in Belgium must carry the expenses themselves). At the moment, nothing seems to be able to stop the so-called “Thalys babies”.

Biotechnological developments raise a series of fundamental ethical questions and put them on the political agenda. By looking at how both the design and the implementation of “biopolicies” are affected by characteristics of actors representing diverging interests and values, and by institutional rules at the national and international levels, political scientists might gradually fill in the gap in political science research on this topic. This will require additional cross-country and cross-sector studies, which go far beyond our exploratory analysis of ART regulation in Belgium and France.

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