

HEALTH POLICY MAKING ON BIOETHICS: ASSISTED REPRODUCTIVE TECHNOLOGIES IN HUNGARY

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Abstract

In my thesis I define how bioethics changed the conventional process of health policy making by the state: how ethical considerations may appear, how these considerations are perceived, what kind of procedural and professional needs as well as requirements emerge. Therefore I elaborate a framework on the role of experts in policy making on bioethics: why experts are involved in the policy making process and how differently the legislative process is framed due to this involvement of experts in policy making. I introduce the disciplinary fields of health policy making and bioethics, showing how bioethical questions shape health policy making towards an expert-based consultative process in the rational-political model of boundary organizations. Then I present assisted reproductive technologies and the ethical considerations arising by gamete and embryo donation and surrogacy. Finally, I present the case of the policy making process of the Hungarian 1997 Health Care Act. I scrutinize how the codification process was framed by the Government: the work and institutional framework of the Operative Codification Group and the Codification Committee based on interview done with the head of the Operative Codification Group. I analyze the legislative period of the Act by applying the method of content analysis. I argue that the wide ranging work of codification resulted in the slight number of changes during the legislative period due to the work of experts who were involved in the codification. I suggest that efficient health policy making on bioethics is done by experts.

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Introduction

The twentieth century brought the fast scientific development that changed our lives from many aspects: the length, the quality and the style of living. Meanwhile health became a social and public issue, health care is one of the central (re)distributive fields of modern societies. The framework of public health and health care – whether they are privately or publicly financed – is created by states. Due to the development and appearance of new scientific technologies and their applications in health care, and the breakthrough caused by them in the concepts of beginning and end of life, the new discipline of bioethics emerged. Bioethics as an interdisciplinary field mixes legal, medical and ethical considerations concerning new technologies that have an effect on the traditional concept of natural endowments and bodily integrity.

In my thesis my aim is to define how bioethics changed the conventional process of health policy making by the state: how ethical considerations may appear, how these considerations are perceived, what kind of procedural and professional needs and requirements emerge. Therefore I elaborate a framework on the role of experts in the policy making on bioethics: why experts are involved in the policy making process and how differently the legislative process is framed due to this involvement of experts in policy making.

First, I introduce the disciplinary fields of health policy making and bioethics, putting emphasis on the common grounds of the two, and showing how bioethical questions shape health policy making towards an expert-based consultative process in the rational-political model of boundary organizations. Second, I present assisted reproductive technologies and the ethical considerations arising by gamete and embryo donation and surrogacy. Third and last, my aim is to present the case of the policy making process of the Hungarian 1997 Health Care

Act. This Act was the first law that dealt with new assisted reproductive technologies that I will base my analysis on. I will scrutinize how the codification process was framed by the Government: the work and institutional framework of the Operative Codification Group and the Codification Committee and the bill elaborated by them. I will analyze the legislative period of the Act with the help of a content analysis, arguing that the wide ranging work of codification resulted in the slight number of changes during the legislative period due to the work of experts involved in the codification: efficient health policy making on bioethics is made by experts.

1 Bioethics in Health Policy Making

When considering the appearance of bioethics in health policy making, there are two definitions to give in advance to be able to circumscribe the field my thesis is concerned with. These are the definitions of bioethics and health policy reshaped by bioethics. Therefore in this chapter first I introduce bioethics and its role and place in policy making in health, defining both the concept of bioethics and health policy. Then I will argue that the questions in health policy raised by bioethics cause a very important change in policy-making: the emerging role of experts in the decision making on bioethical questions. My aim is to elaborate a framework of health policy making in bioethics that I will use as a basis for the analysis of the policy making process of the bioethics-related sections in the 1997 Health Act in Hungary .

1.1 Two Definitions: Health Policy and Bioethics

Bioethics has emerged due to the fast technological development in science and its therapeutic applications. This development has caused the increasing capability to influence conditions of life that had been perceived as given and unchangeable before. Transplantation, genetic surgeries and new reproductive technologies, among several other therapies and surgical interventions allow humanity to change – or even to produce – the capacity to live and the quality of life. According to the definition of Pellegrino (2006), bioethics is “the study of ethics of a whole range of moral issues attendant on the application of biomedical science to human affairs” (571). These technologies draw implications not met before: the limits of the power to change, to intervene into natural endowments and human autonomy have to be defined. That is what the interdisciplinary field of bioethics does.

However, some historically and socially given conditions had to be met for the development and relevance of bioethics. As Pellegrino (2006) states in his article, there are three reasons of the rise of bioethics in public discourse in pluralist societies:

- The “revolution of the ‘Sixties’” (Pellegrino 2006, 574) that was a challenge to all traditional values and the authorities and resulted in the victory of individual self-determination, preference and choice of values and morals;
- “The erosion of formal religious authority” and “the loss of the idea of any source of moral authority beyond man” (Pellegrino 2006, 574) that resulted in moral relativism where life is governed by values rather than norms;
- “The unprecedented power of biotechnology as an explanatory, and a practical force shaping modern culture” (Pellegrino 2006, 574).

As authors of bioethics argue, due to the above outlined democratization, publicity and transparency of public decision making and politics, “bioethics [got] into the public square where law, policy and adjudication of conflicts take place. Bioethics thus become ‘politicized’” (Pellegrino 2006, 570). This politicization is most apparent in policy making, where the law, policy and adjudication appear at the same time, in the same arena.

As a first step in analyzing the complex relationship between bioethics and health policy making, I present the definitions of health policy and bioethics.

1.1.1 Health Policy

Health and health care are strongly influenced by ethical considerations: the process of curing is in itself a moral enterprise between the doctor and the patient. In this sense, “health [care] policy can be framed in one of three ways: as a species of social policy; as a species of labour market policy; and as a species of industrial policy” (Moran 2006, 221). *Health care policy* is

the sub-category of health policy: health care policy is restricted to the theory of redistributive and allocative policies in health care. While health care policy is to arrange the practicalities, the forms of redistribution and reallocation in health care, *health policy* is to control the matters of principle, the moral-ideological foundations in any field having effects on the health status of human beings.

Health care policies have to follow the principles laid down by health policies, and define the particular rules and processes in health care. As the definitions show, health policy is the conception of arranging principles, basic rights and duties, therefore the field of ethics. Both health policies and health care policies are “shaped intensively by [...] cultural patterns, by the workings of economic interests, by the manoeuvrings of bureaucratic politics – and by recent historical experience” (Moran 2006, 221). Both policies react to these impacts, however, in a different time-range. Health policies are in principle more stable, they are the results of critical junctures in public thinking and social development therefore they are influenced more by cultural patterns and historical experience. Compared to this, health care policies are more susceptible to short-run effects: to economic interests and bureaucratic politics. For example, the principles that define the range of access to certain health care services are included in health policies, while the financial conditions of the access are elaborated in health care policies.

Public policies, so health policy and health care policy consist of legal rules to follow. Rules and principles, the tools of health policy in my definition appear in the legislation, which means that their place is in legal instruments created by the assigned bodies of parliament or executives. Health policy that defines the rules of the game, the basic principles, is embodied in laws created by the legislative body, the parliament.

In conclusion, health policy understood in the broader sense includes the guiding principles and values that the health care system is directed by. In the following sections I use this broader concept of health policy, arguing that it is feasible to integrate ethical considerations raised by new technologies appearing in the health care system.

1.1.2 Bioethics

Due to the development and appearance of new technologies in health care, and the breakthrough in the concepts of the beginning and end of life, the question emerges what bioethics means and how it relates to the above introduced concept of health policy.

First of all, the meaning of bioethics has to be defined. Using the work of Sándor (2007) and Andorno (2009), bioethics may have two meanings:

- “The [first] meaning refers to the purely *ethical* dimension of life sciences. From this perspective, bioethics is just *a part of ethics*” (Andorno 2009, 224). In this sense it basically makes a distinction between right and wrong and its intent to find the way to the good. As Sándor (2007) states, in this view, bioethics is “the moral analysis of the present and future of life” (144).
- In the second view, Sándor (2007) argues for the institutional approach of bioethics, claiming that “[b]ioethics [...] is a new way of approaching and resolving the moral conflicts generated by the new scientific and technological advances in medicine” (144). According to Andorno, “in addition to biomedical *ethics*, [the term of bioethics] also includes the *legal* aspects of biomedical issues (sometimes called ‘biomedical law’ or simply ‘biolaw’)” (Andorno 2009, 225, *Italics in the original*). As law aims to define the governing rules of a democratic society, it is not necessarily directly concerned with morality, “even if legal norms certainly have an indirect positive

impact on the moral fulfillment of persons” (Andorno 2009, 224). However, in this sense of bioethics, where law is incorporated in the definition, the aim of morality (efforts to achieve the good) and aims of the law (“that the rights of each individual, as well as the common interests of society as a whole, are guaranteed” (Andorno 2009, 224)) are present in the definition.

Comparing the definitions of health policy and bioethics, their common ground can be found if the second definition of bioethics is used. The principles that health policy lays down in biomedical issues described above are what is called biolaw or biomedical law. In addition, during the creation of biolaw, the elaboration of principles to follow, several issues and arguments emerge that are considered to be bioethical and represent a narrow segment of health policy. What I am interested in is the nexus between these fields: how biolaw is created, how bioethics in the broad sense comes into being in the framework of health policy making.

This introductory section leads to a more detailed description of the effects that appear in health policy and biolaw making: the role of experts and bioethicists in policy making on new technologies.

1.2 Experts in Health Policy Making

In the field of policy making during the legislative process scientific issues appear in a special manner. The appearance of life sciences and natural sciences in politics brings new participants in the process of policy making because politicians are rarely experts or even familiar with these branches of science. As life science and natural science are fields to regulate or make policies on – like in the environmental, health and research policies –, the problem of the decision makers’ knowledge about ethics and technical details is of major

importance. Informed decision making and the ability to take into consideration all the related ethical problems are central as far as the effectiveness and stability of policy making is considered, not to speak about the legitimacy of the policies created. In health care, the development of (bio)technology and (bio)medicine, the new inventions make health policies even more complex as new ethical considerations appear about moral dignity and autonomy as well as on the beginning and end of life.

1.2.1 Health Policy Making *by* Experts or *with* Experts?

However, even if experts are needed for informed decision making in the policy making process, many authors of the field argue that the bias is inherent in policy making conducted exclusively by experts.

Eric Cohen (2006) approaches the problem of policy making in bioethics from this viewpoint. He argues that scientific knowledge is not always benevolent, scientists are selfish enough to “seek knowledge without moral limits” (Cohen 2006, 787), therefore people themselves should decide what kind of scientific development they would permit and at what (ethical) costs. Scientific knowledge is needed for this decision but it is not guaranteed to be a wise decision if only scientific knowledge is used to make the decision. Cohen (2006) emphasizes the special role of democratic decision making: the experience of authoritarian regimes proved how science can be used by oppressive powers for their own sake, for example through eugenic policies.

However, Cohen (2006) argues that even in democracy there are two different ways of politicizing science. Firstly, on the pessimistic account some may distort “scientific evidence to promote one’s own ideology and agenda” (Cohen 2006, 789). Secondly, which is the optimistic scenario, politicizing science should mean that “self-governing people of democracy [...] govern the direction of science” (Cohen 2006, 789). As Cohen argues, this

distinction between the rational choice interest- and rent-seeking based pessimistic approach and the trust in deliberative democracy is the central problem in health policy making of biolaw. Cohen (2006) claims that science in itself is not able to act upon moral value-judgments: even specialists of different fields would make different decisions. He states: “Science is power without wisdom about the uses of power” (Cohen 2006, 793). In conclusion, Cohen’s (2006) main argument is that as far as scientists have incentives to act along their self-interests and have the monopoly of knowledge, they should not make policy decisions on their own as these decisions may negatively affect the public. A democratic arena is needed where public opinion is taken into account but at the same time – as shown above – professional knowledge is introduced. This arena is *per definitionem* politics: this is the agora where all the decisions are made that have an effect on the society. Conclusively, health policy making and experts should take place in the arena of politics.

The role of experts in the bioethical health policy making process is twofold. First of all, as shown above, experts are needed for informed decision making. Second of all, they represent the constraint in the pursuit of politics as experts have the knowledge to be able to create wide-ranging and effective policies on bioethics.

When considering politics, Pellegrino (2006) divides partisan politics into two parts (572): constructive and destructive partisan politics. While the former refers to the primacy of the ethical foundation and common good, the latter is based on the opposite motivation of power and selfishness. In this manner, experts can put constraints on self-interested destructive politics. Pellegrino (2006) argues for the responsible attitude of the experts of the bioethics community: their duty is “to foster and protect the proper usage of partisan politics, to refuse to indulge itself in any distortion of its right use, and to provide a model of ethical sobriety to mitigate the misuse of partisan politics” (Pellegrino 2006, 573). Their “purpose should be to

provide the basis for the kind of moral considerations upon which good policy rests” (Pellegrino 2006, 578). In his perception experts should take part in health policy making to provide information, input of knowledge for decision makers in the political arena to enable the participants of the policy making process to make valid and informed decisions.

Conclusively, the role of experts is extremely important in health policy making on bioethics. However, several cleavages open up that did not appear in Pellegrino’s (2006) approach. According to Turner (2008), there may be four reasons of controversies and disagreements in policy formation regarding the role of experts:

1. The moral politics of technologies: “different political parties commonly have different core values, social agendas, policy platforms” (Turner 2008, 39). These differences appear in their diverging views on what kind of “substantive ethical, legal, social, and economic judgments [to make]” (Turner 2008, 39). Moreover, “considerations about safety, risks, harms, benefits, respecting “core” moral norms, and protecting public good” (Turner 2008, 40) as political questions are also contested ideologically.
2. The politics of authority: “science advisory boards and other committees intended to provide recommendations and policy alternatives to government agencies are staffed by particular individuals” (Turner 2008, 41). It is a field of political manipulation to select experts because this selection is always inherently biased.
3. The politics of knowledge: “disagreements [...] about what constitutes reliable, accurate, credible knowledge” (Turner 2008, 42). Several examples from the past show how politics uses facts for its own sake to avoid or to meet the need to make policy decisions on a specific issue, especially on emerging new technologies.

4. The politics of uncertainty: “existing scientific research can provide only limited insight into the long-term consequences of particular policies” (Turner 2008, 41-43). During the policy making process, politicians have to consider the long-run stability of their statements and decisions in order to avoid abuses on moral stances: “Technologies are often used in ways unanticipated by their early proponents” (Turner 2008, 44).

Moreover, not only experts and politicians but “religious groups, ethnic groups, community associations, political bodies and other social organizations” (Turner 2008, 31) also have different opinions about health policy making. The fragmentation of value orientations seems to become even more complex if the differences “across generations, intraethnic groupings, gender lines, socioeconomic status” (Turner 2008, 32) etc. are taken into consideration, which in pluralistic societies create serious cleavages. Just like Pellegrino (2006), Turner (2008) argues for the importance of comprehensive and wide-ranging agreements to make. The most important controversies, however, appear in the politician–non-politician division and in the scientist–non-scientist cleavage. The process of policy making along these cleavages is balanced if they are put in a framework where consensus and negotiation stand in the centre of the process. In the following section I investigate the institutional setting they act in, going one step further in the scrutiny of the group of participants in the health policy making process.

1.2.2 Boundary Organizations

As introduced above, the two cleavages (or boundaries) along groups of scientists and politicians have an extremely important role as far as the legitimacy, success and extent of health policy making is considered. In the following pages the concept of boundary

organizations will be presented. Boundary organizations are the institutional settings of bioethical health policy making.

These organizations are created to handle the problem of the need for experts in the policy making process and the clashes between the interests and competences. The realization of deliberative and comprehensive policy making suggested by Pellegrino (2006) and Turner (2008) seems to be necessary to balance between cleavages, but is really difficult at the same time. Therefore it is rational to create an environment where this wide-ranging public discourse can be attained in an effective way. Kelly (2003) argues for an institutional setting of public bioethics committees. She states that boundary organizations such as public bioethics bodies play three key roles (Kelly 2003, 340):

1. “[T]hey help manage boundary conflicts over who is to decide about scientific activity”;
5. “[T]hey use the language of “consensus building” as a means of defining legitimate participants in bioethical discussions”;
6. “[T]hey relegitimize the professional autonomy of scientists against moral and political demands by various publics through the discursive ambiguity and subsequent “repurification” (quoting from Jasanoff 1987, 1990¹) of ethics advisory roles and expertise.

As she claims, “The biomedical ethics framework is [...] an appropriate strategy for engaging public disputes about science in pluralist democracies in that it provides a predominantly

¹ Jasanoff, S.S. 1987. Contested boundaries in policy-relevant science. *Social Studies of Science* 17(2): 195-230.

--- 1990. *The fifth branch: Science advisors as policy makers*. Cambridge, MA: Harvard University Press

secular, rational and “neutral” discourse [...] for negotiating the competing value complexes of various public interests” (Kelly 2003, 342).

Boundary organizations still encounter the above outlined clashes between various interests, but they link the worlds of politics and science, thereby creating the institution of bioethics of the comprehensive sense. As Kelly (2003) states: “Boundary organizations provide scientists and nonscientists identifiable and deployable strategies of interaction and interdependence as they engage in boundary work” (343). Moreover, boundary organizations serve as “public displays” (Kelly 2003, 343), which means that they are able to convince and demonstrate to the public that an extensive debate and negotiation stands behind the results of the work of the organisation. Besides, if these organizations work in an accountable and transparent way, the chance of rent-seeking from both sides of scientists and non-scientists decreases.

However, boundary organizations do not replace public deliberation because they are hardly representative bodies. Although the achievement of consensus in the society would be a “highly democratic arrangement” (Kelly 2003, 349) in the age of value pluralism, boundary organizations are not able to achieve the wide ranging social consensus at the organizational level of legitimacy. Therefore, as Kelly (2003) argues, even if boundary organizations are more effective and flexible, which is the most important argument for creating them, to correct the lack of legitimacy, they have to stand for public opinion and public deliberation as much as possible.

Boundary organizations bring advantages and disadvantages with themselves: the lack of public deliberation is a major counterargument against their pursuit. However, this argument does not eliminate the advantage offered by boundary organizations: the efficiency and feasibility of the policy making process in this framework. Moreover, as suggested, the problem of legitimacy can be decreased if boundary organizations take public opinion into

consideration. In the following section my aim is to elaborate the theory of boundary organizations in more detail to create a framework of health policy making on bioethics that will be the basis of my analysis in the third chapter.

1.2.3 The Rational-Political Approach of Boundary Organizations

The rational-technological model of Wiktorowicz and Deber (1997) describes the institution of the health policy or biolaw making process from the viewpoint of rational choice institutionalism. I use the framework elaborated by them to introduce the rational-political approach of boundary organizations in health policy making on bioethics. Following their train of thought, first the actors of health policy making have to be identified, presuming that the above suggested framework of boundary organization prevails. The key actors participating in the boundary organization are the following:

- Government and politicians;
- Expert groups like scientists, doctors, etc.;
- Interest groups of doctors, patients, etc.

The groups may be overlapping, but the common grounds of the group of actors can be identified, they can be perceived to be homogenous: all the groups have competing objectives. However, “the range of policy actors involved, the level of their organizational development and the nature of their participation” (Wiktorowicz-Deber 1997, 134) are of major importance in the results of health policy making.

In the rational-political approach the organizational framework of the boundary organization enables the actors to mediate the interests and pressures among each other in order to achieve consensus. The framework is elaborated by the following criteria: timing, stages of process, “how participation takes place and [...] the weighting different goals will receive”

(Wiktorowicz-Deber 1997, 121). These are the crucial points of the policy making process, and their effects can be identified throughout the successes and failures of the result.

Taking these criteria into consideration, the authors identify the following institutional constraints of the work of boundary organizations (Wiktorowicz-Deber 1997, 121):

- “[T]he level of procedural burdens placed on participating groups”;
- “[T]he extent to which adversarial or negotiating stances are assumed”;
- “[T]he extent and timing of opportunities for participation”.

In conclusion, these constraints have to be taken into consideration in the analysis of the health policy making process to be able to give detailed and comprehensive arguments in the explanation of failures in the process. Institutional-organizational settings and the constraints caused by them are to be investigated in this approach.

Thus far I introduced general points of reference to analyze policy making processes. However, the second and third pillars of my model are the modified concepts of the rational-technological model elaborated by Wiktorowicz and Deber (1997). As originally they created their model for *health care policy analysis* and technology assessment, I modified the concept to be able to use it in the analysis of *health policy making*. My model – called rational-political model – consists of two steps of analysis as well. The results of the two steps of the analysis are matrices that include the actions and statements of policy actors, shown in the following figure.

Step I. Experts' matrix

	Policy Actors - Experts
Relevant problems	Outlining the relevant problems, and giving answers to them – the consensus-based level of experts

Step II. MPs' matrix

	Policy Actors - MPs
Policy actions	Identifying new problems, giving answers to them, changes in the answers given by experts in Step I.

Figure 1: The Matrices of the Rational-Political Model

The first matrix called 'experts' matrix represents the needs identified, the ethical problems defined to be relevant by experts. These problems include new controversial questions arising due to the appearance of new technologies, like the beginning and end of life, bodily integrity, autonomy and dignity of human beings. Strongly connected to this matrix, the identified problematic fields become parts of the second matrix, called 'MPs' matrix.

This mechanism of the rational-political model gives the toolkit for analyzing health policy and biolaw making. The two steps allow me to identify how actors behave during the policy making process, what are their reasons and arguments, what are the questions these actors emphasize and what are the answers and solutions they represent during the negotiation. Therefore the two matrices, combined with the above introduced analysis of the institutional setting give the framework for health policy making analysis in my interpretation. I will use this framework to identify arguments and value-judgments in both the experts' and MPs' matrices of bioethical policy making on the example of the 1997 Health Act in Hungary.

1.3 *International Agreements*

Although health policy is made on the national level, the appearance of bioethics, due to its universal importance across borders became an issue negotiated on the international level as well. Bioethics on the international level, however, has a different meaning from that of on the national level. The reason for this difference is that international statements and agreements made thus far are not enforceable, therefore they cannot be called biolaw: the aim of the international organizations during the process of creation was to provide principles for nation states to act upon. In this section I argue that international instruments of bioethics play an important role and are guiding documents on the national level of legislation and biolaw making. Therefore international agreements are the umbrella above national legislation on bioethical questions that has to be taken into account during both steps of the above presented health policy making analysis.

There are two basic international documents on bioethics thus far. The Convention on Human Rights and Biomedicine of the Council of Europe (the Oviedo Convention) was the first international contribution to bioethics in 1997. In 2005, the UNESCO published its Universal Declaration on Bioethics and Human Rights. Although there are differences between the two instruments regarding their vocabulary and content – which is not the scope of this paper to investigate – both of them are international agreements declaring rights and principles in the field of bioethics. The drafters aim to define the basic concepts and consensual principles that may be derived from two facts acknowledged: that national “law is not able to keep pace with the rapid and revolutionary developments” (De Wachter 1997, 14), and that the new scientific development affects principles of human rights, therefore international standards are needed.

However, the classification of these legal instruments is highly debated. As already shown above, Andorno (2007 and 2009) stands for the *international* biolaw approach. He argues that

“[t]hese documents are [...] conceived as an extension of international human rights law into the field of biomedicine. In other words, they are legal (though not binding) instruments whose content is also of legal nature” (Andorno 2007, 124). Andorno (2007) identifies “three general characteristics of international biolaw” (124):

- “The recognition of human dignity as the overarching principle of biolaw” (Andorno 2007, 124): he argues that human dignity is the “source of all human rights” (Andorno 2007, 124-125);
- “The use of a human rights framework” (Andorno 2007, 125): the instruments of international biolaw adopt the framework of the Universal Declaration of Human Rights, and apply it for the case of bioethics. “Modern international human rights principles, beginning with the Universal Declaration of Human Rights of 1948, attach fundamental significance to the human being and respect for his or her dignity as such” (Vincent 2002, 24-25), offering a stable basis for bioethical considerations;
- “The adoption of a set of broad principles” (Andorno 2007, 126): the principles included in the instruments of international biolaw are formed in general terms.

However, Sándor (2007) refutes the approach of Andorno (2007) on the classification of the international instruments on bioethics as international biolaw. She argues that although human rights, bioethics and law have linkages, these international instruments express “generalized, guiding principles” (Sándor 2007, 144). These principles have to be transformed into rules by legislation to become law by definition. In conclusion, international agreements have to be ratified and followed by national legislation, have to lose their characteristics of soft law and become hard laws on the national level so that the binding quality comes into being. Therefore these international instruments cannot be defined as biolaw. However, “although [international instruments] are not law in a strict legal sense, they may have moral authority

and obtain direct legal significance if incorporated in national legislation or referred to in court decisions” (Gevers 2002, 30).

Until the time of ratification and hard law making comes, however, international instruments provide an important input to drafters of policies and legal instruments on the national level. The principles declared in the international instruments are indeed guiding principles. The Convention of Human Rights and Biomedicine (Council of Europe, 1997) declares the following ethical principles (via Galton, 2007, 20):

Area of concern		Ethical principle
General	1	Guarantee individual rights and fundamental freedoms of all individuals
	2	Welfare of individual to prevail over sole interest of society
	3	Equitable access to genetic tests and consequences for all
	4	Any intervention to be carried out in accordance with relevant professional and accreditation standards
Consent	1	Any intervention requires free and informed consent
	2	Appropriate information as to the purpose and nature of the intervention must be given
	3	Freedom to withdraw consent
Privacy	1	Rights to privacy of information about health status
	2	Rights for access of individual to their health information that has been collected (also rights not to know if so wished)
Sanctions	1	Appropriate sanctions (removal of accreditation, removal of licence to practice, fines) shall be applied in the event of any infringement
	2	A person suffering damage as a result of such procedures is entitled to fair compensation according to the processes of law

Table 1: The Ethical Principles of the Convention on Human Rights and Biomedicine.
Source: Galton (2007, 20)

Similarly, Sándor (2007, 145-152) identifies the following major principles in the UNESCO Declaration on Bioethics and Human Rights (2005):

Dimension		Ethical principle
Human Rights	1	Human dignity, upon which other principles (like the principle of autonomy) rest
	2	Non-discrimination and non-stigmatization based on genetic characteristics
Human Rights and Bioethical Dimensions	1	Informed consent and the right of individual self-determination
	2	Privacy as a principle of non-interference on private spheres of the individual and confidentiality in the doctor-patient relationship
	3	Equality, justice (treating equals equally) and equity
Twin Principles	1	Autonomy (individuals' authority to make autonomous decisions) and individual responsibility
	2	Seeking benefit and minimize possible harm
	3	Respect for cultural diversity and pluralism

Table 2: Ethical principles of the Declaration on Bioethics and Human Rights. Source: Sándor (2007, 145-152)

Both international instruments use the same basis of human dignity and the principles derived from it to declare the most important guiding principles, using the language of general, bioethics-based soft law. The aim of harmonizing the national legislations and policies on new technologies therefore is clear as far as the adoption of general principles on human dignity and autonomy are concerned. The adoption of general principles, however, does not necessarily induce the total uniformity of the hard laws on the national level, only the consensus on the basic principles.

In conclusion, the influence of international soft laws on bioethics has to be taken into consideration because these instruments promote consensual principles compatible with human rights. Therefore and due to the generality of concepts and principles, social trends and public opinion are perfectly reconcilable with the content of the international instruments.

In the first chapter of my thesis I presented the definitions of health policy and bioethics, the effect of the appearance of bioethics on the health policy making process, and the emerging role of international instruments on bioethical issues. These three pillars of the chapter (with the strongest emphasis on the rational-political model of boundary organizations) will give the theoretical background of the case study of health policy making on assisted reproduction in Hungary presented in the third chapter of the thesis. However, one major pillar is still missing to be able to turn to the case study. This pillar is the ethics of assisted reproduction, which is necessary to draw conclusions on the efficiency and deepness of the health policy making on this issue.

2 The Ethics of Assisted Reproduction

Assisted reproduction, an invention of the twentieth century changed the traditional idea of procreation, although the need for the development of this technology stems exactly from that traditional view of the family. The birth of the first test-tube baby, Louise Brown in 1978 changed not only the lives and hopes of infertile couples, but of those who due to their social or sexual identity were not able to have a child in the “normal”, biological way, or did not want to give up their moral stand and go into unwanted sexual relationship: single women and homosexual couples. The donation of sperm, egg or both, or the donation of embryos is needed in these cases due to social determinants rather than to biological necessity. This means that not simply the change in the concept on the beginning of life and the moral status of the embryo, but also the question of access raises controversies in this field.

First and foremost, my aim is to show what assisted reproductive technologies mean. I do this introduction only briefly, without deep theoretical and medical details, as not the process of the intervention, but its social consequences and its effect on the idea of reproduction what matter during my investigation. Assisted reproductive technologies may be separated into two different technological solutions:

- Artificial insemination, when the man’s semen is “inadequate in quantity or quality” (Human Procreation 1984, 14), therefore the woman gets fertilized by the semen of the father or a donor artificially;
- In vitro fertilization (IVF), when “egg cells are removed from the mother” (Human Procreation 1984, 15), fertilized by the father’s or donor’s semen outside the mother’s body, and then the embryo is “reimplanted to the mother’s womb” (Human Procreation 1984, 16).

As it can be seen, regarding the usage of donated cells the major difference is that in the case of insemination only semen may stem from a third party while in the case of IVF both “parents” may be changed by donation, or even a donated embryo can be used. The fact that semen and embryos are open to get frozen and stored without losing their capability to be used for fertilization or implantation, and the availability of donating eggs² complicates the range of ethical considerations further.

Originally these techniques served as help and enhancement to couples who lost their ability to reproduce in the natural way due to some type of infertility: Scientists wanted to help those (married heterosexual) couples who due to reasons of infertility needed medical contribution to be able to found a family, to have children. However, the use of the technology may not be restricted to infertile couples: the possibility of reproduction without sexual interaction, with assistance (artificial insemination) or even outside the body of the woman (in vitro fertilization) opens up at the same time new opportunities to socially infertile people to have a child. This new perspective changes the concept of reproduction, raising the problem of reproductive rights.

Apart from the inquiry on the controversial theoretical issue of reproductive rights, the following techniques will be investigated in detail:

- Donation (gamete and embryo): the gamete of the mother or of the father or of both of them stems from a third person, or the embryo used for implantation stems from another couple;
- Surrogate motherhood – that is technologically feasible due to the development of artificial techniques but controversial due to the appearance of a third person and

² Eggs are too vulnerable to get frozen, therefore the donation of eggs happens usually without cryopreservation.

raises the question of hiring the body with the purpose of substitute the biological mother.

Both donation and surrogacy involve the contribution of a person who does not take part in the upbringing of the child, therefore they can be classified under the header of “collaborative conception” (Blank-Merrick 1995, 90). The new participants in the reproductive process not only change the concept and definition of family but raise the questions of human dignity and human autonomy.

After the brief introduction of assisted reproductive technologies, in the following parts of the chapter my aim is to define what kind of ethical considerations may appear in legislation in the light of the raised bioethical knowledge thus far. My aim is to present the complexity of the bioethical questions concerning assisted reproductive technologies in order to elaborate the fourth pillar for the analysis of the health policy making on bioethical questions based on the case study of the related parts of the Hungarian 1997 Health Act.

2.1 *General Ethical Issues*

Jackson (2001) argues that assisted reproductive technologies, the existence of the medical intervention in itself raises “three different types of argument” (169) as far as the ethical problems are considered:

1. Assisted reproductive techniques are unnatural;
7. Assisted reproductive techniques do not promote children’s welfare;
8. Assisted reproductive techniques reinforce damaging gender stereotypes.

The first argument of *unnaturalness* is self-evident: it suggests that all the techniques that depart from the natural way of procreation through sexual interaction are unnatural, therefore

goes against nature. As Jackson (2001) states, it is “undeniable that the discontinuity between conception and sexual contact may complicate the narrative of our origins” (172). This concept of biological necessities in parenthood and the requirement of heterosexual sexual relationship is questioned by the techniques of assisted reproduction. The development of assisted reproductive technologies renewed the concept of having a family and a child. As I mentioned before, these technologies allow medically infertile couples to have a chance in procreation on the one hand, and permit also socially infertile people to found a family on the other hand. This means first of all that the issue of reproductive rights is not bound to couples of physical inability anymore, and second of all that reproductive freedom may not exclusively mean a negative freedom. As Blank and Merrick (1995) state: “Reproductive rights have expanded from a right not to have children, to a right to have children” (216). However, “the asymmetry between the right not to reproduce and the right to reproduce is that the decision to reproduce involves other persons, at a minimum the person to be produced and the other biological parent” (Blank 1997, 281).

This change in the concept of reproductive rights from the negative idea of ‘freedom of’ towards the positive right approach (‘freedom for’ or ‘right to’) is, however, one of the most controversial issues in assisted reproduction. The positive right of reproduction would imply that everyone – even socially infertile people – has the right to procreate, which would require the state to provide the access to the technology to everyone in order to enable citizens to live with their right.

Even more controversial is the question of the access of socially infertile people: the access of single women and homosexual couples to assisted reproductive technologies raises serious and socially debated questions about the concept of the family. In conclusion, the unnaturalness argument states that “[p]rocreation which requires neither a heterosexual sexual

relationship nor biological infertility opens up the possibility of parenthood, with all its social and cultural significance, for people whose [...] way of life would previously have been incompatible with reproduction” (Jackson 2001, 173). In this sense, the problem of access of the socially infertile to assisted reproduction is strongly related to the cultural differences, the level of acceptance and inclusion of sexual minorities and of single parents in the society.

The second argument against assisted reproduction states that there is a “possibility of a *negative impact upon children’s welfare*” (Jackson 2001, 173 *Italics added*). Two different approaches can be found in the background. One of them is related to the above mentioned problems concerning the traditional idea of the family: that the biological and sociological parents are not necessarily the same. However, many argue that this argument does not prevail as there is no scientific evidence that would prove the unambiguous and absolute harm of the child’s interest if the child is brought up by socially infertile or genetically dissimilar people. The second argument states that the artificial environment the gametes or the embryo may be stored or fertilized within, can cause harms to the children on the long run, meaning that these people may be less resistant to diseases or may have some type of medical disorders³. This argument is based on the concept of evolutionary theory and states that the weaknesses that arise due to the artificial way of conception may be transmitted to the future generations. However, just like in the case of the parenting argument, there is no evidence to prove the truth of this argument, because the research done this far were unable to detect it due to the low number of cases and the short time period since assisted reproduction has been performed.

³ See for example: Beydoun, Hind A. et al. (2010)

The third argument states that assisted reproductive techniques *reinforce damaging gender stereotypes*. This critique of feminists against assisted reproductive technologies is threefold. First of all, it is stated by feminists that “reproductive technologies degrade women by reinvigorating the patriarchal premise that a woman’s principal function is to become a mother” (Jackson 2001, 175). However, as Jackson (2001) argues, the “separation of heterosexual sex and procreation might help to subvert [this argument] by facilitating motherhood in single or lesbian women” (176). Second of all, feminists argue that the “medicalisation of conception”, the doctors’ “power over women’s reproductive lives” (Jackson 2001, 177) and the fact that the woman gets treated even if the man is infertile make women become oppressed due to assisted reproduction. Third and last, feminists argue that the treatment of assisted reproduction is demanding physically and emotionally, therefore only fully informed consent is acceptable. This argument draws practical consequences rather than ethical considerations, not to mention that the requirement of informed consent is not gender- and technology-specific at all.

The general ethical considerations raised by the mere existence of assisted reproductive technologies give only a rough introduction into the morally demanding issues on collaborative conception. In the following parts of the chapter I present the core ethical points of donation and surrogacy.

2.2 *Donation*

As Robertson (1983) states, the new reproductive “techniques enable persons to separate the genetic, gestational, and rearing aspects of procreation and to recombine them in striking new ways, making reproduction a collaborative enterprise” (421). The case of donation here only the genetic and rearing aspects of reproduction are considered. The gestational aspect, which

brings new issues in addition to the ones of donation give a separate section of the chapter on surrogate motherhood.

In the case of donation, two major types of paternal roles are possible:

- In case of gamete-donation one of the rearing parents is a genetic parent as well;
- In case of embryo-donation both parents are only rearing parents.

The most important objection to assisted reproduction even in the case of heterosexual couples stems from the concept of natural procreation (Liu 1991, 50). The use of donated gametes makes the issue of assisted reproduction even more controversial as the presence of a third party – who is the genetic parent – in the process harms the sanctity of marriage. This argument of unnaturalness already appeared among the general ethical considerations of assisted reproduction, therefore I only refer back here to the details explained there.

However, two principles are to be considered here, as both the donor and the recipient side of the process have to be taken into account:

1. *The principle of autonomy* as far as the donor is considered: “competent individuals [should] be permitted to act as they choose as long as they do not harm others” (Landau 1999, 192). This principle requires informed consent, and respects the decision of the future parents. Bahadur (2004) argues that the donor has to give his or her “written, informed consent” (Bahadur 2004, 297) to retrieve and store his sperm, egg or embryo as well as to use it for procreation or implantation.
9. *The principle of beneficence* as far as the recipient is considered, putting emphasis on the child: “[...] furthering the well-being of the individual and protecting him or her from damage or harm” (Landau 1999, 193). Landau (1999) emphasizes the importance of the two-parents’ family as the single-parent family puts a heavy burden on both the

mother and the child. Therefore this principle gives “priority to the well-being of the child over the adult’s desire for parenthood” (Landau 1999, 193).

Thus far the ethical aspects of donating and receiving reproductive materials were considered. The aspects of the genetic and rearing parents as the two main actors of the process always have to be taken into consideration: their motivations and individual decisions may lead to socially inappropriate or immoral consequences.

People who want to have a child, found a family, would do almost anything to achieve their goal. The future parents may want to get gametes from donors of special characteristics, or without any harmful genetic inheritance. In conclusion, future parents put huge emphasis on the quality of the received gametes or embryo that – according to some arguments – leads to the commodification of the children of assisted reproduction. This commodification may be further enhanced by the commercialization, the marketization of the gamete- or embryo-donating process. However, if donation is motivated by financial gain, the question arises whether the incentive of donating for financial compensation may be harmful for personhood. The “undesirable collective consequences” (Daniels 2000, 208) like any harm for humanity and personhood may be avoided by government intervention. According to Daniels (2000), this government intervention should follow two basic principles:

1. “[F]ully informed consent, free from any inducement or pressure is fundamental to gamete donation” (Daniels 2000, 209);
10. “[T]he potential for human life inherent in a donation made with the specific intent to producing children should be respected” (Daniels 2000, 209).

As it can be seen, the two principles of Daniels (2000) do not exclude the possibility of donation, but they allow to prevail the values that are inherent in the society. The balance

should be found between family values that promote the non-commodification and non-marketization of children and genetic material and between commerce that – as it is argued by many scholars and economists – cannot be eliminated even with prohibition: the needs create their own market anyways. Moreover, another strong argument for the government intervention is that “[t]he commercialization of reproductive services threatens to exacerbate social inequalities and undermine efforts to ensure adequate regulation of these technologies” (Blank-Merrick 1995, 227).

Beside the above introduced issues of gamete- and embryo-donation, the case of the embryo donation raises special questions about the beginning and end of life that should be taken into account. The approach that is used to evaluate the embryo’s moral and legal status is crucial as far as the permissibility of embryo-donation is considered. “There are three options by which to consider the legal status of the pre-embryo⁴” (Eisenberg-Schenker 1998, 54):

1. The pre-embryo is only a bunch of cells, therefore it has no moral status: “the donors have full rights regarding the pre-embryo” (Eisenberg-Schenker 1998, 54);
2. “The pre-embryo has the full moral status of a human being” (Eisenberg-Schenker 1998, 54). This means that the embryo has rights on its own, the donors, however, do not have any, therefore only the best interests of the embryo are considered;
11. The pre-embryo bears the *potential* to become a human being, which potential bestows the embryos with dignity. Therefore the ‘cause no harm’ principle prevails: the interests of all the affected participants have to be taken into account.

⁴ Pre-embryo is the fertilized egg before the differentiation of embryonic tissue. Although it is a more precise and medical designation of the fertilized egg, for the sake of convenience I use the name embryo instead elsewhere.

The third concept of the pre-embryo is the most widely used. This concept is a balanced view between the first two: it allows donors, recipients and the embryo to have their own rights that do not harm each other. However, the reconciliation of these rights is a demanding issue: as the future child's welfare is of major importance, the selection of donors and recipients as well as the type of information stored should be defined in detail in order to enable the child to acquire the most important information about her genetic background, and to prevent her from inheriting medical disorders or being raised in an inadequate family.

This latter judgment about the inadequacy of the rearing family, however, opens up the question of the access of socially infertile people to assisted reproductive technologies and to embryo donation. The 'unsuitability' concept of socially infertile persons states that the interests of the children should be considered (Liu 1991, 55): the clash between the principles of reproductive autonomy versus the principle of the welfare of the child may result in the prejudicial statement that single or homosexual people "are less capable of parenting" (Liu 1991, 57). However, as it was already mentioned in the section of general issues, there is no scientific evidence that would prove the truth of this biased statement that is based on the traditional concept of family.

After the introduction of the cases of genetic and rearing parents, I turn to the case of gestational parents: to the case of surrogate motherhood.

2.3 Surrogacy

In the case of surrogacy not 'only' the gametes or the embryo is donated but the physical service of a woman who lends her body for somebody else's will and need to found a family. The considerations on the access and permissibility of surrogate motherhood are fundamental, and are not only controversial from the viewpoint of socially sterile people, and not only due

to the fact that donation is involved during surrogacy. The fundamental question is “whether individual’s right to reproduce and / or to found a family are sufficiently broad as to include freedom of surrogacy” (Liu 1991, 94).

Surrogate motherhood may be of two types. First, the womb of the surrogate is used as a donor while the child stems genetically from the couple. The embryo is implanted into the surrogate’s body after in vitro fertilization – in this case the surrogate is a carrying, gestational mother. In the second case the man’s semen is used for the fertilization of the surrogate’s egg by insemination (artificial insemination by donor). Here the third party, the surrogate provides her egg and womb for the couple: she is carrying and genetic mother at the same time. In both cases the surrogate and the rearing parents make an arrangement in the form of a contract that includes the conditions of the service and the requirement that the surrogate surrenders the child to the rearing parents after delivery.

In the following section I present the controversies of surrogacy that cause much more serious objections than procreation by donated gametes and embryo. I do not consider the biological and medical reasons why a couple or a person may apply for the services of a surrogate mother, and I would like to concentrate on the ethical considerations regarding the role and duties of the ‘third’ party (the surrogate mother) and the arrangement between the surrogate and the rearing parents.

2.3.1 The Surrogate

The controversies related to the service delivered by the surrogate are strongly attached to the fact that “the biological experience of bearing and giving birth is so important for women that it should be recognized as an independent exercise of procreative freedom” (Robertson 1983, 409). Besides, according to feminists, lending the womb for somebody else’s child may seem to be analogous to prostitution (Niekerk-Zyl 1995, 345). It is not only an unnatural practice

(“it is contrary to a woman’s natural post-natal ‘instinct’ to part with a child after parturition” (Liu 1991, 96)) but it is alienated labor: “it commodifies women’s reproductive labor” (Niekerk-Zyl 1995, 346). As the objections state, “women’s reproductive labor should not be compared to and treated in the same way as other forms of physical labor” (Niekerk-Zyl 1995, 346). One solution for this problem, offered by Niekerk and Zyl (1995) is to have a surrogate “who is a close friend or relative of the commissioning parents” (348), thereby diminishing alienation.

The strong relationship between the child and the surrogate gives the second major counterargument to surrogacy. There exist a biological link, a bond between the mother and the fetus that is torn after the birth and surrender of the child to the rearing parents. As Robertson (1983) states, pregnancy is an important part of reproduction by procreation and child-rearing. In this sense the broad or narrow concept of motherhood may have different implications to surrogacy. However, even if the broad concept is taken, and gestation is seen as an inherent part of motherhood, “there is no scientific evidence which establishes that psychological and emotional harm are inevitable consequences for a surrogate” (Liu 1991, 98), although the possible sense of loss cannot be rejected. Anyhow, the harm caused by surrogacy is not more than the experiences of the adopted child and his or her biological mother, therefore there is no apparent reason why a similar approach [to the arrangement of adoption] could not be adopted” (Liu 1991, 100) in the case of surrogacy.

The other side of the coin however is that surrogate motherhood “could be beneficial, socially and personally [for the surrogate], to provide childless couples with children genetically linked [at least] to one of them. [Therefore] the host mother [...] should have the right to make a free, voluntary, and informed decision” (Human Procreation 1984, 66). In this libertarian sense there should be no limits of freedom and liberty even in the case of

surrogacy: if the host mother takes the risks and consequences of surrogacy and is ready to contract with those who want to found a family in this way, the above mentioned objections lose their strength. The surrogate mother has the autonomy to get into the arrangement, which means that no one (the state neither) has the right to interfere into the process of surrogacy. However, the contract between the host mother and the rearing parents and its content may be the second controversial point of surrogacy.

2.3.2 The Contract

The parties in the case of surrogacy make a binding contract about the use and the lending of a woman's womb. Pregnancy requires the host mother to make many sacrifices in order to deliver a healthy child. The contract includes the expected life-style, nutrition and behavior of the host woman and first and foremost, the requirement that the host mother surrenders the child after birth. Apparently the surrogate has to give up many of her freedom to fulfill the requirements of the contract. The question is unambiguous: What does she get in return?

Commercial surrogacy, when the host mother lends her womb for money paid by the rearing parents is one of the most controversial issues in the field of assisted reproduction. Although liberal scholars acknowledge the right of women to give up their bodily integrity, they do not agree on the justifiability of the appearance of surrogate motherhood on the free market. Some even argue that "the involvement of money payment in a surrogacy arrangement changes the essential character of the agreement". The question is: "Might the introduction of monetary considerations render a surrogacy agreement sufficiently morally reprehensible as to *justify interference with an individual's freedom to found a family [...] by employing surrogacy [...]*?" (Liu 1991, 101, Italics added)

Many argue that the answer is definitely 'yes'. The arguments that support the claim that surrogacy for fee is inconsistent with human dignity used by Liu (1991) are the following:

- It is morally objectionable because “it is analogous to slavery” (Liu 1991, 103).
Women in poverty might be willing to contract as a surrogate, which means that the financial incentive makes the voluntary character of surrogacy disappear.
- Gestation for a fee goes against the self-esteem of the host mother and degrades the value of pregnancy and motherhood.
- Treating the surrogate as a means to an end (“as a machine for the production of a child” (Liu 1991, 103)), paying for the services of the woman is equal to the commodification of the child and the surrogate at the same time. Commodification involves exploitation of both parties: the surrogate as a means to an end, and the people who cannot afford surrogacy as those whose right to found a family is constrained.
- Paying for surrogacy is not else than baby-selling: the birth of a child should not be the subject of bargaining. Just like in the case of adoption, money-payment should be banned as the profit-motif is morally objectionable to appear in any interpersonal relationship related to human life.

Some authors like Anderson (2000) argue that contracting pregnancy even without financial compensation equals to the commodification of children and women. She states that “contract pregnancy amounts to the literal sale of parental and custodial rights over children” (Anderson 2000, 20). In her opinion the reproductive capacity and autonomy is inalienable from the woman, and should not be the matter of contracting. Other scholars argue for the non-enforceability of the surrogacy contract, which means to provide the possibility for the surrogate to deny the surrender of the child.

The unenforceability criterion is already a result of a theoretical compromise between banning and commercializing surrogacy. The functional argument states that “surrogate motherhood

should not be prohibited by law. For one reason, such law would probably be unenforceable, and for another, the procedure might be justifiable in very exceptional circumstances. It might be considered justifiable only when a couple have a physical inability to have a child in any other way, and never for purposes of convenience” (Human procreation 1984, 51). Besides, the non-voluntary surrogacy contract is morally objectionable, and the possibility that women may contract for being surrogate due to financial needs is unacceptable.

In conclusion, surrogate motherhood raises all the controversial issues that can be found in the bioethics of assisted reproduction, and even goes beyond that: contracting the bodily service of the woman aggravates the problems further. However, the technological availability, the need and the willingness to surrogacy create a situation where a compromise should be made between our old idea of human dignity and bodily integrity, and between human autonomy.

In this chapter on the ethical considerations of assisted reproductive technologies I gave a summary of the issues that are ethically problematic and that provide the pool that during the policy making process, in the first step of identifying problems the policy makers can be drawn upon.

3 The Analysis of the Policy Making Process of the 1997 Health Act in Hungary

In the previous chapters I introduced both the theory of health policy making on bioethics and the ethical considerations of assisted reproductive technologies. My aim was to show how scholars think about the importance of bioethics in policy making, why it is a cutting edge issue that shapes thoughts on how to elaborate health policy. The results prove that the specialty of bioethics make the involvement of experts necessary on the one hand, and relying on international soft law on the other. These two changes in the health policy making on bioethical issues of new technologies may allow the drafters of health policy to create a law that is legitimate and effective in the long run and does not harm basic human rights.

In this last chapter of my thesis my aim is to shed light on the realization of the previously introduced theories, principles and suggestions. For this purpose, I analyze the policy making process of the Hungarian Act CLIV of 1997 on Public Health Care (1997 Health Act), more specifically the parts concerning human reproduction (the sections from 165 up to 184) through an interview made with the head of the former head of the Operative Codification Group of the Health Act, and the content analysis based on the available public documents of the process in Parliament and its Committees: I will investigate the proceedings of the sessions of the related committees (Welfare and Health Care, Constitutional Affairs and Human Rights, Minority and Religion Committee) and the Parliamentary debate of the 1997 Health Act.

First, I present the content of the 1997 Health Care Act, based on the version of the Act accepted by Parliament on 15 December 1997. Second, I investigate the codification process of the bill. This part of the analysis gives the experts' matrix presented in the first chapter. In

the last part of the analysis I elaborate the MPs' matrix based on the investigation of the legislative process.

3.1 The 1997 Health Care Act

The reasons why I analyze the Hungarian 1997 Health Care Act are manifold. First of all, after the regime change in 1989 this Act was the first large scale comprehensive legal instrument that changed and reformed the regulation, the basic concepts of health care from that of the socialist regime to a democratic one. The Act founded the concept of patients' rights in Hungary and was concerned with public health, the guiding principles and quality of the health care system, the rights of the health care employees etc. Second of all, the 1997 Health Care Act was the first legal instrument that dealt with new technologies that already were in practice in Hungarian health care, however, in an unregulated way. These new technologies were those of assisted reproduction. In 1996, when the drafting work of the Act began, "there was relatively little public awareness of the ethical and legal issues surrounding assisted procreation" (Sándor 2000, 210), although the first IVF-baby was born in 1989 in Hungary. Moreover, "[t]he discourse of reproductive rights has been lacking in legal debates in Hungary" (Sándor 2000, 208). The initiative in 1996 by the government to create the bill and include assisted reproductive technologies therefore began in an environment that lacked both public and political awareness.

Moreover, "before this Act only a decree on artificial insemination and another one on sterilization existed" (Sándor 2003, 112), therefore the Operative Group did not have any basis to refer to regarding terminology, principles and scopes. Consequently it was necessary to create a totally new regulation of the field. All of this work fell on the group of experts on bioethics, law and medical science, as it will be shown below.

Before presenting the process of codification, I introduce the content of the Health Care Act concerned with the ‘Extraordinary Treatments of Human Reproduction, Research on Human Embryos and Gametes, Sterilization’, more exactly the sections 165-184 of the bill adopted by Parliament on 15 December 1997. I outline only the most important parts of the Act, those of ethical concern.

3.1.1 General Conditions of Assisted Reproduction

The following techniques were permitted by the Health Care Act: in vitro fertilization and transfer, homolog and heterolog artificial insemination, gamete donation, embryo donation and surrogacy. The general conditions of assisted reproduction contain the requirement of providing information to the patients in order to enable them to give informed consent in all cases of medical intervention of any of the assisted reproductive technologies. This duty to inform patients fits into the guiding principle of the Health Care Act, namely the importance of patients’ rights.

Access to assisted reproductive techniques is guaranteed to medically infertile heterosexual married couples and “persons in civil law marriage” (Sándor 2003, 112). One of the most progressive elements of the Act was the Europe-wide unique possibility to “the continuation of reproductive services in case of divorce or if the spouse dies if the fertilization of the ovum has been completed”, called the “right to continuation of the infertility treatment” (Sándor 2003, 112-113). With the permission of the continuation of the treatment the codifiers acknowledged the extra burden on women during the infertility treatment, thereby accepting the feminist arguments.

3.1.2 Gamete Donation and Deposit

Gamete donation is permitted for the purposes of assisted reproduction and medical research if the donor fulfils the medical requirements, on condition that no financial rewards are involved. The gametes become the property of the health care provider “authorized to receive donated gametes” (Sándor 2003, 117) and chosen by the donor. These providers store data about the donors’ health conditions without the possibility of personal identification.

Patients have the right to ask for the storage of their own gametes. In this case of deposit, the purpose is the later use by the donors themselves.

3.1.3 Embryo Donation and Deposit, Embryo Research

Embryos can be donated for the same purposes as gametes: either for future reproduction or for medical research. As the embryo bears the genetic inheritance of both parents, the rights over the embryo can be practiced together, until the death of either of the parents. The other crucial difference lies in the moral status of the embryo and the possible outcomes of genetic intervention: the Health Care Act permits “[p]rocedures directed at influencing the sex of the child before birth only where there is recognition of a sex dependent hereditary illness, so as to prevent the development of such illness” (Sándor 2003, 120). The same applies to genetic interventions that change the characteristics of the child: they are only permissible if they are preventive or curative, even in this case only to the minimal necessary level.

3.1.4 Surrogacy

The Health Care Act permitted surrogate motherhood if the surrogate mother was a close relative of one of the genetic parents and already had at least one child. In the case of surrogacy, only non-financial incentives were permitted, therefore marketing and rewarding

surrogacy was prohibited. Besides, only medical need could be the reason of claiming for the help of a surrogate mother.

In conclusion, the Health Act in 1997 declared comprehensive, wide ranging ethical principles and practical rules regarding the everyday practice of assisted reproduction. It contained the description of the permissible techniques on the one hand and the rights and duties of doctors and patients on the other. However, there are several arguments and ethical considerations that did not appear in the Act, like the access of socially infertile people, and others that were erased from the Act later on, like the regulation of surrogacy⁵. During this research I consider both of these questions of non-appearance and elimination, although the case of elimination, the future of the Act will be only partly touched upon as it is the result of the afterlife of the codification and legislation. My aim is to conduct this research only along the elaboration of the 1997 Health Care Act from its preparation to its announcement on 23 December 1997.

In the following two sub-chapters I elaborate the analysis of the process of the codification of the 1997 Health Care Act along the theory presented above on health policy making on bioethical questions of new techniques on the one hand and the ethical considerations of assisted reproductive technologies on the other. Therefore I will constantly refer back to the arguments and principles introduced in the first two chapters, showing their empirical relevance. First, I present the codifying work of the experts, based on an interview made with Gábor Kapócs, head of the Operative Codification Group of the Health Care Act and on the bill introduced to Parliament as the result of the Operative Codification Group's activity.

⁵ The paragraphs of 183-184 were overruled by the CXIX Act of 1999.

Second, I turn to the period of codification when Parliament and its committees discussed the bill.

3.2 Step 1 – The Experts' Matrix

The intent to create a new bill on health care came into being in 1996. The legislative challenge was to work out a comprehensive bill to renew health care legislation including the development of the regulation on new techniques. The aim of the government was to create a comprehensive social dialogue during the preparation of the bill on Health Care: it was not only a legal duty but a political intent to create the Act in this deliberative way. This dialogue was intended to be an extensive discussion of representatives, not of citizens.

However, the question arises whether the dialogue that we call social conciliation was possible at that time. In its classic definition, social conciliation may mean that all the citizens can express their opinions, which is only feasible if there is a social consciousness and in this case some type of consensus about the issue policy makers can rely upon. As I already noted before, this precondition was not fulfilled in 1996 and 1997, as even assisted reproductive technology was not widely known about in society. To be able to take a stand, citizens need information, which was missing. According to a Eurobarometer survey made in 2006, of the twenty-five countries of the European Union Hungarian citizens were (with Lithuanians) the most in favor of scientific delegation in science policy making.

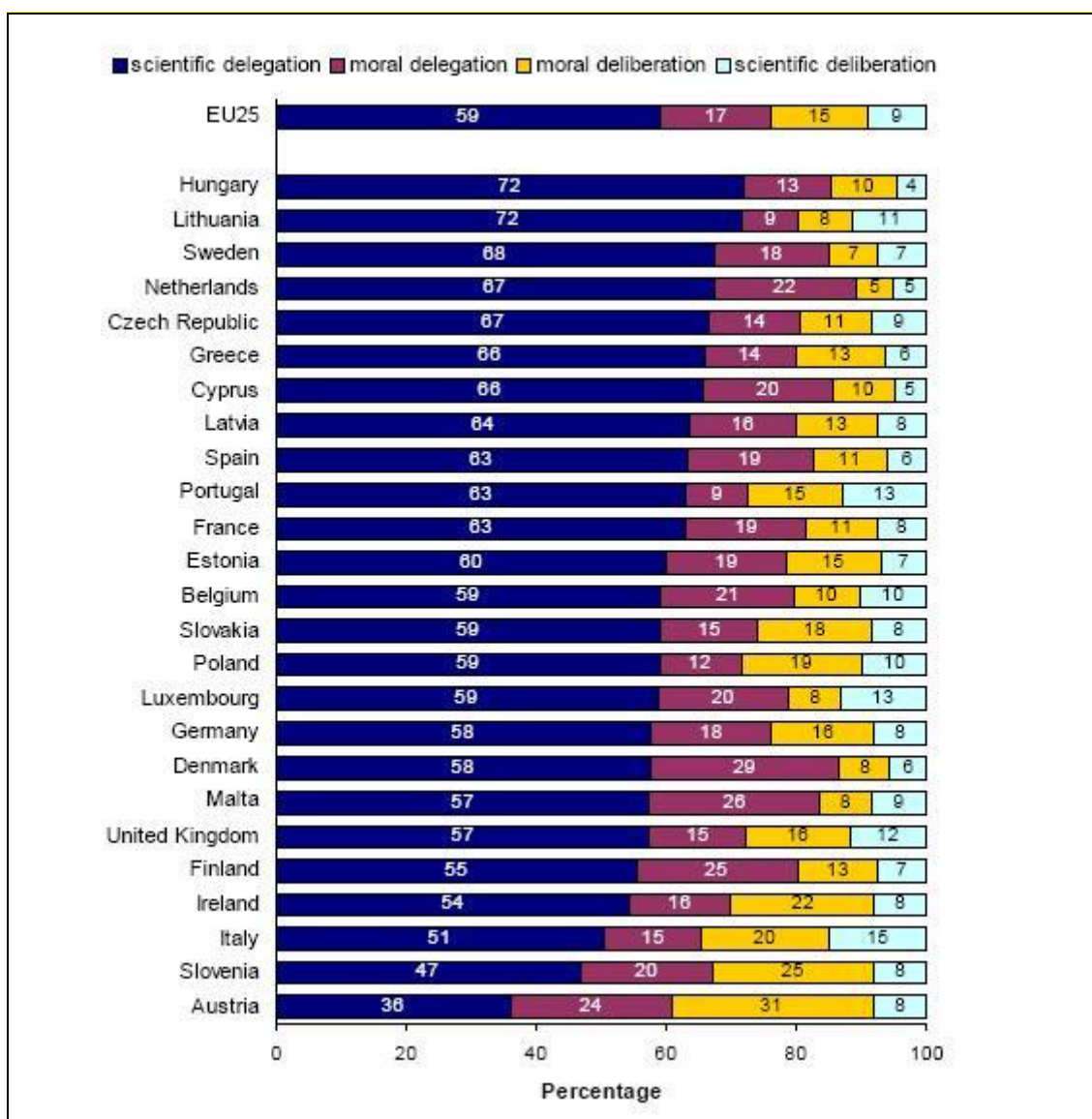


Figure 2: Principles of Governance across Europe. Source: Special Eurobarometer. 2006.

Seventy-two percent of the respondents support scientific delegation, which means that this proportion of Hungarians are for policy making based on scientific knowledge and evidence. Deliberative policy making is supported by only fourteen percent of the citizens in Hungary. Taken into consideration all the facts available, the social environment allowed only a moderate level deliberation: to involve influential professional and social organizations to represent social interests and opinions. In this sense it can be argued that not only the facts

outlined in the first chapter but also the social environment was inappropriate for a wide-ranging public debate.

3.2.1 The Operative Codification Group and the Codification Committee

The structure of the health policy making process is a complex institutional setting that I investigate from the viewpoint of the rational-political approach of boundary organizations introduced in the first chapter.

The institutional framework was based on two institutions, both of which can be called boundary organizations. However, a formal hierarchy can be identified between them, although in practice, the work of the two organizations was collaborative and parallel. Both institutions had the declared aim to consolidate arguments and mediate interests in order to achieve consensus and create a bill of efficiency and stability.

First of the two boundary organizations, the *Operative Codification Group* of the Health Care Act was established by the government at the beginning of 1996 with the aim to assign the preparatory work to experts. The formation of the group was the intent of the executive and the executive was neither obliged, nor motivated by law: it was a new institution that had never existed before in health policy making. Realizing the importance and weight of the Act to be prepared, the working group was established in the Ministry of Welfare to create the framework and the first draft of the bill. The Ministry's basic idea was to involve experts of health policy and of the special fields that were to be regulated.

The task to invite the experts to take part in the preparation was assigned to the head of the group, Gábor Kapócs. Although the list of experts was suggested by the Ministry as a sign of '*politics of authority*' (see page 10) and the government along political commitment, the members of the group were requested in a comprehensive way, irrespective of their political

attitudes. The guiding principle was to involve experts of all viewpoints to create a useful debate inside the operative group that would result in a bill of consensus. As a result, all the chapters of the Health Care Act were elaborated by sub-groups of three to seven experts. In accordance with the principle outlined above, the aim was to create heterogeneous groups: experts of theory and practice and of different age were involved. About one hundred-fifty experts took part in the preparatory work, many of them intensively involved in the work on several chapters, they were the so-called primary experts.

The sub-group of the chapter on assisted reproduction consisted of the following experts:

- Judit Sándor, head of the sub-group: lawyer, bioethicist, political scientist;
- Béla Bodnár: gynaecologist;
- József Kovács: bioethicist, medical doctor;
- Zoltán Papp: obstetrict-gynaecologist;
- Ferenc Oberfrank: bioethicist;
- Gábor Jobbágyi: lawyer;
- János Konc: obstetrict-gynaecologist, IVF-specialist.

Apparently the group assigned to elaborate the chapter on assisted reproduction was representative as far as the professional and theoretical fields were considered. Many of the experts had spent several years abroad therefore they had the opportunity to use their experience and knowledge of best practices during the discussions. The representatives of the Ministry of Welfare took part in the codification in order to express the Government stance.

The heterogeneity of the group resulted in the following in-group cleavages:

- There was a non-concordance between lawyers and government representatives and obstetricians along the issue of reproductive rights: “lawyers and government

representatives supported a limited concept of the right, while obstetricians [...] preferred a broader approach, emphasizing that their services can be regarded as a form of treatment of infertility” (Sándor 2000, 211).

- Experts committed to religious views and religious ethics refused to take part in discussing the questions of embryo-donation and surrogacy due to their objection to the practice of destruction and exchange of embryos that hurt the moral status of the embryo as a human being.

Consequently, the result of their work was based on a comprehensive and consensus-based negotiation that involved international experiences on legislation of assisted reproduction. Besides, the availability of international best practices on assisted reproductive technologies and the knowledge on the content of the Oviedo Convention, that was in the making at the time of the legislative work, enhanced the trust in the high European-level quality of this part of the bill on assisted reproductive technologies.

After the elaboration of the first drafts of the chapters the bill of the Act was framed and all the participants had the opportunity to express their opinion on each and every chapter. This inner transparency and accountability made the bill cohesive and stable: all the chapters were based on the principles of patients’ rights and informed consent.

The Act XI of 1987 declares the rules of legislation, including the institutional framework of the codification of laws. Under the head of ‘Responsibility for the Preparation of the Laws’ the Act states that the government *can* establish a codification committee for the preparation of important bills. The Government grasped the opportunity and declared the tasks and principles of the preparation of the bill in its 1093/1996. (VIII. 30.) Government decree. In this decree the Government – in accordance with its rights defined in the Act on the Rules of

Legislation – established a tripartite *Codification Committee* to coordinate the legislative work. The members of the Codification Committee were the representatives of the concerned

- Ministries;
- Professional organizations of health care;
- Representative patients' organizations.

The Codification Committee was assigned to negotiate with the Government in order to agree on the final version of the bill that got to Parliament. This negotiation happened iteratively: the bill was checked and sent back to the Committee three times by the Government until they accepted it as ready to present in the Parliament. The Codification Committee's central role was to express its views on the draft versions and to finalize the bill. The head of the Committee was the Minister of Welfare, who mediated between the Committee and the Government. In this sense, the Codification Committee stood above the Operative Codification Group in the hierarchy as the Committee negotiated with the Government who introduced the bill: they represented the link between professional and civil opinion and politics.

This means that the Codification Committee represented two groups of participants of the boundary organization described by Wiktorowicz and Deber (1997): government and politicians on the one hand, and interest groups of doctors and patients on the other. The third pillar of experts got a separate organization of the Operative Codification Group that in return for its subordinate role became the initiator and main drafter of the bill.

Besides, in the decree 1093/1996. (VIII. 30.) the government requested some of the most influential organizations to take part in the preparatory work as well as declared that it was of major importance to enable professional and social organizations to report their opinion and

give their suggestions during the preparation. This request, however, was the duty of the government as the opinions of the influential organizations had to be part of the codification process according to the Act on the Rules of Legislation.

The versions of the bill were all discussed by the Operative Group and the Codification Committee who were considering the comments of interest groups and professional organizations received. During this constant negotiation between the Operative Group and the Codification Committee social conciliation began: an open, public and comprehensive dialogue of organizations interested in and affected by the new Act on health care. However, although the opinions were taken into consideration, only those suggestions were built into the Act that were seen as fitting into the concept. Even if this strong commitment to the draft elaborated by experts is taken into consideration, the fact should be acknowledged that the codification was based on consensus building, and experts were able to manage the boundary conflicts between interest groups and to enforce the professional viewpoints.

3.2.2 The Bill

The work of the preparatory group, the codification committee and the comprehensive conciliation resulted in the bill introduced in Parliament on the 3 June 1997. This first bill gives the basis of the analysis of the process of codification: the first bill and the final accepted version of the Act are the two ends to compare. The differences between them show the most important and controversial questions. However, interestingly, the bill did not lose any parts, only got amended during the legislative process. In this section, I introduce the differences – the questions not dealt with in the bill.

First of all, the following table shows the comparison of the ethical issues regarding assisted reproduction introduced in the second chapter and the issues that were identified in the bill:

	Ethics of assisted reproductive technologies	Appearance in the bill
Access	Medical infertility	Heterosexual couples in marriage or in common law marriage
	Social infertility - Single women	Permissible only in case of divorce or death of the partner after the creation of embryos
	Social infertility - Homosexual couples	Prohibited (not included)
Donation	Commercialization of gametes and embryos	Donation is permissible only without financial rewards - principles of non-commodification and non-commercialization
	The legal status of the embryo	The embryo has the potential to become a human being, cause no harm principle, no property rights
	Data on the donors	Anonymity, necessary medical information
Surrogacy	Surrogate	None
	Contract	None

Table 3: Standpoints on Bioethical Questions in the Bill

The first draft of the bill introduced in Parliament, as it is argued widely, was already a really liberal and European-level bill, even if the later amendment of non-commercial surrogacy is not considered.

Comparing the bill introduced by the government as the result of the codification work with the version enacted, the following issues were not present in the former:

1. The limit in the use of donated embryos;
2. Excluding statement about the use of embryos in case of single women due to divorce or death;
3. Certificate to give by the health care provider in case of proceeding to arrange the legal status of the child;
4. Surrogacy.

From the three omitted issues, however, the issue of surrogacy was clearly elaborated by the operative group of assisted reproduction. The reason of its omission was the opposition of the

representatives of the Ministry of Justice: they argued that several laws should have been changed and the legal environment was unsuitable for the enactment of the part on surrogacy.

The fact that almost all the suggestions elaborated by the Operative Group and the Codification Committee remained unchanged needs explanation. I argue that the reasons are the following. First of all, the institutional framework of the drafting work allowed to create a consensual proposal as it was harmonized in a comprehensive way by several organizations, not to mention the comprehensive work of experts and the presence of the Codification Committee. Second of all, the lack of knowledge of politicians on the assisted reproductive technology and on its bioethical questions allowed only non-professional comments to appear on the one hand, and trust in the work of experts in the operative group on the other. This latter argument will be investigated in the following section on the legislation in Parliament.

3.3 Step 2 – The MPs' Matrix

The bill prepared by this wide ranging consultative work and conciliation was introduced in Parliament on 3 June 1997. From that date on, the parliamentary period of the legislation began. In this sub-chapter of my thesis I analyze the content of the debates in the plenary sessions of Parliament and in the sessions of its assigned Committees.

The following figure shows how the legislative process in Hungary takes place:

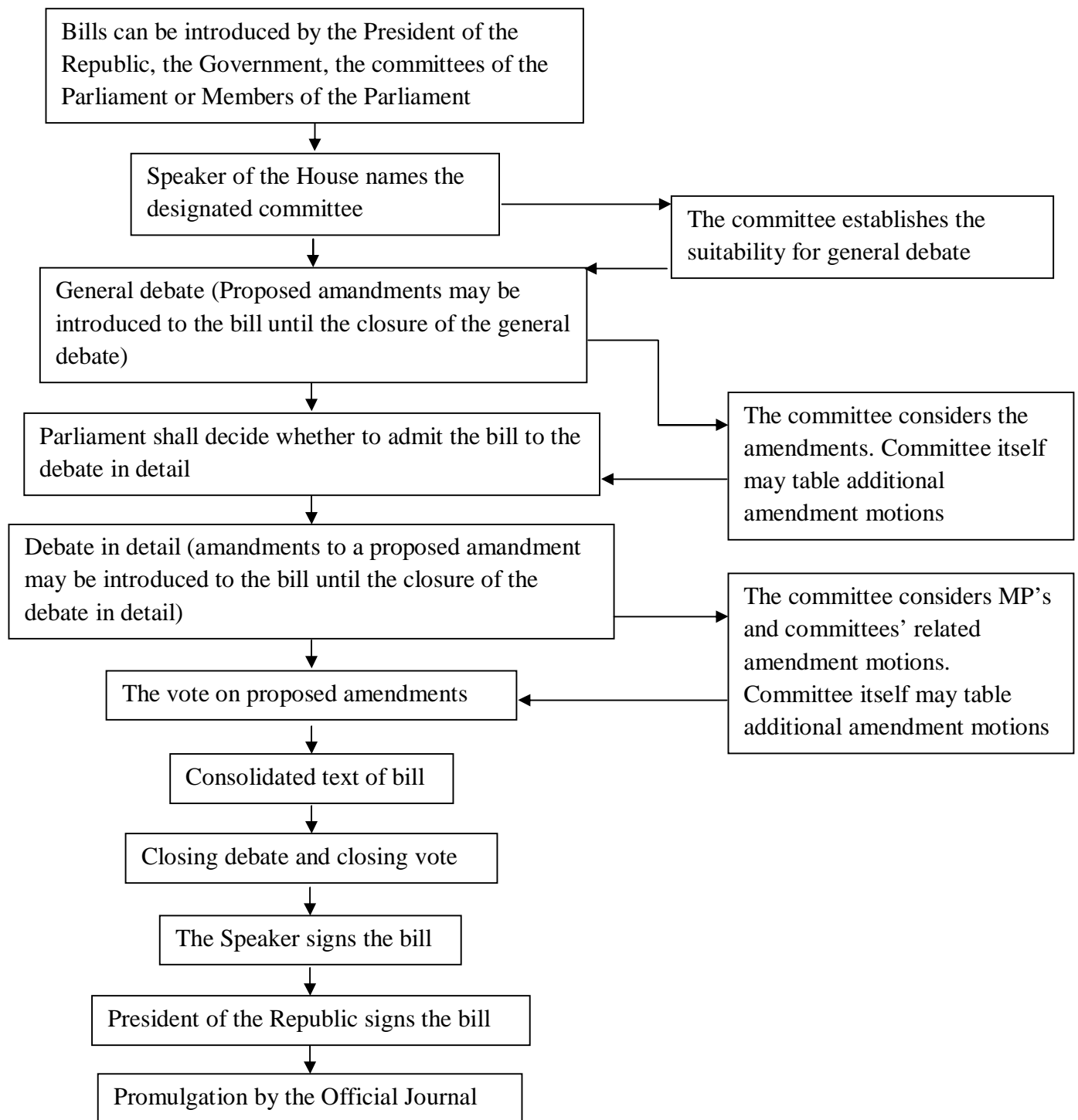


Figure 3: The Process of Legislation in the Parliament of Hungary. Source:

<http://www.parlament.hu/angol/legislation.jpg>

The Hungarian legislative process – in my interpretation – can be followed along the two main debates: the general debate and the debate in detail. During the general debate the introduced bill is discussed if the assigned committees find the bill suitable for it. Until the end of the general debate, amendment motions may be introduced that are considered by the assigned committees. The committees also have the opportunity to introduce amendment motions. The second session of the debate in detail deals with the amendments and changes in the bill. After that the assigned committees consider the introduced related amendment motions, Parliament votes on the proposed amendments that are supported by one third of the MPs in the assigned committees.

The assigned parliamentary committees were the following in the case of the bill T/4459 that later became the 1997 Health Care Act of Hungary:

- Committee of Human Rights;
- Committee of Environmental Protection;
- Committee of Local Governments;
- Committee of Welfare and Health Care.

The Committee of Constitutional Affairs negotiated the bill due to its obligation by the Standing Orders of the Parliament. Besides, the Committee of Environmental Protection and the Committee of Local Governments did not deal with the issues of assisted reproduction as their work concentrated on questions they were competent in. As during their session the chapter of assisted reproduction was not mentioned at all – not surprisingly –, I only analyze the debates in the Committee of Human Rights, of Welfare and Health Care and of Constitutional Affairs.

For the sake of convenience, I analyze the content of the discussions along the two debates of parliamentary sessions. The general debate and the sessions of committees on the decision on suitability form the first part of my analysis as the original version of the bill was discussed. The second part is formed by the discussions on the amendments and the amendment motions of the bill, both on parliamentary and committee sessions under 2a-b-c. I focus on the following questions:

- What were the questions raised about assisted reproduction? What did they focus on: practical, ethical or legislative problems?
- How were these questions considered, what kind of arguments were raised: scientific, non-professional, legal or political?

During the analysis of the two parts of the legislative process, I seek to answer these questions. My aim is to show the inherent difference between the experts' and the MPs' matrix, and how the input given by experts facilitated the work of MPs on the issue of assisted reproduction and its bioethical consequences.

3.3.1 General Debate

In the first part of the content analysis I introduce the Committees' debates on the suitability of the bill, whereby several preliminary questions about the most important problems were raised. Similarly, during the general debate of the plenary sessions the importance of the new bill on health care was emphasized on the one hand, and regarding assisted reproduction the need for appropriate regulation on the other.

The issues found as being controversial during the sessions of Committees were the following:

- In the *Committee of Human Rights* Gábor Kapócs, the Head of the Operative Codification Committee and the representative of the government emphasized the need for regulation due to the legal, ethical and scientific development and biotechnology as professional challenges. He also mentioned the possible need for regular review of the bill for the same reason: because of the fast scientific development.
- During the sessions of the *Committee of Welfare and Health Care* the length of the section on assisted reproduction was debated: it was considered to be disproportionately long. Gábor Kapócs, however, argued for the placement of assisted reproduction in law and not in regulation. Therefore, the principles and rules of assisted reproductive technologies had to be worked out in detail and in high standard.

This section of the discussions in the Committees on the bill was mainly concerned with the most basic general issues. Prior to the plenary session of the general debate in Parliament the aim of the codificators was to introduce the bill and convince the members of the Committees that the bill was worth establishing as suitable for debate. As a matter of fact, this procedure of conviction was rather formal as – just like in Parliament – the governing coalition was in a two third majority.

During the general plenary debate only a little more complex issues were raised, however, the general debate was still the introductory phase of legislation. Some MPs argued that the fast scientific development provoked social debates and ethically controversial questions, however, these debates were not concluded even at the international level. Therefore – as many argued –, strict regulation was needed. This regulation included the prohibition of positive genetic intervention and manipulation, genetic data and genetic selection, all in accordance with international agreements.

The most controversial issue during the general debate was the problem of embryo donation and deposit. First, the Parliamentary opposition argued that embryo donation and deposit are equal to the commodification of the human being. According to this argument, the embryo has the full moral status of human being, therefore the number of procreated embryos should not exceed the number of implanted embryos. Second, as far as embryo donation and deposit was considered, the need for the efficient regulation in the long run raised the problem whether the presumption of deposit without informed written consent was sufficient.

During the Parliamentary general debate most of the MPs used the language of non-competence, brought legal and conservative ethical arguments, many of which were based on asymmetric and sloppy information on international best practices (like about the destruction of unneeded embryos in France) and on the use of the technology (like the non-existing practice of creating as many embryos as get implanted and that of unlimited possibility of choosing characteristics through genetic selection). Conclusively, the tiny part of the debate concerned with assisted reproduction dealt with legal and ethical problems, emphasizing the need for legislation and on embryo donation.

3.3.2 Debate in Detail

During the general debate MPs and Committees had the opportunity to introduce amendment notions. In this section first I present all the amendment motions – even those that were not supported by the Committees to vote on in the plenary session – that were related to assisted reproductive technologies: in vitro fertilization, insemination, gamete and embryo donation and surrogacy. Second I analyze the debate in detail of the plenary sessions and all the sessions of the Committees that dealt with the amendment motions and the related amendment motions concerning assisted reproduction.

The following table shows the amendment motions listed according to the number of introduction.

Number of the Amendment Motion	Section of the Bill to Modify	Topic	Accepted?
50	171.§ (6) b)	Donation and data on donors	-
83	166.§ (1)	Surrogate motherhood, complementing the first section	+
85	183-184.§	Surrogate motherhood, the whole section on it	+
115	245.§	Criminal responsibility in the regulation of gamete and embryo donation	-
147	167.§ (1)	The criterion of the non-married status in the access of those in common law marriage	+
158	179.§ (4)	Legal status of the child - certificate about assisted reproduction	+
160	178.§ (4)	Embryo deposit, single woman, excluding statement	+
161	168.§ (4)	Written informed consent of those in common law marriage	+
162	167.§ (2)	Single woman, official excluding statement	+
163	168.§ (1)	Single woman, official request for the continuation of the treatment	+
189	167.§ (5)	Number of embryos created equals to the number of embryos implanted	-
190	175-179§	Deleting embryo donation and embryo deposit. Reason: embryos should not be commodified	-
309	175.§ (3)	Against the presumption of the willingness of embryo deposit: written informed consent is needed	-
382	166.§ (3)	Use of gamete from braindead persons	+
391	175.§ (4)	Number of couples receiving embryos from the same couple	+
396	184.§	Child of surrogate mother is the child of the genetic parents as far as the child's legal status is considered	+

Table 4: Amendment Notions during the Legislative Section. Source: <http://www.parlament.hu/iromany/04459ir.htm>

Unsurprisingly, the grouping of the amendment motions coincide with the difference between the first bill and the final result of the legislation (see page 47), however, the amendment motions show a more various picture as far as the answers giving for the controversial issues are considered.

Motions that were strongly related or aimed to solve the same ethical, legal or practical problem were debated together. Although the amendment motions were introduced to the Committees, many of them were not discussed or only superficially: these were mainly judicial problems like the requirement of certificates, requests and statements to ensure the legal enforceability and legal status of those involved in assisted reproduction. Being aware of these presumptions, now, I turn to the exact content analysis of the second part of the legislative process. Doing this, I put the emphasis on the issues raised, the topics of the introduced amendment motions, and not on the exact timeline they were discussed.

The debate in detail in Parliament was the first occasion when the *Convention on Human Rights and Biomedicine* (Oviedo Convention) was mentioned. The importance of the international instrument of the European Commission was emphasized in the context of genetic screening, genetic interventions and of the danger of genetic discrimination. At the time of the legislative process the Convention was still under elaboration. However, Hungarian experts who took part in the work could follow the mainstream direction of the first international soft law on bioethics. Using the argument of the international best practice and soft pressure shows the importance of following western policies in Hungary. This argument puts the emphasis on the path dependence of the region on the one hand and it is the tool of persuasion on the other.

Just like in the general debate, the question of the *number of couples receiving embryos donated by one couple* was raised during the debate in detail as well. Moreover, it was

debated in the Committee of Constitutional Affairs and in the Committee of Welfare as well. Here the central argument for the limitation of the number of couples using embryos of the same genetic inheritance stated that it is necessary just like in the case of gamete donation. However, during the codification the limitation regarding gametes was already elaborated. As far as the embryos are considered, it happened only during the legislative period. The only debated question about the limitation was the limit itself: in the Committee of Constitutional Affairs the legislators acknowledged that any number determined (and exceeding one) would have been controversial. Finally the number of two seemed to be rational, as according to gametes the bill determined four possibilities to use and for example during sperm donation several embryos could be procreated.

The second issue related to embryo donation and the *command over the future of the embryos* was also highly debated, however, only during the sessions of the Committee of Welfare and Health Care. The controversy arose around the lack of command over the embryos: the bill stated that in these cases the intent of embryo deposit was presumed. Some arguments emphasized the legal aspects and the legal need for this passage. As the parents cannot be forced to make a command over the future of the embryo, some kind of presumption was needed. In this sense the deposit of the embryos is the least controversial compared to donation or research. Other arguments stated that the lack of command might have caused the commercialization of embryos. This issue raised the problem of non-competence for the first time: it was stated during the session of the Committee explicitly that the lack of professional knowledge should have resulted in the trust in the opinion and arguments of the experts. Conclusively, the statement about the presumption of embryo deposit remained in the bill.

The third and most dismissive amendment motions of the conservative side of the opposition argued for the *complete elimination of embryo donation* from the bill both in the general

debate and in the debate in detail. This issue is the most apparent existence of the *moral politics of technologies* (see page 9), as the core values of the opposition differed highly from that of the experts and the governing coalition. However, although these arguments were raised in the plenary sessions, they did not generate any debate and were not considered at all. The Committee of Welfare and Health Care touched upon the topic insofar that the difference between the legal status of gametes and embryos was concerned during the debate on embryo donation. Besides, the Committee of Constitutional Affairs accepted the property rights over gametes can only belong to a health care provider but no one else, while rejected the concept of property rights over embryos: it became declared that only the right to use could be applied for embryos.

The most debated issue was *surrogate motherhood* during the legislative period. The reason for its popularity in the plenary sessions and in the sessions of the Committee of Human Rights as well as of the Committee of Welfare and Health Policy was the extra work of the legislative body that was needed to its legal enforcement. The fact that family laws, criminal laws and civil laws should have been amended was the most important basis of the rejection of the amendment motion of surrogacy. However, many arguments were used to override this problem: the fear from marketization and of ethically controversial practices (see: *the politics of uncertainty*, page 9), the intent to avoid commercial surrogacy and the rejection of the commercialization of both the embryos and surrogates provided strong arguments for the amendment of the bill: the permission of non-commercial surrogacy seemed to be better than the illegal practice of commercial surrogacy. The problem of the need for amending several basic laws was solved by later coming into force of the passages on surrogacy (on 1 January 2010) compared to other parts of the bill (which were enacted on 1 January 1998).

The legislative section of the preparation of the bill was different from the process of codification for several reasons. The institutional framework of the two sections were totally dissimilar, in the legislative process the motivation of the participants was mainly political, the language used by them was often non-competent, and as a matter of fact, due to non-competency, the ethical debates were replaced by legal debates on the date of coming into force, fictions of law and the length of the section. Conclusively the matrices of experts and MPs could be easily separated during the study of the Hungarian health policy making of 1996-1997. The comprehensive work of experts, the complexity and size of the whole bill where assisted reproductive technologies gave only one of eighteen sections, the trust in the boundary organizations, the international soft pressure and last but not least the two-third majority of the coalition parties in Parliament gave the environment for this distinctive processes on the levels of codification and legislation. Although assisted reproduction raises several highly debated ethical questions, they remained mostly unknown in Parliament.

Conclusions

Biotechnology is one of the fastest-developing scientific fields that appear to be challenging for the legislative bodies and policy making decision makers. Assisted reproductive technologies were amongst the first widely known biotechnological medical services not only in Hungary but all around the world. In my thesis I investigated how experts and politicians differ in perceiving the moral and ethical questions related to these technologies, and how these considerations appear in the health policy making process. I argued for the need for the contribution of the experts in health policy making on bioethical questions, showing how effectively rational-political boundary organizations cope with the challenge to find a consensus. Besides, I emphasized the emerging role of international soft law instruments in the field of bioethics and I presented the ethical considerations of assisted reproductive technologies, showing all the appearing aspects regarding the caused moral challenges.

These issues helped me to elaborate the analysis of the concerning parts of the Hungarian 1997 Health Care Act. I found that the health policy making process perfectly met the requirements of the concept of the experts-based rational-political model of boundary organizations. I argued that the fact that a wide ranging conciliation that moved on with the relevant social actors during the codification, allowed the legislative body to amend and discuss the assisted reproductive technologies related parts fairly slightly. However, the case of surrogacy was controversial enough that the Government decided only in the last minute to support the integration of it into the Act. The content analysis of the documents of the sessions during the legislative process proved that ethical questions are approached in a non-professional manner by politicians, rather using the legal language and being open to get convinced by arguments of international soft law instruments like the Oviedo Convention.

In conclusion, as the example of the Hungarian codification and legislation on assisted reproductive technologies showed, the work of experts and bioethicists is proved to be necessary.

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