POLITICS OF BIOTECHNOLOGY IN HUNGARY – BETWEEN REGULATION AND THE MARKET

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Executive Summary

Based on Cass R. Sunstein's argument, this thesis seeks to answer the question whether the state should play a more active role in the Hungarian cord blood banking market by establishing a publicly owned cord blood bank. According to Sunstein, if citizens have all available information and opportunities in the current situation, they are not constrained in their decision-making.

The thesis overviews briefly the history, background and medical debates of cord blood banking in general. It depicts the regulation of harvesting, processing, storing and transplanting cord blood stem cells in Hungary. Additionally, the thesis presents the operating cord blood banks of Hungary, takes a look at the ethical concerns raised in the literature, and examines whether they are valid in Hungary. In order to broaden the picture on the Hungarian cord blood banking market, it relies on a series of qualitative interviews and the content analysis of relevant legal documents.

The thesis finds that generally the beneficence of private cord blood banking is highly debated. The technical standards are regulated in Hungary, but a regulation niche can still be found in the current policy. Even though citizens can access all information, not all of them have the opportunity to access and use the services of cord blood banks.

This thesis argues for state intervention in the Hungarian cord blood banking market according to Cass R. Sunstein. Citizens are biased in their decision-making because the opportunity is lacking. The principle of equality of opportunity is harmed as some citizens cannot enjoy the blessings that cord blood stem cells offer.

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Introduction

Regulate or not to regulate – that is the question in the market of cord blood banking in Hungary.[1] Should the Hungarian legislation defend the *status quo* by allowing the market of cord blood banking function the way it is now without further regulation, or should it regulate it to promote the idea of equality of opportunity by establishing a public cord blood bank? This thesis attempts to specify the role of the Hungarian state in umbilical cord blood banking with a focus on the issue whether it should enhance the foundation of a public cord blood bank or not. Currently, the Hungarian state plays but a minimal role in this field, as there is no operating public cord blood bank. In order to support the view that regulation may serve the public in general, this thesis will apply Cass R. Sunstein's thoughts to the Hungarian umbilical cord blood banking market.

Sunstein defends regulation against minimal state (in the case of Hungarian cord blood banking, the minimal state means no further intervention) on three accounts to be discussed below: "Aspirations, Collective Action, and the Dependence of Preferences on Context" (1990, 38). Firstly, he claims that the state can never be neutral because it has the power to distribute rights, goods, and power, all of which affect the preferences of citizens (Sunstein 1990, 45). Secondly, Sunstein argues that regulation is capable of solving collective action problems by way of enabling people to do what they want, paradoxically by means of coercion (1990, 45). Regulatory coercion promotes liberty by enabling individuals to satisfy their preferences by way of "decisions reached with a full and vivid awareness of available

[1] Cord blood contains hematopoietic stem cells, which can currently be used to treat some hematological diseases, and research suggests that more diseases will be treatable in the future (Hermerén et al. 2004, 5-7). The stem cells derived from cord blood are stored in cord blood banks. In general, there are two types of cord blood banks: public and private ones. Public cord blood banks function similarly to blood donations: the donor gives the blood voluntarily to an unknown individual without any charges, and the blood is stored in the bank awaiting transplantation (Gunning 2006, 2). Private cord blood banks offer the service of cord blood storage for family use for possible future transplantation (Gunning 2006, 2). Currently, in Hungary there is no publicly owned umbilical cord blood bank where samples could be stored and donated to those in need. For the explanations of medical expressions used in this paper see Glossary, for details of brief history and background of cord blood banking see Chapter 1. In this thesis, the translations of articles, interviews, laws and decrees from Hungarian to English in are mine if not otherwise stated.

opportunities, with all relevant information" (Sunstein 1990, 40). Thirdly, citizens make their choices according to their preferences and beliefs, but these preferences and beliefs are not consistent and permanent as they change and adapt to the situation of the day (Sunstein 1990, 46). Once there is a "limitation on both available opportunities and information", citizens make decisions on the basis of inadequate information and scares opportunities, and this might be solved by regulation – argues Sunstein (1990, 46).

For the purpose of this thesis Sunstein's claim on the decisive role of available information and opportunities shaping individuals' preferences is crucial. Current Hungarian regulation does not ensure the equality of opportunity as many do not have access to private cord blood banking. Some parents, despite their financial constraints, would like to make sure that their children are safe if a disease treatable with stem cells derived from umbilical cord blood rears its head. However, parents who would like to provide everything possible for their children but do not have the opportunity to have their babies' umbilical cord blood stored at a private cord blood bank cannot provide the same kind of safety for their children that some wealthy parents can. The solution could be the regulation of the market through the establishment of a public cord blood bank to which less wealthy families can apply for stored umbilical cord blood stem cells if needed. The question of regulation is relevant to the extent that the establishment of a public cord blood bank could enhance the well-being of all citizens and thus ensure the equality of opportunity as the service of a public cord blood bank would be accessible to everyone.

This, of course, does not imply that private cord blood banks' operation should be constrained; all it means is that parents could decide whether they choose a private cord blood bank to store their babies' cord blood for themselves or prefer to opt for a public cord blood bank whose samples are available to all citizens. This solution would harmonize free enterprise with solidarity. Currently, as experts of the European Group of Ethics (EGE) put:

"[t]he values of freedom and free enterprise can conflict with the principles of solidarity and justice…" (Hermerén et al. 2004, 17).

At the same time, there are arguments against regulation as well; in particular the benefits of stem cell therapies are debated by researchers and hence not evident enough to justify further state intervention, and there are some ethical concerns as well. Regulation as a form of state intervention might hinder market competition; therefore the justification of further regulation must be carefully underpinned. To answer the main question 'regulate or not regulate', this paper attempts to review and to contrast arguments for and against the regulation of cord blood banking in Hungary in line with Sunstein's claims. For this purpose several subquestions need to be answered.

First of all, what umbilical cord blood stem cells are good for? Though cord blood banking was started less than twenty years ago in the early 1990s, its literature has grown huge. Umbilical cord blood had been considered a waste for a long time, but recently physicians have realized that the cord blood is "clinical gold" (Thompson 1995, 805).[2] Doctors now use the stem cells derived from cord blood as an alternative for bone marrow, and research suggest the broader use of stem cells derived from cord blood in the future (Gunning 2003, 79). Umbilical cord blood banks have recently mushroomed all around the world, and parents have started to use the services offered by these banks to secure their family's future health (Gunning 2003, 79). Approximately a quarter of cord blood banks around the world are private ones (Gunning 2003, 83), even though the necessity of the collection and storage of such stem cells for autologous transplantations is a topic of constant debate in medicine, being a 'scientific knowledge gap' (see debate in *Nature Review Cancer* 2008).[3]

[2] In this paper, the terms 'umbilical cord blood' and 'cord blood' are used as synonyms.
[3] I am grateful to Enikő Demény for introducing me this expression.

This 'scientific gap' leads to the next subquestion: to what extent physicians recommend the storage of stem cells derived from cord blood at public cord blood banks? Those in favor of cord blood banking emphasize that the harvesting of cord blood is less invasive than that of bone marrow, the sample is immediately available, and stem cell treatment has great potentials for the future (Verter 2010a, b). Those against it highlight that the scope of the current use of cord blood is limited and might be used only as an alternative to bone marrow or peripheral blood; and the chances for the development of a disease that can be treated by autologous cord blood transplantation are low (Annas 1999, Masszi 2002).[4] A brief overview of the medical debate is therefore necessary before exploring the possible further regulation of cord blood banking.

Another subquestion that has to be discussed before answering whether the Hungarian state should intervene into cord blood banking or not is, what is the status of current regulation? Generally, regulation is lagging far behind the development of medicine and of the private health sector (Sándor 2003, 18), and the findings of this paper suggest that this is the very case in Hungary in the field of cord blood banking. There is no specific law as yet to regulate cord blood stem cell banking in Hungary. One may argue that private companies offering the service of umbilical cord blood storing have found a niche in the market and had emerged before any substantial regulation on their operation was passed. Regulation must address at least three areas, namely the technical standards (i.e., the rules of harvesting, physical storage and transplantation), the ethical issues (i.e., personal data protection, secrecy etc.) and the regulation of the scope of state engagement (i.e., the foundation of a public cord blood bank). The technical standards of cord blood processing, storing and use are specified in the directives of the European Parliament and of the Council, which have already been introduced into the Hungarian legislation. A chapter of this thesis examines whether the

[4] The opponents of cord blood banking take side against private cord blood banking, researchers agree on the beneficence of public cord blood banks.

ethical concerns raised elsewhere are valid in the Hungarian context, and how the domestic policies address these issues. The regulation on the extent of state engagement is the very topic of this paper.

Another subquestion has to do with the issue of the current status of private cord blood banking in Hungary. This paper presents three private cord blood banks which operate and have an office in Hungary, one small bank for 'directed donations', and the failure of a Hungarian public cord blood bank initiative. Private cord blood banking is a growing business in Hungary, there are advertisements appearing in different media outlets - not only in the ones dedicated exclusively to pregnant women, thus one may assume that the number of contracts will increase.

The last subquestion of this paper attempts to investigate whether the consumers of private cord blood banks are well-informed or not, i.e., citizens can make a decision based on adequate information. Cautious parents may opt for this service in the hope that they will do everything possible for their child, but there are still some issues to be discussed, especially the ethical concerns raised by scholars. The issues concerned – in line with George J. Annas (1999) and Ellenchild Pinch and Kennedy-Schwarz (2001) – include the questions of ownership, consent, privacy, and commercialization.

Once the main question of this paper has been answered by analyzing whether decision-makers have adequate information and opportunities; and further state regulation seems to be more convincing, then the question needs to be addressed to what extent the Hungarian state should interfere with umbilical cord blood banking. If parents' access to information and opportunities is limited, then it is the job of the state to enable its citizens to live autonomously without the coercions of the market in line with Sunstein's claim.

Having the subquestions answered, the main question of this thesis can be addressed. In line with the questions raised above, the present paper firstly offers a brief overview of the history, background and medical debates of umbilical cord blood banking in general. Then it reviews the current regulation on both the European and domestic levels by way of analyzing directives, laws and decrees; and introduces the few, currently existing, private cord blood banks in Hungary. Afterwards, this thesis presents the ethical concerns pursuing the debate on private cord blood banking and discusses the extent how warrant these concerns are valid in the Hungarian context. The examination of the validity of ethical concerns is carried out firstly based on content analysis of information sheets, contracts and supplements available on the websites of the three private umbilical cord blood banks, and secondly based on personal semi-structured interviews conducted with representatives of the private cord blood banks and representatives of other segments of the field.[5] The paper is concluded by a tentative answer to the question whether there is a need for state intervention into the cord blood banking market in a way of establishing a public cord blood bank in Hungary, or not.

[5] I am grateful for the help that experts, representatives of companies, doctors and professors, provided me when answering my questions and advising some of the issues discussed in this paper.

Chapter 1: History and background of cord blood banking

Scientists used hematopoietic stem cells for transplantation for the first time in the early 1960's when transplantation was performed using bone marrow to treat a disease (Kapócs 2003, 460). The next step took place in the early 1980's when physicians used stem cells derived from peripheral blood at transplantation (Kapócs 2003, 460). Umbilical cord blood transplantation was performed in 1988 for the first time successfully, when a little French boy suffering from Fanconi's anemia received stem cells procured from his sister's cord blood (Steinbrook 2004, 2255).

Umbilical cord blood contains hematopoietic stem cells, which can currently be used during the treatment of several diseases. Such diseases include autoimmune disorders, acute myeloid leukemia, Non-Hodgkin's lymphoma, Amyloidosis etc. (Copelan 2006, 1814). Frances Verter distinguishes three categories of the uses of both autologous and allogeneic cord blood stem cell treatments: "standard therapies", which are mainly to treat "disorders of blood cell lineage" (2010a). "Therapies in clinical trials" are the ones not adopted as standard therapies, and "experimental treatments", which "have not been proven to have efficacy in human beings" (Verter 2010a).[6] Standard therapies include: leukemias, lymphomas, hematopoietic disorders, metabolic disorders, etc. There are clinical trials on the treatment of diabetes type 1, Crohn's diease, Lupus, breast cancer, etc. Experimental treatments are:

[6] There is an inconsistency between Edward A. Copelan and Verter: Copelan regards Non-Hodgkin's lymphoma treatable by autologous transplantation (2006, 1814), while Verter considers the same disease treatable by allogeneic transplantation (2010a). Both consider the treatment of this lymphoma as common treatment/standard therapy.

Scleroderma, Alzheimer's and Parkinson's disease, stroke recovery, etc. (Verter 2010a).[7] The list of diseases of the three categories keeps changing, as the scientific knowledge is constantly increasing.[8]

Many scientists assume that stem cells derived from umbilical cord blood have a great potential for the future, especially in cell therapy and regenerative medicine; not only because the collection is not an invasive process, but also because here no embryo has to be destroyed to gain stem cells (see Gunning 2004, 4 and Samuel et al 2008, 535). One of cord blood's most promising characteristic according to medical experts is that it contains pluripotent stem cells (Gunning 2003, 91), which are famous for their ability to convert into any kind of cell that should be needed at a treatment. Future will answer the question whether daily medicine will utilize this knowledge about cord blood stem cells or other medical innovations will be used.

Currently umbilical cord blood is used mainly in transplantations as alternatives for bone marrow cells, as it is a source of blood cells (Hermerén et al. 2004). The hematopoietic stem cells ensure the quick engraftment (Copelan 2006, 1819) meaning that the transplantation has been successful and the recipient has started to produce blood cells with the help of the transplanted stem cells (Samuel et al 2008, 533). An advantage of the stored cord blood is that its procurement from the cord blood bank lasts only one week or two, while to find a bone marrow donor can take three to six months (Kurtzberg et al 1996, 165). Also, the number of transplantation survivals when using cord blood is higher, although it may depend on the patients' age (Rocha et al 2000). Edward Copelan assumed that the "outcomes [of autologous or allogeneic hematopoietic stem cell transplantations] vary according to the

[7] Verter's list of standard therapies includes more than 80 diseases, there are twenty diseases listed to be in clinical trial status, and there are 19 diseases on the list of diseases in experimental status (2010a). For full list see the website Parentsguidecordblood.org.

[8] It has to be noted that it is not sure that treatments in clinical trial or experimental status are ever going to become standard therapies.

type and stage of disease, the age and functional level of the patient, the source of the stem cells to be transplanted, and the degree of HLA mismatch" (Copelan 2006, 1822).[9]

The first banks collecting umbilical cord blood for siblings were set up in 1992 (Gunning 2003, 83). In general, there are both private and public cord blood banks for siblings for families where there is a child with a treatable disease. When this child happens to have a little sibling, then the sibling's cord blood is stored for transplantation for the diseased child (Gunning 2003, 83).[10] There are non-profit public cord blood banks for allogeneic unrelated transplantations, which is similar for the simple blood donation, where blood is received by someone in need after donation and storage (Gunning 2003, 83). Finally, there are for-profit private banks storing cord blood for autologous use, when the cord blood is saved for the child himself for a possible later use if the child ends up diseased (Gunning 2003, 83). This type of cord blood banks appeared in the early 1990's offering a special kind of 'insurance'. The success of cord blood banks is shown by the fact that by the early 2000s there were more than 100 private or public banks storing umbilical cord blood worldwide (Gunning 2003, 83).

Göran Hermerén and colleauges pointed out that 75 per cent of the cord blood banks are public or private non-profit banks worldwide, and the rest is private for profit banks (2004, 9). Scholars agree that an important concern on private umbilical cord banks is that once people opt for the storage of cord blood for autologous use in private banks, they are not willing to donate this blood for public cord banks (Gunning 2004, 2–3 and Hermerén et al. 2004, 19). But they also agree that public banks function on a regional basis, possible donations out of the region are not accepted, and this problem does not exist as private banks cover the whole territory of the country (Gunning 2004, 2–3). David T. Harris claims that

[9] For the explanations of medical expressions see Glossary.
[10] This is called "directed donation" as we will see in Chapter 3.

both public and private umbilical cord blood banks are needed due to the first one's territorial limitation (2008, nrg2418-c2).

The umbilical cord blood is harvested after the delivery of the baby, but its amount is usually no more than 180 ml, which would be enough for a patient of less than 50 kg (Steinbrook 2004, 2255 and Gunning 2004, 2). Lately scientists have figured out that there is a possibility of "double cord transplants", which means that umbilical cord bloods can be mixed, thus the amount of the stem cells in the sample can be enough for the treatment of an adult too (Samuel et al 2008, 533).[11] Additionally, there are techniques arising on how to multiply the number of stem cells (Nietfeld 2008, nrg2418-c1).

In order to avoid infections, umbilical cord blood is usually harvested when the placenta is still in the uterus. The harvesting is usually done by the staff of the hospital. Physicians or midwives receive a kit for the harvesting from the cord blood bank via the mother, who carries the kit with herself to the hospital for the delivery. Once the blood is harvested, the cord blood bank is called on a 24/7 line and the cord blood is sent to the bank by a courier (Parson 2004, 8). During the delivery and after the collection of the cord blood there are several screenings seeking infections; and the HLA type of the blood is determined too. These are necessary steps for the safety of the blood for later transplantation. After screenings and processing, the cord blood is stored in liquid nitrogen at -196 ºC waiting for the possible transplantation (Hermerén et al. 2004, 8).

The transplantation is currently a standard therapy for a number of hematological diseases. It is doubtful whether anyone would be able to estimate how many diseases would be treated by standard therapies using stem cells derived from umbilical cord blood in ten, fifteen, twenty or more years. One may argue that the justification of storage in a public cord blood bank based on future possibilities is unsatisfactory, as it is based on uncertainty.

[11] Naturally, this option exists only in case of allogeneic transplantation.

Nevertheless, once a cord blood sample is stored, only the then available technology can determine its use.

Section 1.1 Changing function and role of cord blood

Before recognizing the potential hidden in umbilical cord blood, the cord was wasted after the delivery. When scientists figured out its usefulness, cord blood started to be regarded as "clinical gold" (Thompson 1995, 805). The value that is represented by the harvested cord blood sample is different for a cosmetic company whose aim is profit maximization by selling creams created from the cord blood (Andrews and Nelkin 2001 cited by Waldby and Mitchell 2006, 115), for a researcher, who can conduct research on samples, for a physician whose aim is to treat people with different (lethal) diseases, and for parents who decide to store the blood of their baby, creating a special type of insurance for their child and possibly for the whole family as well. Obviously the role of stem cells derived from cord blood is different for the private cord blood banks. Generally in the case of body parts scientists use words like "banking, investment, insurance, compensation, and patenting" (Nelkin and Andrews 1998, 34–35).

As Catherine Waldby and Robert Mitchell point out umbilical cord blood is now a "biological venture capital" thanks to the private banks (2006, 123). The authors emphasize the possible developments of biotechnology in the future, when the cord blood account – a "form of speculative investment" (2006, 126) – can offer healing:

> [i]n its prudential aspect, a private cord-blood account is organized according to the neoliberal principles of private insurance, which offers personalized risk-management services as a hedge against the uncertainties of the future. (Waldby and Mitchell 2006, 125)

The authors see cord blood banking as a sort of time manipulation, as individuals are enabled to live in a "double biological time" (Waldby and Mitchell 2006, 125). The body may age, but

the frozen samples keep their capacities and when needed, they can help in restoring the blood system (Waldby and Mitchell 2006, 119 and 125). According to the authors, the "potential speculative value" of the cord blood accounts outweighs the concerns raised about their current usability (Waldby and Mitchell 2006, 129).[12]

Such nominal commodification and hinted commercialization of these samples contradicts the traditional judgment of tissues, as for a long time they and other samples were regarded and treated as gifts in bioethics and policy-making. The mushrooming of private umbilical cord blood banks has changed this discourse creating the paradox that now there is a legal relationship between the sample and the person in case of umbilical cord blood banks (though the parts – the person and the cord blood – are separate), and at the same time the account is "an open source of biological material for commercial interests" (Waldby and Mitchell 2006, 123).[13]

Additional characteristic of stored umbilical cord blood stem cells is that they may offer a "personalized treatment": the medicine is created from the patient's own cells, and the medicine is good for only the patient (personal communication of a representative of a cord blood bank). Such treatments would radically change medicine, and one's perception on healing.

As it was mentioned above and will be detailed below, Hungarian citizens do not have to face the dilemma of where to store the blood: donate it for an unrelated use or store it for the own child. Citizens are constrained by the narrow state engagement, as basically no public bank exists.

[12] On medical concerns see upcoming section on "Medical debates".
[13] However, it must be noted that even if a body part is commodified, it is not sure that it gets commercialized as it may be the case that commercialization is forbidden in a given country. I am grateful to Janet Radcliffe Richards to reveal me this point.

Section 1.2 Medical debates

There are several concerns raised by scholars from different fields about private cord blood banking. The contradicting views do not help decision-making based on adequate information. This section interprets the arguments and counterarguments formulated by scholars on private cord blood storage for autologous use. The first debate is about the overall probability of the appearance of a disease currently treatable with stem cells derived from cord blood, and its use so far, the second is about the possible storage time of the cord blood samples, the third encompasses safety issues, and the fourth is about the comparison of cord blood to bone marrow.

The basic problem with umbilical cord blood banking is that there are debates even between researchers themselves, as it embodies a 'scientific knowledge gap'. As noted in the previous section, the knowledge on possible uses of cord blood stem cells keeps growing in this field, which fuels the medical debate. But some illustrious institution argue that according to the available technology of the day, it does not seem reasonable to store the cord blood based on medical and ethical reasons (See Hermerén et al. 2004, and the opinions of the American Academy of Pediatrics, the Royal College of Obstetricians and Gynaecologists, the World Marrow Donor Association, cited in Sullivan 2008, 557).[14]

Annas assumed that the probability of appearance of a disease that would need the transplantation of the patient's own hematopoietic stem cells in the first twenty years of a human life is approximately 1 in 20 000 (Annas 1999, 1523). Other scholars cited a report of American obstetricians assuming the odds are about 1 in 200 000 (Ellenchild Pinch and Kennedy-Schwarz 2001, 55). Michael J. Sullivan estimated that 1 in 15 000 is the possibility

[14] On ethical concerns see Chapter 4.

of the need of an autologous transplant in childhood, but mentioned several conditions which suggest that the probability is even less (2008, 561). Whichever is the correct number, the possibility is deep below 1 per cent that someone in the first twenty years of his life - or below 50 kg - will develop a hematological disease.

Verter collected the list of "autologous treatments" since 1998 up until now,[15] and listed more than 200 cases from all over the world (2010b).[16] Gábor Kapócs reported that in Hungary there were only three allogeneic transplantations, and no autologous transplantation had been performed at all (Kapócs 2003, 462).[17] Cord blood account was requested from a Hungarian private bank only once, because the baby died and the doctors wanted to make the genetic analysis on the stored sample (personal communication of a representative of a private cord blood bank).

According to the available technology, the cryopreserved umbilical cord blood can be stored safely – meanwhile viable – for about 15 years (Ellenchild Pinch and Kennedy-Schwarz 2001, 55). But J. J. Nietfeld claims that the technology for cell expansion is developing and methods of cryopreserving may develop further; thus the viability of stem cells may be increased, and some argue that theoretically they can be preserved for a "lifetime" (2008, nrg2418-c1).

It may happen that during the harvesting either unwanted infection or contamination occurs, or the sample does not contain enough stem cells worth storing for future use

[15] Note the difference between "transplantation" and "treatment". As indicated above, due to the development of research on stem cells derived from umbilical cord blood the scope of its use keeps growing. Umbilical cord blood stem cells are not only used as alternatives of bone marrow to treat hematological disease, but other treatments and therapies as well.

[16] According to Verter's data the treated diseases have fallen into these categories (the numbers in brackets indicate the proportion of the given disease treated by stem cells derived from umbilical cord blood): "Cerebral Palsy" (61 per cent), "Brain Injury" (16 per cent), Type I Diabetes (11 per cent), Other Regenerative (3 per cent), and Not Regenerative (11 per cent) (2010a).

[17] In early 2010 still no autologous transplantation has been performed in Hungary (personal communication via phone of a representatives of a cord blood bank May, 2010).

(Gunning 2004, 3).[18] In all these cases the sample is useless (though with the development of technology it might change). Earlier infection may stay hidden, because the screening is quite expensive, and private banks cannot afford it (Masszi 2002, 314). Tamás Masszi assumed that private for-profit umbilical cord blood banks "do not care about the quantity and quality appropriateness of cryopreserved cells for a later transplantation, thus they are not appropriate and no one will transplant them" (Masszi 2002, 314). Gunning assumed that private banks either charge the costs of screening and processing to the clients or they simply do not offer this service routinely in their contracts (Gunning 2004, 4).[19] Masszi overcame this problem by proposing the routine use of peripheral blood derived from the body of the one in need to treat his or her hematological disease (2002, 314). Representatives of private cord blood banks claim that adult hematopoietic stem cells are not "naïve", thus they are not that efficient for treatment (personal communications).

A comparative research did not support that cord blood was superb to bone marrow: "[i]n our study, overall survival did not differ significantly between recipients of cord-blood transplants and recipients of bone marrow transplants…" (Rocha et al. 2000). The authors of the research came to the same conclusion as the authors of the Opinion No 19 of EGE saying "[t]he legitimacy of commercial cord blood banks for autologous use should be questioned as they sell a service, which has, presently, no real use regarding therapeutic options" (Hermerén et al. 2004). Naturally, if parents choose to ask for this service, they should not be impeded. But experts of EGE warn that

[18] Quality problems may arise even if everything seems to be fine according to the used protocols in the given country. It already happened that the cord blood sample harvested and stored in the USA was delivered to Germany for transplantation and after the thawing it came out that the sample did not contain enough viable cells for the transplantation (Gunning 2003, 131). The timing is also important when it comes to quality problems. Experiences show that the harvesting preferably needs to be done within the first 30 seconds after the delivery (ETT-TUKEB 2002, 5).

[19] In Hungary there are examples for both. However, Gunning's statement is true in Hungary as well: the service of the company which does not perform the screening is the cheapest. See Chapter 4.

> future therapeutic possibilities [of the sample] are of a very hypothethical nature and that up until now there is no indication that the present research will lead to specific therapeutic applications of one's own cord blood cells (Hermerén et al. 2004, 21).[20]

Rather, EGE promotes voluntary tissue donation to public umbilical cord blood banks in its different opinions (Lenoir et al. 1998 and Hermerén et al. 2004).

However, it has to be noted that researchers and scholars agree on the beneficence of public cord blood banks, especially in the case of ethnic minorities in a society. The representation of ethnic minorities in bone marrow donor registries is low (Copelan 2006, 1820; Samuel et al 2008, 534 and Sullivan 2008, 561); and their HLA types are usually different than that of the society (Kapócs 2003, 461 and Masszi 2002, 2). A public cord blood bank could overcome the shortcomings of the donor registries.

This seemingly never-ending medical debate does not help the citizen to see clear on the whole issue of private umbilical cord blood storage, though valid and reliable information would help the citizens' decision-making. But as far as there is a gap in the scientific knowledge, uncertainty will not remain only amongst researchers, but citizens as well. The storage of umbilical cord blood is in its infancy and keeps developing. Parents may ask for the freezing of their babies' cord blood in the hope that by the development of medicine, these samples may not only offer treatment for hematological diseases, but other 'evils' as well. But the expectant parents deciding to resort to the services of a cord blood bank depends crucially to whom they believe and what resources they find; and whether they have both options: to store cord blood in a public or in a private cord blood bank. The expectant parents' decision-making is coerced by the lack of adequate information and opportunities in general.

[20] The authors revealed that some members of the EGE even wanted to ban the operation of private banks, but finally they determined that these banks can function, but under strict regulation (Hermerén et al. 2004, 20).

Chapter 2: Regulation

Section 2.1 Regulation in the European Union

The regulation of cord blood banking is diverse amongst the member states of the European Union. Some countries have prohibited the operation of private banks on their territory (for instance Italy, Gunning 2003, 114 or France "because cord blood is considered a national resource" Verter 2010c); in some countries the state itself promotes public banking (like in the United Kingdom, Gunning 2003, 117); and in some others regulation on cord blood banking does not exist (for instance in Greece, Verter 2010c).[21] Albeit the regulations vary from country to country in the European Union, the international recommendations on cord blood banking are clear.

Though the Oviedo Convention – signed and ratified by numerous countries, including Hungary – stipulates that "[t]he human body and its parts shall not, as such, give rise to financial gain" (Oviedo Convention 1997, Article 21).[22] The Additional Protocol of the Oviedo Convention specifies that "[t]he provisions of this Protocol applicable to tissues shall apply also to cells, including haematopoietic stem cells" (2002, Article 2).[23] In case of umbilical cord blood the concern of financial gain might not be valid. In Hungary, the Scientific and Ethical Committee of Medical Research Council (Egészségügyi Tudományos Tanács Tudományos és Kutatásetikai Bizottsága, hereinafter ETT-TUKEB) argued that the

[21] For a detailed depiction of worldwide umbilical cord blood banking see Gunning 2003.
[22] For the full names of the Convention and the Protocol, directives, decrees and laws mentioned in this paper see the Reference list.
[23] The Additional Protocol does not apply to the "blood and blood derivatives" (2002, Article 2).

cord is an object, thus the leftover material of a delivery is not regarded as a part of a human body any more, thus it can be owned (ETT-TUKEB 2002, 7).[24]

The European Union's "Directive 2004/23/EC on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells" applies to cord blood stem cells as well, but it does not specify the operation of private cord blood banks. It does stipulate that "Member States shall endeavour to ensure that the procurement of tissues and cells as such is carried out on a non-profit basis" (2004/23/EC directive, article 12). The directive itself has recommendations regarding the authorization and monitoring of "tissue establishments", the traceability of the tissues from the donor to the recipient, and informed consent. Directive 2006/86/EC sets the implementation of Directive 2004/23/EC.

The authors of "Directive 2001/83/EC on the Community code relating to medicinal products for human use" defined "somatic cell therapy medicinal product" as somatic living cells manipulated in different ways, such as the "expansion or activation of autologous cell populations ex vivo" (part 4, 2), which is done to the hematopoietic stem cells before transplantation. "Somatic cell therapy medicinal product" is identified as "advanced therapy medicinal product" in Regulation (EC) No. 1394/2007 of the European Parliament and of the Council. This latter document regulates the marketing authorization requirements and stipulates the specific technical requirements for the characteristics of the cells (Regulation (EC) No. 1394/2007, 4-5). The Directive 2001/83/EC has been amended by Directive 2002/98/EC.

[24] Note that the word-by-word translation of the Hungarian name of the entity is "Scientific and Research Ethics Committee of the Health Science Council".

Section 2.2 Domestic regulation

It is general, that new scientific medical discoveries appear in a given country before any laws regulating the given field would operate. As Judit Sándor put it: "[i]t is not surprising that law and ethics cannot keep up with the rapid changes in scientific paradigms" (2003, 18). This was the very case in Hungary as well, where the use of blood derived from umbilical cord blood had been already debated in 1989 (Sándor 1994, 160); but the rules on harvesting, storing and transplanting hematopoietic stem cells have been legally specified only later.

There are several laws, ministerial and governmental decrees that have an affect on the harvesting, processing, storage and use of umbilical cord blood. The directives of the European Parliament and the European Council were introduced mainly into these already existing laws without creating a new, specific act on the harvesting, processing, storing and transplanting stem cells derived from umbilical cord blood.

The collection can be processed only by health care providers stipulated in section 124 of the Act CLIV of 1997 on Health Care (hereinafter: Health Care Act), but basically those, who have proof of adequate quality and obey the standards set. If the processing and storage of cord blood does not take place at the same health care provider, then the participants must have a contract.

The Ministerial Decree 60/2003 (X. 20.) of the Ministry of Health, Welfare and Family on Professional Minimum Conditions Necessary for Health Care Provision (hereinafter decree 60/2003) settles the minimal personal and material conditions for health care providers in case of cord blood stem cell collection. Its general provisions on cord blood collection are: at the medical check-up pregnant women must be treated if they were blood donors, and when it comes to the minimal conditions of cord blood harvesting, decree

60/2003 specifies that "[d]uring the harvesting, processing, transportation and storage and use of cord blood, the regulations on bone marrow transplantation must be used" (515). Decree 60/2003 lays down the personal, material and other conditions of the collection of umbilical cord blood.

The storage of genetic data is regulated by Act XXI of 2008 on the Protection of Human Genetic Data, but as it defines "biobanks" as the "collection of genetic samples and the related genetic and personal identifier data for the purpose of human genetic diagnosis and human genetic research as defined in this act"; which criteria are not valid in the case of private banks for autologous treatment purposes.

Umbilical cord blood banks are regarded as tissue banks, and the provisions of the Ministerial Decree 18/1998 (XII. 27) of the Health Ministry on the execution of the provisions of Act CLIV of 1997 on Health Care on Organ and Tissue Transplantation, Storage and Tissue Examinations (hereinafter decree 18/1998) stipulate the requirements of medical documentation. The documentation stipulates how cord blood is harvested, when tissues are stored, and the requirements of sample labeling. Decree 18/1998's attachment number eight refers to Decree 18/1998 (VI. 3.). The latter one stipulates that tests on HIV1, HIV2, Hepatitis A, B and C have to be made (section 24).

The Governmental Decree 96/2003 (VII. 15.) on General Conditions of Health Care Provision and Proceeding of Operational Permission (hereinafter Decree 96/2003) 2003 regulates the process of authorization of health care providers in general. The most important stipulation of this decree for the sake of this paper is that a health care service provider has to have the permission of the ÁNTSZ (article 7) – in accordance with the 2002 opinion of ETT-TUKEB.

Cord blood bank companies have to comply with strict regulation in Hungary, and ÁNTSZ regularly checks the operation of these banks. Furthermore, ÁNTSZ has to send a report to the European Union every three years about the measures taken according to Directive 2004/23 (article 26).

Dr. Zsolt Kovács, the chief medical officer of ÁNTSZ admitted that the regulations (implementations of the common directives into the national legislation) are "hectic and multicolored", which raises some methodological problems when it comes to monitoring.[25] As Dr. Kovács pointed out, the operation of ÁNTSZ as an authority is not that broad as the workgroup of the European Union would like them to have. Dr. Kovács admitted that ÁNTSZ would like to harmonize with other member states, but the authority does not have capacity for that.

The Health Care Act contains regulation on tissue transplantation, but it excludes blood tissues (section 202, ac). However, section 206 of the Health Care Act determined bone marrow and hematopoietic stem cells as tissue, and the practical use of cord blood implicates that cord blood has to be considered as tissue and not blood (ETT-TUKEB 2002, 7). The above mentioned Additional Protocol to the Oviedo Convention (2002) was ratified by Hungary by Act LXXX of 2006. As noted above, the Additional Protocol of the Oviedo Convention does apply to "haematopoietic stem cells", but it does not to the "blood and blood derivatives" (2002, Article 2). According to the implementation of the Protocol and section 206 of the Health Care Act one may assume that the Hungarian legislation regards the frozen umbilical cord blood as hematopoietic stem cells (see Health Care Act, article 206), thus as tissue.

The Health Care Act (section 215) and the Act LXXX of 2006 have some provisions on the transplantation of tissues. The specification of the technical standards of

[25] The personal interview with Dr. Kovács was conducted in July, 2009.

transplantation is stipulated in the above mentioned Decree 18/1998. The opinion of ETT-TUKEB highlighted that cord blood banks must function by a license issued by the National Public Health and Medical Officer's Service (Állami Népegészségügyi és Tisztiorvosi Szolgálat, hereinafter ÁNTSZ) (2002, 8).

However, ETT-TUKEB declared that transplantation of stem cells derived from cord blood for therapeutic use is regarded as research, unless stem cells are used to treat a hematological disease as if it were bone marrow (2003, 3).[26] Thus the regulation is different if stem cells are used to treat a hematological disease, or if they are used for other therapeutic purposes. The process and technical requirements of medical research are stipulated in several decrees.

The application and monitoring of the correct laboratory practice is regulated by ministerial decree 9/2001 (III. 30), which touches upon research and examination on "cell systems" (chapter VII). Though the use of "medicinal products for human use" is regulated by directives of the European Parliament and the European Council, they are still in clinical trial phase in Hungary, thus these products can only be used for research purposes. Medicinal research on humans is regulated by ministerial decree 23/2003 (V. 9.). The research of "medicinal products for human use" is regulated by governmental decree 235/2009 (X. 20.). The clinical examination of "investigational medicinal products" is regulated by ministerial decree 35/2005 (VIII. 26). Provisions of the ministerial decree 52/2005 (XI. 18.) are effective if a medicine is created from the cord blood. This decree regulates the "specific requirements" of "advanced therapy medicinal product" as the ratification of Directive 2001/83/EC.[27]

[26] This document was the starting point of the "stem cell trial". See next section.
[27] Since 2005, a clinical trial with hematopoietic stem cells is going on lead by the Medical and Health Science Center of University of Debrecen (Debreceni Egyetem Orvos és Egészségügyi Centruma), Hungary, though the source of the stem cells is not umbilical cord blood but bone marrow. The participants of the clinical trial are

Apart from the technical standards of any kind of use of stem cells derived from cord blood, there are other sorts of provisions. For instance those of Act LXIII of 1992 on Data Protection, which have relevance at the discussion of umbilical cord blood banking, as those who resort to the service of a private cord blood bank provide "personal" and "special data". But as the expectant parents consent the processing of their data by signing the contract, the cord blood bank is entitled to manage their data. Also, there is a separate Health Care Data Act (Act XLVII of 1997), which contains specific regulation on data generated during health care provisions.

Section 2.3 The stem cell trial

The operation of umbilical cord blood banking in Hungary was not smooth in the beginning. The first private cord blood banking started its operation in 2002 in Hungary. Little afterwards, ETT-TUKEB issued a "professional resumé" in January, 2003. In this document apart from transplantation where the stem cells derived of cord blood are used instead of bone marrow, the authors did not regard the therapeutic use of cord blood stem cells as "routine", because other therapeutic use was "currently under research" (ETT-TUKEB 2003, 3). More importantly the resumé stated the need of permission for the "clinical use of stem cells" (2003, 3).[28]

By then, only one private bank, Sejtbank offered the service of cord blood stem cell banking due to the lack of state regulation – without permission. Zoltán Merhala, the manager of the private cord blood bank commented that the practical problem was that the National Medical Officer (Országos Tisztiorvosi Hivatal) asked data from the hospitals, and the

patients after a heart attack, and hematopoietic stem cells are introduce to help the regeneration of the heart muscles (Sejtterápia n.d.).

[28] As Dr. Zoltán Papp, the president of ETT-TUKEB, informed me that the resumé is still the valid (personal communication via phone May, 2010).

hospitals did not dare to harvest the cord blood. Merhala claimed that the operation of Sejtbank became "impossible" because of the resumé of the ETT-TUKEB (Jogiforum 2003a). Dr. Zoltán Papp, the president of ETT-TUKEB reasoned that the fact that only wealthy families could afford this opportunity was an "unacceptable discrimination" (Jogiforum 2003a). The plaintiffs, the company and an expectant father, brought to court the defendants, the Health Ministry and ETT-TUKEB, asking the court to declare: the professional resumé was "unlawful" as the ETT-TUKEB exceeded its powers (Jogiforum 2003b).[29] The plaintiffs assumed that there was a niche in the legislation and claimed that the service offered by the private cord blood bank did not belong under the authority of the Health Care Act (Jogiforum 2003b). Later the plaintiffs modified the charge asking the court for the assumption of "unlawfulness" on the basis that the harvesting of the cord blood is not a research conducted on humans (Origo 2003); and later they asked the court to assume the aggrievement of the right to self-determination and claimed for indemnification (Vikman 2003).

Barnabás Lenkovics, the then parliamentary commissioner for civil rights, issued his opinion on the debate diagnosing that the lack of regulation of private umbilical cord blood banking caused a constitutional thwarting; and that the professional resumé of the ETT-TUKEB unnecessarily and disproportionately constrained the civil autonomy (2003, 5). In his statement Lenkovics underlined that the state has to defend the life and health of its citizens, but if the

> state cannot finance a curative device or treatment, then (…) it must enable the citizens to finance it for themselves based on their personal and financial autonomy (2003, 5).

Lenkovics warned for two aspects of such "commercialization": it cannot be anti-constitutional (he stipulated that private umbilical cord blood banking is lawful and is in

[29] The plaintiffs wondered that how come that ETT did not object the process in its opinion published in 2002, but it did in the resumé published 2003. The plaintiffs assumed that there were economic interests in the background of the opinion change (Vikman 2003).

accordance with the Hungarian constitution), and the promotion of equality of opportunity must prevail (2003, 5). Later the parliamentary commissioner for civil rights remarked that there was a "scientific risk" in cord blood banking, but due to the uncertain future, "this chance should be given in this field too" (Jogiforum 2003c).

Finally the court assumed that the opinion of the ETT-TUKEB was lawful and rejected the plaintiffs' claim on the aggrievement of the right of self-determination and their claim on indemnification as well (Vikman 2003). The judgment of the appeal court confirmed the earlier decision: the opinion of ETT-TUKEB was lawful, though it was not binding, thus the indemnification claim was not justified neither (Index 2004). Merhala regarded the whole case as a sort of advertisement for the company: the service got publicity (personal communication).[30] The completion of the legal case opened up the opportunity for other private banks: Krio started its cord blood banking activity in 2004, and Humancell in 2008.

Section 2.4 State intervention

Just like Lenkovics, ETT-TUKEB also recognized the necessity of enabling the equality of opportunity in the field of cord blood banking by offering a model to overcome the unfair characteristics of the current situation (2002, 3). It was called the "triplet operational model", which would guarantee most ideally the "principle of justice" in accordance with the opportunities of the health care system (2002, 3). The three pillars of this model should have been: private autologous banks; public allogeneic banks, and a public foundation, which would have the main task of "determination of potentially threatened individuals according to professional and social aspects and the financial assistance of them" (ETT-TUKEB 2002, 3).

[30] The personal interview with Zoltán Merhala was conducted in July, 2009. Enikő Demény assessed the same (the trial being an advertisement) in her paper presented at PUG Workshop in Rome (2003).

This latter would have meant an opportunity for those who may need stem cell transplantation because they are susceptible to diseases treatable with hematopoietic stem cells, but cannot afford private banking. An initiative of such a model was introduced in Hungary, but it has failed.

Zelion Őssejt Kft. (hereinafter Zelion), the stem cell bank set up in 2005 for the public storage of umbilical cord blood stem cell units based on the opinion of ETT-TUKEB (2002). Zelion operated as a tripartite consortium. The National Health Institution Center (Országos Gyógyintézeti Központ - OGYIK) was to lead the banking activity; the task of Human Biotechnology Research Centre (Humán Biotechnológiai Kooperációs Kutatási Központ) was to organize, and Zelion Kft. was to arrange the logistics (Komornik n.d.). In the beginning, Zelion was to save samples of families who do pay for the service as in case of private banks, and the plan was that in the future the consortium would be able to create a public donor bank with a few thousands samples (Komornik n.d.). Before the bank initiative could have started to operate as a public bank, the storage capacity of the consortium arrived at the end, and the state did not want to broaden the storage further (Kun J. 2008). A member of the consortium, OGYIK ceased, and its legal successor, the National Blood Service (Országos Vérellátó Szolgálat - OVSZ), did not want to "attach a profit oriented service to blood supply" (Kun J. 2008).

Zelion went bankrupt later in 2008. The company issued a press release stipulating that the storage of the blood samples was safe and uninterrupted (Spirk 2008). As the press release assumed, OVSZ disposed of the stored samples, and a colleague of the company confirmed again that the samples were safe, there was no liquidation because of bankruptcy against the company, the only change was that they no longer store new clients' samples (Rist 2008).

Balázs Sarkadi, medical expert of the field explained that the deal of the initiative was to set up a "limited public bank", where the storage of the samples was to be covered by the families (2008). However, in case of families with a medical reason, the fee would have been covered by a foundation (Sarkadi 2008) according to the proposal of the opinion of ETT-TUKEB (2002). Although Sarkadi did not mention the name of the private company one may suspect that it was the consortium. The inventory of the consortium included around 2000 samples, but in the "chaos of the health care system reform the whole organization and operation were wasted" (Sarkadi 2008). OVSZ continued the storage, but without state funds it stopped the operation of the bank (Sarkadi 2008). One may assume that Gunning had the point, as she observed that the costs of the storage maintaining the appropriate quality standards are really high (2003, 130). Perhaps that is why the state did not want to broaden the storage capacity of the consortium, and the realignment of the public health institutions lead to the collapse of the initiative.

The decision-makers of the Hungarian state wanted to set up a public cord blood bank for the benefit of all citizens on the long run. Though during the existence of the 'limited public bank', between 2005 and 2008, there was an attempt to increase the state intervention in cord blood banking. This state engagement should have opened up the opportunity for poor citizens as well: anyone could have donated their babies' cord blood for the benefit of the public. Additionally, ethnic minorities should have had better chances, as cord blood could have been stored for their needs too.[31] These citizens knew that if needed, they could have received a stem cell treatment just like any other citizens. But by the failure of the public cord blood bank initiative, poor families and members of ethnic minorities lost the opportunity of

[31] As noted in Chapter 1, ethnic minorities are underrepresented in bone marrow registries. In Hungary the ethnic minority underrepresented in registries is that of the Roma population (personal communications of representatives of cord blood banks). Estimations assess the number of ethnic Roma citizens around 400–600 000 (Hungarian Foreign Ministry 2004). Hungary's total population was 10.009 millions in February, 2010 (Géczy and Kökény 2010).

donating their babies' cord blood for the benefit of the public. Since 2002, the appearance of the first cord blood bank in Hungary, only well-off families can afford to enjoy the blessings of stem cells derived from cord blood in case of need: the opportunity is not given to all citizens. Private cord blood banking had a kick-off after the court case of Sejtbank: two new private cord blood banks, Krio and Humancell, appeared soon afterwards.

Chapter 3: Umbilical cord blood banks in Hungary

An estimation states that the market of private umbilical cord blood banking in Hungary is at about 2-3 billion forints per year (Spirk 2008). The harvesting of the umbilical cord blood, processing and storing it for twenty years requires a decent amount; in Hungary, it is approximately 350 000 forints.[32] If we assume that the market is only at about two billion forints, it is still more than 5700 contracts per year[33] in a market, where in 2007 there were 97,613 live births in Hungary according to the data of the Hungarian Central Statistical Office (Géczy and Kozák 2010).[34] The companies regard the quantity of stored samples as business secrets, but some estimate that there are more than 10 000 samples stored of babies born in the territory of Hungary (personal communications of representatives and medical experts).

There are three for-profit private banks storing samples for transplantations in Hungary and one small non-profit bank led by the Saint László Hospital of Budapest (Fővárosi Szent László Kórház). This hospital stores samples of cord blood of the newborn siblings of the diseased child for a possible later transplantation (Masszi 2002, 312). A representative of Humancell told during the interview that it is their company which physically stores the samples of the hospital. To clarify the situation regarding this small cord blood bank, an interview was conducted with Dr. Krisztián Kállay, the assistant professor of Child Hematology and Stem Cell Transplantation Department (Szent László Kórház

[32] In Western Europe the fees are rather similar: fees of contracts for twenty years range between 1185–1800 euros (Gunning 2004, 3).
[33] If we count with the average fee 350 000 forints /storage for twenty years.
[34] In 2009 there were 96,450 live births in Hungary (Géczy and Kozák 2010); thus *ceteris paribus* the number of signed contracts should be similar. However, the global crisis might have had its effects on the Hungarian cord blood bank market as well.

Gyermekhematológiai és Őssejttranszplantációs Osztály) at the Saint László Hospital of Budapest.[35]

Dr. Kállay has explained that the bank of the hospital exists since 1992 and is for 'directed donations', which means that if a diseased child will probably have a transplantation, and he or she happens to have a sibling to be born, then the umbilical cord blood of the latter is stored at this bank until the transplantation. Since its foundation, there were 2-3 transplantations from this small bank. The problem is, as Dr. Kállay outlined, that the chance of eligibility of the stored sample is only 25 per cent, and in the residual 75 per cent the stored samples will not be used.[36] He remarked that the hospital does not dare to waste this 75 per cent due to the lack of legal regulation. Dr. Kállay indicated that Humancell offered 10-20 places in the company's freezing tank for the hospital for free, and actually the samples stored at Humancell are the ones which surely will not be used for transplantation for the diseased elder sibling.[37] Dr. Kállay explained that the storage of stem cells for possible donations at the hospital is not financed by the state directly: the hospital has to manage the financial sources given to the transplantation as a whole. Dr. Kállay emphasized that children from the whole territory of the country might use this service of the hospital, as the child hematology in Hungary is very well organized: they are aware of all children with leukemia.

Apart from this cord blood bank for siblings, three are a few for-profit private cord blood banks. These are firstly, in alphabetical order, Humancell MCC Health Care Provider Ltd. (Humancell MCC Egészségügyi Szolgáltató Kft., hereinafter Humancell) stores cord blood is stored in Hungary. Secondly, Krio Cell and Tissue bank privately held joint stock company (Sejt- és Szövetbank Zártkörűen Működő Részvénytársaság, hereinafter Krio) started its cord blood banking activity as a member of a consortium with Polish and

[35] The phone interview was conducted on May 13, 2010.
[36] The HLA type must match at transplantation, and even in the case of siblings, the probability of an HLA match is 1 in 4 (personal communication of Dr. Kállay).
[37] I asked him what is the point of storing them then, Dr. Kállay replied that that was a good question.

Hungarian investors (the samples are stored in Budapest and Miskolc, Hungary). Thirdly, Tissue Cell Health Care Provider Ltd. (Sejtbank Egészségügyi Szolgáltató Kft. hereinafter Sejtbank), a member of the Cryo-Save group (this company only collects and delivers the cord blood samples to Belgium, the place of the storage). Finally, there is a Slovak company called Ceptra, which collects cord bloods in Hungary too (Kiss 2008). This latter company employs only sales persons and the collected cord blood is stored in Slovakia (ETT-TUKEB 2002, 2). As no traces could be found of an office in Hungary this company is disregarded from this analysis.

The documentations of the three companies at the Registry Court of Budapest are freely accessible to anyone who visits the office personally. These documentations include the foundation charter of the companies, their annual accounts of liabilities and assets and any changes in the forms of the companies from their establishment up until the day. Such background data of these umbilical cord blood banks are helpful in understanding the cord blood banking market in Hungary.

Both Krio and Humancell have permissions from ÁNTSZ on "stem cell banking activity (congelation and storage of congelated stem cells derived from umbilical cord blood)". Their permissions can be found in their documentations held at the Registry Court. That of Krio was issued in February, 2004; that of Humancell was issued in April, 2008 (until then, Humancell had a temporary permission). For Sejtbank a permission of storage was not necessary, as the company only collects the cord blood, the samples are not stored in Hungary, but in Belgium. Zoltán Merhala, the manager of the company highlighted that it was Sejtbank itself, which kept on asking for permission on the collection and transportation of the cord blood samples from ÁNTSZ (personal communication). The permission was finally given to the company. The umbilical cord blood banks operating in Hungary are

presented below in alphabetical order based on their documentation available at the Registry Court of Budapest.

Section 3.1 Humancell

The main activity of Humancell founded in 2005 is "other human-health care provision", but according to the foundation charter it has assigned other activities as well, for instance publishing, trade, opinion surveying, translation, gambling. The company handles cord blood samples since 2007. Apart from cord blood storage, Humancell deals with the congelation of sperm and ova. The company's revenue has been rhapsodic in the last years as Table 1 shows below.

Table 1: Figures of revenue of Humancell between 2006 and 2008[38]

Financial year	**2006**	**2007**	**2008**
Revenue after tax and allocations (in thousand Fts)	-5 379	-29 494	7 281

Source: Registry Court, Budapest

Section 3.2 Krio

The legal ancestor of the company was dealing with financial counseling, realty utilization and market and opinion surveying. The name of the company did not resemble to Krio at all: in 1998 it has converted into Krio Zrt. from the former BANKINVEST Financial and Bank Counseling Joint Stock Company (BANKINVEST Pénzügyi és Banki Tanácsadó Rt.). The former company's financial activity somewhat suggests that Waldby and Mitchell were right

[38] When considering the revenues realized, please note that all companies have other activities than that of the storage of umbilical cord blood accounts.

in understanding the congelated cord blood accounts as a "form of speculative investment" (2006, 126), i.e. that the samples can be regarded as some kind of insurance for the self and/or for the family. Of course the activity change can be owed to mere haphazard as well. Krio is engaged with cord blood banking since 2004.

In the foundation chart of the latter formed Krio Zrt. the new company names only "other human-health care provision" as its main activity. Apart from that, the document names two other activities: "general and specialist out-patient provisions". The company deals with the congelation of umbilical cord blood, sperm samples and ova. The company's financial gain has been increasing precipitously as Table 2 shows below.

Table 2: Figures of revenue of Krio between 2006 and 2008

Financial year	**2006**	**2007**	**2008**
Revenue after tax and allocations (in thousand Fts)	7 991	14 233	49 398

Source: Registry Court, Budapest

As noted above, the firm has permission on storage. The permission additionally stipulated that the storage of the umbilical cord blood samples can be done if only the company is cooperating according to the contract with the Hospital and University Teaching Hospital of B.A.Z. province's Child Health Care Center Child Hematology and Bone Marrow Transplantation Division (B-A-Z Megyei Kórház és Egyetemi Oktató Kórház Gyermekegészségügyi Központ Gyermekhaematológiai és Csontvelőtranszplantációs Osztály).

Section 3.3 Sejtbank

Sejtbank was founded at the end of 2001 with the main activity "other human-health care provision", but other activities involved publication, trade of health products, data processing, business counseling, and education. The company deals with umbilical cord blood banking since 2002. In 2008 they reduced the list of activities for only "other human-health care provision". Recently Sejtbank introduced a new service: that of storing the cord itself. The explanation is that it contains the Wharton's jelly, which is another potential source of (Mesenchymal) stem cells. These cells are responsible for the regeneration of used and diseased tissues and organs (Sejtbank n.d.b, 4). Table 3 shows the company's unsteady performance based on the revenues.

Table 3: Figures of revenue of Sejtbank between 2006 and 2008

Financial year	**2006**	**2007**	**2008**
Revenue after tax and allocations (in thousand Fts)	57 382	98 578	43 508

Source: Registry Court, Budapest

Sejtbank is a member of the international Cryo-Save AG. based in Switzerland. Main economic activities of Cryo-Save AG. are: "holding activities and financial services". Sejtbank does not store the samples in Hungary, but they send it to Belgium, the main laboratory of Cryo-Save AG.

The analysis of the documentation of the umbilical cord blood banks suggests that since 2004 there is competition on the field. Some of the companies perform better according to the fiscal reports. If Hungarian citizens decide to store their babies' cord blood samples, they can choose between these companies, if they are able to pay the service fee. But if they

cannot, the principle of equality of opportunity is harmed, as they are constrained by the existence of private cord blood banks only.

Chapter 4: Ethical concerns

Scholars agree that the most important ethical aspects of cord blood banking are the questions of consent, ownership, privacy, and commercialization (see for instance Annas 1999, 1522 and Ellenchild Pinch and Kennedy-Schwarz 2001, 55). The examination of these aspects is important to determine the adequacy of information for decision-making. The content analysis of the documents of the companies, Humancell, Krio and Sejtbank, and the interviews carried out with their representatives out accordingly.[39]

Two interviews were conducted personally with the representatives of the companies Humancell and Sejtbank, and Krio replied to the questions raised via e-mail.[40] It must be noted that at one of the companies a secrecy declaration had to be signed before the interview; and for the sake of confidentiality the use of the companies' names is avoided, arbitrarily the names are mentioned only when it is necessary. In general, during the personal interviews and the questions sent by e-mail the clarification of the statements in the information sheets and contracts was asked. This chapter focuses on the following ethical concerns: consent based on adequate information, whether the ownership of the stored sample is settled, whether the privacy of the family prevails, and whether the stored sample is commercializable or not after the expiry and/or annulment of the contract on storage.

[39] Throughout this chapter documents and information sheets mean the handouts and any material (contracts and supplements) on umbilical cord blood stem cell banking, the process of harvesting, screening, storage etc., which are downloadable from the websites of the companies. The analysis reflects what these documents contain at the time of writing of this manuscript in early 2010 (see references). It has to be noted that the content of some documents changed positively since I accessed them approximately one year ago preparing an early draft. In early 2010, the information given by some companies on their websites are broader than they were in May, 2009.

[40] The two personal interviews took place in April, 2009, and Krio sent me the responses via e-mail in July, 2009.

The concern of consent is raised based on whether the companies provide adequate information for the parents on how umbilical cord blood can be used now and in the near future as the companies might also mention possible utilizations which are in clinical trials, or in experimental status. In these latter cases there is an uncertainty of the introduction of the regular use of those therapies in the future. Adequate information includes that private banks do not wash together the certain with the uncertain, and parents know exactly what these tissues can be currently used for and might be used for in the future. Adequate information includes that parents are aware of the probability of the development of a disease treatable with stem cells derived from cord blood, and the probability of healing if the child ends up suffering from such disease. By providing adequate information, expectant parents undertake the service offered by the private bank by an informed consent, voluntarily.

Another concern is the question of ownership, as children cannot exercise their rights over their property before they are 18 years old. One of the sections analyzes who and until when has property rights over the stored umbilical cord blood.

The third concern is whether the right to privacy prevails: if data protection functions sufficiently – keeping the personal data of the pregnant woman and child safe. This concern encompasses the system and instruments that a private bank uses in order to guarantee the safety of the family's data, and whether the personal data of the mother and the child can be given to third parties.

The last concern presented in this chapter is whether banks can have financial gain derived from the samples which are not contracted any more. Is there a possibility of commercialization of the stored blood samples, especially when it comes to possible patenting? This latter might occur, when the parents are not financing the storage any more, the contract expires, and the private company might use or sell the samples for research or other gainful activity.

Section 4.1 Informed consent

Based on Ruth R. Faden and Tom L. Beauchamp one may create a concept of *informed consent* in case of umbilical cord blood banking that a "competent" person "comprehends" what is at stake, undertakes it "voluntarily", and this person "consents" to the process (1986, 275). Informed consent is relevant to be able to answer the main question of this paper. If expectant parents do not possess the adequate information, their consent is not informed. Then parents are constrained in their decision-making and according to Sunstein the state should act to overcome this bias.

Some authors highlight that private banks communicate a false hope for parents as they use terms like "life saving", "miraculous" (Ellenchild Pinch and Kennedy-Schwarz 2001, 56); "life insurance" (Masszi 2002, 313); "low cost edge on an uncertain future" and "in case of emergency it is »immediately available off the shelf«". The concern is that parents may give their consent based on such exaggerating slogans. As Kapócs put it:

> the essential problem [of private umbilical cord blood banking] is that parents without appropriate and fair information may think that the stored stem cells can defend their child from every harm (2003, 461).

Pregnant women have to go for several prenatal tests, take care of their bodies and the foetus within by taking vitamins and avoiding harmful activity. They do everything possible for the arriving children absorbing all information connected to their status. In such a vulnerable situation expectant mothers may undergo every kind of tests and opt for debated opportunities. Even the service offered by private umbilical cord blood banks may play on the "risk-aversive sentiments" of the parents and may "exploit parental guilt – the desire to »do right« by one's children" (Nelkin and Andrews 1998, 34). Authors are concerned by the vulnerability of the expectant parents (see for instance Vawter 1998, 37).

The concept of "best interest" is well-know for practicing physicians. Doctors have to seek the "best interest" of the patient, regardless what the family wants. Parents usually also seek for the "best interest" of their child. This may imply that as they want to provide everything for their child, looking for the baby's "best interest", thus they would create an umbilical cord blood account. It does not mean harm for the baby or to the mother, as the harvesting is not an invasive process. But what if they do not opt for this service? Later, when the adult child develops a disease, which could be treated by stem cell transplantation derived from the cord blood, can this child prosecute his/her parents for negligence? Can he/she claim that the parents were not seeking his/her "best interest"?[41] One may argue that by having this fear, parents are even more willing to have their babies' cord blood stored.

According to Waldby and Mitchell, parents opt for private cord blood banking because they feel "obliged to secure their child's cord blood in case of a future need" (2006, 123). Naturally, parents as decision makers can evaluate a saved cord blood as a response for the uncertain disease developed by the child later in his/her life. In this sense, the parents can regard the odds of the appearance of a treatable disease 0.5 (it either develops or it does not), and it is reasonable for them to act accordingly: opt for the service of a cord blood bank, thus increasing the survival possibility of their child. As we saw above, in Hungary expectant parents are coerced by the lack of public cord blood bank, and those who cannot afford the services of a private bank cannot act according to their preferences. The rest of this section explores whether there is a lack of adequate information as well.

The documentations of the three companies are identical if one compares the content of them. The issues mentioned in all companies' documentations are: explanation of what a stem cell is, what the advantages of the umbilical cord blood are, what GVHD is, how the umbilical cord blood can be used, what kind of research exist, how cord blood is collected,

[41] To my knowledge, so far no such case occurred, but the decision of the courting such a case would definitely be interesting.

what tests have to be done before the storage, what the therapeutic use of the cord blood is, what the possible uses of stem cells are in the future (Humancell n.d.a, Krio n.d.a, Sejtbank n.d.a, b). Humancell and Krio have the additional handouts on cord blood banking as a supplement to the contracts (Humancell n.d.h, Krio n.d.e).

Humancell warns that the treatments are "not routinely performed", though stem cell research is "the most promising area of medicine" (n.d.a). Krio claims that cord blood stem cell is not a "panacea" (n.d.a). Sejtbank remarks that the treatments of some diseases are in clinical trial, and not all treatments are available in all countries (n.d.a, 2). Thus one may argue that the private banks in Hungary stipulate clearly that the use of stem cells derived from cord blood is currently limited.

The information sheets collect the advantages of the storage of the umbilical cord blood. Both Humancell and Krio mention the possible collection of stem cells from the peripheral blood, thus call the attention to this alternative in a written form (Humancell n.d.a, Krio n.d.a). Humancell highlights the painless and riskless harvesting of cord blood, while Krio emphasizes that the use of the alternatives (bone marrow or peripheral blood) may cause complications later, and that these stem cells are "older" than those harvested at birth (Humancell n.d.a, Krio n.d.a). Both Humancell and Krio highlight the limitations of the cord blood stem cell transplantation: Krio states that the success of the transplantation depends on the disease and the cell number of the stored cord blood sample (n.d.a); while Humancell warns that the success of transplantation depends on the age of the patient, the diagnosis, and the stage of the disease (n.d.a).

All three companies provide lengthy lists about the diseases, which currently can be treated by cord blood stem cell transplantation (Humancell n.d.a, Krio n.d.a, Sejtbank

n.d.a).[42] Krio mentions the possible future use of cord blood stem cells, but indicates that these treatments are either in clinical trials or are tried only on animals (n.d.a). In such a manner they predict that stem cells derived from cord blood may be used to treat injured heart muscles, diabetes, and that these stem cells might be converted into neurons (Krio n.d.a). Humancell lists degenerative diseases, muscle atrophy, several metabolic and neurologic disorders, brain damage that might be treated in the future by cord blood stem cells (n.d.a). Humancell cites numbers on already performed transplantations as well, though does not distinguish between autologous and allogeneic transplantations (n.d.a), which somewhat contradicts to the contract, where the company offers the storage of the sample for autologous use (n.d.g, 3). During the interview the representative of Humancell highlighted that some of their clients use the services of their company for 'family banking' purposes, i.e. the stem cells might be used by a family member, not exclusively by the offspring.

Sejtbank does not clarify the distinction between stem cells and hematopoietic stem cells: the company just calls them "stem cells". This becomes problematic only when in its information leaflet Sejtbank depicts the capability of "stem cells" to become neuron- liver- muscle-or pancreas-cells implicating the possible use of such cells in the future (n.d.b, 3), though they seem to mean umbilical cord blood stem cells. Humancell does make a difference between hematopoietic stem cells and stem cells, and clearly only mentions diseases that can be treated by stem cells derived from cord blood. Krio explains in detail the evolution of stem cells from the conception, and that the stem cells in the cord blood are hematopoietic stem cells.

One representative during the interview reasoned that the great potential of stem cell treatments must be communicated to the expectant parents as they have the opportunity of storage at the time of the delivery only. During the conversation it was also highlighted that

[42] The lists broadly coincide with Verter's collection (2010a) of standard therapies mentioned in Chapter 1.

the company is dedicated to profit-seeking, but parents have the opportunity to search for information and other opinions anywhere else. The representatives of this and another company indicated that they do call attention to the alternatives (bone marrow, peripheral blood) personally to the expectant parents. A representative asked me: "why does informed consent function only if I am skeptical about something?" – referring to his view that informed consent does not necessarily mean the rejection of the storage. Representatives of the companies highlighted that the only chance to save one's cord blood is at birth. This chance is non-recurring, if the cord blood is not saved then it is wasted (personal communications).

All companies try to defend themselves as much as possible in the formalization of adequate information giving, the informed consent. They use such sentences in their contracts and their supplementary declarations as:

> I have read, understood and accepted the information written in the information sheet. I had opportunity to raise questions related to the contract and I received satisfactory answers to all my questions. I have no more question, I consent to the planned intervention. I gave my consent based on the understanding of the information free from any constrain. I am aware that the collecting of the umbilical cord blood of my child to be born happens according to the conditions stipulated in the contract. (Humancell, n.d.h, 5)

The companies generally use such expressions as "my own responsibility" and "free will" (Humancell, n.d.e, 1), that parents give their consent "voluntarily" and "free of influence" (Krio n.d.c, 1) making them acknowledging the currently "limited" use of cord blood (Krio n.d.c, 1 and Sejtbank n.d.c, 1).

Naturally, the official form is one thing and usually reality is another. A research surveying opinion was tried to be conducted for this paper, but the return of the filled questionnaires was so low (N=4) that its quantitative analysis would not give a meaningful

result.[43] However, the answers expectant women gave might be helpful in understanding their motivations, or at least the thoughts of these four women.[44] In the questionnaires the expectant women were asked about the current use of stem cells derived from umbilical cord blood, to see how informed they were by offering a list of diseases of which some can be currently treated, some of their treatments are in clinical trials, and at some the research on cord blood stem cell is in experimental state. Correctly all four women ticked leukemia.[45] Three of the respondents ticked diseases where the use of cord blood stem cells is in clinical trials, and one of them ticked a disease in which the treatment with cord blood stem cells is in experimental status.

To the question why they harvest the baby's blood, two of the respondents ticked the box "because I want to give everything to my child", and the two others ticked the box "because the research on this topic is very promising, later on more and more diseases can be treated by stem cells derived from umbilical cord blood". After the poor return of questionnaires a phone interview was conducted with a salesperson of Humancell, who highlighted two other usual motivations.[46] The first such motivation is when someone in the family already had transplantation or was diseased, and they do not buy a life insurance, but rather save the cord blood stem cells of the child. The salesperson called "prestige" the second motivation as expectant parents claim that "in the street everyone saved it" or "I can give to my child even this". One representative of a private cord blood bank said that they had a signatory whose bone marrow was harvested earlier; and this person "does not wish

[43] For the English version of the questionnaire see Annex 1. The survey was conducted in Hungarian by expectant mothers after signing the contract with Humancell in autumn 2009. The salesperson of Humancell gave the questionnaires for mothers in those cases where they regarded the negotiation easy. I would like to thank here the great help of the representatives of Humancell.

[44] The research seeking the motivations of the parents is scare. Waldby and Mitchell cites one Canadian study assuming that only 14 per cent of women preferred private cord blood banking (versus public banking), because "it was a good investment for the child, and that they felt obliged to secure their child's cord blood in case of future need" (2006, 123).

[45] For the sake of simplification, the type of leukemia was not specified in the questionnaire.

[46] The phone interview took place in October, 2009.

that pain to anyone". Another company's representative answered that parents "are motivated by the promises that more and more diseases can be treated".

One may conclude that informed consent depends on the expectant parents, as all information can be found browsing the full documentation of the company chosen, naturally in Hungarian language. Informed consent does not depend on infrastructure (disposing with internet) either: parents have the opportunity to raise their questions and get to know the current limitations of the use of the cord blood stem cells at all companies before signing the contract. The informed consent based on available information is not harmed: parents can get all adequate information for decision-making if they want to. It could be a topic of another paper to investigate the basis of expectant parents' decision-making.

Section 4.2 Ownership

The owner of the cord itself is the minor newborn child, thus the parent must give the consent, as the parent is the legal representative of the child for 18 years.[47] However, nearly all analyzed Hungarian cord blood banks offer a contract for 20 years only; while a child becomes an adult at the age of 18 according to the Hungarian law. This means that there are two years, where in theory the grown child can make, and has to make a decision on his or her own property, but according to the contract signed 18 years before, the child cannot exercise the disposal right. Nonetheless, the child reaching his or her 18th birthday can withdraw and cease the contract.

Until the majority of the child, age 18, s/he is represented by the legal representative when practicing the disposal right. The contract is signed for twenty years at companies Sejtbank (n.d.c, 2) and Humancell (n.d.b, 2); while at Krio it can be made for 5, 10, 15, and

[47] In Hungary both parents must give their consents for the harvesting and storing of the cord blood (See: ETT-TUKEB 2002, 7).

20 years (n.d.b, 2). Krio admits that due to the legal incapacity of the child only his legal representative can make decisions (n.d.b, 4), as Sejtbank puts it: until the majority of the child, her/his parent/legal representative practices the gained rights and commitments from the agreement (n.d.c, 2). None of the companies offer the option that the child reaching majority can renegotiate the contract, but all leaves open the possibility of contract renewal after the expiry of the contract. Krio warns the family two months prior to the termination of the contract (n.d.b, 2), Humancell warns them three months before (n.d.g, 10), while Sejtbank calls the family's attention six months prior to the expiry (n.d.c, 2).

During the interviews, the companies were asked why they offer 20 years storage, and one representative told me that "this is a period made up by someone, which was followed by others". At another company I was told that "it is probably the parents who are going to pay for the storage for another 20 years anyway".

A company needs the signature of the mother only, because „the mother is certain" as one representative clarified during the interview. However, Act IV of 1952 on Marriage, Family and Guardianship states that parental surveillance is practiced by the parents together – even if they do not live together (section 72). Parental surveillance includes such issues as nursing, education of the child, and the handling of the child's fortune (section 71 and 72 of Act IV of 1952 on Marriage, Family and Guardianship). As the stored umbilical cord blood account is the child's property, in other words the child's fortune, the disposal right should be practiced by both parents, not only by the mother.

One may conclude that the question of ownership is settled in Hungary: the child may cease the contract when s/he is 18 years old, thus this right is not harmed.

Section 4.3 Privacy

Before storage the cord blood has to be screened for different diseases and the mother has to give her personal data and case history, thus the *privacy* of the mother may be harmed on the basis that third parties might be able to access the medical documentation or the samples themselves rich in genetic data.[48] The topic of the following sections is whether the data of the family is protected adequately in the private cord blood banks in Hungary.

Section 4.3.1 Personal data

All companies stipulate in their contracts that the personal data of the signatory of the contract is treated, processed and stored according to the Hungarian laws (Humancell n.d.g, 11; Krio n.d.b, 12; Sejtbank n.d.c, 2). However, some companies hold the right of giving the data to third parties, if it is necessary. In the contract form of Humancell there is an article that the signatory consents that the company can endorse a financial demand partially or totally to a third party and the documentation related to the process (Humancell n.d.g, 11). Sejtbank adds that they treat the data according to "medical secrecy", but if it is necessary for the safety of the service, Sejtbank "can assign all rights and obligations partially or totally to third parties" (n.d.c, 2). Krio states that "the company disposes with the health documentation, and the signatory disposes with the data within" (n.d.b, 4). The contract also stipulates that "the personal data must be treated confidentially and can be transmitted to the entitled [the signatory] only" (Krio n.d.b, 4).

During the interview one representative admitted that the Hungarian regulation on coding and keeping data is very strict. In the interviews companies revealed that they use

[48] As noted in Chapter 2 the law, Act XXI of 2008 on the Protection of Human Genetic Data, which regulates genetic data does not involve umbilical cord blood banks.

coding systems, although different ones. One of them uses an international coding system which creates a „security key" during the processing of the sample; the second one identifies the sample at five points; the third uses an "anonymous identifier". All these coding systems guarantee that the blood samples are not going to be mixed in the freezing tanks.

In general, the personal data of the family members seem to be safe, even though cord blood banks might delegate some data to third parties; they call the attention of families to this fact in their contracts. Furthermore, the coding systems that the companies use seem to defend families' data as well. The safety of personal data is not harmed.

Section 4.3.2 Case history

At Humancell the mother has to attach a long and detailed case history to the contract answering questions as: has she had piercing or tattoo in the last six months, or if the mother suffers from addiction to alcohol, medicine, or drugs (Humancell n.d.c). These questions may seem irrelevant and might be understood as an intrusion into one's privacy at the first sight, but during the interview it was said that the reason is that then the blood behaves differently.[49] If the mother cheats in the case history, the tests delivered by Humancell reveal it anyway claimed the representative of the company. Humancell declares that they keep the medical secrecy and prevent third parties to get the data (n.d.g, 12).

Krio also asks for a case history (n.d.b, 3) including immunological, hematological and infectious diseases and microbiological tests, of which validity has to be acknowledged by the doctor of the expectant mother (n.d.b, 11). The tests must be repeated after the

[49] Enikő Demény highlighted that the more data can be attached to the sample, the more valuable it is. This is relevant in case of a possible later use of the sample for research purposes.

delivery, and the results have to be sent to Krio (n.d.b, 5).[50] Krio has been asked why the company do not screen the blood, and the answer was that "you have false information", as it is unique that they test the pregnant's blood twice (before and after delivery), and the cord blood sample as well. As Krio was not happy with giving me answers, which could be felt in the tone of the e-mail and the fact that they were not willing to meet personally, asking for further clarification of the contradiction between the two documents was not enforced.

Sejtbank delegates the testing ("bacteriological, virological, quantitative and qualitative") to the Cryo-Save, and parents are notified about the results via phone (n.d.c, 1-2). The quantitative and qualitative analysis is important, as if the sample does not qualify for storage, it will be destroyed (Krio n.d.c, 2). Humancell makes a quantitative and qualitative test for the sample as well, and the parents may opt not to store and destroy the sample, or they can store it despite the fact that "the later use cannot be guaranteed" (n.d.f, 1).

One may assume that the privacy prevails in the case history as well, as once parents sign the contract, they acknowledge its submission. If they do not want to submit the case history of the mother, expectant parents may choose a company where they do not have to. Consequently, the privacy of the family is not harmed.

Section 4.4 Commercialization

Some scholars reject private cord blood banking, as they regard it as the commercialization of the body, based on the argument that cord blood is the product of the child birth and no financial gain should be derived from it; which is especially relevant in the case of patenting

[50] Gunning's assumption on screenings is valid in the Hungarian case: the private banks either charge the costs of the screening to the clients or they simply do not offer this service routinely in their contracts (2004, 4). From the three companies only Krio does not make the screenings and the company's storage service for 20 years is the cheapest (Kiss 2009).

(Nelkin and Andrews 1998, 34). However, since the Moore case it is unlikely that a family would be reimbursed for patenting of a cord blood after the expiry of a contract.[51]

In case of Hungary, the authors of the opinion of ETT-TUKEB derived it from the Hungarian Civil Code that "as a detached, separated, lifeless part [of the body] is an object, it can be owned" (2002, 7). This shows that cord blood can be commodified in Hungary. According to the Health Care Act "[d]onation of organs and tissues shall only take place without consideration given in return" (section 207).[52]

One may assume that commercialization may happen only if the contract is ceased or expired. As one representative pointed out, as this service is relatively new in Hungary, there are no examples on contract expiry. Another representative considered that either they would destroy the cord blood (which simply means the thawing of the sample), or they would offer it for research purposes, or it may move to a system like Eurocord.[53] Naturally, for the donation of the sample, the company would ask for the permission of the (ex)owner – emphasized the representative. The third company, Krio ignored my question stating that it is a "business secret", but in their contract it is stipulated that if the parents do not want to renew the contract, they consent that Krio can either donate the sample or destroy it (n.d.b, 13).

The only point where the possibility of commercialization emerges is when the contract on storage ceases, and the private cord blood bank concedes the blood for research purposes. The scientists participating in the research may have financial gain from the

[51] In the landmark case Moore v. Regents of the University of California, 1990, the plaintiff, Mr. Moore asked for conversion, as the doctor, one of the defendants realized financial gain from the discarded cells (former property) of Mr. Moore. The claim was rejected on the basis that Mr. Moore did not have property rights on those cells, though the doctor missed to inform Mr. Moore on the usage of his cells for lucrative purposes. The Court added that usage of conversion in such cases would impede the development in medical science "by restricting access to the necessary raw materials"- to the human cells (Moore v. Regents of the University of California, 1990).

[52] Translation is not mine, but found on the internet (www2.ohchr.org/english/bodies/.../E.C.12.HUN.3-Annex10.pdf, last accessed May 9, 2010).

[53] Eurocord is the "European Registry of patients treated by cord blood transplants" (Hermerén et al. 2004, 11).

published works and findings based on the research conducted on such an 'abandoned' sample, though the effect of one single sample is minimal. Another issue is if the scientist makes an invention, and can own and sell the patent rights. But again, since the Moore case, one may assume that the (ex)owner of the cord blood sample should not have high expectations.

One may conclude that the answer on whether commercialization means a problem in Hungary will be given when contracts expire in masses, and then the companies decide what to do with the stored samples; or when the state regulates what to do with such samples.[54]

[54] As noted in Chapter 3, even the Saint László Hospital of Budpaest does not dare to waste samples which will never be used due to lack of regulation.

Conclusion

The main question this paper investigates is whether umbilical cord blood banking should be more intensely regulated and whether a public cord blood bank should be established. Should the state maintain the *status quo* and allow cord blood banks to function in line with the rules of the market or not. Based on Sunstein's claims (1990), it has been argued that if citizens are coerced by the availability of opportunities and information, then it is the state's role to enhance their preferences by way of providing them with a wider scope of opportunities and information.

To be able to answer this complex question, this paper has offered a brief overview of the history of umbilical cord blood banking and a description of its medical background. It has also presented the heated debate between researchers and physicians. The conclusion has been that there is a 'scientific gap' on the necessity of private cord blood banking, as not even researchers agree on it. A distinction needs to be made between uses of stem cells derived from cord blood cells: some of them are expansively used for standard therapies, others are in clinical trials and some treatments are in experimental status (Verter 2010a). Due to the debates and the uncertainty of the outcome of current research, it seems reasonable to establish a public cord blood bank in order to store the samples that may treat hematological diseases, as these treatments are amongst standard therapies. At the same time, it is questionable whether cord blood stem cells for therapies which are in clinical trials or in experimental status should be stored, as the outcome of such therapies is uncertain. Nevertheless, once samples are stored in a public cord blood bank, they might be regularly used in currently not standard therapies in the future.

Furthermore, the current Hungarian regulation has been presented showing that the technical standards of harvesting, processing, storing and transplanting of cord blood stem cells are ratified according to the directives of the European Union. Although the technical standards are regulated in Hungary, the destruction of the samples which are never going to be used for transplantation is out of the scope of the regulation. There is a regulation gap. This paper revealed that private cord blood banks have various solutions for the further utilization but it seems unclear which option they will use in the future. Even the small bank for directed donations does not dare to destroy the samples never to be used because of the lack of regulation. Only legal clarification on what to do with these samples could solve the problem.

Additionally, three private umbilical cord blood banks have been presented in this thesis in order to understand the cord blood banking market in Hungary. As more than one company operates in Hungary, the conclusion has been that although there is no public cord blood bank, at least there is competition on the market. Furthermore, those parents who have a child with leukemia, and these parents happen to have another offspring to be born, have the opportunity to store the cord blood of the newborn for the transplantation of the diseased sibling.

Lastly, this paper has presented the ethical concerns regarding umbilical cord blood banking and questioning the extent of information that expectant parents dispose with. The chapter on the ethical aspects has concluded that all information is given to the parents, but it is dubious whether they make their decisions based on the available information.

Having an analysis conducted on the Hungarian cord blood banking market, one may argue that all information, but not all opportunities are given to the citizens, as there is no public cord blood bank. Based on Sunstein's claim, one may argue that the lack of public cord blood bank biases the preferences of citizens, thus they are constrained in their decision-

making. All this evidence supports the idea that the state has to show a broader engagement in cord blood banking in Hungary by way of establishing a public cord blood bank for the benefit of the whole society, and especially poor citizens and ethnic minorities. Currently these groups unfairly may not enjoy the blessings of stem cells derived from cord blood.

The Hungarian public cord blood bank initiative would have provided an opportunity for all citizens of the country in the long run, but its failure withdrew all plans, and the *status quo* persisted. The chance that the available opportunities might be broadened for the public had faded away.

It is not the aim of this paper to determine details of the exact operation of a public cord blood bank to be set up by the state. It could either function in cooperation with private cord blood banks which have the infrastructure; or the public cord blood bank could function as a completely new entity to be set up.

There are several topics within cord blood banking that cannot be discussed in this paper, but are worth to consider further investigation. Such topic is the comparison of umbilical cord blood and blood, the similarities and differences in their perception and the attitudes toward them. Another topic may be a more in-depth analysis of current research on stem cells derived or created from other tissues than umbilical cord blood. If other technologies or methods are more advanced or are more promising, then the need for umbilical cord blood banks might become questioned. Obviously, the findings of this future paper do not question the current task of umbilical cord blood banks: to provide stem cells to treat hematological diseases.

Glossary

Umbilical cord blood	blood harvested from the umbilical cord at birth; it contains several types of stem cells, but mainly differentiated, hematopoietic stem cells. Umbilical cord blood is currently used as an alternative to bone marrow and peripheral blood in medicine (Hermerén et al. 2004, 5-7)
Public umbilical cord blood bank	is a place where cord blood is stored for the benefit of the public. It functions similarly to blood donations: the donor gives the blood voluntarily to an unknown, without any charges (Gunning 2006, 2)
Private umbilical cord blood bank	is a place where cord blood is stored for the benefit of the contractor (and family). Private cord blood banks offer the service of storage of the cord blood for family use for possible future (either allogeneic or autologous) transplantation (Gunning 2006, 2)
Allogeneic transplantation	the donor and the receiver are not the same persons (Sullivan 2008, 555)
Autologous transplantation	the donor and the receiver is the same person (Sullivan 2008, 555)
HLA (human leukocytic antigen)	its type is "determined by proteins present on the surface of leukocytes that allow the cells form the individual to be recognized", and the type has to be known before transplantation, as it is a key for successful transplantation (Hermerén et al. 2004, 4). The HLA is tested both at allogeneic and autologous transplantation to reduce the risk of GVHD (Copelan 2006, 1813).
GVHD (graft-versus-host disease)	a serious reaction of the body after transplantation, it might end up in death (Samuel et al. 2008, 533). Research show that the GVHD is reduced when umbilical cord blood stem cells are used for the transplantation (Samuel et al. 2008, 534)
Hematopoietic stem cells	Stem cells, which are able to convert into any kind of cells present in the blood (Hermerén et al. 2004, 4).

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Ministerial Decree 60/2003 (X. 20.) of the Ministry of Health, Welfare and Family on Professional Minimum Conditions Necessary for Health Care Provision – 60/2003 (X. 20.) ESZCSM rendelet az egészségügyi szolgáltatások nyújtásához szükséges szakmai minimumfeltételekről

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vizsgálati készítmények klinikai vizsgálata, valamint az emberen történő alkalmazásra szolgáló, klinikai vizsgálatra szánt orvostechnikai eszközök klinikai vizsgálata engedélyezési eljárásának szabályairól

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Annex 1 – questionnaire for expectant mothers

Dear Madam,
This questionnaire is made for my thesis in which I analyse the situation of the private umbilical cord blood banks in Hungary. The filling of the questionnaire does not take more than five minutes, and it means a huge contribution to my thesis. The filled questionnaires are anonyms, the processed data after their analysis will be treated aggregately.

Borbála Tóth

1, Mother's highest degree:
□ primary school or less
□ vocational
□ vocational high school
□ high school degree
□ BA degree
□ MA degree
□ doctoral degree
□ do not know/do not answer

2, Father's highest degree:
□ primary school or less
□ vocational
□ vocational high school
□ high school degree
□ BA degree
□ MA degree
□ doctoral degree
□ do not know/do not answer

3, Do You (and your family) feel the payment of nearly 400 000 HUF as a heavy burden?
□ not at all
□ a little bit
□ mediocre
□ very much
□ do not know/do not answer

4, Are you a member of a voluntary pension scheme?
□ yes
□ no
□ I plan to join one
□ do not know/do not answer

5, Do you have a life insurance?
□ yes
□ no
□ I plan to have one
□ do not know/do not answer

6, How many children do you have already?
□ 0
□ 1
□ 2
□ 3 or more
□ do not know/do not answer

7, You, or the child's father makes the important decisions?
□ I do
□ the father of the child
□ we make decisions together
□ do not know/do not answer

8, Where have you heard about the opportunity that the cord blood of your child can be harvested? (more answers can be given)
□ gynaecologist
□ friends
□ print media
□ pregnant excercise classes
□ internet
□ other, namely:.....
□ do not know/do not answer

9, Why do you ask for the harvesting of your baby's blood? (more answers can be given)
□ because I want to give everything to my child
□ because there was already a disease in the family, which could be treated by umbilical cord blood stem cells
□ because the child has a sick sibling, who can be treated by the implementation of umbilical cord blood stem cell
□ because my friends asked for it too
□ because the research on this topic is very promising, later on more and more diseases can be treated by stem cells derived from umbilical cord blood
□ other, namely:.....
□ do not know/do not answer

10, As far as you know, what kind of diseases can be treated by the implementation of umbilical cord blood stem cells these days? (more answers can be given)
□ several types of leukemia
□ several types of diabetes
□ Alzheimer-disease
□ Parkinson-disease
□ Huntington-disease
□ Down-syndrome
□ several types of anemia
□ regeneration of heart muscle cells injured in a heart attack
□ other, namely:.....
□ do not know/do not answer

11, From where you got information on the umbilical cord blood bankinkg activity of Humancell?
□ from gynaecologist
□ internet
□ friends
□ pregnant excercise classes
□ clinical contact proposed
□ prospectuses
□ other, namely:.....
□ do not know/do not answer

12, Do you feel that the information was adequate?

□ yes
□ maybe
□ no
□ do not know/do not answer