IS THE BATTLE OVER? THE NEW LITHUANIAN LAW ON ASSISTED REPRODUCTION

VALENTINAS MIKELĖNAS, Vilnius University (Vilnius, Lithuania)

RASA MIKELĖNAITĖ, Vilnius University (Vilnius, Lithuania)

DOI: 10.17589/2309-8678-2018-6-1-119-132

The Law on Assisted Reproduction was adopted by the Parliament of Lithuania (Parliament) on 14 September 2016. This law entered into force on the 1 January 2017 and replaced the Order of the Ministry of Health of 1999 which regulated assisted reproductive technologies (ART) until then. After the adoption of the new Civil Code in 2000, Parliament recommended that the Government prepare a draft law on ART by 2002. The first "liberal" draft was presented to Parliament in 2004. Its opponents also prepared a "conservative" draft. Both drafts were rejected. Only in 2010, a new draft was prepared but the adoption of this law was delayed until 2016. This article could be one of the first to present an overview and analysis of the history of legal regulation of ART in Lithuania; it also describes the main features of the new law, reveals its shortcomings and gaps, and explains the main reasons for such a long legislative process in this area.

Keywords: anonymity of donor; assisted reproductive technologies; embryo; Lithuania.

Recommended citation: Valentinas Mikelėnas & Rasa Mikelėnaitė, *Is the Battle Over? The New Lithuanian Law on Assisted Reproduction*, 6(1) Russian Law Journal 119–132 (2018).

In Lithuania, the necessity of legal regulation of the use of assisted reproductive technologies (ART) was first raised in legal literature in 1985,' seven years after the

¹ Mikelėnas V. Santuokos ir šeimos teisinis reguliavimas, 7 Mokslas ir gyvenimas 16 (1987) [Valentinas Mikelėnas, Legal Regulation of Marriage and Family, 7 Science and Life 16 (1987)].

birth of the first ART baby in the United Kingdom.² The need for legal regulation in this area was explained not only by the developments in ART, but also by the infertility data and demographic problems in Lithuania. Around 10 to 15 percent of families in Lithuania are infertile nowadays. It is estimated that there are over 50,000 infertile couples of childbearing age in Lithuania and this number has been increasing by about 2000 each year.³ On the other hand, the demographic situation in the country is very complicated. The population of Lithuania decreased from 3.7 million in 1991 to 2.8 million in 2016.⁴ There are two main reasons for this decline. First and foremost is the high level of emigration: about 650,000 citizens of Lithuania have emigrated since 1990. This massive emigration is the main reason for the decline in the population, being responsible for about 73 percent of the loss. Second is the natural decrease which caused 27 percent of the decline. The crude rate of a natural population change (per 1,000 people) decreased from 8.8 in 1970 to 3.9 in 2013. The total fertility rate in 2013 was 1.59 (live births per 1,000 people), while the most favourable demographic situation is observed where the total rate stands at around 2.1.⁵ There also exist more factors which have an impact on infertility in Lithuania, for example, postponement of marriage and childbirth. In 2013, the mean age of first marriage was 29.3 years for men and 27 years for women. Consequently, the mean age of women at childbirth was 29.2 years and the mean age of women at the birth of their first child was 26.8 years.⁶ Demographic problems cause a variety of social and economic problems. Therefore, increasing fertility is a vital task for society. Due to the demographic problems in Lithuania, the attitude of the public to ART is quite positive. According to sociological research undertaken by the company Vilmorus in 2000, 77 percent of all respondents supported the introduction of ART, 65.3 percent of all respondents thought that ART was needed to treat infertility, 52 percent would be interested in using ART procedures if they did not have children, 61.3 percent would support ART but only if applied exclusively in the woman's body, and 38.4 percent were opposed to ART for religious or moral reasons.⁷

⁵ Demographic Yearbook 2013 7 (Vilnius: Statistics Lithuania, 2014).

² Patrick C. Steptoe & Robert G. Edwards, *Birth after the Reimplantation of a Human Embryo*, 2 Lancet 366 (1978).

³ Démesys nevaisingumo problemoms, Sveikaszmogus.lt [Attention to Infertility Care, Healthyhuman. lt] (Jan. 9, 2018), available at http://www.sveikaszmogus.lt/Ginekologines_ligos-4127-Demesys_ nevaisingumo_problemoms.

⁴ Stankūnienė V. & Baublytė M. Lietuvos demografinė situacija: kokios galimybės demografiškai atgimti?, Alfa.lt, 2016-12-21 [Vlada Stankūnienė & Marė Baublytė, Lithuanian Demographics: What Are the Opportunities for Demographic Rebirth?, Alfa.lt, 21 December 2016] (Jan. 9, 2018), available at http:// www.alfa.lt/straipsnis/50119175/lietuvos-demografine-situacija-kokios-galimybes-demografiskaiatgimti.

⁶ *Id.* at 39.

⁷ Dirbtinio apvaisinimo įstatymo projekto Nr. IXP-1966(2) aiškinamasis raštas [Draft Law No. IXP-1966(2) on Assisted Reproduction: An Explanatory Note] (Jan. 9, 2018), available at https://e-seimas.lrs.lt/portal/legalAct/lt/TAK/TAIS.223433?jfwid=-88erf9ddb.

1. The First Legal Act on ART

The first legal act in this field was adopted on 24 May 1999 when the Minister of Health issued the Order on Artificial Insemination (No. 248).⁸ In terms of global practice, this Order may be viewed as a controversial legal act which did not cover all major ART-related problems that needed to be legally regulated. In addition, it had gaps and was not up to date in terms of contemporary Lithuanian society, i.e., it did not sufficiently regulate embryo and gamete protection, donation of female oocytes and auto donation, issues relating to sperm banks, surrogacy, requirements for donors of reproductive cells, or liability for violations of the legally-established procedure for artificial insemination. The fundamental problem was that assisted reproduction was only allowed for a married woman and only with her husband's sperm, in spite of the fact that, in 2000, there were already about 55,000 unmarried heterosexual couples in Lithuania and about 30 percent of children were born out of wedlock.⁹

The Order under discussion identified five possible assisted reproductive technologies: intrauterine insemination (IUI); gamete intrafallopian transfer (GIFT); *in vitro* fertilisation (IVF); intracytoplasmic sperm injection (ICSI); and zygote intrafallopian transfer (ZIFT).

According to Art. 3.1 of the Order, all the procedures of ART in Lithuania were based on several mandatory requirements:

 – fertilisation could only be carried out for women over 18 years of age, and the procedure could only be provided for a married woman;

 a married woman could only be artificially fertilised with the written consent of her husband;

- the artificial insemination procedures could only be applied to women between the ages of 18 and 45;

 artificial insemination was only possible if the health of the woman and her husband allowed it;

- the woman and her husband had to be fully informed about the nature of the procedure. Before signing their consent, they had to have all ethical, medical and legal consequences explained;

 – artificial insemination could only be performed by a physician who had the right to practice obstetrics/gynaecology and only in a healthcare institution which had the right (i.e., a licence) to perform the procedure;

- no more than three embryos could be placed in the woman's uterine cavity;

 the artificial insemination procedures would be paid for by the patient (the State Patient Fund did not compensate these procedures).

⁸ Dėl Lietuvos Respublikos sveikatos apsaugos ministro 1999 m. gegužės 24 d. įsakymo Nr. 248 "Dėl dirbtinio apvaisinimo tvarkos patvirtinimo," Valstybės žinios, 1999, Nr. 47-1497 [The Order of the Minister of Health No. 248 of 24 May 1999 on Artificial Insemination, State Gazette, 1999, No. 47-1497].

⁹ Moterys ir vyrai Lietuvoje [Women and Men in Lithuania] 33 (Vilnius: Statistics Lithuania, 2005).

Despite the limitations of this legal act, ART procedures were widespread in Lithuania. Currently, Lithuania has 12 private clinics that are licensed to provide ART services.¹⁰ The price of the treatment is around EUR 2,000,¹¹ and the number of treatments in 2008 was about 3,000.¹²

2. The New Civil Code

The legal regulation of ART by the Order of Ministry of Health was criticised from the beginning of its adoption. The drafting of a new Civil Code was a good opportunity to improve the situation. A proposal to regulate the issues relating to ART in the Civil Code was based on several arguments. First, given the importance of the problem, the issues of ART must be regulated by a legislative act, i.e., a legal act adopted by the Parliament of Lithuania (Parliament). Second, it is more difficult to change the rules of the Civil Code than the rules of a ministerial decree. Third, a consideration of a draft in Parliament would allow the opinions of all groups in society to be considered. For these reasons, Book Three of the draft Civil Code, entitled "Family Law," included a chapter on artificial insemination (Arts. 3.134–3.162). In the initial version of the draft, it was proposed to legalise fertilisation of woman's eggs by sperm other than that of her husband. However, after fully considering the problem, i.e., its special nature, its close link with several ethical questions, the experience of other states, ethical trends prevailing in Lithuanian society, Catholic teaching and its significant influence on society, and other aspects, the Working Group decided to propose alternatives to the regulation of ART. The two competing principled positions were submitted to be discussed by the public and politicians, thereby giving politicians the opportunity to decide which way to turn, i.e., to legalise the donation of sperm or only to allow fertilisation by the sperm of a spouse. As expected, the main debate was on the question of sperm donation. Though the discussions were not only on this issue. For example, the draft Civil Code was discussed from the point of view of the constitutional principles of equality before the law (e.g., whether to allow IVF procedures for unmarried as well as married women). Given the dominant opinions, especially that of the Catholic Church, the version which allowed the donation of the sperm of a donor was rejected. The final version of the draft Articles provided the following rules:

 – all questions related to ART should be decided on the basis of the best interests of the child;

¹⁰ Fertility Clinics Lithuania, WhatClinic.com (Jan. 9, 2018), available at http://www.whatclinic.com/ fertility/lithuania.

¹¹ Fertility Treatment in Lithuania, Fertility Treatment Abroad (Jan. 9, 2018), available at http://fertility. treatmentabroad.com/countries/lithuania.

¹² Patrick Präg & Melinda C. Mills, Assisted Reproductive Technology in Europe: Usage and Regulation in the Context of Cross-Border Reproductive Care in Childlessness in Europe: Contexts, Causes, and Consequences 289, 292 (M. Kreyenfeld & D. Konietzka (eds.), Berlin: Springer, 2017).

- ART could be used only by licensed healthcare institutions;
- the use of ART is possible if the women are from 18 to 45 years of age;
- the use of ART is prohibited in the event of medical contraindications;
- the use of the cells of a dead person is prohibited;
- the used of ART is only possible for married couples;
- only the sperm of the husband of the woman could be used;
- surrogacy is prohibited.13

However, even such a conservative draft did not receive support in Parliament. Therefore, in order not to prevent the adoption of the entire Civil Code, it was decided to eliminate the whole chapter on ART. What remained in the Civil Code was only Art. 3.154, which established a blanket rule that ART was allowed but that the concrete methods of ART and all other preconditions for ART services were to be left to a special separate law. The Civil Code was adopted on 18 July 2000. Under the Law on the Implementation and Entry into Force of the Civil Code, Parliament recommended that the Government prepare a special law on ART by 1 May 2002.

3. Unsuccessful Attempts to Adopt Law during the Period between 2000 and 2015

The first draft law on ART was prepared by the Ministry of Health in October 2002. This draft provided quite a liberal regulatory system for ART, including the possibility of using artificial insemination procedures for unmarried women and sperm and embryo donation.¹⁴ In December 2003, the Ministry of Health further developed an improved the draft law on ART. Unfortunately, this draft abolished the rules of the former draft which enabled single women to seek fertilisation by donor sperm and embryo donation. In January 2004, a group of members of Parliament prepared an alternative draft. All three drafts received a wide range of criticism which led to the stalling of the adoption of the law. The "liberal" draft was criticised by ART opponents while ART proponents found fault with its "conservative" equivalent. ART opponents argued that the "liberal" draft law created preconditions for a risk of incest. The following arguments against the "liberal" draft were raised:

- the possibility that spouses or partners could be individuals born from the same donor gametes;

- the likely negative consequences for the small Lithuanian gene pool;

the draft did not take into account a person's inherent right to know their origins;

¹³ The Draft Civil Code of the Republic of Lithuania (Jan. 9, 2018), available at https://www.e-tar.lt/portal/ lt/legalAct/TAR.8A39C83848CB.

¹⁴ Lietuvos Respublikos pagalbinio apvaisinimo įstatymo projekto aiškinamasis raštas [Draft Law on Assisted Reproduction of the Republic of Lithuania: An Explanatory Note] (Jan. 9, 2018), available at http://www. lrs.lt/pls/proj/dokpaieska.showdoc_l?p_id=56058&p_query=&p_tr2=&p_org=&p_fix=n&p_gov=n.

- in order to protect the child's right to know their origin, the import of gametes should be banned;

 in order to guarantee the protection of embryos, the export of embryos should be banned;

- consent to ART procedures should be approved by a public notary;

 - in the event of any negative consequences resulting from ART procedures, it would be necessary to offer psychological and social counselling which would be provided by persons not linked to ART services;

 – since abuses of ART procedures could lead to serious consequences, it would be necessary to establish criminal liability for violations of unauthorised actions and manipulation of human gametes and embryos;

 ART services could be performed only for a married woman, and only using her husband's sperm *in vivo*;

- the development of germ cell banks allow commercial abuse and different legal and social problems;

 donation of germ cells denied the inherent right of the child to know their biological parents;

– the "liberal" draft legitimised the creation of an excess number of embryos, embryo destruction and indefinite embryo freezing, which would result in the killing of a huge number of unborn babies in order to allow parents to choose a phenotype, which could be equated to the eugenic manipulations condemned by the Nuremberg Tribunal.¹⁵

On the other hand, the alternative draft was criticised for its conservatism. It stipulated that ART procedures would only be allowed for married couples or unmarried heterosexual partners. This draft proposed allowing artificial insemination using only the spouse's or life partner's gametes and prohibited the donation of eggs and sperm. In 2006, both the "liberal" and "conservative" drafts were debated in a session of the Parliamentary Health Committee and the conclusion of the committee was to accept the "liberal" draft law but, at the Plenary session, Parliament returned the draft to its drafters for some improvements. However, the world financial crisis started in 2008 and pushed the issues of assisted reproduction into the background. Therefore, the improved draft was only returned to Parliament in 2010.¹⁶ The draft established an opportunity to provide ART services to both married women and unmarried women living in with partners, legalised cell donation and germ cell banks, and also provided for

¹⁵ Lietuvos vyskupų spaudos konferencija dėl dirbtinio apvaisinimo [Lithuanian Bishops' Press Conference on Artificial Insemination] (Jan. 9, 2018), available at http://www.lcn.lt/bzinios/bz0210/210bl2. html/.

¹⁶ Zubrauskaitė V. Lietuvos politikai ignoruoja vienišas nevaisingas moteris, Vakarų ekspresas, 27 spalio 2003 [Vaida Zubrauskaitė, Lithuanian Politicians Ignore Lonely Infertile Women, West Express, 27 July 2003] (Jan. 9, 2018), available at http://www.ve.lt/naujienos/lietuva/lietuvos-naujienos/lietuvospolitikai-ignoruoja-vienisas-nevaisingas-moteris-381434/.

125

ART procedures to be paid for out of the compulsory health insurance fund. Therefore, the "liberal" draft was submitted to Parliament once again. However, in a similar situation to that of 2002, this draft immediately attracted criticism and resistance, resulting in the registration of four alternative drafts. One of them prohibited gamete donation and excluded the possibility of ART procedures to being paid for out of the compulsory health insurance fund.¹⁷ Another alternative draft established exclusively strict embryo protection conditions, and allowed for a maximum of three embryos to be created per procedure.¹⁸ Due to the abundance of alternative drafts, Parliament only reached a decision on which version to discuss further at the end of 2015. The "conservative" version of the draft was selected by the majority of the members of Parliament. The debates over this draft lasted until mid-2016 and only in 28 June 2006 did Parliament adopt this law. 66 out of 74 members of Parliament voted in favour of the draft with three voting against and three abstaining.¹⁹ Although the law allowed the use of ART procedures for spouses and unmarried heterosexual partners, it banned gamete donation. The law also imposed limitations on the creation embryos, i.e., no more than three embryos could be created. The law did not allow the financing of ART procedures from the compulsory health insurance fund. However, the law no longer determined the maximum age by which a woman could apply for an ART procedure. Such conservative law-making caused great dissatisfaction in Lithuanian society and among medical professionals. Numerous public organisations appealed to the President asking her to veto the law. Even the Ministry of Health asked the President for her veto.²⁰ The President did not sign the law, and, by a decree of 5 July 2016, returned the law to Parliament for revision. During repeated debates, Parliament substantially amended the draft and a more liberal law on assisted reproduction was adopted in 14 September 2016.²¹ Such a long procedure for the preparation and adoption of this law – sixteen years – was caused by several reasons. First, the position of the Lithuanian Catholic Church.

¹⁷ Dirbtinio apvaisinimo įstatymo projektas (Nr. XIP-2502) [Draft Law No. XIP-2502 on Assisted Reproduction] (Jan. 9, 2018), available at https://e-seimas.lrs.lt/portal/legalAct/lt/TAP/TAIS.382967.

¹⁸ Pagalbinio apvaisinimo įstatymo projektas (Nr. XIP-2502(2)) [Draft Law No. XIP-2502(2) on Assisted Reproduction] (Jan. 9, 2018), available at https://e-seimas.lrs.lt/portal/legalAct/lt/TAP/TAIS.399026.

¹⁹ Pagalbinio apvaisinimo įstatymo projektas (Nr. XIP-2502(6)) [Draft Law No. XIP-2502(6) on Assisted Reproduction] (Jan. 9, 2018), available at http://www3.lrs.lt/pls/inter/w5_sale.klaus_stadija?p_ svarst_kl_stad_id=-23609.

²⁰ Meta Adutaviciute, Ultraconservative Assisted Reproduction Law Crushes the Hopes of 50,000 Couples, Liberties, 8 July 2016 (Jan. 9, 2018), available at https://www.liberties.eu/en/news/lithuania-assistedreproduction-law; Lithuanian Seimas Passes Assisted Insemination Law, The Baltic Course, 29 June 2016 (Jan. 9, 2018), available at http://www.baltic-course.com/eng/legislation/?doc=122581.

²¹ Dėl Lietuvos Respublikos Seimo priimto Lietuvos Respublikos pagalbinio apvaisinimo įstatymo Nr. XII-2491 grąžinimo Lietuvos Respublikos Seimui pakartotinai svarstyti (2016 m. liepos 5 d. Nr. 1K-704) [Decree No. XII-2491 on the Reconsideration to Parliament of the Republic of Lithuania of the Law on Assisted Reproduction] (Jan. 9, 2018), available at https://e-seimas.lrs.lt/portal/legalAct/lt/TAD/9 30e9e7042ed11e68f45bcf65e0a17ee?jfwid=-wd7z7l9la.

According to the population census data, 80% of Lithuanian citizens consider themselves Catholics.²² During the Soviet period, the Catholic Church was oppressed by the regime and was one of the main institutions of resistance against the Soviet regime. Therefore, the popularity of the Church and its position in society is high. For example, public opinion polls conducted by the company Vilmorus between 1 and 10 July 2016, showed that about 54 percent of respondents trusted and respected the Catholic Church.²³ The history of the legal regulation of ART in other countries also confirms that conservative laws were adopted precisely in those countries where the Catholic Church's influence on society was significant (Italy, Spain, Portugal).²⁴ Second, political parties that promote liberalism have little influence in Lithuania. Since 1990, Lithuanian political parties that represent liberal views have never had a parliamentary majority and have either been in opposition or the smallest coalition partner. Meanwhile, the conservative parties usually have a majority in Parliament, or act as the biggest partners in ruling coalitions. After a Constitutional Court ruling in 2011 which recognised that a family could be created not only by marriage but also by an heterosexual partnership, conservative members of Parliament initiated an amendment to Art. 38 of the Constitution of Lithuania. Draft Art. 38 of the Constitutional amendment law stipulates that marriage is the only basis for the creation of a family. As many as 101 members of Parliament (out of the total number of 141) voted in favour of this draft. If this draft is adopted, heterosexual partnership will no longer have a legal basis and heterosexual couples will be banned.²⁵ Some of the conservative members of Parliament also initiated a draft law to provide for an absolute protection of the embryo and a ban on abortion. Third, there has not been enough use of the comparative legal method during the legislation process.

4. The Main Features of the Law of 14 September 2016

The main innovation of this law is that it has legalised donation of reproductive cells when one of the spouses or partners have damaged or insufficient reproductive cells which cannot be used for assisted fertilisation, as well as in cases when they have a high risk of transmitting a disease likely to cause significant disability. The law established

Pagalbinio apvaisinimo įstatymo projektas (2016 m. birželio 28 d. Nr. XII-2491) [Draft Law No. XII-2491 on Assisted Reproduction] (Jan. 9, 2018), available at https://e-seimas.lrs.lt/portal/legalAct/lt/TAP/ d065c8a042a411e69f7afa4bbf73635e.

²³ Ar Jūs pasitikite, ar nepasitikite šiomis Lietuvos institucijomis?, Vilmorus [Do You Trust or Do Not Trust These Lithuanian Institutions?, Vilmorus] (Jul. 20, 2017), available at http://www.vilmorus.lt/index.ph p?mact=News,cntnt01,detail,0&cntnt01articleid=2&cntnt01returnid=20.

²⁴ Giovanni Comandé, Medical Law: Italy in International Encyclopaedia of Laws: Medical Law 268 (H. Nys (ed.), The Hague: Wolters Kluwer, 2016); Carlos M. Romeo-Casabona, Medical Law: Spain in Id. at 176; Paula Lobato de Faria, Medical Law: Portugal in Id. at 137.

²⁵ Konstitucijos 38 straipsnio pakeitimo įstatymo projektas (Nr. XIIP-1217(2)) [Article 38 of the Constitution: Draft Law for Amendment] (Jan. 9, 2018), available at https://e-seimas.lrs.lt/portal/legalAct/lt/TAP/ 0be20cb0348411e6a222b0cd86c2adfc.

that gametes and embryos cannot be an object of commercial transactions. At the same time, the law establishes the right of gamete donors to compensation for the donation of gametes. The Government, or an institution authorised by the Government, has to set the order of compensation procedure and payment procedures. Nevertheless, the law has banned embryo donation (Art. 3(8)) and surrogacy (Art. 11).

The law provides for access to a healthcare institution which provides ART services to take gametes and preserve fertility in case of certain health or potential health problems, or when prescribed treatment raises reasonable doubt as to that person's subsequent fertility and the abovementioned conditions are confirmed by the relevant conclusions of a doctor (Art. 9). If a person whose gametes are stored in the bank dies, the bank is to destroy the gametes (Art. 8). A deceased person's gametes can be used for an individual assisted fertilisation if that person gave his consent to the use of gametes before his death. Nevertheless, the law prohibits the removal of gametes from a dead person and/or using them for ART (Art. 8(2)).

In addition, the law provided a conservative regulation of the use and the protection of embryos. The law provides that it is permitted to create as many embryos as it is possible to create at one instance, but that the final decision on the number of embryos is made by both spouses (partners) in consultation with a doctor (Art. 9). Before transfer to the woman's body, embryos can be grown in vitro (outside the woman's body) for up to six days after fertilisation (zygote formation). At the same time, the law provides that the number of embryos transferred to the woman's body at a time cannot exceed three. The created embryos that are not transferred to the woman's body are stored in a germ cell bank. When embryos are stored in a germ cell bank, other embryos of the same woman cannot be created for ART. The Minister of Health prescribes the requirements for the storage and usage of germ cell bank embryos for the purposes of healthcare. The law establishes that biomedical research on embryos may be carried out only in accordance with the Law on Ethics of Biomedical Research (adopted on 11 May 2000).²⁶ Lithuania has ratified the Convention on Human Rights and Biomedicine adopted by the Council of Europe in 1997. The Law on Biomedical Research sets very strict rules for biomedical research with embryos. According to Art. 3 of the Law on Biomedical Research, creation of human embryos for biomedical research purposes is prohibited. Biomedical research can only be performed if the expected benefit to the human embryo and on the human foetus outweighs the risks. It is prohibited to carry out biomedical research on human embryos and foetuses that died after an abortion performed at a woman's request in the absence of medical problems. Biomedical research with human embryos or foetuses, during which or after which a human embryo or human foetus is destroyed or the human embryo is not transferred to the

²⁶ Lietuvos Respublikos pagalbinio apvaisinimo įstatymas (2016 m. rugsėjo 14 d. Nr. XII-2608) [Law No. XII-2608 on Assisted Reproduction] (Jan. 9, 2018), available at https://www.e-tar.lt/portal/lt/leg alAct/074c2b707e7311e6b969d7ae07280e89.

woman's uterus, is also prohibited. It is also prohibited either to import to, or export from, the territory of the Republic of Lithuania, human embryonic tissues, embryonic stem cells and their cell lines or foetal tissue taken from their stem cell lines.

The law also establishes that ART services can be provided for both married women and those living in a registered partnership (Art. 1). This is also considered progress because ART procedures were previously only permitted for married women.

The law also sets other conditions for the application of ART procedures. The techniques of ART comprise artificial insemination *in vivo* and artificial insemination *in vito*. However, the law does not cover all the possible procedures of ART, while Art. 6 provides that the ART techniques have to be approved by the Minister of Health.

According to Art. 5, ART procedures can be performed only when infertility cannot be cured by any other treatment or the said procedures do not ensure a real chance of success, as well as in those instances when it is desired to avoid occurrence of severe disability caused by diseases, the criteria for which are established by the Minister of Health, or to provide its treatment. ART is prohibited in the presence of medical contraindications included in the list approved by the Minister of Health.

The law provides that all matters relating to ART must be addressed in the context of the best interests of the child who will be born as a result of ART and giving priority to the woman's health considerations. All decisions relating to ART must be taken upon assessing the benefits and the possible harm to the mother and/or child, and exercised with caution (Art. 3(3)).

Before the start of ART, the healthcare provider who carries out the ART must clearly inform both spouses (partners) of the anticipated employment of ART techniques, any alternatives, the benefits, risks, possible procedures for medical, psychological consequences of multiple pregnancy, the risks to the mother and the foetus, the probability of success of ART by indicating clinical pregnancies and births attributable to the prospective application method (Art. 7). The information provided before beginning ART is to be submitted in writing and spouses (partners) shall complete and sign the patient's informed consent form. Before signing the informed consent form, the spouses (partners) shall be notified in writing of the estimated price of ART. The time period between the day of the signing and the day of ART must be at least seven calendar days.

ART techniques cannot be applied as a tool for germline genetic identity modification. ART procedures cannot be used to provide certain features for a child, including the desired sex, unless the aim is to avoid severe disabilities caused by the diseases, the list of which is established by the Minister of Health, or to treat such diseases (Art. 3(5)).

The law also establishes the principle of confidentiality: the personal data of the germ cell recipient, the germ cell donor, and the child, are confidential. The identity of the donor is not disclosed to the germ cell recipient, his or her spouse (partner), or to children born using a donor gamete. The identity of the germ cell recipient, his spouse

(partner) and the child's identity are not disclosed to the donor either. However, a child who was born using donor gametes and germ cell donors can get confidential information with court permission if this information is necessary for the health of either the child or the donor or for any other important reasons (Art. 3(10)).

ART services and/or gamete banking services may be provided in Lithuania only by a legal entity or by a branch of a foreign legal person entity or other organisation established in Lithuania and, as provided for in the law, having been granted a licence to provide healthcare stating that they have acquired the right to provide licensed ART and/or gamete banking services (Art. 4). Licensed healthcare clinics and germ cell banks are obligated to provide registration and investigation of any serious adverse events and to inform a competent authority of the same. They are also obligated to keep records of gametes and embryos, their use, acquisition, handling, storage, and distribution. All data about germ cell storage in the bank, their distribution and use, the methods of ART, the number of transferred embryos, and the number of pregnancies and births after ART must be recorded in the ART system which has been established by the Government of Lithuania. All data must be kept for at least 30 years after the use of gametes or the storage deadline (Arts. 13, 14). The law also requires that the Minister of Health appoint a competent authority to supervise the taking, examination, preparation, storage and distribution of the reproductive cells; to supervise the development and implementation of a system for germ cells and embryonic traceability and exercise the monitoring of this system; to organise inspections and take control in the eventuality of any serious adverse event and/or reaction; to perform an audit at least every two years in order to establish whether or not the ART services offered comply with the requirements determined by legal acts and to make public the conclusions of the audit (Art. 15).

5. The Amendments of 17 January 2017

In October 2016, a new political force, the political party of Farmers and Greens, won the parliamentary elections and formed the majority in Parliament. The parliamentary faction of Farmers and Greens immediately initiated amendments to the Law on Assisted Reproduction which was not yet in force. On 1 December 2016, 57 members of this faction registered a draft which proposed abolishing the possibility of payment of compensation to donors; lifting donor anonymity; prohibiting gametes and embryo imports and exports, except when they are intended for autologous use; generating no more than three embryos; and postponing the entry of the law into force until 30 June 2017.²⁷ Another parliamentary group presented an

²⁷ Pagalbinio apvaisinimo įstatymo Nr. XII-2608 3, 10 ir 17 straipsnių pakeitimo ir papildymo įstatymo projektas (Nr. XIIIP-169) [Law No. XII-2608 on Assisted Reproduction: Draft Law No. XIIIP-169 of Amendment and Additions of Articles 3, 10 and 17] (Jan. 9, 2018), available at https://e-seimas.lrs.lt/ portal/legalAct/lt/TAP/e1d6f430b7a011e6a3e9de0fc8d85cd8.

alternative draft which allowed for embryo donation as well as limited anonymity of donors.²⁸ When debates erupted not only in Parliament but also in society at large, Parliament decided to request an independent legal opinion regarding both drafts.²⁹ Professors of Vilnius University and Kaunas University of Health Sciences provided an independent legal opinion. The experts unanimously supported the more liberal version of the draft.³⁰ On 10 January 2017, the Parliamentary Committee on Health Affairs also approved the more liberal version of the draft³¹ and, on 17 January, Parliament adopted amendments to the law, with 96 out of 100 members of Parliament present voting in favour and two abstaining.³² These amendments are important for several reasons. First, they have legalised embryo donation. According to para. 8 of Art. 3, donation of embryos stored in the germ cell bank is possible if the spouses (partners) reject the embryo in writing. Such refusal is not possible before the expiry of two years after the beginning of ART. Second, the amendments abolish the right of a gamete donor to claim compensation. Third, limited anonymity for donors and recipients has been established. According to Art. 3.10, a court may permit disclosure of information about the donor(s) and children if this information is necessary for the child's or the donor's health or for any other valid reasons. When a child born using ART procedures reaches 18 years of age, the donor's identity may

Pasiūlymas dėl Pagalbinio apvaisinimo įstatymo Nr. XII-2608 3, 10 ir 17 straipsnių pakeitimo ir papildymo įstatymo projekto (Nr. XIIIP-169) [Law No. XII-2608 on Assisted Reproduction: Draft Law No. XIIIP-169 of Amendment and Additions of Articles 3, 10 and 17. The Proposition] (Jan. 9, 2018), available at https://e-seimas.lrs.lt/portal/legalAct/lt/TAK/b2181e50c2d011e682539852a4b72dd4?jf wid=-wd7z7l4wg.

²⁹ Dėl Lietuvos Respublikos pagalbinio apvaisinimo įstatymo Nr. XII-2608 3, 10 ir 17 straipsnių pakeitimo ir papildymo įstatymo projekto Nr. XIIIP-169 ir Seimo narių pasiūlymų dėl šio įstatymo projekto nepriklausomo ekspertinio įvertinimo (2016 m. gruodžio 13 d. Nr. SV-S-45) [Law No. XII-2608 on Assisted Reproduction: Draft Law No. XIIIP-169 of Amendment and Additions of Articles 3, 10 and 17 and Proposal for an Independent Expert Assessment, 13 December 2016, No. SV-S-45] (Jan. 9, 2018), available at https://e-seimas.lrs.lt/portal/legalAct/lt/TAD/562bbde2c1fe11e682539852a4b7 2dd4?jfwid=-wd7z7l4wg.

³⁰ Ekspertinio įvertinimo išvada dėl Pagalbinio apvaisinimo įstatymo Nr. XII-2608 3, 10 ir 17 straipsnių pakeitimo ir papildymo įstatymo projekto (Nr. XIIIP-169) [Law No. XII-2608 on Assisted Reproduction: Draft Law No. XIIIP-169 of Amendment and Additions of Articles 3, 10 and 17. The Conclusion of Independent Expert Assessment] (Jan. 9, 2018), available at https://e-seimas.lrs.lt/portal/legalAct/lt/T AK/7282ce60ce6611e6a476d5908abd2210?jfwid=-wd7z7l4wg;https://e-seimas.lrs.lt/portal/legalAct/ lt/TAK/a79d2aa0ce6611e6a476d5908abd2210?jfwid=-wd7z7l4wg.

³¹ Pagrindinio komiteto išvada dėl Pagalbinio apvaisinimo įstatymo Nr. XII-2608 3 ir 10 straipsnių pakeitimo įstatymo projekto (Nr. XIIIP-169(2)) [Law No. XII-2608 on Assisted Reproduction: Draft Law No. XIIIP-169 of Amendment and Additions of Articles 3, 10 and 17. The Conclusion of the Main Committee] (Jan. 9, 2018), available at https://e-seimas.lrs.lt/portal/legalAct/lt/TAK/e9581ec0d7ce1 1e69c5d8175b5879c31?jfwid=-wd7z7l4ij.

³² Pagalbinio apvaisinimo įstatymo Nr. XII-2608 3 ir 10 straipsnių pakeitimo įstatymo projektas (Nr. XIIIP-169(2)) [Law No. XII-2608 on Assisted Reproduction: Draft Law No. XIIIP-169(2) of Amendment of Articles 3 and 10] (Jan. 9, 2018), available at http://www.lrs.lt/sip/portal.show?p_r= 15275&p_k=1&p_a=sale_klaus_stad&p_moment=20170117&p_kl_stad_id=-59827.

also be disclosed with the latter's consent. Fourth, import of gametes and embryos into Lithuania is allowed. Nevertheless, the import of gametes and embryos into Lithuania may be carried out only by the university hospitals which are licensed to provide ART procedures and offer germ cell bank services (Art. 3(11)). Fifth, it has been decided not to restrict the number of created embryos. Art. 10(1) provides that as many embryos can be created as it is possible to create at a time, and the final decision on the number is taken by the spouses (partners) in consultation with the doctor. However, no more than three embryos can be transferred to a woman's body at a time. The law prohibits destruction of an embryo which has been developed but not transposed into a woman's body (Art. 10(7)).

Conclusion

The adoption of the first Law on Assisted Reproduction in Lithuania is commendable. However, not all the problems associated with ART have been solved. In addition, there are some gaps in the law and these gaps will undoubtedly create several problems in the course of its application. First, it is forbidden to perform ART procedures for single women. Therefore, single women will travel from Lithuania to those countries where such restrictions are not applied, thereby promoting fertility tourism. Second, although the law allows ART procedures for unmarried heterosexual partners, they have not been able to use them yet. The Civil Code of 2000 legalised registered partnerships between couples of opposite sexes (Arts. 3.229-3.235), but for these rules to enter into force, adoption of a special law on the procedure of registration of partnership is necessary. Regretfully, such special law on the procedure of registration of partnership still needs to be adopted. In the meantime, it is not clear when Parliament will adopt such a law, because the relevant draft has been rejected several times. Therefore, unmarried heterosexual couples living as partners have no possibility to prove their partnership. Third, the law does not regulate the time limit for embryo storage or the reimbursement of storage costs. Fourth, although ART procedures are expected to be financed from the health insurance budget funds, due to a lack of funds, it will be impossible to ensure full coverage. Fifth, it is not clear who will perform the functions of the competent authority. Sixth, the law does not regulate the right of spouses (partners) to withdraw their consent to germ gamete (embryo) donation. Taking into account that every second marriage is terminated in Lithuania,³³ there are likely to be far more than a few instances when, after a divorce, a former spouse (partner) would cancel their previous agreement. Seventh, the law does not provide for the number of times the same donor gametes can be used for artificial insemination. The main reasons for the abovementioned shortcomings of the new law are insufficient use of the comparative legal method

³³ Available at https://osp.stat.gov.lt/statistiniu-rodikliu-analize?indicator=S3R224#/.

and the unwillingness of the legislators to benefit from the experience of foreign countries where these issues are clearly regulated. Sooner or later, the legislator will be forced to fill in these gaps. And which will undoubtedly mean a return to a stormy debate. Thus, the battle for the legal regulation of ART in Lithuania is not yet over.

References

Comandé G. *Medical Law: Italy* in *International Encyclopaedia of Laws: Medical Law* 268 (H. Nys (ed.), The Hague: Wolters Kluwer, 2016).

De Faria P.L. *Medical Law: Portugal* in *International Encyclopaedia of Laws: Medical Law* 137 (H. Nys (ed.), The Hague: Wolters Kluwer, 2016).

Mikelėnas V. Santuokos ir šeimos teisinis reguliavimas, 7 Mokslas ir gyvenimas 17 (1987).

Präg P. & Mills M.C. Assisted Reproductive Technology in Europe: Usage and Regulation in the Context of Cross-Border Reproductive Care in Childlessness in Europe: Contexts, Causes, and Consequences 289 (M. Kreyenfeld & D. Konietzka (eds.), Berlin: Springer, 2017).

Romeo-Casabona C.M. et al. *Medical Law: Spain* in *International Encyclopaedia of Laws: Medical Law* 176 (H. Nys (ed.), The Hague: Wolters Kluwer, 2016).

Information about the authors

Valentinas Mikelėnas (Vilnius, Lithuania) – Faculty of Law, Vilnius University (9 Saulėtekio Av., Vilnius, LT-10221, Lithuania; e-mail: valentinas.mikelenas@tf.vu.lt).

Rasa Mikelėnaitė (Vilnius, Lithuania) – Faculty of Medicine, Vilnius University (21 M.K. Čiurlionio St., Vilnius, LT-03101, Lithuania; e-mail: rasa.mikelenaite@gmail.com).