http://dx.doi.org/10.12775/CLR.2022.004

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A CRITICAL ANALYSIS OF THE LEGAL REGULATION OF ASSISTED REPRODUCTIVE TECHNIQUES AND BIOMEDICAL RESEARCH IN THE SLOVAK REPUBLIC IN THE CONTEXT OF NATURAL LAW

Abstract

The study critically analyses the Slovak legal regulation of assisted reproductive techniques and biomedical research through the prism of natural law attributes. The study confirms the hypothesis that the legal regulation of assisted reproductive techniques and biomedical research in the Slovak Republic is insufficient, does not reflect the actual practice, and allows interpretations and application that are not in line with natural law. The identified shortcomings do not correspond to the fact that the Slovak Republic is one of the countries with a restrictive biopolitics. The study demonstrates that even in the case of conservative legislation, the natural-law basis can be undermined or denied if the legislation does not sufficiently reflect all contexts. For comparison, we present selected legislation from the Czech Republic, which is more precise and consistent, although more liberal. The study also contains specific de lege ferenda proposals that are based on natural law foundations and at least partially remedy the identified shortcomings.

Keywords

technologies – assisted reproduction – biomedical research – legal shortcomings – Slovak Republic – natural law

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Introduction

In today's world, we are surrounded by technology at almost every turn. In many aspects of our lives, technology enhances and simplifies our daily activities. However, it is necessary to evaluate individual technologies in the light of the implications of their use and to think about their application in a holistic way, analysing the whole process of implementation, not just the outcome. Following the natural-rights perspective,[1] our focus is on technologies whose implementation cor-

[1] Natural law, which is the result of natural law theories, can be described as a phenomenon whose ideas are reborn when justice is disturbed or when 'real' justice and morality are sought in society. Different conceptions of natural law can be distinguished, depending on the basis the theory takes as the origin of natural law (e.g., theological, rationalist, etc. conceptions). We understand the natural law foundations as a platform for determining an ideal law that is independent of the state and springs from reason and the nature of man. From the perspective of modern natural law theories, natural law is a set of basic practical principles that show us the basic forms of human development as goods to be pursued, to be realized, and to be used in one way or another by everyone; it is also a set of basic methodological requirements of practical reasonableness that distinguish right from wrong practical reasoning and that provide criteria for distinguishing between acts that are good-reasonable and those that are bad-unreasonable, and enable us to formulate a set of general moral norms that should be part of positive law. Cf. J. Finnis, *Prirodzený zákon a prirodzené práva.* Absynt, 2019, p. 62. The issue of natural law, its development and different approaches is treated in a variety of ways in the Slovak and Czech legal scientific environment. Cf. for example: p. Holländer, "Pozitivismus versus iusnaturalismus: nekončící příběh (pokus o strukturování problému)", *Právník*, 1997, Issue 3, pp. 201–220; E. Barány, "O prirodzenom práve", *Právny obzor*, 1999, Issue 6, pp. 457–467; R. Alexy, *Pojem a platnosť práva,* Kaligram, 2009; J. Pinz, *Přirozenoprávní theorie a moderní právní stát*, OPS, 2010; S. Sousedík, *Svoboda a lidská práva, jejich přirozenoprávní základ*. Vyšehrad, 2010; p. Osina, *Nová teorie přirozeného práva*, Leges, 2019; V. Čunderlík Čerbová, *Prirodzenoprávna teória v práve Katolíckej cirkvi*, Leges, 2016; M. Nemec, "Prirodzené právo a jeho odraz v rímskom právnom myslení", in *Ius naturale – ius civile – ius gentium. Miesto a úloha prirodzeného práva v prostredí rímskeho práva*, Univerzita Komenského v Bratislave, 2013, pp. 72–79; M. Skřejpek, "Vztah přirozeného a platného práva", in *Ius naturale – ius civile – ius gentium. Miesto a úloha prirodzeného práva v prostredí rímskeho práva,* Univerzita Komenského v Bratislave, 2013, pp. 119–132; J. Pinz, "Ius naturale a genese filosofie práva", in *Ius naturale – ius civile – ius gentium. Miesto a úloha prirodzeného práva v prostredí rímskeho práva*, Univerzita Komenského v Bratislave, 2013, pp. 90–96; V. Vladár, "Koncepcia prirodzeného práva v Graciánovom tractatus de ligibus" in *Ethica et aequitas in iure: pocta prof. JUDr. Alexandre Krskovej, CSc.*, Typi Universitatis Tyrnaviensi, 2017, pp. 178–206.

relates with the value of human life and human dignity. In this context, our study focuses on biomedical technologies related to the creation of human life, specifically on assisted reproduction techniques and their legal regulation in the Slovak Republic. Closely related to the actual performance of assisted reproduction techniques is also the topic of biomedical research or scientific research activities that are carried out with these techniques.

The fundamental question from which the answers to the moral permissibility of some technologies derive is the question "when does man come into being?". Modern medical science is clear on this question, and the conclusions have been empirically demonstrated for a considerable time.[2] As philosophical and ethical theories enter into the social debate

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[2] "*Human development begins after the union of male and female gametes or germ cells during a process known as fertilization (conception). Fertilization is a sequence of events that begins with the contact of a sperm (spermatozoon) with a secondary oocyte (ovum) and ends with the fusion of their pronuclei (the haploid nuclei of the sperm and ovum) and the mingling of their chromosomes to form a new cell. This fertilized ovum, known as a zygote, is a large diploid cell that is the beginning, or primordium, of a human being.*" K.L. Moore, *Essentials of Human Embryology*, B.C. Decker Inc, 1988, p. 2; "*The development of a human being begins with fertilization, a process by which two highly specialized cells, the spermatozoon from the male and the oocyte from the female, unite to give rise to a new organism, the zygote.*" J. Langman, *Medical Embryology*, 3rd edition, Williams and Wilkins, 1975, p. 3; "*Almost all higher animals start their lives from a single cell, the fertilized ovum (zygote) (...) The time of fertilization represents the starting point in the life history, or ontogeny, of the individual.* B.M. Carlson, *Patten's Foundations of Embryology*, 6th edition, McGraw-Hill, 1996, p. 3, "*Development of the embryo begins at Stage 1 when a sperm fertilizes an oocyte and together, they form a zygote.*" M.A. England, *Life Before Birth*, 2nd edition, Mosby-Wolfe, 1996, p. 31; "*Embryo: the developing organism from the time of fertilization until significant differentiation has occurred, when the organism becomes known as a foetus.*" Cloning Human Beings. Report and Recommendations of the National Bioethics Advisory Commission, GPO, 1997, Appendix-2. "*Embryo: An organism in the earliest stage of development; in a man, from the time of conception to the end of the second month in the uterus.*" I.G. Dox, et al, *The Harper Collins Illustrated Medical Dictionary*, Harper Perennial, 1993, p. 146; "*Embryo: The developing individual between the union of the germ cells and the completion of the organs which characterize its body when it becomes a separate organism. (...) At the moment the sperm cell of the human male meets the ovum of the female and the union results in a fertilized ovum (zygote), a new life has begun. (...) The term embryo covers the several stages of early development from conception to the ninth or tenth week of life.*" D. Considine (ed.), *Van Nostrand's Scientific Encyclopaedia*, 5th edition, Van Nostrand Reinhold Company, 1976, p. 943.

on these topics,[3] often, especially for political reasons, there is a deliberate reformulation of scientific conclusions in the interests of one of the prevailing currents of thought, as a result of so-called logical, rational argumentation.[4] The legislation is consequently a compromise, but not a good solution in all circumstances.

The problems associated with low birth rates, as well as the increasingly frequent complications in the natural conception of offspring in the context of the development of modern biomedical technologies, are closely related to medically assisted procreation (hereinafter referred to as the "MAP"), especially assisted reproduction methods. MAP is generally considered to be the only reliable treatment for infertility. However, the question arises as to whether, in the case of assisted reproduction methods, we are talking about treatment at all. However, the issue of assisted reproduction also raises many ethical, moral and legal questions relating to the protection of the conceived life (the human embryo) and respect for the integrity and dignity (in our opinion, not only of the conceived life, but also of the spouses/partners who enter into the pro-

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[3] One of several possible examples is the work of the in many ways controversial Australian philosopher Peter Singer, who is an advocate of both abortion and euthanasia. Cf. e.g. p. Singer, *Spisy o etickom žití*, Vydavateľstvo spolku slovenských spisovateľov spol. s r.o., 2000.

[4] "[A]nimal biologists use the term embryo to describe the single cell stage, the two-cell stage, and all subsequent stages up until a time when recognizable humanlike limbs and facial features begin to appear between six to eight weeks after fertilization. (...) [A] number of specialists working in the field of human reproduction have suggested that we stop using the word embryo to describe the developing entity that exists for the first two weeks after fertilization. In its place, they proposed the term pre-embryo. (...) I'll let you in on a secret. The term pre-embryo has been embraced wholeheartedly by IVF practitioners for reasons that are political, not scientific. The new term is used to provide the illusion that there is something profoundly different between what we nonmedical biologists still call a six-day-old embryo and what we and everyone else call a sixteen-day-old embryo. The term pre-embryo is useful in the political arena – where decisions are made about whether to allow early embryo (now called pre-embryo) experimentation – as well as in the confines of a doctor's office, where it can be used to allay moral concerns that might be expressed by IVF patients. 'Don't worry, it's only pre-embryos that we're manipulating or freezing. They won't turn into real human embryos until after we've put them back into your body,' a doctor might say." Cf. L.M. Silver, *Remaking Eden: Cloning and Beyond in a Brave New World*, Avon Books, 1997, p. 39.

cess of assisted reproduction). Our intention is to critically analyse the legal regulation in this area in the Slovak Republic and to point out the problematic aspects related to its insufficiency and ambiguity. We start from the hypothesis that the legal regulation of assisted reproduction techniques in the Slovak Republic is insufficient, does not reflect the implemented practice, and allows interpretations and application that are not in accordance with the natural law assumptions. In the field of the legal regulation of biomedical research, the hypothesis applies equally. Our considerations also include *de lege ferenda* proposals for regulation based on natural law foundations.

I. Assisted Reproduction Techniques and Legal Regulation in the Slovak Republic

1. Assisted Reproduction Techniques

Assisted reproduction can be understood as a set of procedures aimed at conceiving a child. The World Health Organisation defines assisted reproduction as "any process or treatment that works in vitro with human oocytes and sperm or embryos to achieve pregnancy. These include, but are not limited to, in vitro fertilisation, transcervical embryo transfer, gamete intrafallopian transfer (GITF), zygote intrafallopian transfer (ZIFT), embryo-tube transfer, cryopreservation of embryos and gametes, oocyte donation, embryo donation, and surrogacy. Assisted reproduction does not include assisted insemination (artificial insemination), which uses the sperm of a partner or donor."[5]

The most commonly used method of assisted procreation is IVF (in vitro fertilisation). In this technology, hormonal stimulation of the ovaries is carried out first in order to obtain enough biological material. This is followed by the artificial fusion of male and female sex cells under laboratory conditions, which produces a zygote or fertilised egg. This is further cultured or observed under laboratory conditions. Next,

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[5] *Asistovaná reprodukce v České republice 2017–2018*, Ústav zdravotnických informací a statistiky ČR, 2021, p. 8, available at: https://www.uzis.cz/res/f/008365/asistreprodukce2018-2019.pdf [last accessed 29.3.2022].

the embryos are selected and transported, *i.e.* the embryo/embryos are transferred to the mother's uterus.[6]

Thus, the ethical-moral and legal dilemmas in the issue of MAP are the protection of conceived life,[7] overproduction of embryos, and the undignified and destructive treatment of surplus embryos. The means of resolving these issues, in our view, may be the application of natural law, on the basis of which we should be able to draw a conclusion as to the morality or immorality of these technologies and, on the basis of the result, to amend the relevant positive legislation. In line with natural law tendencies, in our opinion, the state's legislation in this area should also include alternative approaches for citizens who reject assisted reproduction techniques.

2. Legal Regulation of Assisted Reproduction Techniques and Their Practice

The first legislative act in connection with MAP techniques in our territory was the Measure of the Ministry of Health of the Slovak Socialist Republic no. 24/1983 regulation on the conditions of MAP.[8] Interestingly, this measure has not yet been repealed, and some of the conditions

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[6] We do not consider it essential in terms of the issue under study to discuss the IVF process in technical and medical terms in more detail. For more specific information on step-by-step IVF methods, see: I. Fraser, et all, *Report of the Independent Review of Assisted Reproductive Technologies*. Assisted Reproductive Technologies Review Commitee, available at: https://www1.health.gov.au/internet/main/publishing.nsf/content/79D96DD80F01073ECA257BF0001C1ABB/$File/artrc_report.pdf [last accessed 29.3.2022]. See below: *Priebeh asistovanej reprodukcie. IVF krok za krokom*, available at: https://unica.cz/cs/fertility-treatments/ivf-step-by-step [last accessed 29.3.2022] or *Čo Vás čaká v centre asistovanej reprodukcie*, available at: https://www.gyn-fiv.sk/wp-content/uploads/2020/05/%C4%8Cov%C3%A1%C5%A1-%C4%8Dak%C3%A1-v-centre-AR-web.pdf [last accessed 29.3.2022].

[7] This problem is, of course, also related to the issue of abortion.

[8] The measure allows MAP techniques only in the case of spouses, either with the husband's sperm or with donor sperm. Assisted procreation, according to the Measure, means a medical procedure whereby insemination is performed on a woman with the husband's semen or the semen of another man. Assisted procreation is allowed only for medical reasons (conceived very broadly, as there are also other obstacles for which the spouses cannot have healthy offspring together) and the age limit for a woman is 35 years. Ministry of Health of the Slovak Socialist Republic Measure No. 24/1983 on the

it lays down have been replaced by new legislation. At the same time, it can be written about the legal regulation of assisted reproduction techniques in Slovakia that, according to several experts (not only from the environment of experts implementing assisted reproduction techniques), it is insufficient, outdated, and unconceptual.

There are several centres of assisted reproduction in Slovakia, which provide a wide range of services, while the scope of care provided does not correspond to the quality of the legal regulation of these techniques.[9] Until 2017, the issue of performing MAP techniques was regulated by secondary legislation.[10]

Considering how many moral, ethical, and legal issues are related to the implementation of MAP techniques and how significantly these

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conditions of MAP, No. 23–24, Bulletin of the Ministry of Health of the Slovak Socialist Republic, 28.11.1983, Vol. XXXI.

[9] According to the information available on the websites of assisted reproduction centres, these centres perform the following procedures: artificial insemination (intrauterine homologous and heterologous forms), in vitro fertilization, including forms where donor gametes are used, pre-implantation genetic diagnostics, storage – cryopreservation of sperm, oocytes and embryos, cryoembryo transfer. Cf. e.g. *Asistovaná reprodukcia*, available at: https://www.sanatoriumhelios.sk/asistovana-reprodukcia/ [last accessed 30.3.2022].

[10] Government Regulation of the Slovak Republic No. 20/2007 Coll. on details on procurement, tissue and cell donation, criteria for selection of tissue and cell donors, laboratory tests required for tissue and cell donors, and procedures for procurement of cells or tissues and their acceptance by a health care provider, as amended by Government Regulation No. 119/2014 Coll.; hereinafter Government Regulation of the Slovak Republic No. 622/2007 Coll, laying down details on the processing, storage, warehousing, or distribution of tissues and cells and on the reporting and investigation of adverse reactions and events and the measures taken, as amended by Government Regulation No 9/2016 Coll, Decree of the Ministry of Health of the Slovak Republic of 17 December 2012 No S09229-OL-2012, which regulates the details of organ and donor characteristics, labelling of the transport container, record of organs removed, and record of organs transplanted (Notification No 426/2012 Coll.) and Decree of the Ministry of Health of the Slovak Republic of 17 December 2012 No S09229-OL-2012, which regulates the details of organ and donor characteristics, labelling of the transport container, record of organs removed, and record of organs transplanted (Notification No 426/2012 Coll.). S09602-OL-2012 of 17 December 2012 laying down the particulars of the consent for the export of tissue or cell outside the territory of the Slovak Republic and the model application for consent for the export of tissue or cell outside the territory of the Slovak Republic (notification No 427/2012 Coll.), as amended by Decree No 04114-OL-2013 of 24 June 2013 (notification No 197/2013 Coll.).

techniques interfere with human rights, the protection of dignity and the obligations arising from international conventions to which the Slovak Republic is bound and which take precedence over national legislation, it is, in our opinion, unacceptable in a state governed by the rule of law for these issues to be dealt with for such a long period of time only by norms with lesser legal force.

In 2016, a law was adopted which transposed six legally binding acts of the European Union, namely directives, [11] namely Act no. 317/2016 Coll. on Requirements and Procedures for the Collection and Transplantation of Human Organs, Human Tissues and Human Cells and on Amendments to Certain Acts (Transplantation Act) as amended (hereinafter referred to as the 'Transplantation Act'). However, the truth remains that we do not yet have a legal definition of assisted reproduction in our conditions, and the legal regulation of these techniques is fragmentary and chaotic. Despite this fact, however, these techniques are[12]

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[11] 1. Directive 2004/23/EC of the European Parliament and of the Council of 31 March 2004 on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells, OJ L 102, 7.4.2004, p. 48–58; 2. Commission directive 2006/17/EC of 8 February 2006 implementing Directive 2004/23/EC of the European Parliament and of the Council as regards certain technical requirements for the donation, procurement and testing of human tissues and cells, OJ L 38, 9.2.2006, p. 40–52, amended by Commission Directive 2012/39/EU of 26 November 2012, OJ 327, 27.11.2012, p. 53–54; 3. Commission Directive 2006/86/EC of 24 October 2006 implementing Directive 2004/23/EC of the European Parliament and of the Council as regards traceability requirements, notification of serious adverse reactions and events and certain technical requirements for the coding, processing, preservation, storage and distribution of human tissues and cells, OJ L 294, 25.10.2006, p. 32–50, amended by Commission Directive 2015/565 of 8 April 2015 amending Directive 2006/86/EC as regards certain technical requirements for the coding of human tissues and cells, OJ L 93, 9.4.2015, p. 43–55; 4. Directive 2010/53/EU of the European Parliament and of the Council of 7 July 2010 on standards of quality and safety of human organs intended for transplantation, OJ L 207, 6.8.2010, p. 14–29; 5. Commission Implementing Directive 2012/25/EU of 9 October 2012 laying down information procedures for the exchange, between Member States, of human organs intended for transplantation, OJ L 275, 10.10.2012, p. 27–32; 6. Commission Directive (EU) 2015/566 of 8 April 2015 implementing Directive 2004/23/EC as regards the procedures for verifying the equivalent standards of quality and safety of imported tissues and cells, OJ L 93, 9.4.2015, p. 56–68.

[12] Artificial insemination techniques, which according to the World Health Organization do not fall under assisted reproduction methods, are not covered by public health insurance. Similarly, many individual procedures provided by assisted repro-

financed by public health insurance.[13] Assisted reproduction services paid from public health insurance are subject to the indication set out in the secondary legislation.[14]

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duction centres (e.g., pre-implantation diagnosis of embryos, embryo cryopreservation, among others) are not covered by public health insurance and clients are obliged to pay for these procedures individually. However, for the sake of completeness, it should be noted at this point that private health insurers, as a form of benefit for their insured persons, reimburse some assisted reproduction centres or contribute a certain amount for the procedures in question, which is a public commitment of the health insurer and is implemented through individual contracts with specific assisted reproduction centres. However, this is also a case of public funding, since the health insurance company finances these contributions, over and above the legal regulation, from the compulsory contributions of all its insured persons. See for example: *Príspevky na výkon asistovanej reprodukcie*, available at: https://www.union.sk/wp-content/uploads/2020/11/Prispevky-na-vykony-asistovanej-reprodukcie_infografika.pdf [last accessed 1.4.2022].

[13] Government Regulation No. 776/2004 Coll., which issues the Catalogue of Health Performances, as amended, specifies one cycle before oocyte retrieval, one cycle with oocyte retrieval for in vitro fertilization, without embryo transfer, and one complex cycle with embryo transfer as a health care procedure for assisted reproduction. Accordingly, the regulation does not address in precise terminology the specific methods offered by assisted reproduction centres.

[14] Pursuant to Government Regulation No. 777/2004 Coll. issuing the List of Diseases for which medical procedures are partially reimbursed or not reimbursed by public health insurance, as amended, artificial insemination, in vitro fertilization (in a test tube) and other assisted methods of fertilization (which others are not specified) are reimbursed by public health insurance on the basis of the conditions set out in the Regulation in question. Public health insurance shall reimburse a maximum of three cycles of assisted reproductive procedures for women up to the age of 39 in the following cases: 1. Missing fallopian tubes or irreversible damage to the fallopian tubes diagnosed laparoscopically or laparotomically, except for conditions resulting from previous sterilisation or abortion. 2. Endometriosis of a woman that is diagnosed laparoscopically or laparotomically. 3. Irreversible damage to the ovaries that is confirmed biochemically, laparoscopically or laparotomically, if this damage is not the result of an abortion. 4. Idiopathic sterility that is unsuccessfully treated for one year in a specialized medical facility. 5. Male sterility factor – azoospermia, asthenospermia, ejaculatory dysfunctions, and diseases related to chemotherapy or post-traumatic conditions that are verified by an andrologist. 6. Immunological causes of sterility verified by laboratory. 7. risk of hereditary disease that prevents the couple from having healthy offspring, verified by a geneticist. 8. Endocrine causes of sterility verified by an endocrinologist. Considering the conception of diagnosis number 4, it is obvious that any cause can be included under this reason, for example, the case of a couple who are not comfortable trying to conceive in a natural way for more than one year. Furthermore, other acts are also covered by public health insurance for which no conditions are already laid down. These are complica-

However, in our view, it cannot be assessed that the current state of the law is adequate. The volume of activities of assisted reproduction centres is evidenced by the statistics. These data which would be available on the basis of Act No 77/2015 Coll. amending Act No 580/2004 Coll. on health insurance and amending Act No 95/2002 Coll. No. 95/2002 Coll. on Insurance and on Amendments and Additions to Certain Acts, as amended, and amending certain Acts, should be collected by the National Registry of Assisted Reproduction, which is a 'new' registry included in the list of registries when Act No. 153/2013 Coll. on the National Health Information System and on Amendments and Additions to Certain Acts was amended. The data from the registry are to be the basis for obtaining information on the trend of infertility, diagnostic, and therapeutic procedures in the form of assisted reproduction according to selected health and demographic indicators at the national and regional level, as well as on the success and results of assisted reproduction. The data from the registry will also serve as a basis for international comparisons in the databases of the World Health Organization, OECD, EUROSTAT and international professional societies. However, the registry has not yet been launched and its implementation is still in progress.[15] The volume and scope of the activities of assisted reproduction centres as a tissue facility [16] are mapped by the National Transplant Organization.[17] The National Transplant Organisation also reports on the Slovak Republic's reproductive tissue procurement and implantation

tions associated with MAP techniques (infection associated with MAP techniques, ovarian hyperstimulation, complications when attempting to introduce a fertilised egg after in vitro fertilisation, complications when attempting to introduce an embryo during embryo transfer, other complications associated with MAP techniques and unspecified complications associated with MAP techniques). It is clear from the wording in question that assisted reproduction centres are also covered by public health insurance for complications which, in our view, should be borne as a business risk in the context of their business activity in a highly specialised professional field.

[15] *Národný register asistovanej reprodukcie*, available at: https://www.nczisk.sk/Registre/Narodne-zdravotne-registre/Pages/Narodny-register-asistovanej-reprodukcie.aspx [last accessed 30.3.2022].

[16] Pursuant to the provisions of Section 7(3)(h) of Act No. 578/2004 Coll. on Health Care Providers, Health Care Workers, Professional Organizations in Health Care and on Amendments and Additions to Certain Acts, as amended.

[17] Pursuant to the provisions of Section 33(1)(b) of the Transplantation Act.

activities in both partner and non-partner donation in its annual report and statistics on its website.[18] However, in the sense presented in the

[18] Based on these annual reports, it can be stated that the numbers of couples treated in assisted reproduction centres from 2018 to 2020 are slightly decreasing (2018–6291, 2019–6128 and 2020–5499), and the numbers of embryo transfers (both fresh and frozen) are also slightly decreasing (2018–6969, 2019–6359, 2020–6267). However, it should be noted that the range of information published since 2017 is considerably narrower than the range of information last provided in 2016. The aforementioned may be due to the legislative establishment of the National Register of Assisted Reproduction, the establishment of which is only at the level of a legal norm, but the practical implementation of the activity has still not taken place. In 2013–2016, the National Transplantation Organization also reported in its annual reports the number of embryos transferred (both fresh and frozen), the number of clinical pregnancies, the number of births, as well as the number of babies born. From these figures, a simple calculation can be made to determine the success rate of assisted reproduction techniques in each year for the partners. It is also interesting to note that the numbers published in the annual reports of the National Transplant Organisation do not correspond with the numbers reported by the same organisation in the statistics section (the years 2013–2014 differ in the numbers of embryos transferred, clinical pregnancies, births and babies born, often by hundreds of cases. Annual reports from 2015–2016 are not published on the website and therefore the numbers in the statistics and annual reports cannot be compared). The success rate of assisted reproduction techniques in 2015 was 15.74% (the ratio of the number of fresh and frozen embryo transfers to the number of clinical pregnancies). In terms of live births, the success rate in 2015 was 9.7% (the proportion of the number of transfers of fresh and frozen embryos and the number of live births). In terms of the number of live births in 2015, the success rate was 10.06% (the ratio of the number of transfers of fresh and frozen embryos to the number of live births). The success rate of assisted reproduction techniques in 2016 was 13.44% (the proportion of the number of fresh and clotted embryo transfers and the number of clinical pregnancies). In terms of live births, the success rate in 2016 was 6.3% (the proportion of the number of transfers of fresh and frozen embryos and the number of live births). In terms of the number of live births in 2016, the success rate was 3.5% (the proportion of the number of transfers of fresh and frozen embryos and the number of live births). It is not clear from the published data that there is a difference between the number of live births and the number of births, which are reported in different numbers. The question remains as to what the success rate of assisted reproduction techniques actually is. Is it pregnancies or births? Logically, the goal of these techniques is offspring. From this point of view, therefore, a success rate of 9.7% in 2015 and 6.3% in 2016 is a very low figure, which is still considered an experimental treatment in professional circles. Another shortcoming in the published data is the not insignificant fact that they are not fully distinguishable (it is not possible to verify numerically the difference between the number of embryos created and the number of fresh embryos transferred in a given year, so it is not possible to calculate the number of embryos that remained "surplus" beyond those destined for cryopreservation). In view

footnote, it is not possible to compile comprehensive information in assisted reproduction techniques from these figures.

3. Ethical and Moral Dilemmas of the Techniques of Assisted Reproduction Wording of the Legal Order of the Slovak Republic

One of the ethical problems arising from the implementation of MAP techniques is the hormonal stimulation of the client's ovaries, when oocytes are overproduced in order to create more embryos, from which suitable embryos are selected for transfer or cryopreservation by preimplantation diagnostics. In this procedure, embryos are overproduced and those that are not suitable for transfer or cryopreservation become redundant. The issue is therefore how such surplus embryos are dealt with and how this is addressed by Slovak legislation. In this procedure, a much larger number of embryos is destroyed than in the case of abortions.[19]

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of the ethical and moral dilemmas of these techniques, these figures are, in our opinion, very necessary for an overall evaluation of the activities in question. The above information is based on published data from the National Transplant Organisation, available at: https://www.nto.sk/statistika/ [last accessed 1.4.2022].

[19] The legal regulation of abortion uses the terminology of interruption. We cannot identify with term "interruption" and do not use it, since the result is not the termination of the pregnancy, but its ending. It is an irreversible process in which the embryo is killed, and therefore the term termination is, in our opinion, neither correct nor appropriate. We do not address the issue of abortion in our study as it is an issue that could be treated separately. However, abortion is related to the issue of the protection of life and human dignity in assisted reproduction techniques and has a common unresolved issue, namely the social consensus on the moment when a human being is created and from what moment he/she is entitled to legal protection. The answer to this question depends on the approach taken by the respondent, namely liberalist (the embryo is not a human being because it does not meet the qualifying characteristics of a human being as formulated by various philosophical and ethical theories) or conservative (the embryo is a human being and is entitled to legal protection on the basis of theological or biological grounds). On this issue, see: Centro di Bioetica UCSC, "Identita a štatút ľudského embrya", in *Medicina e Morale, Supplemento al. n. 6*, Universita Cattolica del Sacro Cuore, 1996; p. Volek, "Problém ontologického statusu ľudských embryí", *Filozofia*, 2006, Issue 2, pp. 119–135; p. Sýkora, "Treba život každej ľudskej zygoty bezpodmienečne chrániť?", *Filozofia,* 2006, Issue 7, pp. 562–568; p. Sýkora, *Ľudská prirodzenosť – prírodovedná perspek-*

Human rights are of an internationally recognized nature and are not dependent on recognition by the state, which does not decide on their existence, but only on whether and to what extent it provides them with adequate legal protection.[20] What about the protection of unborn life in terms of legislation in Slovakia? The answer to this question has several possible approaches.[21] In the context of our topic and assisted

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tíva, available at: http://www.health.gov.sk/Zdroje?/Sources/dokumenty/eticka_komisia/Sykora_LP_text.doc [last accessed 4.4.2022]; V. Thurzo, "Identita, ontologický a etický štatút ľudského embrya. Epistemologický problém a jeho riešenie", *Acta facultatis theologicae Universitatis Comenianae Bratislaviensis*, 2015, Issue 1, pp. 42–59; p. Volek, "Ľudské embryá ako indivíduá a osoby", *Filozofia*, 2010, Issue 6, pp. 514–525; T. Doležal, "Hodnota lidského života na pozadí wrongful life a wrongful birth žalob – slovo úvodem", *Časopis zdravotníckeho práva a bioetiky*, 2013, Issue 3, available at: http://medlawjournal.ilaw.cas.cz/index.php/medlawjournal/article/viewFile/54/60 [last accessed 4.4.2022]; M. Vácha, M. "Definice lidského embrya a jeho status", *Vesmír*, 2008, Issue 4, pp. 216–219, available at: https://vesmir.cz/downloadfile.html?d=16556&f=23551&hash=510f5465f503d7ad7b1b6b8a45e35f64ffec050228da8ccbb282bdf341a97fa4355ec41e6da4c142d3776053fbced727ccc38c4b32361625e2c8e10086b747c5 [last accessed 4.4.2022]; I. Pascal, *Je zygota lidskou osobou?*, Triton, 2012; D. Černý, *Lidské embryo v perspektivě bioetiky*, Wolters Kluwer ČR, 2011; D. Černý, "Personální identita a interupce", *Filozofický časopis*, 2014, Issue 6, pp. 805–817. The Constitutional Court of the Slovak Republic has also commented on the issue of abortion and the compliance of certain provisions of Act No. 73/1986 Coll. on abortion, as amended, with Article 15 of the Constitution of the Slovak Republic, stating unequivocally that „*its task is not to answer the philosophical, moral or ethical question of when human life begins, nor the question of the rightness or morality of abortion, nor the question of what the optimal legal regulation of abortion in the Slovak Republic should look like.*" Ruling of the Constitutional Court of the Slovak Republic PL. ÚS 12/01-297, 4.12.2007.

[20] The latter should reflect social and scientific reality or should see modern embryological knowledge as a certain argumentative basis for determining the legal status of the unborn child, but also of the zygote or embryo. With regard to ethics, this is a question of values and principles. The extent to which we as a society have respect and regard for human life is, in fact, mainly determined by the way in which we are willing to protect and acknowledge the smallest among us who are at the mercy of our decisions. It is also a demand for the equality of all people in dignity and rights, which, while applying the principles of solidarity, can be considered one of the foundations of any advanced democratic society. Cf. J. Valc, "Hodnotové pojetí a právní ochrana nenarozeného života v kontextu biomedicínského vývoje", *Jurisprudence*, 2017, Issue 4, p. 18.

[21] In connection with the possible argumentative approach to this question, namely what is the protection of unborn life under the legal order of the Slovak Republic, the Constitutional Court of the Slovak Republic has already provided this in its reasoning in the mentioned ruling No.PL. ÚS 12/01-297, 4.12.2007. The Constitutional Court based the existence of protection of unborn life up to the first 12 weeks on the protection of the pregnant employee under labour law norms, on the protection of the foetus during the

reproduction techniques, we consider it important to point out that our legislation lacks a clear definition of what an embryo is considered to be, and therefore the treatment of surplus embryos created by MAP techniques is left to no one's approval.[22] The issue of the activities of MAP techniques is framed by legislation in the Transplantation Act. The Transplantation Act defines reproductive human cells in the provision of Article 2 (5) as human tissue or human cells intended for the purpose of assisted reproduction. However, it is not defined within the Act whether human cells intended for assisted reproduction purposes also include embryos.[23] However, the fact that a comment was made in connection with this matter in the inter-ministerial comment procedure seems interesting.[24] This comment was substantial and the sub-

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entire pregnancy under criminal law, on the direct civil protection of the property rights of the nascitura, provided that it is born alive. Ruling, *supra* note 21.

[22] In connection with MAP techniques, destruction, storage and preservation and use for scientific research activities are possible.

[23] The Transplant Act has transposed European directives on quality and safety standards in the donation, procurement, testing, processing, preservation, storage, and distribution of human tissues and cells. Directive 2004/23/EC of the European Parliament and of the Council of 31 March 2004 on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage, and distribution of human tissues and cells in the recital, in paragraph 7, it mentions reproductive cells, specifying in brackets that these are eggs and sperm. In contrast, however, Commission directive 2006/17/EC of 8 February 2006 implementing Directive 2004/23/EC of the European Parliament and of the Council as regards certain technical requirements for the donation, procurement and testing of human tissues and cells Article 1 defines reproductive cells as all tissues and cells intended for assisted reproductive purposes, without specifying that they should be limited to eggs and sperm. The conclusion that in the case of this implementing directive, which has also been transposed into the Transplantation Act, the European Union already has embryos in mind in the context of reproductive cells is supported by the fact that Annex III. The selection criteria and laboratory tests required for reproductive cell donors referred to in Articles 3(b) and 4(2) of the implementing directive in question state that *„Reproductive cells that are processed and/or stored and reproductive cells that will result in the cryopreservation of embryos must meet the following criteria"*. Cf. Commission directive 2006/17/EC of 8 February 2006 implementing Directive 2004/23/EC of the European Parliament and of the Council as regards certain technical requirements for the donation, procurement and testing of human tissues and cells, OJ L 38, 9.2.2006, p. 40–52, amended by Commission Directive 2012/39/EU of 26 November 2012, OJ 327, 27.11.2012, p. 53–54.

[24] Institute for Human Rights and Family Policy, o.z. commented that the following should be added to the definition of reproductive cells intended for assisted reproduc-

mitter agreed with the reasoning of the civic association and accepted the comment. Therefore, the petitioner introduced the following definition in the draft Transplantation Act: the provision of Article 2(15) of the draft Transplantation Act, "*Reproductive cells are tissue or cells intended for the purpose of assisted reproduction. A human embryo shall not be considered as reproductive cells.*" Such a proposal was directed to the Legislative Council of the Government of the Slovak Republic, a permanent advisory body of the Government of the Slovak Republic, which at its 5th meeting on 12.07.2016 recommended modifying the proposal according to its comments (221[25]) and submitting a new, amended version to the Government's deliberations.[26] At the meeting of the Government on 16.08.2016, a modified and new version of the draft Transplantation Act was approved by the Government, in which the proposed provision of Section 2(5), which accepted and incorporated the essential comment from the inter-ministerial comment procedure, was not used and the original definition of reproductive cells was included in the draft: "*Reproductive human cells are human tissue or human cells intended for the*

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tion: "A human embryo is not considered to be a reproductive cell." It correctly reasoned that the transposed directive deals only with eggs and sperm in the case of reproductive cells. At the same time, it argued that the definition of embryo according to the case-law of the Court of Justice of the European Union in Oliver Brüstle v. Greenpeace e.V, Case C34/10, Judgment of 18.10.2011, E.C.R. 2011, p. 0, para 38, *"A human embryo is any human ovum from the stage of fertilisation, any unfertilised human ovum into which a cell nucleus from a mature human cell has been implanted, and any unfertilised human ovum which has been stimulated by parthenogenesis to divide and develop further"*. The civil association pointed out that the proposed clarification would help to avoid interpretative ambiguities about the definition of reproductive cells – namely whether or not an embryo (in particular an embryo created in vitro) should also be considered as such. *Vyhodnotenie medzirezortného pripomienkového konania* LP/2016/572, available at: https://www.slov-lex.sk/legislativne-procesy/-/SK/dokumenty/LP-2016-572 [last accessed 6.4.2022].

[25] The specific objections raised, and thus the reasoning in relation to the definition of reproductive cells for assisted reproductive purposes, were not publicly available. According to the information from the Legislative Department, Government Legislation Section of the Office of the Government of the Slovak Republic, no records are made of the proceedings of the Legislative Council of the Government of the Slovak Republic where the comments made are specified. Government Legislation Section, Office of the Government of the Slovak Republic, 1.4.2022. Personal communication.

[26] Minutes of the 5th meeting of the Legislative Council of the Government of the Slovak Republic in VII. election period held on 12 July 2016, available at: https://lrv.rokovania.sk/data/att/152319_zaznam.doc [last accessed 6.4.2022].

purposes of assisted reproduction".[27] This legitimately calls into question the purpose and relevance of the interdepartmental comment procedure and the function of the essential comments. Likewise, the present process causes application ambiguities in connection with MAP techniques. In view of the above, it is not excluded that the interpretation of the definition of reproductive cells in the sense of the transposed European directives concludes that reproductive cells intended for assisted reproduction are also embryos, not only ova and sperm.[28]

Another shortcoming of the legislation contained in the Transplantation Act is the issue of informed consent. According to Article 4(3) of the Transplantation Act, *"the written informed consent of the donor of reproductive human cells intended for partner donation shall include, in addition to the purpose of use, the possibility of using unused reproductive human cells for other reproductive purposes, for scientific research purposes, or their disposal*". If it is interpreted that reproductive human cells intended for partner donation include embryos,[29] according to the legal regulation, these can also be used for other reproductive purposes, other than partner donation.[30] The extent of the instruction within the framework of informed consent is also debatable.[31] In our view, the scope of the information

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[27] 17. rokovanie Vlády Slovenskej republiky, available at: https://rokovania.gov.sk/RVL/Material?SearchText=transplanta%C4%8Dn%C3%BD&EvidenceDateFrom=&EvidenceDateTo=&CompanyID=5&MaterialType=&IsAccepted=true&IsAccepted=false&IsPreparing=false&SearchInDocuments=true&SearchInDocuments=false [last accessed 6.4.2022].

[28] In our opinion, the interpretation in question is also implemented in the practice of assisted reproduction centres, since, in the case of the a contrario argument, assisted reproduction centres would dispose of surplus embryos outside the legally supported procedure. Both possible scenarios, *i.e.* that the reproductive cells intended for assisted reproduction purposes are also embryos, or the fact that the disposal of embryos that have not been used for application (for human use or because they have simply been assessed as "poor quality" in the pre-implementation diagnostic), storage or preservation, are disposed of without any procedures, arbitrarily, are, in our opinion, unacceptable from the point of view of moral and ethical criteria.

[29] An interpretation presented by us, which is possible due to insufficient legal regulation.

[30] What other reproductive purposes mean and what acts can be subsumed under them are not legally and legislatively defined.

[31] The aforementioned civic association objected to these facts in the inter-ministerial comment procedure. It proposed to reformulate the wording of the proposed provision of Section 4(3) of the draft Transplantation Act so that it would not be possible to use

required in the informed consent does not correspond to the scope required by Commission Implementing Directive 2006/17/EC implementing Directive 2004/23/EC of the European Parliament and of the Council.[32] There is no explicit mention in the Slovak requirements of specific instructions for liquidation, which in our opinion could raise justified moral and ethical dilemmas in clients.

4. Evaluation and Proposals *De Lege Ferenda*

Assisted reproductive techniques have become a common part of people's lives all over the world. It is a field that is growing exponentially and an increasing number of people are using these techniques. The Slovak Republic is no exception. Despite this fact, the legislation regulating these techniques is inadequate and raises justified concerns about the actual implementation of the related acts that make up the process of individual techniques. Conceived human life is treated as a consumable material which, if it does not meet the quality requirements, is destined for disposal, the criteria for which are not laid down in the legislation. The person who undergoes assisted reproduction techniques and who hands over reproductive cells for the implementation of a particu-

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an embryo created in a partner donation for other reproductive purposes of other persons, as well as for scientific research purposes. This substantive comment was rejected on the grounds that the proposed provision corresponds to the wording of the transposed Commission directive 2006/17/EC of 8 February 2006 implementing Directive 2004/23/EC of the European Parliament and of the Council as regards certain technical requirements for the donation, procurement and testing of human tissues and cells., OJ L 38, 9.2.2006, p. 40–52. *Vyhodnotenie*, *supra* note 24.

[32] According to Annex 4, point 2.5(a) of Commission Implementing Directive 2006/17/EC implementing Directive 2004/23/EC of the European Parliament and of the Council, informed consent in the case of reproductive cells intended for partner donation should include the consent, including the purpose(s) for which the tissues and cells may be used (e.g. for reproductive purposes only or for research purposes), and any specific instructions for the disposal of the tissue or cells that have not been used for the purpose for which consent was obtained. Cf. Commission directive 2006/17/EC of 8 February 2006 implementing Directive 2004/23/EC of the European Parliament and of the Council as regards certain technical requirements for the donation, procurement and testing of human tissues and cells, OJ L 38, 9.2.2006, p. 40–52, amended by Commission Directive 2012/39/EU of 26 November 2012, OJ 327, 27.11.2012, p. 53–54.

lar technique does sign a written informed consent, but in our opinion, this fulfils a rather formal criterion. The instruction and informed consent do not reflect the ethical and moral dilemmas of the acts in question. In our opinion, in this respect, the initiation of the processes of conscience and the evaluation of the consequences by the person giving the consent in question cannot even occur.

Notwithstanding the roots of natural law,[33] we assess that the legal regulation of assisted reproductive techniques in Slovakia is not in line with its requirements. In our opinion, it does not fundamentally protect conceived human life, as it does not give clear legal boundaries to the implementation of assisted reproduction techniques.[34]

We consider it necessary to point out at this point that the above presented shortcomings of the legal regulation of assisted reproduction techniques have been continuously persisting since the adoption of the Transplantation Act. From the point of view of *de lege ferenda* considerations, we propose, as part of at least partial elimination of ethical and moral dilemmas in connection with MAP techniques and overproduction of embryos, and thus the application of the requirements of the Natural Law, to specify the definition of reproductive cells intended for the purposes of assisted reproduction. In particular, we propose to determine whether or not embryos are also embryos in current practice. In view of the objections relating to the protection of life before birth, we propose that embryos should not be considered as reproductive cells within the meaning of the Transplantation Act.

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[33] That is, whether we are talking about natural law rooted in theological foundations, or natural law based on reason or laws of nature.

[34] We assess that a society-wide ban on assisted reproductive techniques would be a utopian scenario and therefore suggest that legislation should include limits on this activity and reasonable alternatives. The Czech Republic's legislation in this area is described as liberal. Irrespective of the ethical and moral assessment of this legislation, it should be noted that, despite the criticism voiced by the Czech scientific community, the Czech legislation reflects the practice carried out. It defines the term assisted reproduction and also names the various techniques of assisted reproduction. For more details, see the provisions of Section 3 of Act No 373/2011 Coll. on Specific Health Services, as amended. The Czech legislation is also more precise in the scope of informed consent. It explicitly requires consent also for the procedure in the case of surplus embryos. Cf. Ibid., Article 9.

Another critical remark in connection with the moral and ethical dilemmas in the field of assisted reproduction techniques is that the current legislation and the possibilities of financing infertility treatment from public health insurance in Slovakia do not provide persons who refuse assisted reproduction techniques[35] with any alternatives, even though alternatives do exist. It is the restorative reproductive medicine (hereinafter referred to as the 'RRM'). RRM includes lifestyle changes to improve health and reproductive function, educating women/couples to understand their fertility cycle and the fertile window, medical treatments supporting ovulation, implantation, immune function, spermatogenesis, and other physiologic processes related to fertility, and surgery to remove pathologic tissue and restore normal anatomy and function.[36] Central to the RRM approach is seeking to identify underlying causes or contributing factors.[37] A specific model of RRM is called natural procreative technology (also known as NaProTechnology), developed at Creighton University School of Medicine and the Saint Paul VI Institute for the Study of Human Reproduction.[38] It includes a stand-

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[35] From moral, religious, or any other reason.

[36] P.C. Boyle, T. de Groot, K.M. Andralojc, T.A. Parnell, "Healthy singleton pregnancies from restorative reproductive medicine (RRM) after failed IVF", *Front Med (Lausanne)*, 2018, Issue 5, available at: https://doi.org/10.3389/fmed.2018.00210 [last accessed 2.8.2022].

[37] Cf. T.W. Hilgers, *The medical and surgical practice of NaProTechnology*, Pope Paul VI Institute Press, 2004, pp. 477–494; p. Boyle, J. Stanford, "Natural procreative technology – a multifactorial approach to the chronic problem of infertility", *Biomedicina*, 2011, Issue 3, Vol 21, pp. 37–42.

[38] NaProTechnology was developed by American professor Thomas Hilgers and his collaborators. It is an abbreviation of the English "Natural Procreation", or "natural conception". The idea is precisely to look for the cause of a couple's failure to conceive and to treat it by the most natural means possible, so as to achieve a physiological state of the woman's and man's body optimal for natural conception. The founder of the method, Professor Hilgers, proclaims a success rate of 70-80% at his university department with excellent laboratory and surgical facilities. The real success rate achieved by clinical sites in Europe and North America is 40-50%. Compared with assisted reproductive techniques, this is therefore a comparable success rate. A certain disadvantage is the time aspect – the IVF method is able to achieve its success rate within one or two menstrual cycles, while the basic condition for a couple to participate in the NaProTechnology programme is patience – both diagnosis and treatment take months, sometimes years. However, the clear advantage is the naturalness of the whole process compared to IVF, as well as the cost, which is incomparably lower for the couple and health insurance com-

ardized system for educating couples about the fertility cycle, called the Creighton Model Fertility Care System (Creighton Model), and medical and surgical treatments to support conception in vivo,[39] a treatment using NaProTechnology, which became popular in Slovakia in 2005[40] and since 2012, treatment with this method has been available.[41] Currently, RRM and NaProtechnology often face criticism from mainstream medicine and MAP that they are not an appropriate methods of treatment for some infertility-causing diagnoses.[42] In fact, however, scientific studies have been conducted that confirm the efficacy of RRM and NaProTechnology and demonstrate its superior effectiveness over MAP techniques in the research studies.[43] RRM is also capable of being helpful in diag-

panies. I. Wallenfels, "Podstata NaProTechnológie", in J. Kaššák, *Podstatou naprotechnology je hľadať príčinu neplodnosti – rozhovor s gynekológom MUDr. Ivanom Wallenfelsom*, available at: https://www.unilabs.sk/clanky-invitro/podstatou-naprotechnology-je-hladat-pricinu-neplodnosti-rozhovor-s-gynekologom-mudr [last accessed 7.4.2022]. The entire method of NaProTechnology, as well as the Creigton model, is detailed and described on the basis of many scientific studies in the more than 1200-page medical monograph by prof. Hilgers. See: Hilgers, *supra* note 37.

[39] *Ibid*., pp. 43–56. Cf. Boyle, Stanford, *supra* note 37, pp. 37–42.

[40] Establishment of the civic association the PloDar.

[41] Cf. *NaProTECHNOLOGY – Moderná gynekológia pre vás,* available at: https://www.plodar.sk/napro/ [last accessed 7.4.2022]. In most European countries, the situation is similar to Slovakia, *i.e.* this method is not covered by public health insurance and is not promoted or financed like MAP techniques. The exceptions are countries with a strong Catholic base, namely Ireland, where probably the best NaPro doctor in Europe, Dr Phil Boyle, is based, and Poland, where several dozen doctors are active and NaProTechnology is available in practically every major city.

[42] It is important that the whole body of clinical evidence be taken into consideration. Far too often fields of interest or studies that never have been adequately funded are ignored, even though good science may support their use. What has become quite commonplace in this day and age is the publication of "committee opinions" by various professional organizations. This is particularly true when it comes to The American College of Obstetricians and Gynecologists, which strongly supports contraception, sterilization, abortion, and the artificial reproductive technologies, and, in fact, often is financially supported by these modalities. Thus, their "committee opinions" often ignore the "whole body of clinical evidence" and present an opinion that is biased in support of their own world view and the world view of their financial supporters. T.W. Hilgers, *The NaProTechnology Revolution: Unleashing the Power in a Woman's Cycle,* Beaufort Books, 2021, p. 392.

[43] Cf. Boyle, de Groot, Andralojc, Parnell, *supra* note 36; J.B. Stanford, T.A. Parnell, P.C. Boyle, "Outcomes from treatment of infertility with natural procreative technology in an Irish general practice", *The Journal of the American Board of Family Medicine,* 2008, Issue 5,

noses such as ovarian failure (exclusive of missing fallopian tubes or irreversible damage to the fallopian tubes or irreversible damage to the ovaries), endometriosis, obstruction, or restriction of patency of the fallopian tubes, and male factor infertility.[44]

Another advantage of this method is the search for and elimination of the real causes of infertility, and therefore it is really also a treatment in terms of content.[45] This method respects the human dignity of the couple seeking the cause of their infertility and, once the causes have been removed, conception can take place in a natural way that also respects the dignity of the life conceived. In view of the above, in our opinion, this method should be covered by public health insurance, as an alternative to assisted reproduction techniques. The scientific studies cited show that RRM has good results even after unsuccessful attempts at artificial insemination. RRM looks for the real causes causing infertility, and therefore we agree with the latest scientific recommendation that a full evaluation of underlying factors, and up to 12 cycles of cycle optimization, should be offered to subfertile patients before considering in vitro fertilization treatment.[46]

However, we have indicated the possibilities on the basis of which the legal regulation of assisted reproduction techniques could be adjust-

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pp. 375–384, available at: https://doi.org/10.3122/jabfm.2008.05.070239 [last accessed 2.8.2022]; G. James, L.A. Mclindon, J. Hatch, B.W. Mol, J.V. Turner, "Pregnancy outcomes from a restorative infertility treatment model: a single centre case series", *MedRxiv*, 2021, Issue 4, available at: https://doi.org/10.1101/2021.04.14.21251044 [last accessed 2.8.2022]; J.B. Stanford, P.A. Carpentier, B.L. Meier, *et al*. "Restorative reproductive medicine for infertility in two family medicine clinics in New England, an observational study", *BMC Pregnancy Childbirth*, 2021, Issue 21, available at: https://doi.org/10.1186/s12884-021-03946-8 [last accessed 2.8.2022]; P.C. Boyle, J.B. Stanford, I. Zecevic, "Successful pregnancy with restorative reproductive medicine after 16 years of infertility, three recurrent miscarriages, and eight unsuccessful embryo transfers with in vitro fertilization/intracytoplasmic sperm injection: a case report", *Med Case Reports*, 2022, Issue 16, available at: https://doi.org/10.1186/s13256-022-03465-w [last accessed 2.8.2022].

[44] All of these diagnoses (and others) with treatment through RRM are described in Hilgers, *supra* note 42, pp. 179–376.

[45] In the case of assisted reproduction techniques, we are of the opinion that their essence is not the search for causes or treatment.

[46] Boyle, Stanford, Zecevic, *supra* note 43. We see this recommendation as particularly appropriate in view of cause no. 4, on the basis of which MAP techniques covered by public health insurance are permissible, namely idiopathic sterility that is unsuccessfully treated for one year in a specialized medical facility.

ed, at least in certain directions, in accordance with the requirements of natural law.

II. Biomedical Research and Legislation in the Slovak Republic

"*Medicine is no longer just a means by which we confront disease, as it was in the classical understanding; it becomes a way to expand human possibilities. (...) But it is also a shift in our perception of what medicine is actually about; and an excessive shift can turn it into a set of neutral facts and techniques freely available to the individual, subject only to economic constraints.*"[47] In the 20th century, we witnessed several revolutions. In addition to the revolution in electronics and computer technology, our lives have been marked by the therapeutic[48] and biological revolutions.[49]

The biological revolution has far-reaching consequences for all of humanity: it affects the very essence of man. We can practically control three areas of our lives – reproduction, heredity, and the nervous system.[50] We have to admit that today we can experiment with life, we can

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[47] As early as 1997, such an assessment was made in the Final Report of an international multicentre research project, of which the Slovak medical research group was a part. The participants of the project formulated the challenges facing medicine in the years to come in a very prescient way. The Slovak research group also added to the Final Report its reservations on the issue of birth control and assisted reproductive techniques. The Slovak group expressed the opinion that there should be a more balanced formulation in this area, which satisfies those who promote respect for human life from the moment of conception until death. With regard to the topic discussed above, it is clear that the views of the Slovak research group have not been translated into Slovak legislation. Cf. "Cíle medicíny. Hledání nových priorít. Závěrečná zpráva medzinárodního multicentrického výzkumního projektu", *Medicínska etika a bioetika*, 1997, Issue 1, pp. 3–19.

[48] The therapeutic revolution began around 1937 with the discovery of sulfonamides, which gave man a weapon against diseases such as tuberculosis, syphilis, inflammation of the endocrine glands and the like. Cf. A. Švirková, *Morálne pozadie génových technológií*, p. 148, available at: http://webcache.googleusercontent.com/search?q=cache:DKQzjdGrQewJ:www.pulib.sk/web/kniznica/elpub/dokument/slancova2/subor/svirkova.pdf+&cd=1&hl=sk&ct=clnk&gl=sk [last accessed 9.4.2022].

[49] The biological revolution, which is an attempt by many to decipher the structure of DNA in the early 1950s, has become particularly important, *Ibid*., p. 148.

[50] Cf. *Ibid*.

change it, we can suppress one form of it and create another, and even in the future (with a high probability) we can modify and create people as we want them, with any characteristics, good and bad, even the same, according to our needs and preferences. These potentialities have also emerged with the successful mapping of the human genome, with the knowledge of DNA, and also with modern biotechnologies that make it all possible.[51]

We have presented above that, despite the fact that assisted reproduction techniques have been implemented in our territory since the 1980s, the legal regulation of these techniques in the Slovak Republic is insufficient and we have also pointed out the many natural law problems that arise from it. It is therefore not surprising that the new technologies are not regulated at all. Since the legislator usually lags behind the development of new scientific techniques with its standards, there are also areas of life that are not sufficiently covered by regulated by regulations, although such regulation would be desirable. However, with biotechnology in particular, a particularly important theoretical question is whether some areas of social relations can also be unregulated by legal norms, or whether law as such can be indifferent. In the category of areas that are under-regulated by law, we can usually include those areas of human activity that have, so to speak, newly emerged and had to be 'domesticated' by law, and this is where biotechnology, particularly gene technology, belongs.[52]

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[51] These are differentiated activities, which include, among others, cloning, various practices of reproductive technologies and genetic manipulations, the area of human enhancement precisely on the basis of genetic interventions, not only for therapeutic and preventive purposes, but also (purposefully programmed) for the purpose of various qualities of human beings that we desire. Cf. Z. Plašienková, "Bioetická problematika s dôrazom na vylepšovanie človeka v kontexte liberálnej eugeniky", in Z. Plašienková (ed.), *Biotické výzvy a súčasnosť: z pohľadu nových poznatkov a trendov*, Stimul, 2020, p. 46. It is not our intention to define new technologies in detail, to characterize them or to summarize the latest discoveries. The above is not even objectively possible owing to our qualifications. However, we do point out that new technologies are increasing exponentially, and some of them raise serious ethical and moral concerns that are the subject of debate. These debates concern the nature of man, and therefore natural law.

[52] Look for more: B. Fábry, "Biotechnologické výzvy a nedostatky právnej regulácie", in Z. Plašienková (ed.), *Biotické výzvy a súčasnosť: z pohľadu nových poznatkov a trendov.* Stimul, 2020, p. 68. Several scientific articles point to regulatory shortcomings and practical problems that are being addressed abroad in relation to modern technologies, such

1. Legal Regulation of Biomedical Research in the Slovak Republic

However, new technologies and their development are related to research, and we would therefore like to address the legal regulation of biomedical research and natural law issues at this point. The basic regulation of biomedical research in the Slovak Republic is regulated by Act No. 576/2004 Coll. on health care, services related to the provision of health care, and on the amendment and supplementation of certain acts, as amended (hereinafter referred to as the 'Health Care Act'). In the context of biomedical research, the Slovak Republic is bound by the Convention on Human Rights and Biomedicine with its additional protocols additions. According to the Convention on Human Rights and Biomedicine (1997)[53] (hereinafter '1997, the Convention') the interests and welfare of the human being shall prevail over the sole interest of society or science.[54] At the same time, the 1997 Convention limits intervention aimed at modifying the human genome. It can only be undertaken for preventive, diagnostic, or therapeutic purposes and only if its aim is not to introduce any modification in the genome of any descendants.[55] In the context of in vitro research on embryos, the 1997 Convention requires that where the law allows research on embryos *in vitro*, it shall ensure adequate protection of the embryo[56] a the creation of human em-

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as: I. Humeník, Z. Zoláková, Z. "Vybrané právne otázky s nakladaním so zárodočnými bunkami a embryami I." *Právo a manažment v zdravotníctve*, 2014, Issue 1, p. 2 and following; I. Humeník, Z. Zoláková, Z. "Vybrané právne otázky s nakladaním so zárodočnými bunkami a embryami II", *Právo a manažment v zdravotníctve*, 2014, Issue 2, p. 2 and following; T. Husovský, Z. Zoláková, "Právny status tela a oddelených častí tela I.", *Právo a manažment v zdravotníctve*, 2015, Issue 1, p. 1–5; T. Husovský, Z. Zoláková, "Právny status tela a oddelených častí tela II.", Právo a manažment v zdravotníctve, 2015, Issue 2, p. 1–8; A. Erdösová, "Využitie embryonálnych kmeňových buniek vo svetle ordre public", *Právo a manažment v zdravotníctve*, 2015, Issue 7–8, p. 1–8.

[53] Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine, Convention on Human Rights and Biomedicine, in Oviedo, 4.4.1997, Oznámenie Ministerstva zahraničných vecí Slovenskej republiky č. 40/2000 Z. z.

[54] Article 2 Convention on Human Rights and Biomedicine (1997).

[55] *Ibid*., Article 13.

[56] *Ibid*., Article 18 (1).

bryos for research purposes is prohibited.[57] Specific requirements for biomedical research were added by the Additional Protocol to the Convention on Human Rights and Biomedicine, Concerning Biomedical Research (2005) (hereinafter '2005, Additional Protocol'), which excluded from biomedical research on in vitro embryos and research on foetuses and embryos in vivo.[58] The obligations to which the Slovak Republic committed itself by ratifying the 1997 Convention and the 2005 Additional Protocol are reflected in the provisions of Article 26 et seq. of the Health Care Act.[59] It follows that it is not possible to carry out biomedical research on embryos and that research on embryonic stem cells is also excluded.[60] In this context, however, we consider it necessary to point out, in our opinion, the inconsistency of the Slovak legal regulation in the field of research on this ethically and morally exposed topic. The Health Care Act has set clear criteria in the area of biomedical research. However, the Transplantation Act uses the term 'scientific research purposes'.[61] Despite the fact that international human rights

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[57] *Ibid*., Article 18 (2).

[58] Article 2 (2) Additional Protocol to the Convention on Human Rights and Biomedicine, Concerning Biomedical Research, in Štrasburg. Notification of the Ministry of Foreign Affairs of the Slovak Republic No 494/2007 Z. z.

[59] "*Biomedical research includes any research activity in the fields of biology, medicine, pharmacy, nursing, midwifery, psychology, and medical radiation that may affect the physical or mental health of a person who participates in that research*." Provision of section 26(1) of the Health Care Act. "*Biomedical research shall be carried out freely, respecting the right to protection of dignity, to respect for the physical integrity and psychological integrity, safety and legitimate interests of the research participant. The interests of the research participant shall always take precedence over the interests of science and society.*" Provision of Article 26(3) of the Health Care Act. "*Research without medical indication may not be performed on a living human foetus or embryo.*" Section 26(10)(a) of the Health Care Act.

[60] In this respect, the Slovak Republic ranks among the countries with restrictive biopolitics, along with Poland, for example. (The Czech Republic and France rank among the countries with moderate biopolitics, allowing the creation of new human stem cell lines from supernumerary embryos coming from assisted reproduction clinics. The compromise biopolitics, represented by countries such as Italy and Germany, allow research on existing human embryonic stem cell lines. Permissive biopolitics, represented by countries such as the UK or Belgium, accept the creation of human embryos for research purposes). Cf. Fábry, *supra* note 52, p. 74.

[61] Pursuant to the provisions of Section 3(2) of the Transplantation Act, scientific research purposes are carried out according to standard operating procedures by a tissue establishment (Assisted Reproduction Centres carry out the activities of a tissue

treaties take precedence over national law,[62] and thus the provisions of the Transplantation Act are overridden by the 1997 Convention and the 2005 Additional Protocol, the inconsistency of the Slovak legislation, in our opinion, allows for a speculative interpretation that the regime of scientific research under the Transplantation Act is different from the regime of biomedical research.[63] The foregoing does not mean that the Slovak legislation is in conflict with the 1997 Convention and the 2005 Additional Protocol. In terms of monitoring compliance with the provisions of international conventions, the Health Care Act is a reflection of their requirements. The term 'scientific research purposes', which is introduced by the Transplantation Act and does not define what its content is, is problematic. We perceive this undefined term as a shortcoming of the Slovak legislation regulating biomedical research and related activities, which could have the characteristics of biomedical research in terms of content, but are not limited in any way. By such an interpretation, it may be possible to circumvent the principles protecting human foetuses and embryos[64] from illicit experimentation and research.[65] Partial protection against such a procedure is provided by the provision of Section 161(1)(b) of Act No. 300/2005 Coll. Criminal Act, as amended,

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establishment on the basis of a permit). Pursuant to Section 4(3) of the Transplantation Act, the written informed consent of the donor of reproductive human cells intended for partner donation shall include, in addition to the purpose of use, the possibility of using unused reproductive human cells for scientific research purposes. As noted above, there is no definition of what is meant by scientific research purposes. In our view, it is not biomedical research, since the Transplantation Act does not refer to a specific law, in this case the Health Care Act, for this concept. In our opinion, it may therefore be a different category of research, the limits and boundaries of which are missing from the legislation.

[62] "*International treaties on human rights and fundamental freedoms, international treaties the implementation of which does not require a law, and international treaties which directly create rights or obligations for natural or legal persons and which have been ratified and promulgated in the manner prescribed by law shall take precedence over laws.*" Article 7(5) of Act No. 460/1992 Coll. on the Constitution of the Slovak Republic, as amended.

[63] Which is in accordance with the 1997 Convention and the 2005 Additional Protocol.

[64] Given the definition of reproductive cells intended for assisted reproduction, which we wrote about above.

[65] We do not claim that such activity occurs or that such an interpretation applies. However, we draw attention to the insufficient legal regulation in this area, which is capable of abuse due to the shortcomings we specify.

defining the offence of unauthorised experimentation on a human being and cloning of a human being.[66] However, the criminality of, for example, tissue establishments (assisted reproduction centres) is questionable in this case, since the offence is linked to activities without the relevant authorisation and tissue establishments carry out their activities[67] on the basis of a permit from the Ministry of Health of the Slovak Republic.[68]

2. Evaluation and Proposals *De Lege Ferenda*

Slovak legislation, as already mentioned, is lagging behind in the field of new technologies. New technologies in biomedicine are often the result of research and, because of their sensitivity, encounter ethical and moral boundaries and limits set by natural law criteria. In our opinion, we have also identified very serious shortcomings in this area. Despite the fact that the Slovak Republic is internationally perceived as a state with restrictive biopolitics, the legislation is not clear in some places and allows for ambiguous interpretation.[69] In the field of research, this is the

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[66] *"Whoever, under the pretext of obtaining new medical knowledge, methods or to confirm hypotheses, or for the clinical testing of medicinal products, performs without authorisation the verification of new medical knowledge without medical indication and without the consent of the person concerned, or performs it on persons on whom verification without medical indication is prohibited, or performs it on a human foetus or embryo, or performs it in violation of other legal conditions for verification without medical indication, shall be punished by imprisonment for one to five years."* The wording of this offence has many shortcomings. Cf. Fábry, *supra* note 52, p. 70–71; E. Burda, *Trestné činy proti životu a zdraviu,* Heuréka, 2006, p. 148 and following.

[67] Pursuant to Section 3(2) of the Transplantation Act, scientific research purposes are also the subject of this activity.

[68] Provisions of Section 11(1)(c) of Act No. 578/2004 Coll. on health care providers, health care workers, professional organisations in the health care sector and on amendment and supplementation of certain acts, as amended.

[69] In this context, we would again draw attention to our western neighbours and their regulation. Czech legislation is consistent in the area of research on human embryonic stem cells. Apart from the fact that it allows research in this area on embryos derived from assisted reproduction techniques, it clearly legislatively links consent to research with informed consent in assisted reproduction techniques. Research in this field is regulated in the Czech Republic by Act No 227/2006 Coll. on research on human embryonic stem cells and related activities and on the amendment of certain related acts,

problem presented above with the scientific research purpose regulated by the Transplantation Act. Despite international legal obligations, the protection of life in its earliest stages can be compromised and incipient human life can be used as 'consumables' for scientific purposes. In this regard, we propose that the Transplantation Act legislation be clarified, for example by equating the scientific research purpose under the Transplantation Act with biomedical research under the Health Care Act. This can be done by means of a legislative and technical amendment by inserting a reference to biomedical research in the Health Care Act. However, in our opinion, the scientific research purpose of the Transplantation Act is not identical in content to biomedical research under the Health Care Act.[70] In our opinion, in the case of the scientific research purpose, this may include activities related to pre-implantation diagnosis and testing of reproductive cells and embryos carried out by tissue establishments (assisted reproduction centres) and, of course, other activities. We therefore propose that it should be clearly and precisely defined what is meant by the scientific research purpose, what techniques it involves, and what the ethical requirements are for carrying it out, so that there can be no speculative interpretation of the law and no threat to the protection of life. Accordingly, as we have already suggested above, informed consent should also be clarified with regard to the scientific research purpose in the case of donation of reproductive cells for assisted reproduction purposes.

With regard to the shortcomings of the offence of unlawful experimentation on a human being and cloning of a human being, in our opinion, an interdisciplinary discussion should be opened,[71] the result of which will be a new wording of the facts of the offence, which will reflect the existing legislation, will be in line with the current scientific knowledge, and will sanction universally unlawful acts in this field.

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as amended. In connection with this Act, the Czech Republic has also defined the concept of human embryo as *"human embryo totipotent cell or a grouping of such cells that are capable of being developed into a human individual"*. Section 2(d) of Act No 227/2006 Coll. on Research on Human Embryonic Stem Cells and Related Activities and on Amendments to Certain Related Acts, as amended.

[70] Owing to the complexity and precise requirements defined by the Health Care Act.

[71] For example, the creation of a working group whose members should be representative of different scientific disciplines (at least scientists, doctors, bioethicists, and lawyers).

We have pointed out that even in the case of conservative legislation, the natural law basis may be compromised or denied if the legislation does not sufficiently reflect all contexts. In the conditions of the Slovak Republic, this situation is supported by the shortened legislative procedure, amendments of deputies, which in many cases change the draft in contradiction with the inter-ministerial comment procedure and its evaluation, or the draft law is fundamentally changed by the recommendations of the advisory bodies of the Government of the Slovak Republic.[72]

Conclusion

Technology surrounds us at every turn, and often we many times are not even aware of its presence. In many cases, it makes everyday activities easier, or otherwise complicated tasks simpler. The positive effects of technology are, of course, unquestionable. However, technologies that oscillate around or directly touch or affect the core values of society need to be subjected to rigorous analysis. On the basis of knowledge of all the attributes of the functioning of such technologies, their legal functioning and legal basis must then be enshrined in the rule of law. Assisted reproductive technologies have been part of our lives for quite a long time. However, legislation in many countries lags far behind developments. The Slovak Republic is not one of the exceptions. The question remains as to whether the legislation is lagging behind deliberately, as incomplete legislation allows for a greater dispersion of activities that are not clearly regulated by law, or whether the inadequate and unclear

[72] For example, comments from the Legislative Council of the Government of the Slovak Republic, as was the case with the Transplantation Act. In our opinion, it is contrary to the principle of transparency of the state and public administration that the comments made by an advisory body, which significantly change the text of a draft law that has undergone a regular comment procedure, should not be publicly available and should not be written down at all, as has been confirmed to us by the Government Legislation Department of the Office of the Government of the Slovak Republic. In our opinion, the comments in question should have been duly written down, together with a statement of reasons and the name and surname of the member of the advisory body who made the comment in question.

legislation is the result of the shortcomings of legislative activity and the political clash of conflicting views. Both reasons are of concern. It is therefore worth reflecting on whether this process is leading to a situation where the legislator's action is being replaced by spontaneous developments in biomedical disciplines. In our opinion, the tendencies so far suggest that, on the one hand, the legislator is unable to keep pace with scientific developments when, in spite of the current state of scientific knowledge, it is still legally relegating a nascent human life to being a part of the mother's body or biological material. On the other hand, it is very benevolent with regard to research in this area. Such tendencies carry the risk of promoting so-called biopower, which may in future be substituted for legislative action.[73]

Assisted reproductive technologies, more than other technologies, enter into the human rights arena, into the issue of the protection of the conceived life and human dignity. The Slovak Republic subscribes to these values and is a party to a number of international conventions that enshrine these values. However, in the area of the legal regulation of assisted reproductive technologies, in practical terms, this may only be a declaratory protection. We have pointed out that, in the absence of a legal definition as to whether an embryo is considered as reproductive cells, there may be the unregulated destruction of large numbers of lives conceived by assisted reproductive technologies. Statistics in this area are lacking and the extent of data is insufficient. As of 2015, the competent authorities have not ensured a real start of the functioning of the National Registry of Assisted Reproduction. Its role is partially replaced by the National Transplantation Organisation, whose statistics are incomplete and data are not consistent. In the light of the natural-law assumptions and ethical dilemmas arising from the practical performance of assisted reproduction techniques, without real data and reliable information, society is unable to form an idea of the number of destroyed embryos that have not met the qualitative prerequisites laid down by assisted reproduction centres for transfer or cryopreservation. The ethical context is also difficult for clients giving informed consent to realise, given the requirements imposed by Slovak legislation on the scope of the information required. Another identified shortcoming is

[73] Cf. Valc, *supra* note 20, p. 22.

the absence of alternatives for citizens who for some (any) reason refuse assisted reproduction techniques, even though alternatives exist. In this respect, therefore, there may be discrimination in access to health care covered by public health insurance.

In the context of biomedical research, we have pointed out the possible double-track nature of research, namely, on the one hand, biomedical research, which is a legally limited procedure with precise rules and boundaries, and the scientific research purpose according to the Transplantation Act, which, on the contrary, has no rules and no boundaries. In this area, Slovak legislation cannot even rely on protection through criminal law norms, since the facts of the offence of unauthorised experimentation on a human being and cloning of a human being show significant shortcomings in practical terms.

In our opinion, we have demonstrated the confirmation of the hypothesis stated in the introduction of this study that the legal regulation of assisted reproduction techniques and biomedical research in the Slovak Republic is insufficient, does not reflect the implemented practice, and allows interpretations and application that are not in accordance with the natural law assumptions. At the same time, we have suggested possibilities on the basis of which natural law could be at least partially made sufficient. The modifications we propose would, in our view, alleviate the ethical and moral dilemmas arising from these technologies.

In April 2000, Wired magazine published a controversial article titled "Why the Future Doesn't Need Us", authored by William Joy, cofounder and chief scientist at Sun Microsystems. In this article, Joy called for a moratorium on research in three technological areas – artificial intelligence, nanotechnology and genetic engineering. He noted that while we are poised to make rapid technological advances in each of these three areas, our understanding of the ethical issues that these technologies inevitably raise lags far behind.[74] 22 years have passed since that warning, and many of the concerns are still valid, as developments are moving forward by leaps and bounds. However, the paradox

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[74] W. Joy, "Why the Future Doesn't Need Us", *Wired*, 2000, available at: https://www.wired.com/2000/04/ joy-2/ [last accessed 28.2.2022].

remains that not only is Slovak society lagging behind in addressing the ethical issues of modern technologies, but the Slovak legislation that is supposed to provide human rights protection has not even addressed the understanding of ethical issues in relation to technologies that actually work and are implemented.