



An ethical and juridical characteristics of a fertility protection for the future

Charakter etyczny i prawny zabezpieczenia płodności na przyszłość

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Abstract:

The act on treatment of infertility passed on 25th June 2015, regulates, inter alia, rules for collecting germ cells from patients in order to perform the procedures of medically assisted procreation specified in the act. Collection of gametes, apart from the compliance with medical criteria, also requires an informed consent expressed by a patient who is a donor.

Moreover, the legislator specified an additional germ cells collection mode to protect fertility in the future. Doubts are created here not only as to the establishment of such institution, but also as to admissibility of gametes collection based on the so-called surrogate consent, formulated by a statutory representative or in the form of an authorisation granted by a guardianship court.

Laid down by the act admissibility of germ cells collection without a prior consent expressed by the entities referred to above and subsequent filing of a motion in court for the authorisation, is a separate subject.

The primary aim of the paper is to consider legal structure of fertility protection for the future, and consequently to examine compatibility of legislative solutions, applied in the act on infertility treatment with the standards of a democratic state with the rule of law, specified in the Constitution of the Republic of Poland of 2nd April 1997, in particular in relation to the right to privacy and the principle of proportionality.

Keywords:

fertility protection for the future, medically assisted procreation, infertility treatment act, surrogate consent, democratic state with the rule of law, principle of proportionality, patient autonomy, right to privacy.

Streszczenie:

Uchwalona w dniu 25 czerwca 2015 r. ustawa o leczeniu niepłodności reguluje, między innymi, zasady pobierania od pacjentów komórek rozrodczych w celu przeprowadzenia określonych w ustawie procedur medycznie wspomaganey prokreacji. Pobranie gamet, poza spełnieniem kryteriów medycznych, wymaga również wyrażenia świadomej zgody przez pacjenta, będącego ich dawcą.

Ponadto, ustawodawca określił dodatkowy tryb pobierania komórek rozrodczych w celu zabezpieczenia płodności na przyszłość. Wątpliwości budzi nie tylko powołanie tej instytucji, ale także dopuszczalność pobierania gamet na podstawie tzw. zgody zastępczej, wyrażanej przez przedstawiciela ustawowego lub w formie zezwolenia, wydawanego przez sąd opiekuńczy. Osobnym zagadnieniem jest przewidziana przez ustawę dopuszczalność pobrania komórek rozrodczych bez wcześniejszego wyrażenia zgody przez powyższe podmiotów i następcze wystąpienie do sądu o wydanie zezwolenia.

Celem artykułu jest przede wszystkim rozważenie, jaka jest konstrukcja prawa zabezpieczenia płodności na przyszłość, a w dalszej kolejności zbadanie zgodności rozwiązań ustawodawczych, zastosowanych w ustawie o leczeniu niepłodności, ze standardami demokratycznego państwa prawnego, określonymi w Konstytucji Rzeczypospolitej Polskiej z dnia 2 kwietnia 1997 r., w szczególności z prawem do prywatności oraz zasadą proporcjonalności.

Słowa kluczowe:

Zabezpieczenie płodności na przyszłość, medycznie wspomaganą prokreacją, ustawa o leczeniu niepłodności, zgoda świadoma, demokratyczne państwo prawne, zasada proporcjonalności, autonomia pacjenta, prawo do prywatności.

The issue of human fertility constitutes one of the key questions in bioethics, causing much controversy that is transferred to the political and to some extent, to the social debate. The above matter contains views related to the nature of human existence, start of life, scope of protection of human embryo and foetus, finally the limits of permissible medical interventions, including in particular the realm of biotechnology and genetics. It is essential to note that the subject of fertility triggers strong

reactions, leading to fierce doctrinal disputes and, on the social dimension, to regrettable acts of aggression such as the case of attempts on lives of doctors performing terminations of pregnancy.

The objective this article is intended to pursue is not to present the entire ethical problem related to human biogenesis, nonetheless it is reasonable to present the outline of two major groups of ethical views in this area: those de-

defined as the trend in bioethics taking into account transcendental perspective, and those deriving from bioethics disregarding such perspective [1].

Bioethics allowing for transcendental perspective is based on the assumption there is an instance, higher than human, functioning as a source of moral rights and final indicator of what should be done and what is not worthy of doing. The goal of a man is to properly read and use moral rights which stem from the order of things defined as natural or divine. The main argument referred to by the supporters of the discussed direction in bioethics is the argument of human dignity, instructing

the idea of human dignity, it is defined here in a different manner. Dignity results from a human being, from rational nature which distinguishes it from other living beings. Having reason imposes the obligation on a person to act in a moral manner, for awareness implies taking into consideration the consequences of their actions [3]. In turn, a common and uniform canon of principles that should be used in every situation does not exist, as opposed to individually understood hierarchy of values.

As far as human fertility is concerned, bioethics allowing for transcendental perspective claim that artificial intervention into the natural order of human biogenesis is morally wrong

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to treat human existence as an end and never as a means. This imperative not only sets a certain sphere which cannot be violated by other people, but also creates a scope of obligations imposing a form of internal limitation on every man. Human dignity is inherent and it arises from the act of creation itself [2]. In Polish circumstances the discussed trend in bioethics has mainly the nature of Christian bioethics.

On the other hand, bioethics where transcendental perspective is not taken into consideration, points out an individual must seek moral law within themselves, as only they can function as the indicator of what should be done and what is not worthy of doing. Although this trend in bioethics does not reject

because it leads to instrumentalisation of human fertility, to the opposition against either the natural order or judgements of God [4]. The experience of infertility cannot be recognised unambiguously as wrong, since the suffering connected with it may give rise to self-improvement. It shall be noted here that arguments supporting recognition of medical intervention as natural or artificial are not always sufficiently precise to constitute the basis for scientific discourse. Moreover, the criteria are not fixed but in a strong sense depend on the popularity of a given practice [5].

Supporters of bioethics neglecting transcendental perspective present quite the opposite view. Referring to an individual choice of every human being, as a matter of principle they ar-

gue in favour of the consent for artificial intervention into the sphere of human biogenesis [6]. Its admissibility, as in case of every other act of a man, is determined by evaluation of the consequences of taking or failing to take specific actions and by the analysis of possible infringements of other person's rights.

As it appears from the analysis above, dominating views related to human biogenesis are in contradiction to each other, which makes regulation of this sphere by the legislator in a way that could gain social acceptance, conditioning purpose-related effectiveness of the laid down standards, even more difficult. It must be noted though, that lack of any regulation creates a situation where decision which practices in the field of human biogenesis are admissible is taken by individual entities providing applicable services, in accordance with the principle allowing for everything that is not forbidden. Such state of affairs is hard to accept as proper. Since the state assumed the obligation to protect health of its citizens, it should not allow for taking decisions in that field on the basis of free play of market forces.

On 25th June 2015 the Sejm passed the act on Infertility Treatment (Journal of Laws 2015 item 1087, hereinafter referred to as the act), which includes regulations for medically assisted procreation. The assumed solutions may be deemed as an attempt to reach compromise between extreme positions and expectations. On one hand the legislator prohibits certain interventions which cause the most vigorous ethical reactions (such as creating chimeras and human-animal hybrids), and at the same time it regulates procedures of infertility treatment, against which ethical reactions are slightly more balanced. Topic of this article shall be exclusively limited to consid-

eration of legal and ethical characteristics of future fertility protection, referred to in article 5 clause 1 of the act, as one of the treatment methods.

Article 4 of the act defines rules that must be observed when undertaking medical procedures aimed at infertility treatment, including respect for human dignity and the right to private and family life, with particular regard for legal protection of life, health, best interest and rights of the child. Consequently, the legislator declared respect of the principle of dignity resulting from the Constitution of the Republic of Poland, as well as the right to privacy, which constitute fundamental pillars of a democratic state with the rule of law and at the same time, key values adopted by bioethics, both accepting and neglecting transcendental perspective.

Fertility protection for the future is defined in article 10 of the act as medical actions undertaken in case of the risk of loss or significant impairment of the ability to procreate and aimed at protection of fertility. Interpretation of the above regulation shows that the presented definition is affected by *idem per idem*-type error. For the term of fertility applied therein seems to be nothing else but the ability to procreate. Serious interpretative problem is also related to the phrase used by the legislator, namely: "significant impairment" which has an underdefined character. The act does not determine this notion, provoking possibility of differing interpretations of individual factual conditions, and in consequence, consolidation of incoherent procedures, depending on specific doctors. Medical actions, likewise determined in the commented article, have not been specified in any way, as a result of which the definition of fertility protection for

the future acquires a blanket nature. It shall therefore be assumed the legislator's intention was to admit all medical actions which are not directly forbidden by law in a situation where ability to procreate is exposed to the risk of loss or significant impairment. The procedure of gamete collection from a patient in order to perform *in vitro* fertilization will be of distinct importance, for in accordance with article 31 clause 3 of the act, germ cells collected in order to protect fertility for the future may be used to perform the procedure of medically assisted procreation, both as part of partner as well as other than partner donation.

Explantation of gametes from a patient, performed in order to protect their fertility for the future is admissible after total fulfilment of conditions specified in article 31 clause 1 of the act. The legislator requires a doctor to determine legitimacy of germ cells collection on the basis of the present state of medical knowledge, with the reservation that the collection cannot endanger donor's health and life. Before performing explantation, a doctor is also obliged to carry out medical interview and necessary medical and laboratory examination with a view to assess if the collection-related risk does not exceed tolerable risk for this type of procedures, explantation does not cause significant impairment of the donor's health condition and if it is possible to reduce the risk of significant adverse event or reaction of a donor, recipient or children that may be born as a result of use of the collected cells under the medically assisted procreation procedure. A potential donor is bound to attest in written form that information presented during the medical interview is true and to the best of their knowledge.

In order to perform germ cells collection to protect fertility in the future, a patient must

produce their consent, however, the procedure of granting consent considerably differs from the one defined in article 34 of the 5th December 1996 act on Professions of a Doctor and a Dentist (Journal of Laws 1997 No. 28 item 152) and in article 18 of the 6th November 2008 act on Patients' Right and the Commissioner for Patients' Rights (Journal of Laws 2009 No. 52 item 417) and thus it requires to be discussed in more detail. First of all, the legislator necessitates that a potential donor, prior to their consent is expressed, should receive fully detailed and easily comprehensible information about the type of procedure, its purpose and character, laboratory examinations required to perform it and the right of access to its results, risk related to the procedure and its foreseeable consequences to the donor's health. Moreover, a doctor is required to provide information about medical confidentiality, mode of collecting and protecting personal data of a donor and possibility of using the collected germ cells in medical assisted procreation procedure. The legislator additionally introduced the requirement to ensure that the patient has the possibility to ask questions covering the information referred to above and to obtain detailed information. Such possibility must be confirmed by the patient in writing.

Once the information is provided by a doctor in a manner depicted above, the patient may express their voluntary consent to undergo the procedure of explantation of gametes to protect fertility for the future. It is required by the legislator that the consent should have a written form expressed in a doctor's presence.

In case of a potential donor who is a minor or incapacitated person, the consent may be expressed in writing by a statutory representa-

tive, and an additional requirement includes a written consent of the patient themselves, providing they enjoy partial legal capacity. If, on the other hand, a patient is incapable of giving informed legal consent or obtaining a written consent from a statutory representative is not possible, collection of gametes is authorised by a guardianship court. At the same time the legislator allows for obtaining a sequential authorisation of the court, following performance of the procedure, if particularly justified cases, which have not been defined in the act though, occur. Should the court refuse to grant sequential authorisation or in case a donor, having regained their capacity to give informed legal consent, refuses to provide one, collected germ cells shall be subject to immediate destruction.

It must be pointed here that if patient's death occurs prior to collection of germ cells, then despite earlier expressed consent (from the

admissible, unless their explanation occurs after the donor's death.

As it appears from the presented analysis of provisions in the act on infertility treatment, fertility protection for the future consists in provision of medical services, particularly resulting in the possibility to create an embryo in the future, with the use of germ cells (gametes) collected from a donor threatened with loss or significant impairment of the ability to procreate. Assumption of such definition confirms that the legislator indeed made *idem per idem*-type error in article 10 of the act, while the wording "aimed at protection of fertility" shall be amended accordingly.

Still, the above discussion cannot yet lead to an obvious answer to the question what legal characteristics of future fertility protection is. Pursuant to article 5 clause 1 of the act, it is one of the health care services,

Personal rights to maternity and parenthood cannot be derived from the article 18 of the Constitution, that states that maternity and parenthood are covered by care and protection of the Republic of Poland.

patient or in the form of surrogate consent or authorisation granted by a guardianship court) performance of explantation shall be inadmissible, for explicit prohibition, pursuant to article 24 of the act, shall be applicable. If, however, the expressed consent should cover post-mortem use of the collected germ cells as well as donation of the embryo created with the use of those cells, then pursuant to article 30 clause 1 point 7) their use shall be

while in accordance with article 68 clause 2 of the Constitution of the Republic of Poland, that state is obliged to provide its citizens equal access to such services, if they are financed from public funds. Therefore, if fertility protection for the future is financed or co-financed from the health contributions, the patients could expect principles of provision of the services will be based on the medical criteria exclusively, which does not

exclude granting the citizens right to claim the above services.

Constitution of the Republic of Poland does not establish a separate right of the citizens to have children or to the ability of procreation. Although article 18 of the Constitution indicates that maternity and parenthood are covered by care and protection of the Republic of Poland, personal rights to maternity and parenthood cannot be derived from the above article. Opposite conclusion would lead to bizarre consequences, including the possibility to assign to the state a positive responsibility for enabling an individual to exercise their right to parenthood.

The above line of reasoning is fully supported by the result of application of systemic interpretation. Article 18 was not placed in chapter II of the Constitution, where freedoms, rights and obligations of persons and citizens are defined, but in chapter I entitled "The Republic". The above considerations direct us to accept that article 18 of the Constitution provides a guideline only for the ordinary legislator and does not form basis for personal rights to maternity and parenthood.

The right to medical services provided as part of fertility protection for the future can be derived in turn from the content of article 68 clause 1 of the Constitution, establishing everyone's right to health protection. Since the activities are aimed at recovery from infertility, and thus health protection, they are subject to personal rights of every individual in the Republic of Poland [7].

In a democratic state with the rule of law, health services are provided on the basis of informed, voluntary consent, expressed

by a patient, and forming the fundamentals of partnership-based model of healthcare. Informed consent can be recognised only when it is granted after detailed and easily comprehensible information on the planned medical procedure, its course, foreseeable consequences [8], adverse reactions as well as possible alternative methods, is provided by a doctor. Voluntary character of giving a consent covers minimisation of doctor or other person's influence on the decision to be taken by a patient. The ability to decide on one's own health condition formulates basis for the legislator's recognition of a patient as a legal subject, which is essential in as much as the experience of illness justifies increased protection of such subjectivity.

In the infertility treatment act, apart from allowing for voluntary participation in the procedure of fertility protection for the future by persons who are able to express their informed consent, also situation of those who owing to their age or health condition do not have such competence, is regulated. As mentioned earlier, on behalf of those individuals a surrogate consent is granted by a statutory representative, whereas if such representative is not appointed or their consent cannot be obtained, the authorisation is granted by a guardianship court. Taking the decision on providing medical service on behalf of other person, which constitutes the expression of paternalism [9], is regarded as an exception from the patient's autonomy principle referred to above. Within the legal framework, paternalism shall be considered in the context of limiting the right to privacy and self-determination, resulting from article 47 of the Constitution. Each case of paternalism, constituting a restriction in exercising constitutional right and freedoms, shall be examined for compliance with the

principle of proportionality contained in article 31 clause 3 of the Constitution. In order to find the provision introducing restriction as consistent with the above principle, three conditions, also referred to as tests of: legality, necessity and proportionality as such, must be fulfilled. The requirement of legality means a restriction may be introduced only in an act, the necessity test evaluates if the restriction is necessary in a democratic state for protection of values listed in a form of a catalogue: security, public order, environment, health, public morality or freedoms and rights of other individuals, while proportionality as such is executed in the requirement for the restrictions not to infringe the essence of the restricted freedoms and rights, maintaining at the same time the balance between the purpose of restriction and measures used by the legislator to achieve it.

Analysis of the provisions introducing the possibility of germ cells collection from a patient under surrogate consent, requires in the first place defining what value is placed by the legislator above the gametes donors' right to self-determination, and subsequently, evaluating if the value fits into the catalogue determined in article 31 clause 3 of the Constitution. A separate evaluation shall refer to the provisions regulating conditions for explanation of germ cells from a donor incapable of giving their consent, without prior obtaining a surrogate consent or authorisation from a guardianship court by a doctor to conduct the procedure.

The discussed restriction of a patient's freedom in terms of the choice of medical services was introduced in the act on infertility treatment, and thus the condition of legality resulting from the principle of proportionality

shall be deemed as fulfilled. As refers to the analysis of the introduced restriction's compliance with the necessity condition, it must be noted that the right to fertility cannot be regarded as an autonomous personal right, protected by the Constitution, but only as the element of a wider category of the right to protection of health. Although article 31 clause 3 of the Constitution provides for the possibility of limiting constitutional freedoms and rights by virtue of health protection, still as it appears from interpretation of the whole provision, this does not refer to protection of health of an individual but to the protection of public health. It is primarily demonstrated by the fact that all other conditions for the restriction, expressed in the discussed provision, refer to intersection of legally protected spheres of interest of the individual and the general public, and not to the rights of the individual alone. Claiming that the legislator made an exception only in one case, that is health protection, would thus be groundless. In addition, it must be noted that article 31 clause 3 of the Constitution does not allow for limitation of constitutional freedoms and rights by virtue of life protection. Concluding a fortiori from the above norm, it shall be assumed that since the legislator does not allow for restriction of rights and freedoms of an individual to protect their life, all the more such restrictions are not allowed to protect their health. Thereby, limitation of the patients' right to privacy due to the intention to treat infertility infringes the principle of proportionality in terms of the requirement of necessity.

Also, the proportionality test as such of the discussed solution seems to bring negative results. Bioethics distinguishes several parenthood types [10], including genetic parenthood which consists in the origin of one or

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ganism from the other. Genetic relation does not constitute an indicator of authenticity or quality of interpersonal ties, though. Much stronger bond is defined by social parenthood, characterised by conscious acceptance of the role of a parent, disregarding the fact if true relationship exists or not. Accepted solutions related to fertility protection for the future identify the legislator's recognition of precedence of genetic parenthood over its other types. Attention should be given here to axiological inconsistency of the act on infertility treatment which indeed allows for solutions aimed at taking into account other parenthood types, biological one for example. Pursuant to the rule defined in article 47 of the Constitution, a person has the right to act in accordance with their own view of the world. The legislator's role is not to approximate the citizen's beliefs but to ensure possibility for their co-existence within ideological pluralism [11]. Consequently, ensuring possibility of having children shall not be limited only to provision of genetic information, as it would constitute an unjustified objectification of the donor and donor's reduction to the source of genetic material. The above comment becomes particularly important under the provision of article 31 clause 2 sentence 2 of the act which allows for collection of germ cells

without a consent of both the patient and their statutory representative and without court's authorisation. Granting of sequential authorisation by the court does not result in the state of compliance every person is entitled to by inherent dignity, both in terms of bioethics taking into consideration and disregarding the transcendental perspective. A man cannot be treated only as a means to an end, even if the goal is their own fertility.

It must be underlined here the legislator indicated in the act itself that respect of human dignity must be ensured during the infertility treatment procedures. Collection of germ cells from a person who is not able to express their consent to it shall be regarded as violation of their dignity, which takes on a particularly striking character in terms of explantation performed without a prior surrogate consent or authorisation granted by a guardianship court.

As an aside we might here note that similar doubts were expressed by the President of the Republic of Poland B. Komorowski in his motion to the Constitutional Tribunal to investigate compliance of the act on infertility treatment with the Constitution, as refers to article 31 clause 2, article 5 clause 1 point 6 and article

31 clause 2 in conjunction with article 10. In the President's opinion the contested act may endanger subjectivity of every person, their personal freedom and the right to decide on personal matters [12], which could be defined as the right to dignity and the right to privacy. The Constitutional Tribunal will be required to consider the above plea, but already today careful approach to the possibility of collection of germ cells to protect fertility for the future, from persons who are not able to express their informed consent to it, should be postulated.

The act on infertility treatment constitutes a significant document aimed at regulation of the issue of human biogenesis. As it is depicted in the first part of the article, the questions referred to in the act do not give rise to unambiguous ethical reactions, which is reflected in a difficulty to adopt regulation that will be ac-

ceptable for the majority of society. Nevertheless, creation is no longer within the realm of natural processes only and human interventions into that sphere may be dangerous on one hand and morally dubious on the other. The legislator cannot free himself from responsibility for regulation of the matter, even if the legislative act should result in negative reactions of a part of the society. For, lack of any regulation provokes a situation where decisions on the essential issues related to human biogenesis are taken by entities conducting their activities in the field of infertility treatment for profit, which may cause doubts associated with their ethical sensitivity. Identified threats linked to regulation of fertility protection for the future shall not provide the basis for negation of the entire act, but should serve as a stimulus to undertake work to remove them.

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