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Introduction

We hope the readers of this volume of "Białostockie Studia Prawnicze" [Białystok Legal Studies] will find the issues presented herein not only interesting for lawyers but also representatives of medical environments. This volume is devoted to medical law issues; a new and very dynamically developing branch of law. The articles published herein most of all deal with the patient's rights and their restrictions. Many texts depict a key issue of establishing limits of patient's autonomy in the healthcare system[1]. As long as patients act according to generally adopted rules and follow doctors' instructions, their competence to request the performance of specific interventions or consent to proposed treatment is not questioned. It may be undermined, however, in case of the conflict between the patient's requests and doctors' opinions on the patient's interest. The problem becomes even more complicated when we take into account not only doctors' opinion but also moral attitudes of the public to the admissibility of specific medical interventions. Limits of patient's autonomy are more often than not designated by legal regulations, which does not imply that *modus operandi* expressed therein is not subject to debate and controversy any more.

For the above reason, this volume contains articles devoted to parents' aspirations to create an "optimal child" within the procedures of medically assisted procreation. The authors are also interested in the so-called "windows of life"; the need for their existence and functioning has been shown in the context of fundamental human rights (the right to life *versus* the right to know one's own identify). Most articles (including the review) have been devoted to the issues of establishing limits of autonomy of minor, incapacitated and terminal patients. They are defined as vulnerable persons who require special legislative support followed by unique legal solutions. Another subject considered herein are issues concerning the adoption

1 This problem was the subject of the II National Scientific Conference: Patient's Law. The limits of the patient's autonomy (Białystok, April 15-16, 2016) organized by the Student Circle of Medical and Pharmaceutical Law "Pro Humanae Vitae" and the Department of Civil Law at the Faculty of Law of the University of Białystok. Some of the articles sent to the editorial office are the results of the discussions during the event, for which I would like to express my gratitude to everyone who took part in the conference.

of a specific model of consent for deceased organ transplantation as well as issues connected with the application of involuntary treatment.

Scholars from all parts of Poland including young scientists (PhD and undergraduate students) have been invited to take part in this publication. We hope that considerations contained in this volume will be sufficiently aspiring to evoke a debate leading to further publications.

Urszula Drozdowska
Volume Theme Editor
Białystok, May 2017

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Current problems of Preimplantation Genetic Diagnosis in the Context of Parental Aspirations

Abstract: Preimplantation genetic diagnosis (PGD) is designed to assist in conception when a serious hereditary disease affects a couple and it is necessary to screen out embryos carrying chromosomal or genetic abnormalities. The procedure may therefore be lawfully applied only for medical reasons to avoid a particular risk of transmitting genetic defects to a child regardless if the couple is infertile or not. In practice, PGD raises many ethical objections as a method which – as the doctrine says – commodifies reproduction and enables unwanted practice of positive eugenics (a selection of embryos of a particular sex or carrying certain qualities, let alone particular defects (deafness, blindness, etc.). Parents may be prone to choose the features of their future child and decide, by means of PGD, to have a baby of a certain sex, genetic make-up, or to conceive a tissue match for a living sibling. The legislator should therefore intervene, establish the normative framework for the practice of PGD, and keep continuous control over its application to prevent the abuse of the child's welfare.
Key words: preimplantation genetic diagnosis, medically assisted procreation, embryo selection, sex selection, designer baby, saviour sibling, welfare of the child

1. General comments on preimplantation genetic diagnosis

1.1. The nature and objectives of PGD

IVF (in vitro fertilisation), which in recent years has become a common and constantly enhanced and upgraded technique, allows not only to conceive a child in a laboratory and induce pregnancy[1] but also provides a possibility to control gametes

1 IVF is the most common method of medically assisted procreation (MAP), as a result of which – from the birth of Louise Brown (1978) – approximately 5 million children were born. The effectiveness of this procedure is systematically increasing because of the introduction of improvements, including the use of micromanipulation (for instance ICSI – intracytoplasmic sperm injection). See more on this problem M. Nesterowicz, Prawo medyczne, Toruń 2016, p. 341 and following and in the foreign literature, A.B. Thomas, Avoiding EMBRYOS "R" US: Towarda

and select them properly in order to create an embryo characterized by specific features and genetic profile. In particular, it is possible to carry out preimplantation genetic diagnosis (PGD), i.e. the procedure of retrieving (by biopsy) one or two cells from a developing embryo (in the phase of 4-8 cell blastomere) and the analysis of their DNA as well as chromosome structure before implantation in the mother's uterus or cryopreservation (freezing)[2]. Blastomere's cells that are picked, as emphasized, without detriment to further undisturbed embryo's development contain genetic information of both parents that is crucial for the future child's health and condition[3].

A fundamental purpose of PGD is to evaluate and select non-defective embryos (screening out), whose transfer to the woman's uterus (immediate or subsequent – after cryopreservation) assures high probability of conceiving and delivering a child free of disorders (impairments)[4]. Genetically defective embryos that have an improper anatomical structure or inappropriate chromosome structure are destroyed or designated for research upon the gametes donors' consent[5]. As a rule

Regulated Fertility Industry, "Washington University Journal of Law and Policy" 2008, vol. 27, p. 248.

2 See: R. Słomski, J. Kwiatkowska, H. Chlebowska, Diagnostyka molekularna, (in:) J. Barciszewski, K. Łastowski, T. Twardowski, Nowe tendencje w biologii molekularnej i inżynierii genetycznej oraz medycynie. Tom II, Poznań 1996, p. 331 The first successful PGD procedure was conducted in the United Kingdom in 1989 to determine the sex of the child and thus eliminate the risk of transmission of a sex-linked genetic disease. After the method became popular, in the years 1990-2006 approximately 5,000 cycles of PGD were performed in the world. E. Jackson, *Medical Law. Text, Cases*, *Materials*, Oxford 2006, p. 840. In Poland until the mid-1990s, PGD was an experimental method; The intense development of technology in the 21st century has led to the improvement of procedures from which in the years 2000-2009 about 30 children were born. See: O. Nawrot, Diagnostyka preimplantacyjna w prawodawstwie Rady Europy, "Zeszyty Prawnicze Biura Analiz Sejmowych" 2009, No. 2, p. 43 and J. Kapelańska-Pręgowska, Preimplantacyjna diagnoza molekularna w międzynarodowych standardach wiążących i zalecanych, "Prawo i Medycyna" 2009, No. 2, p. 86.

3 J.K. Mason, R.A. McCall Smith, G.T. Laurie, Law and Medical Ethics, London-Edinburgh 2002, p. 194. Medicine knows also the preconception diagnostics involving the examination of the so-called the directional body of an egg cell, which allows only the genetic material from a woman to be assessed. O. Nawrot, Diagnostyka…, *op. cit.*, p. 42

4 Over 2/3 of the total number of PGD procedures are performed to detect chromosomal abnormalities (e.g., trisomy 21), the risk of which increases with the age of the genetic mother; the remaining 1/3 refers to the already mentioned elimination of serious sex-related genetic diseases (eg Turner syndrome, characteristic of the female sex, hemophilia occurring in the male sex) and the so-called autosomal recessive genetic diseases (eg Tay-Sachs). Cited after E. Jackson, *Regulating Reproduction, Law Technology and Autonomy*, Oxford 2001, p. 242. See also J. Kapelańska-Pręgowska, Zjednoczone Królestwo i Republika Włoska – dwa bieguny diagnostyki preimplantacyjnej, (in:) L. Bosek, M. Królikowski(eds.), Współczesne wyzwania bioetyczne, Warszawa 2010, p. 403 and following.

5 E. Jackson, Medical…, *op. cit.,* p. 840.

(and in compliance with the objectives of the legal systems of most countries), PGD is therefore a method allowing genetically impaired couples to conceive a child without a risk of transmitting a genetic disease or other serious defects and disorders onto their children[6]. PGD may be applied in such circumstances even if a couple is medically fertile and capable of conceiving a child without the need to rely on the procedures of the above-mentioned procreation. IVF, however, allows spouses (partners) not only to avoid a risk of transmitting hereditary defects and disorders onto their children but also enables them to fulfil the parent project and give birth to a child that is genetically related to both parents without the need to use donated gametes in the MAP procedures[7]. On the other hand, different from the so-called prenatal diagnosis carried out after inducing pregnancy and involving a genetic test of an embryo *in utero* (foetus), PGD enables to avoid the transfer if embryo's anatomical or structural irregularities are detected, and thus it prevents possible termination of pregnancy for eugenic reasons[8].

PGD procedure, which is complicated and requires suitable technical equipment as well as specialist preparation and expertise (and thus it is relatively expensive[9]), is subject to constant improvement as it allows identification of a still increasing number of genetic mutations and chromosome anomalies while recently it has even become possible to establish a risk of developing specific types of cancer (e.g. breast or colon)[10]. Despite objections raised by some representatives of the doctrine, ethics

6 *Ibidem.*

7 IVF combined with PGD and the evaluation of embryos formed from the gametes of steam is, in particular, a beneficial alternative to the procedure of artificial insemination by donor's semen (artificial insemination by donor – AID). See: M. Brazier, E. Cave, Medicine, Patients and the Law, London 2011, p. 367.

8 Por. P. Krajewski, Eugeniczna selekcja embrionów, (in:) L. Bosek, M. Królikowski (eds.), Współczesne wyzwania bioetyczne, Warszawa 2010, p. 69 and in the foreign literature, G. Nicolau, L'infl uence des progres de la génétique sur le droit de fi liation, Bordeaux 1989, p. 351 and following. The Authors aptly point to the fact that avoiding the need to perform an abortion in the event of fetal defect detection is important especially for the mental condition of the woman; it saves her serious suffering.

9 The procedure costs from about USD 10,000 to about USD 21,500. The literature emphasizes that these amounts constitute a serious barrier to the use and access to PGD, which otherwise could be carried out preventively in most IVF cycles due to the significant diagnostic value. J. Kapelańska-Pręgowska, Preimplantacyjna…, *op. cit.,* p. 86.

10 Since the application of PGD for the first time in 1991 to determine the embryo's charge on cystic fibrosis (a genetic disorder unconjugated with sex but conditioned by a single gene defect), preimplantation diagnosis enables the detection of the most important chromosomal aberrations and about 30 so-called monogenic diseases (induced, like cystic fibrosis, mutations within individual genes). In the medical literature, however, it is argued that in the near future preimplantation tests are likely to include diseases resulting from the interaction of many genes and environmental factors (e.g. schizophrenia, Alzheimer's disease). J. Kapelańska-Pręgowska, Preimplantacyjna…, *op. cit.,* p. 85. See also J. Bal, W. Wiszniewski, J. Wiszniewska, Diagnostyka

and Church[11], PGD is currently a medical procedure commonly carried out in most countries worldwide (including Poland[12]) in legally and medically justified cases. Bans on the use of preimplantation diagnosis, valid only in the legislation of Germany (until 2011), Switzerland (until 2013) and Austria (until 2015) are not upheld, and they are abolished by the legislators due to the above mentioned benefits provided by PGD on the one hand, and non-compliance of the ban with the right to respect for one's private and family life guaranteed by Art. 8 of the European Convention on Human Rights[13].

1.2. Prerequisites for the application of preimplantation diagnosis

Rules (directives/prerequisites) for the application of preimplantation diagnosis procedures have been depicted in international documents, in particular in the Council of Europe Recommendations, i.e. Ad Hoc Committee of Experts on Progress in the Biomedical Sciences CAHBI titled *Human Artificial Procreation* of 10 January

molekularna, (in:) J. Bal (ed.), Biologia molekularna w medycynie. Elementy genetyki klinicznej, Warszawa 2006..

11 The opponents of PGD argue that preimplantation diagnosis is a manifestation of undesired eugenic practices, because it allows the selection of embryos due to their "genetic quality". Parents who use PGD can create "custom" offspring (designer baby), guided by their own subjective preferences or current social patterns. See: D. King, Preimplantation Genetic Diagnosis and the "New" Eugenics, "Journal of Medical Ethics" 1999, vol. 25, p. 178; Robertson Ethical Issues in New Uses of Preimplantation Genetic Diagnosis, "Human Reproduction" 2008, vol. 18, p. 465 and following and in the Polish literature M. Gałązka Prawo francuskie wobec embrionu in vitro, "Państwo i Prawo" 2000, No. 6, p. 71. In addition, as it is emphasized, PDG is connected with the necessity of creating supernumerary embryos which are destroyed aft er the procedure (which in the Church's teaching is considered a form of abortion practices). See: T. Smyczyński, Aksjologiczne i prawne podstawy dopuszczalności wspomaganej prokreacji, (in:) J. Haberko, M. Łączkowska (eds.), Prawne, medyczne i psychologiczne aspekty wspomaganej prokreacji,Poznań 2005, p. 92.

12 See: art. 26 ust. 1 of the Act of 25 June 2015 on the treatment of infertility (Journal of Laws of 2015, item 1087) [Ustawa z dnia 25 czerwca 2015 r. (Dz. U. z 2015 r. poz. 1087). However, PGD was carried out in a wide range before the Act came into force (INVICTA Infection Clinic is recognized as a pioneer, since the end of the 1990s it has been tested for the identification of cystic fibrosis, Down syndrome, Patau, Turner and Edwards syndrome). Cited after: O. Nawrot, Diagnostyka… *op. cit.*, p. 43.

13 The European Court of Human Rights in the judgment of 28 August 2012 in the case Costa and Pavan vs Italy (application No. 54270/10) expressis verbis stated that the statutory prohibition of PGD, contained in the Italian law of 2004 on medically assisted procreation, violates art. 8 of the Convention. In the Court's opinion, the right to conceive a child free from genetic encumbrances falls within the scope protected by the Convention of private and family life (the case concerned of healthy couple who carriers a cystic fibrosis who after conception of a child burdened with illness and eugenic abortion demanded the use of PGD in order choose embryos free of defects). J. Dute, European Court of Human Rights. ECHR 2013/9 Case of Costa and Pavan vs Italy, 28 August 2012, No. 54270/10 (Second Section), "European Journal of Health Law" 2013, No. 3 (vol. 20), pp. 315-316.

1989[14], and Recommendation R(90)13 of the Committee of Ministers of the Council of Europe of 21 June 1990 on prenatal genetic screening, prenatal diagnosis and associated genetic counselling[15]. As a rule, the legislation of individual countries contains these prerequisites strictly and restrictively. As a desired diagnostic tool enabling identification of impairments and, at the same time, a means of their elimination, PGD may be applied solely in exceptional cases, i.e. when there is a risk of transmitting a genetic disease onto a child or/and other serious defects and impairments (e.g. one or two spouses or partners suffer from a hereditary disease or are its carriers, or they already have a congenital child). This rule is particularly reflected in Art. 2 par. 4 of the Swedish Act of 18 May 2006 on genetic integrity, which stipulates *expressis verbis* that PGD may be applied solely when due to confirmed predispositions of a man or/and woman to develop a serious hereditary disease, a risk of giving birth to a child suffering from a genetic disease or other kind of serious impairment is high. A "medical" prerequisite of PGD's application has been similarly formulated in Art. 1455 of the Greek Civil Code (added by the Act of 27 January 2005 on the above mentioned procreation), in § 2-14 of the Norwegian Act of 5 December 2003 on the application of biotechnology in medicine, Portuguese Act on MAP of 2006 (Art. 7), and the provisions of the Spanish Act of 2006 (Art. 12)[16]. Moreover, most countries additionally introduce (in the practice of hospitals or clinics' activity, or under the law) the obligation to confirm a risk of transmitting a hereditary

14 The 1989 CAHBI recommendation does not explicitly refer to PGD, but indicates that the avoidance of a genetic disease or other serious hereditary condition should be a necessary condition for the legal application of MAP procedures. The wording of Principle 17 results, however, in the admissibility of cell collection from the embryo solely for the purpose of diagnosing the disease or developmental defect and the negative selection of embryos intended for implantation (screening out). The Polish text of the Recommendation – T. Jasudowicz, Europejskie standardy bioetyczne. Wybór materiałów, Toruń 1998, p. 107.

15 The Polish text of the Recommendation – T. Jasudowicz, Europejskie…, *op. cit.*, pp. 123-127. This document, along with the Recommendation of the Council of Europe No. 1100 of 2 February 1989 on the use of human embryos and foetuses in scientific research were a breakthrough in the approach to PGD and meant a change in the policy of the Council of Europe in this area. While the previous recommendations (e.g. Recommendation No. 1046 of 24 September 1986) were to provide individuals and society with protection against threats resulting from interference in the embryo and genetic manipulation, the primary goal of Recommendation R (90) and 1100 was to create unhampered conditions access to PGD by persons (couples) at risk of transmitting hereditary diseases to offspring (see point 9 of Recommendation R (90)) and Annex (A) of the Recommendation No. 1100). More on this subject O. Nawrot, Diagnostics..., *op. cit.*, pp. 53-56. See also the Report of the International Bioethical Committee of UNESCO of 2006 indicating the conditions for the legal conduct of PGD. J. Kapelańska, Preimplantacyjna ..., *op. cit.*, p. 95.

16 About regulations relating to medically assisted procreation in individual European and world countries see Steering Committee of Bioethics (CDBI) – Replies by the Member States to the Questionnaire on Access to MAP and on Right to Know About Their Origin for Children Born After MAP, Strasbourg 9 February 2012, www.coe.int/t/dg3/healthbioethic/Activities/04_Human_embryo_and_foetus_en/INF_2005_7%20e%20MAP.pdf (accessed: 23 December 2016).

disease or genetic defect by an expert. Before undertaking IVG/PGD procedures, the Portuguese Act on MAP of 2006 in particular requires a couple to obtain a written certificate issued by a unit (centre) of prenatal diagnosis confirming that due to a family situation, spouses (partners) are very likely to give birth to a child suffering from a hereditary disease recognized as incurable at the moment of diagnosis[17]. The French law envisages similar rules, where medical legitimacy of the application of PGD is confirmed by the opinion of the Council of Genetics[18] and Belgian solutions[19] modelled thereon. Due to emerging interpretive doubts, on the one hand (especially about the form of a serious disease justifying diagnostic intervention), and objections raised by the opponents of interference in an embryo, on the other hand, the most recent regulations depict the above mentioned PGD's prerequisites more precisely indicating exhaustively cases when this practice is admissible (the British Act on Human Fertilization and Embryology of 2000, hereinafter referred to as HFEA 2008)[20], and even formulating a definition of a hereditary disease justifying PGD (the Austrian Act on MAP of 1992 in the amended reading of 2015)[21]. On the other hand,

17 V.L. Raposo, Assisted Reproduction. Two Models of Regulation: Portugal vs Spain, "Jornal Brasiliero de Reprodução Assistida" 2012, No. 1 (vol. 16), p. 35 and following.

18 M. Nesterowicz, Ochrona osobowości, prokreacja medycznie wspomagana i inżynieria genetyczna w prawie francuskim, (in:) Teoria prawa. Filozofia prawa. Współczesne prawo i prawoznawstwo. Księga pamiątkowa ku czci Profesora W. Langa, Toruń 1998, p. 204. More on this see: A. Laucle, B. Matthew, D. Tabuteau, Droit de la santé, Paris 2009, p. 633 and following.

19 According to art. 67 of the Belgian MAP Act of 2007, the evaluation of the existence of therapeutic interest (medical premise justifying PDG – emphasized by K.B.R.) is done by the MAP clinic, however its final position should take into account the opinion of the human genetic research center (included obligatory in the medical records). G. Pennings, Belgian Law on Medically Assisted Reproduction and the Disposition of Supernumerary Embryos and Gametes, "European Journal of Health Law" 2007, vol. 14, p. 258.

20 HFEA 2008 allows PGD to detect embryos of genetic, chromosomal or mitochondrial disorders (anomalies) and the selection of the future child's sex in a situation where the inheritance of a specific form of defects is gender-related, and the choice allows the conception of offspring-free offspring. On the basis of the provisions of the Act, a woman (couple) can be given preimplantation diagnosis functions, if the risk of transmission of the indicated anomalies is significant and has a specific character in a specific case and will either result in the offspring of a patient suffering from defects or even a healthy child, but disability (serious disability), illness or other form of disorder (other medical conditions) is likely to develop only later in life. More on this subject see: J. Herring, Medical Law and Ethics, Oxford 2012, p. 389 and literature given there.

21 The provision of § 2a, added to the Austrian MAP Act in 2015, permits PGD only in three situations: when, after a minimum of three IVF attempts, pregnancy cannot be invoked, there are grounds to conclude that genetic defects of reproductive cells are the cause, and secondly, in the event of at least three medically proven spontaneous miscarriages or births of a lifted and potentially fatal genetic embryo and, thirdly, when there is a significant risk of miscarriage, stillbirth or a hereditary disease in one of the two parents due to the genetic predisposition of one or both parents (Erbkrankheit). Erbkrankheit was defined in the act as a disease in which maintaining a child's life is possible only with the use of complicated medical equipment or the use of devastating medical procedures significantly reducing the quality of life. The statutory

there are only few legal systems depicting the application of GPD in a general manner while the legislator is merely limited to indicate that preimplantation diagnosis is admissible *verba legis* solely for medical reasons (the same as Art. 26 par. 1 of the Polish Act on Infertility Treatment). Such formulations neither secure interests of entities engaged in the IVF/PGD procedures nor sufficiently protect embryos because, as underlined in the doctrine, they particularly evoke a risk of development of adverse (undesired) practice of positive eugenics[22].

From a juridical point of view, spouses or partners must, first of all, agree for the performance of PGD. As a rule, their consent is written and embraces their will to collect (retrieve) and carry out diagnostic tests necessary to detect potential defects and impairments (the same as, e.g., the above-mentioned Art. 1455 of the Greek Civil Code)[23]. According to general rules referring to the legality of medical interventions, the consent is effective if it is given after the interested parties have been informed about the nature, aims, benefits and typical risks ensuing from the procedure[24]. As far as PGD is concerned, couples are fully and exhaustively informed about the procedure before it is performed even though it is no longer an experimental method implying a wide inclusion of the obligation of information. The obligation to provide a couple with above-standard information about the PGD's nature, purpose, risk and benefits connected with, *inter alia*, biopsy of embryo cells, their assessment and selection, is a consequence of a close relation between PGD and MAP (IVF) procedures whose application requires informing the woman (couple) about all and any medical (and legal) aspects of the undertaken interventions[25]. The rule envisaging a wide scope of the obligation of information has been set forth *expressis verbis* in the laws of many countries, among others in Art. 66 of the Belgium Act on MAP of 2007, which obliges a clinic/hospital performing IVF/PGD to inform a couple about these procedures with due diligence (*une information loyale*)[26]. A wide approach to the obligation of information is desirable and undeniably accurate. Spouses (partners) should be fully informed about the treatment before making a decision as the procedure is, in

concept of inherited disease also refers to diseases manifested by a serious brain injury or other form of an incurable disease that does not promise improvement and causes considerable pain and suffering.

22 See: for e.g. J. Lipski, Opinia prawna na temat rządowego projektu ustawy o leczeniu niepłodności, "Zeszyty Prawnicze Biura Analiz Sejmowych" 2015, No. 4 (vol. 48), p. 145.

23 See also principle 6 of the Recommendation R (90) 13 13 of Committee of Ministers of the Council of Europe of 21 June 1990, according to which prenatal and preimplantation tests should be performed on the basis of conscious and free consent of interested persons. More on this subject see: O. Nawrot, Diagnostyka…, *op. cit.*, p. 56.

24 K. Bączyk-Rozwadowska, Prawo pacjenta do informacji w świetle uregulowań polskiego prawa medycznego, "Studia Iuridica Toruniensia" 2012, No. 1, p. 59 and following.

25 M. Świderska, Zgoda pacjenta na zabieg medyczny, Toruń 2007, p. 324. See also principle 17 of Recommendation CAHBI of 1989.

26 G. Pennings, Belgian…, *op. cit.*, p. 258.

principle, undertaken upon their initiative and in order to conceive a child free of genetic defects and disorders. Awareness of potential risks or failures connected with the treatment may, in particular, impel a couple to consider other possibilities to fulfil the parent project and abandon IVF/PGD for the sake of, e.g., MAP's heterological techniques, especially AID or in vitro fertilisation with the use of gametes (embryos) *ab alieno*.

In some countries (Great Britain, France or Poland) the obligation of information has been complemented by obligatory specialist or/and expert counselling, recommended in international documents[27], to be given to individuals interested in PGD. Mandatory genetic counselling (by the Council of Genetics) is in particular envisaged by the French law[28] as well as Polish Act of 25 June 2015 on Infertility Treatment, which encompasses genetic counselling necessary to apply PGD as an element of medical MAP counselling envisaged in the provisions thereof (Art. 26 par. 1 in connection with Art. 5 par. 1 point 1)[29]. On the other hand, in the system of English law, the rule envisaging obligatory counselling does not ensue from the law but the Code of Good Clinical Practice (HFEA Code of Practice, VIII ed. of 2009, § 10 par. 4-6), which complements statutory HFEA 2008 regulation and sets binding standards of MAP procedure to be applied by experts. Nevertheless, the implementation of obligatory counselling is of great practical significance – it helps explaining doubts connected with the application of IVF/PGD procedures and, in particular, as confirmed by the practice, enables to establish genetic disorders parents would like to avoid in their future child (subjectively finding them serious), and thus assess whether they are encompassed by the statutory definition of serious disability/illness/impairment[30].

In some legislations (e.g. French, Swedish or Norwegian), PGD may be applied solely after obtaining a positive assessment or consent of an appropriate competent interdisciplinary body, e.g. a state committee or bioethical commission[31]. The adoption of such a solution, recommended in international documents (e.g. the CAHBI Recommendation No. 17 of 1989), means that each case of PGD's application is assessed *ad casum*, including an individual situation of a specific person or couple.

27 See principle 14 Recommendation R (90) 13 of the Council of Europe of 21 June 1990, in which Member States were recommended to create conditions for easy access and dissemination of knowledge about counseling in the sphere of PGD.

28 M. Nesterowicz, Ochrona…, *op. cit.*, p. 204.

29 See: J. Haberko, Ustawa…, *op. cit.*, p. 164 and following.

30 M. Brazier, E. Cave, Medicine…, *op. cit.,* p. 368. Por. R. Scott, C. Williams, K. Ehrich, B. Farside, The Appropriate…, *op. cit.,* p. 320.

31 The French law allows PGD after obtaining a positive opinion from the National Bioethics Commission (Agence de la biomédecine); under the Swedish Genetic Integrity Act of 2006, the use of IVF / PGD procedures depends on the approval of the State Social Commission, while the Norwegian Act of 5 December 2003 requires the approval of the state commission appointed by the Ministry of Health.

Arbitrariness, undeniably desirable and approvable, enables to establish real motifs of future parents to perform embryo diagnosis and selection, and may prevent too widespread application of PGD beyond indicated statutory framework and for other reasons than those envisaged by the law (e.g. a selection of gender for social reasons)[32].

Due to its close relation to the procedures of medically assisted procreation (IVF), PGD requires the fulfilment of specified institutional and substantial conditions. In particular, it is necessary to fulfil a mandatory and typical of any MAP manifestation condition to provide treatment by a qualified entity or/and in an authorized centre which has obtained a state licence or permit[33]. On the one hand, this requirement ensues from the need to guarantee a high level of sanitary security to entities taking advantage of MAP (IVF/PGD) procedures as well as a due quality of service provided by appropriately qualified staff in required premises and under appropriate technical conditions[34]. On the other hand, the system of licence provides a State with a possibility of supervising and monitoring PGD practices as well as minimizing a risk of potential abuse in the sphere of medical services which, due to their nature and aim (interference in the process of procreation), should be provided solely within the limits of law.

On the one hand, the introduction of far reaching restrictions to the application of preimplantation diagnosis and its exceptional character (as a medical procedure envisaged solely for individuals affected by or carrying genetic diseases or mutations/abnormalities) result from the above mentioned necessity to counteract undesirable practices, especially positive embryo selection and unjustified manipulation in

32 In countries where the law does not provide for the approval or opinion of a special committee, the burden of making an assessment and making a final decision on the implementation of PGD lies with the MAP clinic (see, for example, the already mentioned Article 67 of the Belgian Act on Assisted Procreation of 2007). Moreover, due to the link between PGD and IVF, the infertility treatment clinic may refuse to undergo diagnostic activities, citing the contradiction of such activities with the good of the future child. The principle of the welfare of the child is in most legislations the final criterion for verifying the legitimacy of subjecting a woman (couple) to MAP procedures.

33 Model solutions for the licensing system are provided by HFEA 2008, according to which individual authorization is necessary to conduct PGD in each of the five permitted cases. (in 2011, the Office for Human Fertility and Embryology issued about 100 permits). More on this subject see: J. Herring, Medical…, *op. cit.*, p. 390 and the literature give there.

34 The obligatory European standard in this regard are set in the so-called tissue directives, in particular 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 EU L 102, 7.4.2004, pp. 48-58) and the 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 (Text with EEA relevance) (OJ EU L 330M, 28.11.2006, pp. 162-174).

human genome. On the other hand, restrictive regulation protects in vitro embryos and appears to sufficiently satisfy the postulate of treating this form of existence with due respect (human being deserving special respect) and in accordance with the adopted concept of respect[35].

Yet the practice confirms that despite creating an organizational framework of PGD's application, both in recommended international standards and domestic law, undesirable cases of going beyond permitted limits do occur. Currently, there are particular aspirations to use PGD for purposes other than original, i.e. the selection of gender for reasons other than avoidance of transmitting a serious disease onto a child such as creation of a child with specific features (designer baby) including, similar to parents, designer disability, or tissue match for older siblings affected by a serious life threatening illness (saviour sibling). If the above practices occur, the legislator is obliged to evaluate them from the perspective of valid laws and principles of ethics (taking into account future parents' interest and child's welfare) and, if necessary, undertake appropriate steps aimed at potential legalization or new bans. The discussed regulation is based on the assumption according to which the performance of PGD diagnosis for health (medical) reasons is morally justified contrary to procedures pursued for other reasons than medically justified.

2. The so-called saviour sibling

Apart from the evaluation of embryos and selection of non-defective ones, preimplantation diagnosis provides a possibility of the so-called tissue typing (HLA typing), i.e. establishing whether a specific embryo matches the so-called HLA Antigen (Human Leukocyte Antigen) of a living child of the couple subject to PDG that is affected by a serious life threatening illness. The child born in effect of such embryo's implantation (saviour sibling) becomes a donor of stem cells contained in cord blood which are used to treat an ill brother or sister when other methods of treatment have failed or are unavailable[36]. Therefore PGD/IVF is performed not only

35 The concept of dignity presupposes that a human embryo is neither a person nor an object (an object of property), but is an intermediate category (interim category), which deserves a particular respect due to the provision of a unique human genetic code and the potential to become a human (potential for human life). See for example the judgment of the Supreme Court of the state of Tennessee in the case *Davis vs Davis* of 1992 (842 S.W. 2d. 588), cited after Ch.P. Kindregan, M. McBrien, Assisted Reproductive Technology. A Lawyer's Guide to Emerging Law and Science, Chicago 2011 (second ed.), p. 113. See also W. Lang, Wstępna charakterystyka problematyki statusu płodu ludzkiego, (in:)W. Lang (ed.), Prawne problemy ludzkiej prokreacji, Toruń 2000, pp. 1617 and O. Nawrot, Status prawny pre-embrionu, "Państwo i Prawo 2009" No. 2, p. 15 and following..

36 M.W. Wolf, J.P. Kahn, Using Preimplantation Genetic Diagnosis to Create a Stem Cell Donor: Issues, Guidelines and Limits, "Journal of Law Medicine and Ethics" 2003, vol. 31, p. 331 and following.

in order to legally select an embryo free of anomalies that older siblings are affected by (screening out) but it also assumes a selection (to establish HLA Antigen match) and choice of an embryo with specific features (screening in), which, as emphasized by the literature, is a manifestation of positive eugenics[37].

By all means, Kant's moral imperative forbidding treating human beings merely as means (treatment of another child) but as an end itself speaks against PGD performed in order to choose an embryo that will be used to conceive a child just to become a donor of cells or tissues. Opponents of such practices argue that a child "designed" as saviour sibling (saviour embryo) may, in their future life, after finding out about the circumstances of their conception, experience serious mental torment especially if the establishment of tissue match does not succeed and donorship will eventually be excluded[38]. According to another important argument raised in the literature, admitting embryo selection in order to conceive "a saviour child" is a step towards the acceptance of further manifestations of positive eugenics, e.g. a choice of an offspring of a specific gender, phenotype, IQ, or other features or predispositions desired by parents (designer baby)[39].

On the other hand, the performance of PGD in order to choose an embryo of a desired HLA structure is supported by the fact that this procedure may prevent death of a terminally ill child (sibling) especially if blood transfusion is the last available therapeutic method. Here benefits of preimplantation diagnosis prevail over its negative aspects, in particular crushing a fundamental argument of tissue typing opponents, i.e. quality selection. Saving sibling's life is principally perceived as a beneficial action that is positive from the point of view of a donor, or at least not harmful to him or her[40]. Moreover, harm that in PGD opponents' opinion may be experienced by a saviour child in his or her future life is only hypothetically possible (potential), and it should not be a barrier preventing a diagnostic procedure. As it is underlined in the literature, we cannot exclude here an opposite situation – joy and other positive feelings ensuing from helping older siblings[41]. What is more, the practice proves that PGD combined with tissue typing in many cases enables to counteract pregnancy termination since parents of an ill child often strive for conceiving next offspring naturally hoping for HLA match and often choosing abortion in case of failure[42].

The first legislation that admitted PGD to determine tissue match due to a scientifically proven lack of a serious risk for a created child and a therapeutic

37 See e.g. G. Pennings, Belgian..., *op. cit.*, p. 258.
38 M.W. Wolf, J.P. Kahn, Using…, *op. cit.*, p. 332.
39 See: E. Jackson, Medical…, *op. cit.*, p. 849.
40 S. Sheldon, S. Wilkinson, Hashmi and Whitaker: An Unjustifable and Misguided Distinction, "Medical Law Review" 2004, vol. 12, p. 137 and following.
41 J. Herring, Medical…, *op. cit.*, p. 396 and the literature given there.
42 E. Jackson, Medical…, *op. cit.*, p. 849.

purpose of this method was enacted in Great Britain. Prerequisites of the legal performance of the procedure developed in connection with a landmark ruling in the case of Hashmi – Quintavalle (on behalf of Comment on Reproductive Ethics) vs. Human Fertilisation and Embryology Authority (3 All ER 257) of 2003, which is the basis of a future statutory regulation (HFEA 2008)[43]. The Court of Appeal ruled that HFEA (Human Fertilization and Embryology Authority) did not violate valid laws issuing a licence to perform PGD in order to select saviour embryo. The Court decided that the practice of admitting PGD combined with tissue typing should be found lawful on the grounds of the Act to the extent in which it assisted to carry a child of a couple affected by a risk of transmitting a genetic disease. The reasons to the judgment emphasized that the process of facilitating woman's pregnancy without a fear that a child will be at a risk of being affected by a serious hereditary illness lies within the limits of a statutory concept of treatment, that is assisted conception[44].

In 2004, in connection with another motion for PGD combined with tissue typing (in the so-called Whitaker case)[45], the prerequisites of the legal performance of embryo selection were updated. The most important change involved the extension of PGD to cover cases where a saved child (alive sibling) suffered from a serious genetic disease, not necessarily inherited from both or one parent but initiated by a self-contained genetic mutation (e.g. Diamond-Blackfan anemia). The scope of admissible interference into the saviour child's body conceived to life for a therapeutic reason also embraced bone marrow aspiration apart from the collection of stem cells from the cord blood (which occurred in the Hashmi case). On the other hand, stricter rules on tissue typing were manifested in the introduction of the prerequisite

43 The case concerned a 6-year-old child suffering from thalassemia beta (a serious genetic disease leading to anemia and requiring frequent blood transfusions) whose parents after subsequent failures in treatment and inability to find a blood donor asked the MAP clinic for tissue typing. The clinic, after obtaining the permission of the HFEA Office, led to the creation of 14 embryos, none of which, however, met the criteria for HLA compliance with a sick child. Further attempts were halted due to ethical circles' opposition, including CORE (Comment of Reproductive Ethics) organization. In a lawsuit filed against the court, CORE questioned the legality of the clinic's activities, undermining in particular the purpose of issuing the license – immoral and unethical creation of a child "on order." N. Karczewska, Prokreacja medycznie wspomagana w prawie angielskim, "PiM" 2010, No. 1, pp. 98-99 See also E. Jackson, Medical…, *op. cit.*, p. 850.

44 M. Brazier, E. Cave, Medicine…, *op. cit.*, pp. 367-368. Por. E. Jackson, Medical…, *op. cit.*, p. 849.

45 The application was submitted by the parents of a child affected by the severe form of Blackstone-Diamond anemia. However, unlike in Hashmi, the HFEA Office did not grant a MAP license to the surgery, justifying the refusal by the fact that the child's illness was not inherited condition, but was the result of a spontaneous genetic mutation. This decision provoked opposition from the legal doctrine and bioethics, who pointed to the unjustified differentiation of children suffering from serious genetic disorders depending on the cause of the disease. Under the influence of criticism, the HFEA Office changed the decision and allowed the clinic to carry out tissue typing for therapeutic purposes. M. Brazier, E. Cave, Medicine…, *op. cit.*, p. 369. More on this subject see: S. Sheldon, S. Wilkinson, Hashmi…, *op. cit.*, p. 137 and following.

of a prior use of all and any therapeutic possibilities available home and abroad to help a living child before a woman or couple could be subject to PGD. In the light of 2004 instructions, HLA typing was assumed to be an exceptional as well as final method of treatment (alleviating symptoms) of a serious genetic disease (option of last resort)[46].

At present, pursuant to the amended HFEA 2008, embryo selection aimed at a choice of "a saviour embryo" is one of the five admissible cases of the legal performance of PDG and requires (the same as each of these options) an individual licence granted by the Human Fertilisation and Embryology Authority. According to the provisions of the Act (Schedule 2 § 1 ZA), PGD combined with tissue typing may be performed solely for therapeutic reasons, i.e. to help the siblings of a child conceived to life provided this help shall be limited to donating stem cells of core blood, bone marrow or other tissues excluding body organs and their parts[47]. Deciding about the legitimacy of performing PGD in each specific case, a MAP clinic is obliged to consider precisely the circumstances of the case related to the living child, a potential donor (saviour sibling) and parents. From the point of view of the siblings, it is, most of all, necessary to consider the nature and kind of an illness, an extent/degree of mental disability, forecast for the illness progress and future prognosis. The clinic should be convinced that the parents have taken advantage of all possible and available therapeutic methods *in casu*. With regard to the child that is to be conceived as a saviour sibling under MAP (IVF) procedure, it is necessary to consider risks connected with the performance of embryo biopsy and psychological and emotional consequences of "saviour conception" in the future, and establish whether the collection of a specific type of cells or tissues does not ensue serious health problems, and whether the procedure will not be too invasive. The clinic should also verify if after birth the child shall undergo one-off therapeutic procedures or whether it will be necessary to repeat (even regularly) specific medical acts in the future. The analysis of the whole family situation of a couple wishing to perform PGD and conceive a saviour child should check, on the one hand, earlier reproductive experiences of the spouses (partners) and current conditions of applying IVF/PGD

46 If a transplant was an available option of the child treatment (for example, bone marrow cells), firstly, parents were required to exhaust the possibility of finding a suitable donor both at home and abroad (prior to submission to PGD combined with typing tissue) (which, as emphasized in doctrine, it is possible in a short time due to the functioning of electronic registers of donors). More on the guidelines of 2004 see: E. Jackson, Medical…, *op. cit.*, p. 849 and following.

47 However, it cannot be ruled out that the parents will attempt to get the organ from a younger sibling, tissue-compatible with a sick brother or sister later, when all other methods of therapy are exhausted. However, this action may fail due to the requirement under the Human Tissue Act of 2004 to obtain the consent of the court to collect the organ from a minor. The doctrine emphasizes that in practice the consent of the court is unlikely because it is a manifestation of circumvention of the HFEA 2008 regulations constituting the prerequisites of tissue typing admissibility). See: M. Brazier, E. Cave, Medicine…, *op. cit.*, p. 369.

to them (including a number of possible cycles and embryos that may be created therein), while on the other hand, a probability of achieving expected results with regard to the older siblings' therapy. What is more, the MAP clinic should also consider a risk of IVF/PGD and tissue typing failure and its potential consequences for the couple as well as verify possible social support if a conceived child proves to be genetically impaired again[48].

Despite evoking continuous and numerous controversy in some representatives of legal doctrine and bioethics (as a manifestation of eugenics), cases of assessment of tissue matching in PGD procedures do occur and, as confirmed by the practice, in many countries they result in delivering children for therapeutic reasons[49]. The above-mentioned diagnostic and therapeutic benefits of PGD combined with tissue typing on the one hand, and the need to provide such activities with organizational framework (to eliminate potential abuse, illegal treatment or even "procreation tourism") on the other hand, have made some countries, with the support of the doctrine, adopt the relevant regulation[50]. The laws are most often modelled on the original British model (i.e. 2004 Recommendations and HFEA 2008), which, however, is distinct in comparison to other countries with regard to precise and exhaustive determination of tissue typing prerequisites.

The need of regulating a controversial technique of establishing tissue matching in PGD procedures was included, among others, in the Spanish Act on MAP of 2006 (Art. 12) and the provisions of the Portuguese Act on 2006, which permit tissue typing as one of the legally admissible cases of preimplantation diagnosis within the narrow framework designated by a therapeutic purpose and respect for the child's welfare[51]. Similar to the English law, most legislations assume that tissue-typing procedures are exceptional in their nature. Apart from the need to obtain cells (tissues) for older, seriously ill sibling (and not other persons, e.g. a parent or other relatives), special regards should support tissue typing *in casu*. It has been rightly decided that a MAP clinic should decide about the performance of these procedures while some countries conditioned it (the same as other cases of IVF/PGD) on obtaining a consent or/and positive opinion of a special committee or board (e.g. State Social Committee in Sweden, or *Agence de la biomédecine* in France). Evaluating every circumstance of a specific case, a clinic or/and committee should especially verify if actions undertaken by a couple to fulfil the parent project are not contrary to the future child's welfare,

48 J. Herring, Medical…, *op. cit.*, p. 394-395.

49 The birth of a child whose stem cells were used to treat older siblings (beta thalassemia) was in Spain (2008) and France (2011), and in other genetic diseases in Belgium and the USA, O. Nawrot, Diagnostyka…, *op. cit.*, p. 49. See also D. Pszczółkowska, Po pierwsze dziecko, po drugie lekarstwo, "Gazeta Wyborcza" of 11.02.2011.

50 Acceptance for tissue typing practices is particularly evident in the Belgian doctrine and medical environments. G. Pennings Belgian…, *op. cit.,* p. 258.

51 *Ibidem*. See also: V.L. Raposo, Assisted…, *op. cit.,* p. 42.

and whether their actual motivation is not limited to saving an older brother or sister but rather aimed at MAP conception to carry a child as a purpose in itself (the same as, e.g., Art. 68 of the Belgian Act of 6 July 2007)[52]. However, it is difficult to verify this prerequisite in practice since, as a rule, parents continue to claim that regardless of other circumstances, they intended to undergo IVF and conceive a second child while the application of PGD was justified by a risk of transmitting genetic disorders that one or both of them have been affected by.

3. "Designing" a disabled child (*designer disability*)

In connection with the possibilities provided by IVF/PGD as to embryo evaluation and selection, the ensuing question is whether parents affected by a genetically conditioned disease or disability (e.g. muteness, deafness, or dwarfism), may demand implantation of impaired embryos in order to conceive a child with the same defect (designer disability). As proved by the practice[53], such a choice is most often justified by peculiar understanding of the child's welfare by parents and a desire for the child's complete assimilation in a family or even community of people affected by the specific illness. At the same time, a demand for the transfer of a defective embryo is an expression of protest against social perception of a specific type of handicap as disability and the need to eliminate it through IVF/PGD procedures[54].

The literature rightly depicts the argument against purposeful conception of a child affected by a defect, according to which such practice, as a new form of eugenics, is an undesirable and dangerous step towards commercialization and instrumentalization of reproduction (free market/laissez-faire eugenics). Parents deciding to conceive a child of a specific health condition are compared to consumers choosing a product according to their own individual needs and preferences (consumer-like choice)[55]. PGD combined with a positive selection of impaired embryos is undeniably contradictory to the principle of the child's welfare, which, pursuant to the legislation of most countries, should be applied while deciding about substantive and non-substantive (personal) sphere of the child's life. Deliberate creation of a child that is either deaf, mute or affected by inherited dwarfism, will not satisfy their welfare, just on the contrary, it is a gross violation thereof and may be perceived as a manifestation of subjective, or even selfish aspirations of parents.

52 G. Pennings, Belgian…, *op. cit.*, p. 258.

53 See: This Couple Want a Deaf Child. Should We Try to Stop Them? "The Observer" of 9.032008 (the UK) and M. Spriggs, Lesbian Couple Create a Child Who is Deaf Like Them, "Journal of Medical Ethics" 2002, vol. 28, p. 283 and following (USA).

54 See: M. Brazier, E. Cave, Medicine…, *op. cit.*, pp. 369-370 and J. Savulescu, Deaf Lesbians, "Designer Disability"and the Future of Medicine, "British Medical Journal" 2002, vol. 325, p. 771.

55 D. King, Preimplantation Genetic Diagnosis and the "New" Eugenics, "Journal of Medical Ethics" 1999, vol. 25, p. 176 and following.

No illness (physical impartment) and mental wellbeing, which are objectively recognized as positive and highly desirable, are, by all means, much more valuable than benefits of the child's assimilation into a specific community and a sense of a lack of distinctiveness from its other members. Moreover, a deliberate conception of a child with defects does not account for the child's future interests, who, after becoming mature or independent due to commencing education, is likely to leave the family community. Life choices are particularly limited not only in a professional field (a choice of study or profession) but also personal (a risk of transmitting defects into future offspring). Even though assimilation is assumed desirable and beneficial for a child, it may evoke opposite effects and excessively bind the child with a specific environment.

On the other hand, few supporters of designer disability claim that admissibility of defective embryo selection and transfer is the right of the spouses (partners) ensuing from procreative autonomy and the right to procreate everyone is entitled to. The fulfilment of the parent project that is medically assisted does not differ from the situation when, in result of a scheduled natural conception, a woman chooses a man affected by a specific inherited defect to be a father of her child ("parental eugenics")[56]. Furthermore, such concepts as equality and disability discrimination ban also support the admissibility of deliberate conception of an ill child. It is emphasised that the rejection of impaired embryos by a MAP clinic as "unsuitable" for implantation manifests a lack of acceptance of specific forms of disability and conveys a negative message of medical environments and society in general towards affected disabled persons[57].

The provisions of valid legislation on MAP worldwide do not regulate straightforwardly a controversial issue of designer disability. Nevertheless, non-admissibility of such kinds of activity results from the already mentioned narrow framework of PGD admissibility adopted by most countries, i.e. the rule that only embryos free of defects and impairments shall be used in implantation, and banned selection of the child's genetic features (e.g. Art. 26 of the Polish Act on Infertility Treatment). Yet the practice proves that the shape of provisions regulating the principles of transfer may evoke doubts and favour aspirations of parents to conceive a child affected by a defect. In Great Britain, pursuant to Art. 13 par. 10 of HFEA 2008, embryos that are known to have a gene, chromosome or mitochondrion abnormality involving a significant risk that a person with the abnormality will have or develop serious physical or mental disability, serious illness, or other serious medical condition, must not be preferred to those that are not known to have such an

56 See: J. Herring, Medical…, *op. cit.,* p. 391.

57 Por. J. Savulescu Deaf…, *op. cit.*, p. 771.

abnormality [58]. Thus, the Act does not establish an absolute ban on the implantation of defective embryos but introduces the principle of transfer priority for healthy embryos. If in one cycle both non-defective and impaired embryos are created, genetic parents may refuse to undergo implantation and undertake next IVF/PGD attempts counting on the creation of exclusively defective embryos satisfying their procreative plans[59]. If the choice is not statutorily regulated, it is theoretically possible, *inter alia*, to implant an impaired embryo based on the argument raised by the parents to support their aspirations, according to which the transfer is the last resort to conceive a child that is genetically related to them. The use of a defective embryo may, however, be found contrary to the child's welfare which, in accordance with general HFEA rules, the clinic is obliged to consider each time a woman (a couple) undergoes MAP procedures (Art. 13 par. 5). In such a situation, in compliance with the principle ordering a thorough analysis of each case *ad casum*, it is necessary to assess potential consequences of specific defects affecting the child and, in particular, verify whether, e.g. inherited blindness or deafness, is serious impairment justifying a refusal to carry out the transfer. If the defect is not connected with a far-reaching harm or disorder of the child, and in effect of a specific type of an illness or disability life would not be as impaired as to be not worth living, a positive selection of an impaired embryo is admissible[60]. However, majority of the doctrine representatives rightly believe that the principle of the child's welfare excludes a transfer of impaired embryos in each case and regardless of the nature and type of a defect. Therefore, the will of future parents to conceive a child affected by an illness may not (and most probably would not have been) considered due to the content of the above-mentioned Art. 13 par. 5 of HFEA[61]. Apart from that, the evaluation of the defect's burden and impact of the ensuing disability on the quality and comfort of the child's life seems impeded or even impossible if, on the one hand, the child has not been conceived yet (*pre-conceptus*), while on the other hand, there are no appropriate measures to assess a degree of both physical and mental torment evoked by the illness due to their highly individualized nature.

58 This principle corresponds to the rule of preference for the gamete donation of this donor, for whom it is known that he is not a carrier of genetic diseases or another form of hereditary defects and burdens (art. 13 par. 9). See: J. Herring, Medical…, *op. cit.,* p. 391.

59 M. Brazier, E. Cave, Medicine…, *op. cit.,* p. 370. This action would be unacceptable in countries whose laws prohibit the creation of new embryos in a situation where the couple have healthy embryos suitable for implantation (France).

60 J. Savulescu, Deaf…, *op. cit.*, p. 771 and following.

61 See: E. Jackson, Medical…, *op. cit.*, p. 843.

4. The selection of the child's sex

Apart from monitoring embryo conditions, PGD enables to choose future child's sex and other features (e.g. phenotype)[62]. However, international documents referring to the issue of assisted procreation apparently indicate inadmissibility of such practices. A general ban on sex selection in connection with the application of MAP procedures[63] was expressed, among others, in CAHBI Recommendation of 1989 (Rule 17), and a basic document in the field of bioethics, i.e. the Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine of 4 April 1997 (The Oviedo Convention on Bioethics, Art. 14)[64].

The ban is founded upon the assumption according to which deciding about the child's sex and other features is excessive, undesirable and unjustified interference in the process of procreation ("playing God"), admissibility of which would be equal to the acceptance of positive eugenics practices. It is assumed that MAP techniques should come as close as possible to natural procreation (*procreatio artificialis naturam imitatur*) where such a choice is impossible[65]. Moreover, the exclusion of admissibility of sex selection counteracts discrimination (it fulfils the moral order to accept a conceived child regardless of its sex) as well as favours elimination of demographic threats, that is births of an excessive number of children of specific sex and a negative impact thereof on the population. Furthermore, the literature underlines that the fact that parents decide about sex of their future offspring entails a risk of evoking negative effects in the child's psyche who, learning about the circumstances of his or her conception, may suffer from serious psychological harm[66].

62 The appropriate selection of donor gametes in cases of using heterologous MAP techniques also has an impact on the traits of the future child. In many countries, the law imposes on the doctor (clinic) the right choice of the donor so that the child shows minimal although similar to the social father, for example in terms of body structure, eye color or hair. The boundary between the "matching" of traits within the created family and the selection of specific, desirable values of the child may turn out to be smooth and even difficult to determine.

63 This selection is possible by selection in PGD procedures and implantation into the uterus of the male or female embryo or the use of appropriate sperm (X or Y) for insemination or IVF.

64 The choice of gender based on insemination with selected sperm (X or Y) is, however, acceptable from 1995 in the US, on a commercial basis. In practice, about 2,000 people (couples) took advantage of this opportunity. Cited after the House of Commons, Science and Technology Committee, Human Reproductive Technologies and the Law: Fifth Report of Session 2004-2005. Volume 1, London 2005, p. 62 and the literature given there.

65 Compare J. Lipski, Opinia…, *op. cit.*, p. 145.

66 The ban also reflects the social attitude to the issue of gender selection, which is opposed by around 80% of respondents. Cited after J. Herring, Medical…, *op. cit.,* p. 392. See also: House of Commons Science and Technology Committee, Human…, *op. cit.*, p. 62-63.

The ban on gender selection has been adopted by most legal systems worldwide. Among others, it is expressed *expressis verbis* in Art. 53 of the Belgian Act on the above-mentioned assisted procreation and disposal of supernumerary embryos of 2007, § 2-13 of the Norwegian Act on the Application of Biotechnology in Medicine of 2003, Art. 1455 of the Greek Civil Code (in the reading enacted by the Act on MAP of 2002) and Art. 26 par. 2 of the Polish Act on Infertility Treatment. Violation of the ban is, as a rule, subject to criminal sanctions: a fine, limitation or deprivation of liberty (see Art. 82 of the Polish Act of 25 June 2015)[67]. The introduction of sanctions is of considerable preventive significance and, in compliance with the legislator's assumptions, it is to counteract undesirable practices and eliminate unauthorized cases of embryos selection[68].

The sex selection ban, however, is not of an absolute nature. CAHBI Recommendation, Oviedo Convention and legislations of individual countries admit an exception thereof, when the choice is supported by medical considerations – the need to avoid a risk of transmitting a serious sex-linked disease (e.g. haemophilia, or Turner syndrome). In other words, if a genetic disease typical of a specific sex may affect a child, the couple may undergo PGD procedure and choose to transfer only embryos of this sex that does not inherit a given type of disorders in accordance with the rules of medical knowledge.

International documents, including the Oviedo Convention (Art. 14), do not define a serious genetic disease whose risk justifies sex selection. The literature has assumed that this term should be defined more precisely by a national legislator, who should accurately determine cases when such a choice is possible to achieve the purpose of the regulation – to counteract abuse[69]. The solution in the form of introducing a list of diseases (*numerus clausus*) has been found inaccurate due to the lack of flexibility and the need to systematically verify and complete this list is result of dynamic development of medical science in recent years[70]. Hence, each acute (serious) hereditary specific sex-linked disease may theoretically justify the

67 However, the Polish legislator limited in art. 82 the application of sanctions provided for in breach of the prohibition in art. 26 par. 2 to unjustified gender selection, despite the fact that the ban is broader and also concerns the choice of phenotypic features of the child other than gender. This solution, as it is aptly pointed out in the literature, is unintentional and overlooked by the legislator. See: J. Haberko, Ustawa…, *op. cit.*, pp. 389-390.

68 In the Polish literaturę it was raised that the ban stipulated in art. 26 par. 2 has too narrow a scope of application, and the protection envisaged in it is illusory, which in turn poses a threat to the development, on a large scale, of the practice of medically unjustified selection of embryos and positive eugenics: J. Lipski, Opinia…, *op. cit.*, p. 145.

69 O. Nawrot, Diagnostyka…, *op. cit.*, pp. 57-61.

70 See: the Report on the Protection of the Human Embryo In vitro of 19 June 2003, www.coe.int/t/dg3/healthbioethic/texts_and_documents/CDBI-CO-GT3(2003)13E.pdf (accessed: 20 February 2017). Compare J. Haberko, Ustawa…*op. cit.*, p. 167. See also J. Pennings, Belgian…, *op. cit.*, p. 258 and J. Kapelańska-Pręgowska, Zjednoczone…, *op. cit.*, p. 409.

selection. In some countries (e.g. Great Britain), to eliminate doubts, the provisions of law have defined a sex-linked disease while underlying the need to determine whether specific genetic impairment (disorder) the parents applying for PGD would like to avoid actually regards one sex exclusively or overwhelming majority of cases (Art. 13 par. 11 of HFEA 2008)[71]. This solution eliminates doubts and is sufficiently flexible because, in accordance with HFEA 2008, each serious hereditary disease, even the new ones that have been recently described in medicine, may justify embryo selection if HFEA Authority issuing a PGD licence is convinced about the existence of the relation between the disease and a specific sex[72].

Despite the restrictive regulation of PGD and explicit statutory ban on sex selection, the practice knows cases of parents demanding the fulfilment of the parent project and the conception of a child of a specific sex most often for social reasons, e.g. family balancing. Its justification is also evoked on the grounds of procreative autonomy and the right to procreate which, as it is sometimes emphasized, may also embrace the selection of a child's sex and his or her other features due to the possibilities provided by MAP. What is more, there are attempts to extend the prerequisite of medical reasons by encompassing therein a mother for whom a refusal to fulfil an intended parent project and conceive a child of a specific sex is a serious psychological threat.

The literature knows at least two cases of parents claiming their "right" to conceive a child of a specific sex (female) for social reasons[73]. In the first case (the so called *Mataró case)* of 1995, the Spanish government found a demand submitted to a MAP clinic for the application of IVF/PGD for the woman, a mother of four boys, to select (and consequently transfer) female embryos unreasonable. The claimant argued that a fear she would not deliver a female child in result of the next pregnancy is a source of serious mental torment for her that may lead to profound depression and nervous breakdown. She believed that her claim was based on medical considerations, which, pursuant to the then valid Act of 1988 on MAP, justified a selection of a child's sex as an exception from the relevant general ban thereon set forth in the Spanish law. Dismissing her claim, the court rightly underlined that medical considerations, which are the only prerequisite of admissibility of sex selection, refer solely to the child who is at a risk of a specific genetic sex-linked disease and not other persons (the mother or second parent) applying for embryo selection[74]. A failed attempt at a wide interpretation of the prerequisite of medical

71 J. Herring, Medical..., op. cit., p. 392. Pojawia się jednak pytanie, czy elastyczność modelu i brak listy nie stwarza zagrożenia w postaci nadmiernego arbitralizmu ocen. Compare: J. Haberko, Ustawa..., *op. cit.*, p. 167.

72 *Ibidem.*

73 However, MAP clinics in some countries (USA, China) offer gender selection services for social reasons. See: http://www.givf.com/familybalancing/ (accessed: 26 February 2017).

74 V.L. Raposo, Assisted…, *op. cit.*, p. 42.

reasons justifying PGD and a selection of a child's sex was an efficient barrier against similar claims in the future.

The application for PGD in order to select embryos of a specific sex was also rejected in the English case of Masterton of 2004[75]. Different from the *Mataró* case, the couple demanding preimplantation control of IVF embryos and a selection of solely female ones for implantation was infertile because after delivering the last fourth child the woman carried out vasectomy. Although humanitarian reasons and rules of community life supported assisted conception (a three-year-old daughter of the couple, born after fifteen years of attempted conceptions and prior births of four sons, died tragically) and the doctrine criticized limiting admissibility of embryo selection to medical reasons, a licence for PGD and embryo selection has not been granted[76]. The refusal was justified by the fact that sex selection is an action contrary to the Act each time it is motivated by other reasons than medical ones (social sex selection), in particular if the parent project assumes the creation of a desirable and sex balanced family composition[77]. In connection with the Masterton case, the doctrine extensively criticized HFEA solutions going as far as raising a postulate to amend the Act and mitigate the criterion of medical reasons. Nevertheless, these proposals have not brought any effect; the legislator not only remained consistent with regard to the maintenance of a medical prerequisite of embryo selection in PGD procedures, but also consequently banned other selection techniques, including sperm sorting to separate X and Y spermatozoon, and use only one type thereof for insemination (e.g. Y in order to conceive a boy)[78].

5. Final comments

The application of PGD providing a possibility of evaluating and selecting embryos before implantation is, by all means, desirable because it helps to conceive a child when there is a risk of transmitting a serious genetic disease or other forms of disorder onto a future child. On the other hand, however, preimplantation diagnosis enables to fulfil the parent project according to parents' subjective needs and beliefs not necessarily corresponding to the interests of the child to be born. Intensive development of biotechnology and growing possibilities of medical sciences change the nature of parents' aspirations and expectations, who intend not only to conceive

75 House of Commons, Science and Technology Committee, Human…, *op. cit.*, p. 63.

76 The couple eventually used the services abroad (Italy) on a commercial basis (for a price of around 30,000 USD). However, male embryos obtained in in vitro procedures have been passed on by genetic parents for anonymous donation purposes. M. Brazier, E. Cave, Medicine…, *op. cit.*, p. 370.

77 S. Wilkinson, Racism and Sexism in Medically Assisted Conception, "Bioethics" 1998, vol. 12, p. 25.

78 M. Brazier, E. Cave, Medicine…, *op. cit.,* p. 370.

and deliver a child despite obstacles (e.g. infertility), but also expect a healthy child who even, as it has been confirmed, has specific features (sex, phenotype, HLA structure, etc.). Hence, it is not only necessary to set limits of IVF/PGD legality and grant these types of procedures appropriate organizational and legal framework (eliminating potential abuse), but also realize further instant attention of the legislator, among others, through the system of licensing MAP (PGD) practices and supervising the activities of entities providing such services. The argument presented in the 1990s, according to which regulation and system of control are excessive and undesirable interference of the State into the personal and intimate sphere of human life ("state controlled procreation") seems to become obsolete[79]. State control and supervision are necessary, most of all, to prevent and counteract MAP development in already indicated and undesired directions. The application of techniques of assisted procreation leads to the conception of human life. Hence, none of the practices may be contrary to the principle of the child's welfare encompassing his or her wellbeing in the personal (and medical) area (sphere) and appropriate security of financial interests. Consequently, each parent project opposite to the above should be inadmissible. Striving to achieve this and provide a child with appropriate protection concurrently satisfy the rule adopted in Art. 3 par. 2 of the UN Convention on the Rights of the Child of 20 November 1989[80], which makes countries undertake action to ensure the child such protection and care as is necessary for his or her well-being.

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79 See e.g.: M. Safjan, Prawo wobec ingerencji w naturę ludzkiej prokreacji, Warszawa 1990, p. 217 and 218.

80 Journal of Laws of 1991, No. 120, item 526 [Dz.U. 1991, Nr. 120, poz. 526].

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Legal Aspects of the "Windows of Life"

Abstract: This study addresses a very important and controversial issue of the legal aspects of the so-called "windows of life's" operation and functioning. The authors present the concept of windows of life as well as explain key issues that arise in discussions on the topic. Based on the content of the Convention on the Rights of the Child, they present a doctrinal approach to the terms of the right to life and the right to an identity. Another issue considered by the authors is granting primacy to one of those rights. The authors attempt to decide whether, from the point of view of the child's welfare, it is more important to save his life or protect his identity and the opportunity to learn about his ancestors and biological origin. Furthermore, the article presents arguments for and against the need for the windows of life. The authors examine the views of the doctrine and practitioners, reflect on the meaning of life and existence of the windows, and present their legal regulation. In summary, the authors draw conclusions from their considerations and present proposals *de lege ferenda*.
Keywords: window of life, the right to life, the right to an identity, Convention on the Rights of the Child

1. Introduction

The problem of abandoning newborn children was common already in ancient times[1]. However, in the wake of time and development of Western civilization, it has become a phenomenon that is clearly negatively evaluated both from the moral and legal point of view. Due to this, already in the Middle Ages, the idea of the so called

1 I. Żuber, Expositio infantis (porzucenie dziecka) w antycznym Rzymie, (in:) Andrzej Pasek (ed.) Dziecko i jego pozycja prawna w dziejach, Wrocław 2014, pp. 29-68.

"windows of life" emerged[2]. Newborn children are abandoned in contemporary times as well. Driven by strong emotions and overwhelmed by the burden of responsibility to raise their own child, mothers often kill or abandon their offspring. In response to this negative phenomenon, "the windows of life" have emerged in Poland too. The first contemporary institution of this type was established on 19 March 2006 in the Single Mother House in Krakow at 39 Przybyszewski Street[3]. Now there are 58 such centres in Poland. Windows of life are usually established within monasteries and orphanages, where mothers may anonymously leave their children. From the very beginning, windows of life were assumed havens (places of safety) both for mothers in a difficult life situation and their newborn children they were either unable or unwilling to take care of. After undergoing appropriate adoption procedures, these children have a chance of finding safety and home in a new family. The public initially approved of the idea of windows of life and their operation as they undeniably served children's welfare. According to their supporters, they are an instrument of protection of every human's inalienable right to life. Nevertheless, discussion thereon was incited by the Recommendations of the UN Committee on the Rights of the Child announced in Poland in 2015. Pursuant to their assumptions, Polish authorities should ban the operation of windows of life and focus on the popularization of alternative forms of relinquishing one's rights to the child[4]. From the legal perspective, the core of the dispute was the Committee's decision according to which the idea of windows of life violates Art. 8 of the Convention on the Rights of the Child[5], which guarantees children the right to an identity. The same the Committee has inspired lawyers to reflect on the question whether priority should be granted to the right to life or the right to an identity. In the light of the above circumstances, considerations of legal aspects of the operation of windows of life and finding the answer to the above question appear absolutely reasonable.

2. The right to life and the right to an identity – definitions

Pursuant to Art. 6 par. 1 of the Convention on the Rights of the Child, States Parties recognize that every child has the inherent right to life. According to the opinion expressed in the literature, the right to life should be understood as the creation of conditions that allow man to survive and a lack of consent for arbitrary

2 A. Żok, I. Rzymska, Problem okien życia – analiza etyczno-prawna, "Poznańskie Zeszyty Humanistyczne", 2015, t. XXV, p. 20.

3 http://www.caritas.pl/okna-zycia-w-polsce/ (accessed: 3 January 2017).

4 http://tbinternet.ohchr.org/_layouts/treatybodyexternal/Download.aspx?symbolno=CRC%2fC%2fPOL%2f-CO%2f3-4&Lang=en (accessed: 6 January 2017).

5 The Convention on the Rights of the Child adopted by the General Assembly of the United Nations on the 20 of November 1989 (Journal of Laws of 1991, No. 120, item 526 [Dz. U. 1991, Nr 120, poz. 526].

deprivation of life of a person under specified age[6]. Due to this, any action undertaken by States Parties that are Signatories to the Convention aimed at rescuing each single child's life should be recognised as action in compliance with the Convention's assumptions and principles. Concurrently, such action will be a manifesto against arbitrary deprivation of children's life.

On the other hand, pursuant to Art. 8 par. 1 of the Convention on the Rights of the Child, States Parties undertake to respect the right of the child to preserve his or her identity, including nationality, name and family relations as recognized by law without unlawful interference. As underlined by the doctrine, identity is a proof of one's existence – one's distinctiveness[7]. Directives providing a newborn child with the right to an identity have been expressed in Art. 7 par. 1 of the Convention. Pursuant to it, the child shall be registered immediately after birth. Furthermore, the child shall have the right from birth to a name, the right to acquire a nationality and, as far as possible, the right to know and be cared for by his or her parents. Hence, it is worth noticing that the right to an indentify should not be limited to equipping a child with personal data such as a name, surname or number in a relevant register because a widely understood concept of identity embraces the child's right to be aware of their origin too.

3. Positive evaluation of windows of life's operation

At the beginning of considerations about positive aspects of windows of life's operation, we should ask about the legal nature of leaving a child in such a window because this institution is not legally regulated. Hence, doubts may arise as to the fact whether a mother leaving a baby in the window of life does not commit an act specified in Art. 210 § 1 of the Criminal Code, which sets forth that whoever despite a duty of care to a minor person under fifteen years of age or to a person who is helpless by reason of his mental or physical condition abandons such a person shall be subject to the penalty of deprivation of liberty for up to three years[8]. Pursuant to the judgment of the Supreme Court of 4 June 2001, the offence of abandonment means "an act of abandoning a child and ceasing to take care of him or her and failure to provide such care by other people. Thus, the essential factor of "abandonment" is leaving a person who should have been taken care of stranded while it means not only an omission to provide care over a minor or helpless person but also preventing

6 G. Michałowska, Międzynarodowa ochrona praw dziecka, Warszawa 2016, p. 39.

7 *Ibidem*, p. 42.

8 The Act of 6 June 1997 – The Criminal Code (consolidated text Journal of Laws of 2016, item 1137 as amended) [Ustawa z dnia 6 czerwca 1997 r. – Kodeks Karny (tekst jedn. Dz.U. z 2016 r. poz. 1137 ze zm.)].

such a person from being granted instant support"[9]. Due to this, it should be acknowledged that leaving a child in a place where a chance of helping him or her is slight, e.g. in a forest or country track, is subject to penalty[10]. Hence, leaving an infant in the window of life cannot be treated as a crime of abandonment since the child is immediately taken care of by specialists as these places are heated and equipped with a bell, which informs carers about a child being placed in the window. A child left in the window of life is immediately taken to hospital. The window's carers inform the adoption centre about the abandoned child, which immediately informs a court about this fact while concurrently submitting two requests with the court: to issue a decision on the custody of the child and on granting him or her an identity, i.e. a name and surname[11].

The right to an identity is closely connected with another aspect of windows of life's legal operation in the Republic of Poland. As already mentioned above, in 2015 the UN Committee on the Rights of the Child requested Poland to abolish the windows of life. According to the Committee, the idea of the windows of life which enable to abandon a child anonymously violates the child's right to an identity, and therefore contradicts the Convention on the Rights of the Child. The right to an identity, by all means, derives from inherent and unalienable human dignity, and it is a vital element of every individual's private sphere. A possibility of being aware of one's own identity, perceived by the doctrine as personal right, is protected by the content of Art. 30 and 72 of the Constitution[12] as well as international regulations, among others Art. 7 of the Convention on the Rights of the Child[13]. On other hand, however, as far as windows of life are concerned, we deal here with the protection of the right to life, which is mentioned in Art. 38 of the Constitution, or Art. 6 of the Convention on the Rights of the Child. It is undeniably the main argument raised by the supporters of the discussed institution. Furthermore, another argument for the windows of life may be the fact that we cannot talk here about full deprivation of human right to an identity because it is a wide notion while the right to know one's own ancestors is only its part. Due to windows of life's anonymity, although a child left there is deprived of a biological dignity, thanks to a new family he or she has a chance

9 The judgmenet of the Supreme Court of 4 June 2001 V KKN 94/99, "Krakowskie Zeszyty Sądowe" 2002, No. 2, item 9.

10 A. Kilińska-Pękacz, Przestępstwo porzucenia dziecka, "Prokuratura i Prawo" 2016, No. 4, p. 26. Differently: S. Hypś (in:) M. Królikowski, R. Zawłocki, Kodeks karny. Komentarz. Tom I, Warszawa 2013, p. 776.

11 http://www.caritas.pl/okna-zycia-w-polsce/ (accessed: 3 January 2017).

12 The Constitution of the Republic of Poland of 2 April 1997 (Journal of Laws No. 78, item 483 as amended) [Konstytucja Rzeczypospolitej Polskiej z dnia 2 kwietnia 1997 r. (Dz.U. Nr 78, poz. 483 ze zm.).

13 A. Wilk, Akt urodzenia, Warszawa 2014, Lex, T. Smyczyński (ed.), Konwencja o prawach dziecka – analiza i wykładnia, Poznań 1999, p. 42.

of developing a sense of belonging to a given social group. We should also remember that the literary reading of the above quoted Art. 7 par. 1 of the Convention on the Rights of the Child stipulates the child shall have the right from birth to know and be cared for by his or her parents "**as far as possible**". Hence, situations when a biological identity of a child will remain unknown for the sake of higher value/interest or under extraordinary circumstances are admissible. Therefore, the Convention on the Rights of the Child will not be violated.

We should consider here whether we may compare the windows of life to the institution of necessity common to criminal law[14]. According to its assumptions, preserving a higher value we can sacrifice a lesser value. Referring this expression to the windows of life, it can be acknowledged that saving a child's life, we sacrifice his or her right to a biological identity. There are absolutely no doubts that life is a fundamental and primary value without which the right to an identity will not exist at all. Apparently, this assumption will be true if a child is left in the window of life instead of being a victim of infanticide or abortion. The windows of life's founders have never intended to replace the procedure of child's adoption. Windows of life are a peculiar safety valve when, for different reasons, mothers cannot cope with the situation they have found themselves in. The accuracy of this statement can be confirmed by informative events carried out by the institutions in charge of the windows of life. One of the Internet portals, in the article of March 2016, informed about Caritas initiative, which prepared fifty thousand leaflets addressed at women in a difficult situation, often hiding their pregnancy. The leaflet informed them that if they are not able to raise a child they will give birth to, they may leave him or her in hospital after delivery[15]. The leaflets were distributed to such places as Municipal Service Centres, parishes or institutions for the poor. The Care and Education Facility "Jedynka", taking care of Białystok window of life, also holds events organized to make women aware of the above problem. The authors interviewed the Head of this institution for the needs of this article[16]. He confirmed that the Facility holds

14 http://stacja7.pl/rodzina/okno-zycia-jeszcze-jedna-szansa-dla-matki-i-dziecka/ (accessed: 3 January 2017).

15 *Ibidem*.

16 The interview with Jacek Przesmycki, director of "Jedynka" the educational and care institution, conducted on January 2, 2017; During the conversation, the director of the institution emphasized that the problem of windows of life is an extremely complex issue. According to the interlocutor, "windows of life" are not an ideal solution. However, due to the fact that they allow to save life, one should notice the need for their existence. In his opinion, people and institutions that stand in the position that the windows of life should be eliminated do not consider the problem comprehensively. The director of the institution understands the arguments regarding the protection of the right to know his own identity, but in his opinion saving life is the overriding goal. He also argued that in the case of leaving the child in the window of life, both the police and the courts take action immediately. The director of the institution confirmed that in situations where the mother of the child who was left reports to the institution running the window of life,

educational events for social groups the centre is working with due to its statutory tasks. He further underlined that even though windows of life's activity is certainly useful, they should be indeed a last resort as there are other, more advantageous institutions envisaged by the provisions of the Polish law for the benefit of a child.

Windows of life appeared in Poland to commemorate ideas advocated by John Paul II and extend the action the Pope had initiated already in the 1970s to save unborn children's lives[17]. Clerical institutions, such as Order of Sisters of Mercy of the Holy Family in Kętrzyn, run most of the 58 currently operating windows[18]. They do not intend to compete with legal institutions regulating adoption. It can be confirmed, *inter alia*, by above-mentioned informational events they hold. Their main purpose to save life in extraordinary situations that are perceived by mothers as hopeless. Police statistics may confirm that the windows of life work as an alternative for infanticide. In 2004, 19 cases of the act committed under Art. 149 of the Criminal Code were reported. In 2014 there were only 4 such acts[19].

The argument for preserving the windows of life in social space is also their effectiveness despite a lack of special legal procedures. It is acknowledged by the Head of Białystok "Jedynka", where two children were left until 1 January 2017. These situations happened on 12 January 2014 and on 14 August 2016. Now the boys are in new adoptive families. Hence, it is wrong to believe that the adoptive procedure takes years in case of an infant left in the window of life.

4. The critique of windows of life's operation

Opinions about windows of life's operation, however, are not socially uniform. There are several arguments against keeping such places.

Most of all, many people believe that the idea of "windows of life" contradicts regulations of unquestionable foundation of the protection of the child's rights – the Convention on the Rights of the Child. Art. 8 par. 1 thereof stipulates that States Parties undertake to respect the right of the child to preserve his or her identity,

it is possible to verify whether she is actually his mother. In his opinion, in such situations, one should not punish a mother who has recovered and wants to regain her child. According to the director of the institution, the functioning of the windows of life is not intended to encourage mothers to abandon children, but it is a symbol of the fact that there are ways to get help in difficult situations. In his opinion, there is a need to create a mechanism by which the mother could get back her child even after a long time. Summing up, the interlocutor stressed, however, that as long as the windows of life fulfill their role and thus save their lives, their liquidation would not be the right step.

17 http://www.oaza.pl/cdz/index.php/pl/obrona-zycia/748-okno-zycia-ratowanie-adopcja.html (accessed: 3 January 2017).

18 http://www.caritas.pl/okna-zycia-adresy/ (accessed: 4 January 2017).

19 http://statystyka.policja.pl/st/kodeks-karny/przestepstwa-przeciwko/63417,Dzieciobojstwo-art-149.html (accessed: 4 January 2017).

including nationality, name and family relations. Within this context, the admissibility of windows of life's operation by the Polish legislator undeniably infringes the right of children left therein to preserve their identity, especially with regard to a possibility of meeting their biological parents and being aware of their own origin. A basic role of the right to know one's indentify is simply our awareness of who we are, where we are from, and what our tradition (background) is. Nevertheless, we should not forget that the awareness of one's identity also embraces knowledge about our health and potential dangers resulting from genetically linked diseases. A lack of any information within the above scope may evoke numerous negative effects in the future threatening health and life of the child left in the window of life. The authors believe that this argument becomes less credible if we compare the right to an identity with the right to life, which should be treated as a priority within the discussed context.

Another controversial aspect of the windows of life's operation is a lack of legal regulations limiting a group of entities entitled to run them. Due to this, there are no practical obstacles for individuals lacking professional skills and experience to undertake this task. Moreover, moral motifs behind carrying out such an activity are not controlled at all. Nevertheless, the practice shows that currently either clerical orders or orphanages run such places. So far, there have been no objections or reservations as to their operation or activity. Hence, the argument of a harmful impact of a lack of legal regulations limiting a group of entities entitled to run windows of life appears wrong. These institutions are opened in places where there is always someone on duty, day and night without a break, so that when a child appears, police and emergency medical services are informed instantly. A child remains in the window of life for only several minutes because the entity in charge of the window must promptly react to the appearance of the infant therein and immediately notify appropriate institutions about it. Further custody of the child is provided in compliance with the order (decision) of a guardianship court. Nevertheless, the above aspect may evoke some fears. If the Polish legislator decides anytime to introduce legal regulations concerning the windows of life, the issue of entities admitted to run such places should be their crucial element.

What is more, we can wonder whether leaving a child in the window of life *de facto* prolongs the adoptive procedure. Apart from carrying out standard actions, state bodies should first undertake activities aimed at the establishment of the child's identity and finding his or her biological parents. Nevertheless, it results from the interview conducted by the article's authors that the adoptive procedure of children left in the windows of life is very efficient. It is commonly known that many adoptive families await newborn children. Due to this, finding an adoptive family for a newborn infant is not a problem. The child may almost instantly find himself or herself in the custody of their future parents. On the other hand, finding the child's biological mother is merely limited to reporting this fact to the police, which, due to

a lack of sufficient data, are usually not able to undertake real and efficient operational activities.

Furthermore, we should consider whether leaving a child in the window of life is reversible. It should be emphasized here that if adoptive procedure is initiated after the child's birth, his or her mother is legally guaranteed to have minimum 6 weeks since the child's birth to reconsider her decision[20]. If the child is left in the window of life, irreversibility of this act cannot be considered too. The practice knows cases of mothers who after leaving the child changed their mind and regained the right and custody of the child[21]. It can happen thanks to the determination of a family relation between the child left in the window of life and the mother looking for her offspring with the help of DNA tests.

Another issue arising controversy is the fact that practically anyone may anonymously leave a child in the window of life. Hence, a person who does not even have parental rights to the child can do it. Parents, especially a mother, may be separated from their child against their will, e.g. under duress of third parties. On the other hand, driven by extreme emotions, a mother may deprive the child's father of disposing his parental rights. The authors believe that the claim according to which the windows of life enable third parties to leave a child against their legal guardians' will is not true. Such conduct fulfils the features of the act under Art. 211 of the Criminal Code, i.e. a crime of abduction. Hence, it is wrong to blame the idea of the windows of life for the situation when, e.g., the mother's partner who does not want her to raise a newborn child takes him or her away and leaves the child in the window of life. He could also take the child and leave him or her in a forest. Hence, this argument is as unreasonable as the claim according to which, e.g., we should abolish large supermarkets because they encourage thieves to steal.

Furthermore, it is argued that the windows of life lead to an increasing phenomenon of out-of-hospital deliveries. It is emphasized that mothers who plan to leave a child in the window of life do not want to have contact with healthcare service because such a contact results in drafting relevant perinatal documents. It implies, however, numerous threats. A lack of specialist midwifery care may threaten health and life of both the mother and the child. The authors think, however, that it is wrong to perceive the windows of life as institutions increasing the phenomenon of out-of-hospital deliveries. Windows of life are not responsible for a woman's decision not to deliver a baby in hospital. What decides about it are individual tragedies and dramas

20 Art. 119^2 of the Act of 25 February 1964 – Family and Guardianship Code (consolidated text Journal of Laws of 2017, item 682) [Ustawa z dnia 25 lutego 1964 r. – Kodeks rodzinny i opiekuńczy (tekst jedn. Dz.U. z 2017 poz. 682)].

21 http://www.dziennikwschodni.pl/zamosc/dziecko-z-okna-zycia-w-zamosciu-wroci-do-matki,n,1000012315.html; https://ekai.pl/wydarzenia/polska/x25785/kielce-dziewczynka-z-okna-zycia-wraca-do-domu/ (accessed: 5 January 2017).

the windows of life are somehow to alleviate. Such places are used, e.g., by women who reside within the territory of the Republic of Poland without a legal permit, and are scared to have contact with any state institutions. The window of life is a message for them: "You are not able to take care of your child? Don't be afraid. Don't hurt him or her. Bring the child here. He or she will be safe here".

The windows of life opponents also argue that, contrary to common belief, there is no relation between opening such places and a decreasing number of victims of infanticide. According to the statistics, a decline therein has been observed since 2000, that is already a few years before the first window of life was created[22]. Since it is not possible to find out the motifs of women who did not decide to kill their own baby, the dispute is unresolved. The authors believe that the future life of a few dozen children left so far in the windows of life has been protected just thanks to the fact that these windows operate in social space. You cannot prejudge what would have happened to these children if windows of life had not existed. Yet it is very probable that some of them could have died.

5. Conclusions and postulates

A reliable assessment of the windows of life must specify their underlying assumption. These institutions are created to provide mothers in profound difficulties with a possibility of leaving their children anonymously in a safe place so that they do not have to hurt them. We talk about exceptional situations here. The window of life is a place for women who often hide their pregnancy, or do not want or cannot deliver a baby in hospital, or are unable to take care of their child after birth. It is a place for mothers who, at the same time, do not see another possibility of solving a difficult situation because they are often paralyzed by shame and fear. Just in such cases the windows of life provide newborn babies with a chance to survive in adoptive families awaiting them. Concurrently, they make biological mothers believe they have not done anything wrong.

Are the windows of life an ideal solution? Certainly not. They deprive a child of the right to know their own biological identity and inherited genetic features, which may evoke negative effects in the future. On the other hand, however, a child is guaranteed the right to life and be raised in a family. Moreover, children are given a chance of developing their own new identity with the support of the environment they are going to grow up within and future education.

Windows of life are institutions serving both mothers and children. Obviously, they are not free of faults but, overall, there are more positive aspects than negative consequences of their operation. In the light of the above comments, it should be

22 http://statystyka.policja.pl/st/kodeks-karny/przestepstwa-przeciwko/63417,Dzieciobojstwo-art-149.html (accessed: 4 January 2017).

emphasized that the creation of new windows of life is not a solution to sometimes extremely difficult situations of mothers. Nevertheless, we should not abolish already existing ones. Most of all, we should stop blaming the windows of life for pathologies and social problems. We should ask ourselves why a woman would rather abandon her baby anonymously in the window of life than take advantage of traditional instruments envisaged by the law. Why don't we create an alternative for the windows of life, persuade society about their usefulness and wait until they bring effects before closing them. Otherwise, we will leave emptiness many women in difficulties will not be able to fill in a way we would expect them to. Perhaps a good solution would be the institution of anonymous adoption. The notion of anonymity should be understood here as a situation when after becoming mature a child might not find out full personal data of his or her mother (parents) but only such information as ethnic origin, age, blood type, or prior illnesses. Thanks to this, we would be able to balance the child's right to find out his or her biological identity and the mother's (parents') right to remain anonymous.

From the legal perspective, the windows of life are interesting insofar as despite a lack of any legal regulations, they are able to operate very efficiently and professionally. In the authors' opinion, they ideally show that social relations and ensuing legal relations do not have to be fortified by a series of laws. The operation of windows of life proves that a good will of individuals, social groups and the whole society is sufficient to generate actions for the common good. Moreover, the windows of life confirm that no legal regulation can do as much to protect each human's fundamental right to life as wise and responsible conduct of people.

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The Limits of Autonomy of a Minor Patient and the Nature of Selected Medical Interventions

Abstract: The aim of the study is to analyze domestic law and selected aspects within international legal regulation connected to the scope of autonomy of a minor patient depending on medical interventions. The starting point is the explanation of the most significant elements of the principle of self-determination: the right to consent and the right to information. It should be pointed out that the scope of patient autonomy is related to typical medical interventions (physical examination, surgery), and it increases when the minor reaches the age of 16. In this context specific regulations are depicted, which provide different solutions as lowering the age to consent (*ex vivo* transplantation), taking into account the minor's actual ability to decide (medical experimentation), or the extended scope of information. To sum up, the principle of autonomy of a minor patient is guaranteed in proportion to the level of the child's development (mainly based on the criterion of age) and under the supervision of a statutory representative or, in some cases, with the court's involvement. This special regulation ensures the rights and interests of minors in an appropriate way.
Keywords: minor patient, patient's rights, patient's autonomy, informed consent

1. Introduction

The paternalistic model of relations between the physician and patient, which was still prevailing several years ago, has gradually evolved into the partnership approach respecting the patient's autonomy who is an active participant of the therapeutic process. However, the principle of self-determination, whose most essential elements contain the right to express consent and the right to information about one's health condition[1], is not of an absolute nature. In order to fulfil the postulate of patient's good/welfare[2], the principle becomes considerably limited,

1 J. Bujny, Prawa pacjenta – między autonomią a paternalizmem, Warszawa 2007, p. 138.
2 *Ibidem*, p. 4.

among others in relation to a special category of patients, i.e. minors. Due to their age, they cannot shape their legal situation themselves, including their conscious decision on medical interventions they are going to undergo. A manifestation of special protection provided to these subjects by the legislator is a formulation of regulation characterized by solutions typical of the paternalistic approach and, in consequence, restriction of the minor patient's autonomy.

A purpose of the article is the analysis of the limits of minor patient's autonomy in the context of provided health services[3] with regard to the criterion of a type of applied medical intervention. Due to the limits of the publication, the study does not embrace introductory issues dealing with consent, obligation of information, or considerations on the statutory prerequisites of admissibility to carry out a given service. A starting point for further considerations are regulations of the Act of 5 December 1996 on the Professions of a Physician and Dentist (hereinafter referred to as APP)[4] and the Act of 1 July 2005 on the Collection, Preservation and Transfer of Cells, Tissues and Organs (hereinafter referred to as ACPT)[5]. A distinct scope of the minor patient's autonomy introduced by the legislator will be analyzed in two levels: the fulfilment of the obligation of information and consent for the provision of a health service. For functional reasons, the issue of informative autonomy of a minor patient will be considered first. Health services analyzed in the above-mentioned aspects have been chosen based on various criteria. This catalogue includes the most common and most frequently performed medical examinations or tests (body examination and physical examination[6] – routine medical actions that do not considerably interfere in patient's physical integrity and do not entail any risk for the patient[7]), other health services (giving medications, or coating plaster)[8] as well as surgeries, methods of treatment and diagnosis posing a higher risk. The author has also selected special interventions which do not benefit a minor directly and do not exert a therapeutic impact on them (a minor donor in *ex vivo* transplantation), or pose a greater risk for a minor patient (medical experiments). It should be stressed that analyzed health services are merely examples whereas the review of so many distinct types of them enables to compare the scope of minor patient's autonomy in

3 More about the concept of health benefits: M. Dercz (in:) M. Dercz, T. Rek, Ustawa o działalności leczniczej. Komentarz, Warszawa 2014, p. 43 and following.

4 Consolidated text Journal of Laws of 2015, item 464 as amended [Tekst jedn. Dz.U. z 2015 r. poz. 464 ze zm.].

5 Consolidated text Journal of Laws of 2015, item 793 as amended [Tekst jedn. Dz.U. z 2015 r. poz. 793 ze zm.].

6 T. Dukiet-Nagórska, Świadoma zgoda pacjenta w ustawodawstwie polskim, "Prawo i Medycyna" 2000, No. 6-7, p. 78.

7 M. Safjan, Prawo i medycyna, Warszawa 1999, p. 45.

8 M. Malczewska (in:) E. Zielińska (ed.), Ustawa o zawodach lekarza i lekarza dentysty. Komentarz, Warszawa 2014, p. 604.

typical situations and special cases. Additionally, minors do not constitute a uniform category of entities for the Polish legislator. In this context, individual groups may be distinguished and the ensuing different scope of self-determination depending on the group category. In the conclusions, the author will present legislation regarding the protection of the minor patient's autonomy as well as factors affecting determination of the limits thereof.

2. Minor patient's autonomy in selected acts of international law – a review

Developing patient's rights, the rights of a minor patient were not included therein for a long time, which actually deprived these subjects of any protection[9]. These tendencies changed as late as in the second half of the 20th century, when minor patients were guaranteed minimum standards of autonomy in a therapeutic process[10].

Before considering this issue under Polish law, it is worth presenting solutions emphasizing autonomy of a minor patient within the above context resulting from the acts of international law. The content of Art. 6 par. 2 of the Convention for the Protection of Human Rights and Dignity of the Human. Being with regard to the Applications in Biology and Medicine: Convention on Human Rights and Biomedicine of 4 April 1997 (hereinafter referred to as EKB)[11], explicitly indicates that where, according to law, a minor does not have the capacity to consent to an intervention, the intervention may only be carried out with the authorisation of his or her representative or an authority or a person or body provided for by law. Concurrently, the opinion of the minor shall be taken into consideration as an increasingly determining factor in proportion to his or her age and degree of maturity. Art. 6 par. 4 of EKB sets forth that the representative, the authority, the person or other bodies shall be given appropriate information as to the purpose and nature of the intervention as well as on its consequences and risks. Furthermore, the invoked regulation envisages special solutions on research on a person without the capacity to consent (Art. 17 of EKB) or ex vivo transplantation (Art. 20 of EKB). Apart from general conditions of medical interventions, the above-mentioned

9 More on the subject of the child's legal situation in health care: M. Dercz, Konstytucyjne prawo dziecka do szczególnej opieki zdrowotnej, Warszawa 2016.

10 J. Zajdel, Prawo medyczne dla kardiologów, Łódź 2009, p. 79.

11 The Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine of 4 April 1997 r. (in:) T. Jasudowicz (translation and ed.), Europejskie standardy bioetyczne: wybór materiałów, Toruń 1998, pp. 3-15. The ECB, adopted by the Committee of Ministers of the Council of Europe, entered into force on December 1, 1999, but it has not been ratified by Poland.

situations also require a written consent for a specific test (recovery/removal) while no objection by the potential donor concerned may be raised. Art. 12 of the Convention on the Rights of the Child of 20 November 1989[12] (hereinafter referred to as KDP) assures to the child who is capable of forming his or her own views the right to express those views freely in all matters affecting the child. The views of the child shall be given due weight in accordance with the age and maturity of the child, which requires individual approach to each case.

3. A minor patient and the right to be informed about one's health condition in the Polish law

A purpose of the information given to a patient before the provision of a medical service is to enable him or her to express an informed consent[13]. A correct fulfilment of the obligation of information is a necessary prerequisite of recognizing the patient's decision as legally binding[14]. The principle according to which a patient is the subject entitled to obtain information about his or her health condition is subject to significant modifications in the case of a minor patient. This right is correlated with the powers (competence) to decide about the scope of medical services being provided.

In the light of the regulated obligation of information within the scope of typical medical services, it becomes apparent that minors are not treated as a uniform group of entities, which has been mentioned in the introduction herein. When a minor person becomes sixteen years old, it is necessary to provide him or her with full information of the minimum scope indicated in Art. 31 par. 1 of APP. This information encompasses various aspects of medical services being provided. On the other hand, when a minor patient is under 16, a doctor is obliged to inform both a statutory representative who has given surrogate consent and the minor patient. However, pursuant to Art. 3 par. 7 of APP, the doctor's obligation with regard to a minor patient has been limited solely to information necessary to assure a correct (regular) course of a diagnostic or therapeutic process, which does not exclude conveying negative information about the minor patient's health condition or unfavourable forecast. Respect for minor patient's autonomy is manifested in the fact that a doctor has to listen to the minor patient after providing him or her with the information. Since a minor patient under 16 has no competence to give consent for the provision of a medical service, it is not binding. Under the present legal

12 The Convention on the Rights of the Child adopted by the United Nations on the 20 of November 1989 (Journal of Laws of 1991, No. 120, item 526) [(Dz.U. z 1991 r. Nr 120, poz. 526)].

13 M. Dercz, H. Izdebski, T. Rek (in:) M. Dercz, H. Izdebski, T. Rek, Dziecko – pacjent i świadczeniobiorca. Poradnik prawny, Warszawa 2015, p. 124.

14 M. Malczewska (in:) E. Zielińska (ed.), Ustawa..., *op. cit.*, p. 592.

state, failure to convey appropriate information does not affect validity of surrogate consent provided by a statutory representative[15]. This solution engages minor patients in a therapeutic process to a certain extent. It is underlined that if the child is more mature, the scope of information should be wider[16]. Fulfilling the obligation of information, it is especially important with regard to minor patients to convey the information in an accessible way, both the message and its content. To achieve this, patient's individual features and his or her perceptive capacity, which depend not only on age but, most of all, a degree of mental development and current health condition, must be taken into account.

A general catalogue of information to be provided may be modified by the provisions of other Acts. Increased obligation of information, which is manifested in two levels, has been envisaged in the case of *ex vivo* transplantation. The first aspect concerns the extended scope of information to be provided, its accuracy and specially regulated possibility of withdrawing consent (Art. 12 par. 1 point 5 of ACPT). The second element is connected with a group of entities implementing this obligation, which embraces both a doctor taking part in a surgery and a doctor not participating directly in it. A purpose of double obligation of information is making sources of information more objective and more numerous, which is further reinforced by the duty to fulfil it in writing.

Compared to regulations concerning typical situations, including medical experiments, the obligation of information looks different. Standards envisaged in Art. 31 of APP are modified by the catalogue contained in Art. 24 of APP, which extends the scope of the obligation of information by depicting a degree of accuracy of data to be provided, including a possibility of withdrawal from the experiment at any time[17]. As far as minor participants of the experiment are concerned, this information should be conveyed to a statutory representative (in the case of surrogate consent), or a statutory representative and minor patient (in the case of cumulative consent).

On the other hand, different from statutory regulations, deontological norms do not envisage the obligation to inform a minor patient about anything regardless of his or her age or perceptive capacity, being limited to the fulfilment of the obligation with regard to a statutory representative or actual guardian, which is set forth in Art. 16 par. 3 of the Code of Medical Ethics[18].

15 M. Świderska, Zgoda pacjenta na zabieg medyczny, Toruń 2007, p. 123.
16 R. Kubiak Prawo medyczne, Warszawa 2014, p. 289.
17 M. Nesterowicz, Prawo medyczne, Toruń 2016, p. 198.
18 The Code of Medical Ethics, hereinafter referred to as CME, http://www.nil.org.pl/__data/assets/pdf_fi le/0003/4764/Kodeks-Etyki--Lekarskiej.pdf (accessed: 16 July 2016).

4. A minor patient and consent to intervention in the Polish law

The legislator generally protects the minor patient's interest within the scope of consent to the provision of medical services on the basis of a model of surrogate consent (given by a statutory representative) or a model of cumulative consent (given in parallel by a statutory representative and a minor). The institution of double consent expresses a strengthened tendency to respect patient's autonomy of the will as early as possible[19]. With regard to typical interventions (examination, other services, surgeries, diagnostic and therapeutic methods of higher risk), the minor's rights within the impact on the decision depend on the criterion of formal age. Once a minor turns sixteen years of age, the model of parallel consent is revised while the minor is given a tool to co-decide about medical services he or she is provided with. It should be emphasized that a younger patient may not decide about the provision of these medical services regardless of his or her health condition, a degree of personal development or ability of making rational evaluations[20]. With regard to this group of minor patients, the respect for their autonomy is also expressed in a manner of resolving a collision of wills of both entitled subjects. In the case of conflict of opinions in the form of objection raised by a minor below 16 years old and the consent of a statutory representative, a decision of the guardian court thereon shall be decisive[21]. Moreover, it is worth depicting here instruments of non-assertive impact of a minor below 16 years old, which have been envisaged in the Act of 25 February 1965 – Family and Guardianship Code (hereinafter referred to as FGC)[22]. B. Janiszewska draws attention to the institution of listening to a minor before giving consent to medical intervention or refusing to make the minor undergo medical intervention depicting the content of Art. 95 § 4 of FGC and Art. 576 § 2 sentence 1 of the Code of Civil Procedure[23]. The above quoted regulation expresses the fact that the autonomy of minor patients undergoing medical interventions who may not bindingly decide about medical services they are subject to because they are under 16 years of age is indeed taken into account.

On the other hand, as far as special interventions are concerned, the legislator introduced different solutions. Regardless of the minor's age, admissibility of *ex*

19 M. Świderska, Zgoda..., *op. cit.*, p. 62-63.

20 B. Janiszewska, Zgoda na udzielenie świadczenia zdrowotnego. Ujęcie wewnątrzsystemowe, Warszawa 2013, p. 667.

21 Compare art. 32 par. 6 and art. 34 par. 5 APP.

22 Consolidated text Journal of Laws of 2017, item 682 [Tekst jedn. Dz.U. z 2017 r. poz. 682].

23 Por. treść art. 95 § 4 FGC (Parents before making decisions on more important matters matters relating to the person or property of the child will listen to them if his mental development, health, and degree of maturity allow it, taking into account as far as possible its reasonable wishes) oraz art. 576 par. 2 sentence 1 CCP (The Court in matters relating to the person or property of the child will listen to them if his mental development, health, and degree of maturity allow it, taking into account as far as possible its reasonable wishes).

vivo transplantation from a minor donor always requires consent expressed by a statutory representative and guardianship court competent with regard to the place of residence of a candidate for a donor. If a minor donor attained 13 years of age, an entity that is additionally entitled to give consent shall be the donor himself or herself (Art. 12 par. 2 of ACPT); therefore, the structure of triple consent shall be applied. What is more, the above invoked regulation lowers the age limit of a minor entitled to give parallel consent by three years enacting it on the level of 13 years of age, which explicitly increases the scope of autonomy of a minor ex vivo donor compared to patients undergoing other medical interventions[24]. Hence, the age limit obliging a doctor to fulfil the obligation of information fully with regard to such a donor is also lowered. A minor who attained 13 years of age may effectively refuse or object to marrow biopsy. On the other hand, if haematopoietic cells are collected from peripheral blood, then regardless of age, the Polish legislator does not require minor's consent[25]. The literature points out that there are no reasons provided for the above presented distinction[26]. The minor patient's autonomy within this context may also be considered in the procedural level. Pursuant to Art. 12 par. 4 of ACPT, court proceedings to obtain permission may also be initiated by the minor's application who attained 16 years of age. However, the court may issue consent only if it has been requested both by the statutory representatives of the minor over 16 years of age and the minor himself or herself[27].

The exception thereof in the Polish law is a solution applied with regard to the regulation of medical experiments. Apart from the age prerequisite of a minor participant of a test/experiment, the legislator introduced a factual criterion of acting with sufficient understating as a factor authorizing giving cumulative consent by a minor. Due to interpretative obscurity, this notion requires a pursuit of an individual assessment in every case[28]. Hence, the structure of parallel consent with regard to medical experiments is also applied to a wider group of individuals than in the case of general regulation or the one resulting from APP. It increases the scope of the minor patient's autonomy also within the aspect of providing him or her with full information. Apart from the minor who attained 16 years of age, an individual under 16 but acting with sufficient understanding is also entitled to the equivalent right to co-decide.

In the light of deontological norms, pursuant to Art. 15 of CME, if a patient is not capable of expressing informed consent, it should be given by his or her

24 M. Świderska, Zgoda..., *op. cit.*, p. 346.

25 J. Haberko, (in:) J. Haberko, I. Uhrynowska-Tyszkiewicz, Ustawa o pobieraniu, przechowywaniu i przeszczepianiu komórek, tkanek i narządów. Komentarz, Warszawa 2014, p. 139.

26 J. Duda, Cywilnoprawne problemy transplantacji medycznej, Warszawa 2011, p. 138.

27 J. Haberko, (in:) J. Haberko, I. Uhrynowska-Tyszkiewicz, Ustawa..., *op. cit.*, p. 136-138.

28 R. Kubiak, Prawo..., *op. cit.*, p. 450.

statutory representative or a person who is actually taking care of the patient. As far as a minor person is concerned, a doctor should also attempt to obtain his or her consent if he or she is capable of expressing such consent consciously. What is more, Art. 37 of CME stipulates that marrow may only be collected from a child upon the consent of his or her statutory representative. With regard to a minor person, he or she should also give such consent if he or she is capable of giving informed consent. On the other hand, medical experiments with the participation of a minor may be performed solely if it is not possible to carry out experiments/tests of comparable efficiency with the participation of individuals capable of expressing consent (Art. 44 of CME).

5. Conclusions

In result of the analysis of the minor patient's autonomy in the context of the nature of medical intervention he or she is subject to, the following conclusions have been reached. A special legal situation of a minor patient and necessary additional legislative protection are manifestations of the paternalistic treatment of this group of patients, which is justified by their welfare. Nevertheless, elements expressing the minor patient's autonomy can also be found in the Polish law. A type of a health service is a factor that significantly affects the scope of autonomy of a minor patient. Distinct limits thereof introduced by the legislator can be perceived in two levels. The first one involves determination of a group of individuals entitled to express consent to undergo medical service including the rights of a minor patient. The second aspect, which is considered analogously, refers to the rights to information.

Basically, the minor's rights to express consent to undergo a health service (test/examination, other services, surgeries, and methods of treatment and diagnosis of higher risk) become extended after the minor turns 16 years of age. In such a case, based on the formal age criterion, the legislator reserves the minor patient's autonomy in the model of cumulative consent, i.e. expressed in parallel by the minor and his or her statutory representative. On the other hand, a minor patient may not express exclusive consent by himself or herself. If a minor does not have a statutory representative, or it is impossible to contact them, the guardianship court's permission must be obtained. In the case of collision of wills between the authorized entities, i.e. a statutory representative and a minor over 16 years old, the court's permission is additionally required, which emphasizes subjectivity of a minor patient whose will shall not be changed by a statutory representative but solely by an impartial court. Moreover, as far as the implementation of the right to obtain information about one's health condition is concerned, a doctor is obliged to convey such information fully to a patient who turned 16 years of age, the same as to an adult and not incapacitated patient. On the other hand, with regard to other minors, a doctor adapts the scope and

form of information necessary to assure a proper course of a diagnostic or therapeutic process thus providing him or her with medical services. Next conclusion ensues that the Polish law also contains special norms, in the light of which respect for minor persons' autonomy becomes considerably enhanced. The example thereof is medical intervention undertaken under exceptional circumstances, which is undeniably affected by the following situations: a non-therapeutic purpose of the service, or the fact it does not directly benefit a minor patient or generates a higher risk he or she will be subject to. In effect of the occurrence of the above quoted factors, minors' autonomy is taken into account to a larger extent, which is manifested in the form of various solutions. One of them is a lowered age limit entitling a minor to express parallel consent, which occurs in the case of *ex vivo* transplantation of a minor donor. The Constitutional Tribunal decided that the legislator is not constitutionally obliged to transfer special solutions onto statutory regulations concerning the provision of basic and massive health services[29].

What is more, increased autonomy is manifested by the inclusion of not only the criterion of a formal age but also consideration of factual capacity of the subject to express consent resulting from patient's individual features. Furthermore, when exceptional interventions such as medical experiments are undertaken, increased obligation of information in relation to a minor patient is revised, which implies a higher degree of accuracy and a wider scope of information being conveyed as compared to the regulations on the provision of typical health services.

Comparing Polish and international legislations, an essential difference is noticed with regard to a choice of the criterion determining the minor's rights to express consent. Regulations combining the right to make a decision with factual competence, which prevail in the international law, have been replaced by the formal age criterion in the domestic legislation. Nevertheless, the doctrine emphasizes the need to consider a degree of mental maturity and free and sufficient assessment of the situation individually with regard to each patient. The argument raised in support of the above opinion is insufficient protection of minors' rights. On the other hand, however, the application of the factual prerequisite with regard to routine services would be difficult in practice. What is more, the above-formulated postulate would require the inclusion of a special course in medical education concerning methodology of such assessments because not objective and inexplicit factual criterion may lead to arbitrary decisions made by doctors. Nevertheless, even revised (changed) educational programme is not a sufficient solution because the skill of making accurate assessments would, most of all, require considerable experience therein.

29 The judgment of the Constitutional Tribunal of 11 October 2011, K 16/10, http://ipo.trybunal.gov.pl/ipo/Sprawa?cid=1&dokument=7 021&sprawa=6145 (accessed: 17 July 2016).

Summing up, it should be acknowledged that legal subjectivity of a minor patient has been emphasized by providing him or her with the right of self-determination. Yet, its fulfilment has been reserved proportionally to the degree of development (basically assessed with the inclusion of the age criterion) and under the supervision of statutory representatives, and sometimes with the involvement of a court as a guarantor of impartiality.

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The Limits of Autonomy of a Young Living Donor in Transplantation

Abstract: The problem of legal regulation of ex vivo graft from a young living donor raises a lot of controversy. According to the Polish Act on the Collection, Preservation and Transplantation of Cells, Tissues and Organs, a minor can be a donor only in exceptional cases – a cumulative number of prerequisites must be met. At the same time, this regulation provides solutions which respect the autonomy of minors. Firstly, the object of transplant from a young living donor involves only cells able to regenerate, that is bone marrow and peripheral blood. Another necessary condition for the legality of transplantation is to determine whether it is legitimate and purposeful. Furthermore, the protection of the interests of a young living donor is reflected in legislation restricting the circle (group) of recipients – minors can only be donors for their siblings. The most important legal safeguard of young donor's interests seems to be the procedure of obtaining judicial authorization for transplant, which is preceded by the consent of his or her legal representatives. Moreover, in the case of bone marrow transplant, the consent of a minor under 13 years of age is required.
Keywords: autonomy, young living donor, ex vivo transplantation, consent for transplant

1. Introduction

With the origin of liberal democracy, its values have started to affect the relation between a doctor and patient. Paternalistic approach reinforced by the Hippocratic oath, where a doctor was a final medical and moral expert while a patient had to be obedient[1], has gradually been abandoned. The partnership model is based on equality between the parties to medical relation that are capable of deciding about themselves and establishing their own priorities by themselves[2]. Nowadays, it is emphasized that

1 P. Łuków, Granice zgody: autonomia zasad i dobro pacjenta, Warszawa 2005, p. 99; J. Hartman, Bioetyka dla lekarzy, Warszawa 2012, p. 105.

2 P. Łuków, *op. cit.*, p. 100.

everyone is entitled to the right to decide about one's own health. Individuals must be guaranteed that their autonomy, which is inalienable, shall be respected. Patients may neither waive this right nor effectively transfer the entire responsibility for medical decisions upon a doctor[3]. The principle of autonomy of patient's will also applies to transplantations involving minors.

The issue of legal regulation of *ex vivo* transplantation from a young (minor) donor continues to evoke a lot of controversy[4]. Since minors cannot shape their own legal situation themselves, it seems necessary to assure them sufficient protection[5]. It ensues from young men's sensitivity, their yet undeveloped character, a lack of ability to evaluate a situation properly due to insufficient life experience as well as unawareness of the gravity of being a donor[6].

A purpose of the article is to establish the limits of autonomy of will of a young living donor within the field of medical transplantations. Taking into account a unique nature of the treatment, we should examine whether, and if yes, to what extent, minors' autonomy is increasing. At the same time, it seems necessary to consider legal solutions increasing the protection of the rights and interests of young donors.

2. An attempt at defining a minor for the needs of the provisions on transplantation

Pursuant to the solutions contained in the Act of 1 July 2005 on the Collection, Preservation and Transplantation of Cells, Tissues and Organs[7] (hereinafter Transplantation Act), a donor of *ex vivo* transplantation can be an adult holding full capacity to perform legal acts. Under Art. 12 par. 2 of the Act, a minor can be a donor in exceptional cases. Transplantation Act does not define the term of a minor. However, based on *a contrario* reasoning, under Art. 10 § 1 of the Civil Code, it is assumed that a minor is a person who has not attained 18 years of age[8]. A basic element of the term

3 J. Hartman, *op. cit.*, p. 106.

4 K. Mularski, Problematyka przeszczepu od małoletniego żywego dawcy, "Państwo i Prawo" 2013, No. 7, p. 54.

5 K.M. Zoń, Dopuszczalność transplantacji ex vivo od dawcy małoletniego w prawie polskim, http://www.bibliotekacyfrowa.pl/Content/42779/44_Katarzyna_Maria_Zon.pdf (accessed: 10 February 2017).

6 N. Kraszkiewicz, Małoletni jako dawca w świetle polskich przepisów transplantacyjnych, http://www.prawoimedycyna. pl/?str=artykul&id=205 (accessed: 10 February 2017).

7 The Act of 1 July 2005 on the Collection, Preservation and Transfer of Cells, Tissues and Organs (consolidated text Journal of Laws of 2015, item 793 as amended) [Ustawa z dnia 1 lipca 2005 r. o pobieraniu, przechowywaniu i przeszczepianiu komórek, tkanek i narządów (tekst jedn. Dz.U. z 2015 r. poz. 793 ze zm.)].

8 Tak m.in. K. Mularski, Problematyka…, *op. cit.*, p. 54; R. Kubiak, Prawo medyczne, rozdział XIV Warunki prawne przeszczepiania komórek, tkanek i narządów, Warszawa 2014, pow. za wersją

of a minor is his or her lack of full capacity to perform legal acts, which results in the inability to shape their legal situation. This generates serious consequences within the scope of consent for the provision of a medical service[9]. Doctrine representatives point out to doubts emerging under Transplantation Act in relation to individuals who became adults according to the principles specified in Art. 10 § 2 of the Civil Code, that is in effect of marriage. Following literal interpretation, such individuals should be treated as minors. It is assumed, however, that systemic interpretation should be applied here including the provisions of the Civil Code and Family and Guardianship Code. In consequence, such individuals are recognized as adults for the needs of Transplantation Act[10].

Ex vivo transplantation from a young (minor) donor is admissible only if numerous prerequisites are cumulatively satisfied. Medical, subjective and legal conditions contained in Art. 12 par. 2-5 of Transplantation Act underline an exceptional nature of this method of treatment[11].

3. Medical conditions of admissibility of transplantation from a young (minor) donor

Pursuant to Art. 12 par. 2 of Transplantation Act, the object of transplantation from a young living donor involves only cells able to regenerate, that is bone marrow and haematopoietic cells of peripheral blood. In the light of statutory provisions, there is an absolute ban on collecting material other than the one enlisted in the Act[12]. Within the context, it should be depicted that Transplantation Act of 1995 allowed to retrieve (collect) solely bone marrow from a minor donor[13]. Thus, the present Act extends the subject catalogue of biological material. Moreover, there are *de lege ferenda* postulates to extend the catalogue to cover other cells and tissue able to regenerate[14].

An indispensable prerequisite of the legality of transplantation is the establishment whether the treatment is justified and purposeful (Art. 12 par. 1 point 3 of Transplantation Act), as it should be remembered that from a donor's perspective,

elektroniczną dostępną w Systemie Informacji Prawnej Legalis.

9 K.M. Zoń, Dopuszczalność…, *op. cit.*

10 R. Kubiak, Prawo…, *op. cit.*

11 K.M. Zoń, Dopuszczalność…, *op. cit.*

12 *Ibidem.*

13 J. Duda, Cywilnoprawna problematyka transplantacji medycznej, Warszawa 2011, p. 138.

14 K. Mularski, *op. cit.*; J. Haberko, (in:) J. Haberko, I. Uhrynowska-Tyszkiewicz (eds.), Ustawa o pobieraniu, przechowywaniu i przeszczepianiu komórek, tkanek i narządów. Komentarz, Warszawa 2014, p. 134.

transplantation is a serious mutilation, which may even threaten his or her life. Hence, such treatment must be reasonably and seriously justified by medical conditions[15].

3.1 Legitimacy of transplant surgery

Transplantation legitimacy is understood as a situation when transplantation will not cause inevitable and morally and legally unacceptable detriment (harm) to donor's health while concurrently contributing to saving the recipient's life or health. Transplantation will be solely justified if it does not cause any foreseeable impairment of the donor's organism while, at the same time, there is no other possibility of saving recipient's life since endeavours to save the recipient may not violate the protected interest of a donor. Therefore, the inclusion of proportionality of benefits for a recipient and risk for a donor becomes one of the most important tasks of a doctor deciding about the surgery[16].

Doctrine representatives underline the necessity of occurrence of a direct threat of the recipient's loss of life which may only be saved through transplantation[17]. An immediate danger to human health is defined as the last stage between a threat of a specific interest and its violation. The Supreme Court's case law depicts that an immediate danger should be understood as "an immediate threat of a specific interest, i.e. to an extent that in case of any delay in launching a rescue operation, it may turn out to be irrelevant; or otherwise, when a violation of interest does not have to be effected immediately but its nature is inevitable while refraining from a rescue operation might increase the scope of imminent harm, or hamper its prevention"[18]. It should be noticed that the causes of a threat do not appear suddenly and rapidly but act inevitably, and without medical intervention they may lead to death[19]. In consequence, it seems that a doctor must assess whether the material must be collected in a given moment immediately and determine how a delayed surgery will affect changes in the recipient's health condition[20].

3.2 Purposefulness of transplant surgery

The second medical condition of transplantation – a prerequisite of purposefulness – indicates that a purpose of transplantation must be saving an immediately (directly) threatened life of a recipient. The improvement of health condition or life comfort is not sufficient in this case[21]. Doctrine representatives emphasize a subsidiary nature of transplant surgeries performed with the

15 R. Kubiak, Prawo…, *op. cit.*
16 K.M. Zoń, Dopuszczalność…, *op. cit.*
17 *Ibidem*; also: J. Duda, *op. cit.*, p. 136.
18 The judgment of the Supreme Court of 30 May 1973, III KR 6/1973, BSN 10/1973, item 163.
19 J. Jaroszek, Przeszczepy w świetle prawa w Polsce, Warszawa 1988, p. 61.
20 Also claims so: K.M. Zoń, Dopuszczalność…, *op. cit.*; R. Kubiak, Prawo…, *op. cit.*
21 K. Mularski, Problematyka…, *op. cit.*

participation of minors. Such interventions are admissible solely if there are no other equally efficient methods while transplantation is the only rescue (last resort) for a recipient[22]. Such a surgery is not justified if the recipient's health or life is not immediately threatened and the surgery may be performed later as it happens that a delay may be sufficient for obtaining *ex mortuo* material, which eliminates the necessity of colleting it from a living donor[23]. In consequence thereof, transplantation will not be admissible if there are other methods of saving a recipient, or possibly improving his or her health condition without the necessity to carry out *ex vivo* transplant[24]. It should be noticed that such a solution has been introduced directly to the so-called European Oviedo Bioethical Convention, signed by Poland but still not ratified[25]. Pursuant to Art. 19 par. 1 thereof, removal of organs or tissue from a living person for transplantation purposes may be carried out solely for the therapeutic benefit of the recipient and where there is no suitable organ or tissue available from a deceased person and no other alternative therapeutic method of comparable effectiveness[26].

If *ex vivo* transplantation is the only therapeutic method, it is necessary to carry out an appropriate evaluation of the balance of gains and losses, positive results for the recipient in relation to negative consequences for the donor and probability of their occurrence[27]. The subject literature underlines that in the situation when "profit is insignificant (e.g. slight alleviation of pain, or short-term prolongation of life) while a donor is seriously mutilated and thus his or her life is potentially shortened, the surgery may appear inadmissible. Hence a doctor should consider the potential chances of transplant acceptance and whether, due to the recipient's condition, forecast for the entire undertaking is positive"[28]. Additionally, it should be emphasized that transplantation will not be admissible with regard to single organs that do not regenerate and possibly pairs of organs that do not regenerate (e.g. both kidneys) since such a surgery finishes with either donor's death or serious detriment to his her health[29].

In the light of the above opinions, it should be acknowledged that transplantation will be justified and purposeful when the surgery is "the only way of achieving highly

22 K.M. Zoń, Dopuszczalność.., *op. cit.*; M. Guzik-Makaruk, Transplantacja organów, tkanek i komórek w ujęciu prawnym i kryminologicznym, Białystok 2008, p. 301.

23 M. Sośniak, Zagadnienia prawne przeszczepów, "Państwo i Prawo" 1971, No. 2, p. 221.

24 R. Kubiak, Prawo…, *op. cit.*; Also claims so: M. Sośniak, *op. cit.*, p. 221. In contrast, according to some representatives of the doctrine, ex-mortuo and ex vivo transplantation is of equal nature – see: M. Guzik-Makaruk, *op. cit.*, p. 302.

25 The convention for the Protection of Human Rights and Dignity adopted on the 4 of April 1997 in Oviedo (CETS No. 164).

26 R. Kubiak, Prawo…, *op. cit.*; J. Duda, Cywilnoprawna…, *op. cit.*, p. 137.

27 *Ibidem.*

28 J. Duda, Cywilnoprawna…, *op. cit.*, p. 155.

29 R. Kubiak, Prawo…, *op. cit.*

probable beneficial results for the recipient's health, on the one hand, while providing a low risk of negative consequences for the donor's health, on the other hand"[30].

4. Subject restriction of the circle of recipients

Enhanced protection of young living donors' interests is also manifested in the regulation restricting a circle (group) of recipients. Pursuant to Art. 12 par. 2 of Transplantation Act, "(…) a donor for their siblings may also be minor". It should be emphasized that from a medical perspective, transplantations are the most effective if a recipient and donor are closely related[31]. A circle (group) of recipients has been restricted in order to assure compliance of the Polish Transplantation Act with the so called European Oviedo Bioethical Convention. It is worth noticing that Art. 9 of the previously binding Transplantation Act of 1995[32] admitted transplantations for a much wider circle of entities, including ascendants and descendants[33]. Moreover, other legislations (e.g. Swiss) envisage that also parents and children may be potential recipients of a minor donor[34].

Furthermore, the literature presents opinions admitting transplantation for the benefit of adopted siblings as well[35]. What is more, it is depicted that not related persons (family members), e.g. spouses, friends, or even strangers who want to help others, should not be refused donation of their material[36]. At the same time, Transplantation Act does not specify a minimum age of a transplant recipient[37].

Exclusion of minor's ascendants from the circle of recipients seems right due to a risk of potential abuses. Such a catalogue of recipients does not allow parents to use the child's health in order to improve or save their health or life. Thus, legal protection of a minor donor has been emphasized[38]. On the other hand, current regulation seems to be too restrictive in relation to the minor's descendants because the minor's parents may not be donors for their own child. In specific and infrequent situations, waiting for transplantation until a minor mother turns 18 years of age may lead to serious and life-threatening consequences for the child's life[39].

30 *Ibidem*.
31 *Ibidem*.
32 The Act of 26 October 1995 on the Collection and Transfer of Cells, Tissues and Organs (consolidated text Journal of Laws No. 138, item 682) [Ustawa z dnia 26 października 1995 r. o pobieraniu i przeszczepianiu komórek, tkanek i narządów (Dz.U. Nr 138 poz. 682)].
33 K. Mularski, Problematyka…, *op. cit.*, p. 57.
34 K.M. Zoń, Dopuszczalność…, *op. cit.*
35 Tak m.in. J. Haberko, Ustawa…, *op. cit.*, p. 132.
36 See: R. Kubiak, *op. cit.* and the literature given there.
37 J. Haberko, Ustawa…, *op. cit.*, p. 132.
38 N. Kraszkiewicz, Małoletni…, *op. cit.*
39 K. Mularski, Problematyka…, *op. cit.* p. 59; compare also: J. Haberko, Ustawa…, *op. cit.*, p. 133.

5. Legal criteria of transplant surgeries

The minor donor's interest is secured by the entities taking part in the transplantation procedure, i.e. the court relying on the expert psychologist opinion, minor's statutory representatives, and the minor himself or herself after they attained 13 years of age[40].

5.1 Court's authorization to collect material from a minor donor

Art. 12 par. 4 and 5 of Transplantation Act regulates the procedure of obtaining a court permission to collect material from a minor donor. The proceedings are initiated upon the request of potential donor's statutory representatives; both parents holding parental authority must submit the request amicably. On the other hand, if a donor is over 16 years old, his or her request (application) is additionally required[41].

Issuing a permission, the court should hear the opinion of the interested party himself or herself with due diligence. Prior to this, he or she should be provided with all and any necessary information conditioning informed consent[42]. Transplantation Act does not specify a minimum age at which a minor donor should be heard; therefore, the expert psychologist opinion is helpful therein. Its purpose is to determine whether a child could make a decision according to his or her will, and whether it will be reliable[43]. At the same time, it should be noticed that such hearing is of an exclusively informative nature because the legislator has not regulated the effects resulting from a potential objection expressed by a minor[44]. What is more, the Act has failed to include directives for the court too, pursuant to which a minor's objection is an obstacle to grant permission[45]. The literature postulates that the objection expressed by a minor should prevent the court from issuing permission. Such interpretation apparently secures the child's interest. One should approve of the opinion according to which it is necessary to resign from the material collection if a minor capable of sufficient understanding of the situation has objected to it[46]. This opinion is grounded in the provision of Art. 20 of the so-called European Oviedo Convention, in the light of which, one of the conditions of admissible explantation

40 K. Mularski, Problematyka…, *op. cit.*, p. 59.
41 R. Kubiak, Cywilnoprawna…, *op. cit.*
42 *Ibidem.*
43 K.M. Zoń, Dopuszczlaność…, *op. cit.*
44 *Ibidem.*
45 T. Smyczyński, Opinia o ustawie o pobieraniu i przeszczepianiu komórek, tkanek i narządów, (in:) Opinie o ustawie o pobieraniu i przeszczepianiu komórek, tkanek i narządów. Zeszyty Biura Studiów i Analiz Kancelarii Senatu, September 1995, No. 264, p. 8.
46 K.M. Zoń, Dopuszczalność…, *op. cit.*; tak też: E. Zielińska, Przeszczepy w świetle prawa w Polsce i na świecie, "Państwo i Prawo" 1995, No. 6, p. 17.

is no objection raised by a potential donor[47]. The application of such a solution guarantees full protection of the minor's rights.

Furthermore, it should be emphasized that following the procedure of granting permission, the court must consider medical reasons; in particular verify whether a transplant surgery will not result in serious consequences for the donor's health. In order to examine the case reliably and expel any doubts, the court should ask for additional information coming from, e.g., the minor's medical records, opinions of medical entities he or she was treated in, or the opinion of a statutory representative. A request (application) for the initiation of the proceedings should contain a medical opinion acknowledging that the collection of bone marrow will not cause a foreseeable impairment of the minor's organism[48]. The doctrine representatives postulate that this requirement should not be limited to bone marrow but it should also include haematopoietic cells[49].

The above-mentioned legislative solution has been positively evaluated by the doctrine. Being an additional condition of admissibility of a transplant surgery, court permissions limit cases of potential abuses by parents willing to use the material coming from one child to save another one. The court issuing permission safeguards parents' undue emotions[50].

5.2 Authorization by the minor's statutory representatives

Another prerequisite of collecting material from an *ex vivo* minor donor is obtaining consent of his or her statutory representatives. Since the legislator has not envisaged formal requirements within this scope, under Art. 60 of the Civil Code, consent of a statutory representative may be given by/through any conduct implying his or her will[51]. The Supreme Court's judgments acknowledge that a failure to make a written statement by a patient giving consent to the surgery does not invalidate the consent while the effects of a failure to follow the required form are specified in Art. 74 of the Civil Code[52]. Taking the above into account, the doctrine representatives argue that the very submission of a request for the court permission for transplantation may be recognized as implied consent for the surgery[53]

5.3 Minor donor's consent and prerequisites of its efficiency

Apart from the requirement of obtaining consent of a minor's statutory representative and the court, another prerequisite of collecting bone marrow from

47 Zwraca na to uwagę m.in. R Kubiak, Prawo…, *op. cit.*

48 R. Kubiak, Prawo…, *op. cit.;* K. Mularski, Problematyka…, *op. cit.*, p. 62.

49 K. Mularski, Problematyka…, *op. cit.*; J. Duda, *op. cit.*, p. 138.

50 R. Kubiak, Prawo…, *op. cit.*; M. Guzik-Makaruk, *op. cit.*, p. 302.

51 K. Mularski, Problematyka…, *op. cit.*, p. 63.

52 The judgment of the Supreme Court of 11 April 2006, I CSK 191/05, OSNC 2007, No. 1, item 18.

53 K. Mularski, Problematyka…, *op. cit.*, p. 62.

a minor is also consent of the minor donor himself or herself. This specific medical intervention is subject to distinct principles regulating the provision of consent to medical treatment[54], which differ from the requirements envisaged by the Act on the Profession of a Physician and Dentist[55]. It results from the fact that transplantation from a young living donor does not satisfy a therapeutic purpose benefiting him or her while implying a detrimental effect for his or her organism. As far as *ex vivo* transplantation from a minor donor is concerned, a special form of consent shall be required. In the light of Art. 12 par. 2 sentence 2 of Transplantation Act, attaining 13 years of age by a minor donor means that they themselves become subjects that are additionally entitled to give consent thereto. Compared to general principles resulting from the Act on the Profession of a Physician and Dentist, the above quoted provision lowers the age limit authorizing a minor to give parallel consent. One should approve of the opinion according to which this solution considerably increases the scope of autonomy of will of a young living donor compared to patients subject to common medical services[56]. Yet, it should be emphasized that consent of a minor who attained 13 years of age concerns solely bone marrow collection. The Act does not introduce the need to obtain his or her consent when they donate peripheral haematopoietic blood. The doctrine representatives have criticized this solution[57].

Prerequisites of efficiency of a minor's consent have not been precisely specified in the Act. Nevertheless, they are determined for donors holding full capacity to perform legal acts (Art. 12 par. 1 point 5 and 7 of Transplantation Act).

Consent for the collection of material for transplantation will be efficient when, prior to it, a potential donor has been precisely informed in a written form by a doctor performing the surgery and a doctor not participating directly in transplantation about a type of the surgery, risk involved and foreseeable consequences for the donor's health in the future[58]. Entities authorized to obtain such information are all individuals due to give consent including minors who attained 13 years of age. The provision of Art. 31 par. 1 of the Act on the Profession of a Physician and Dentist determines a minimum scope of such information and enlists other Acts referring to special surgeries supplementing it by subsequent elements[59]. As depicted by the doctrine, "a characteristic feature of the consent for *ex vivo* transplantation is

54 A.K. Dudzińska, Zdolność do wyrażenia zgody w przypadku transplantacji ex vivo, http://www.prawoimedycyna. pl/index.php?str=artykul&id=112 (accessed 10 February 2017).

55 Act of 5 December 1996 on the Profession of a Physician and Dentist (Journal of Laws of 2005, No. 226, item 1943 as amended) [Ustawa z dnia 5 grudnia 1996 r. o zawodach lekarza i lekarza dentysty (Dz.U. z 2005 r., Nr 226, poz. 1943 ze zm.)].

56 K.M. Zoń, Dopuszczalność…, *op. cit.*

57 J. Duda, Cywilnoprawna…, *op. cit.*, p. 138.

58 K. Mularski, Problematyka…, *op. cit.*; J. Duda, Cywilnoprawna… *op. cit.*, p. 144.

59 K.M. Zoń, Dopuszczalność…, *op. cit.*

increased obligation of information manifested in two levels"[60]. On the one hand, the scope of information being conveyed is increasing since a doctor must inform a patient about the essence, purpose, importance and technical elements of the surgery as well as the ensuing risk embracing data concerning medical intervention itself and the likelihood of possible complications and problems. Additionally, a donor should be aware of foreseeable temporary and potential consequences for his or her health in the future[61].

The above information must be conveyed by two entities: a doctor performing transplantation and a doctor not taking part in the surgery[62]. The doctrine believes that "a double manner of satisfying the obligation of information is to objectivize and increase a number of sources of information"[63].

Consent for transplant surgery should be given freely and in writing before a doctor[64]. This regulation results directly from Art. 12, par. 1, point 7 of Transplantation Act. The doctrine representatives claim that consent may not be replaced by a lack of objection. However, the form of consent is reserved solely for the purpose of keeping evidence; therefore, a failure to follow it does not invalidate the relevant statement[65]. What is more, it is assumed *de lege lata* that the very submission of a request for the court permission to collect material by a minor who attained 16 years of age is not equivalent to his or her consent for the surgery[66]. In principle, the consent should also specify a recipient[67]. The requirement of specifying a recipient of transplantation does not regard the collection of bone marrow or other self-regenerating cells and tissues. The above requirements are to guarantee that a donor has been fully aware of his or her decision[68].

Furthermore, it is worth indicating that Transplantation Act has regulated uniquely a possibility of withdrawing consent. First of all, for obvious reasons, this right must be exercised before the surgery. What is more, Art. 12 par. 1 point 8 introduced the obligation to inform a donor about the consequences for the recipient's life and health since a withdrawal of consent may evoke serious effects for the recipient being prepared for the surgery, both physical – *inter alia* connected with taking medicine to lower immunity – and psychological[69].

60 *Ibidem*.
61 J. Duda, Cywilnoprawna…, *op. cit.,* p. 149.
62 K.M. Zoń, Dopuszczalność…, *op. cit.*; J. Duda, Cywilnoprawna…, *op. cit.,* p. 149.
63 K.M. Zoń, Dopuszczalność…, *op. cit.*
64 K. Mularski, Problematyka…, *op. cit.*
65 K.M. Zoń, Dopuszczalność…, *op. cit.*
66 J. Haberko, *op. cit.*, p. 139.
67 K. Mularski, Problematyka…, *op. cit.*
68 *Ibidem*.
69 K.M. Zoń, Dopuszczalność…, *op. cit.*

6. Conclusion

Conditions of performing a transplant surgery in relation to a young living donor are restrictively formulated and they admit the application of this medical intervention only to a narrow extent. Pursuant to Art. 12 par. 2 of Transplantation Act, a minor may be a donor of bone marrow or peripheral blood haematopoietic cells only if the recipient's life – minor donor's siblings – is directly threatened, and when such a threat could not be avoided in any other way but through transplantation. Material is collected from a minor as an exception, after cumulative satisfaction of numerous prerequisites[70].

Minor's protection is further enhanced by the circle of entities whose parallel consent is required prior to this unique medical intervention. Material may be collected from a minor donor after obtaining consent of his or her statutory representative and permission of a guardian court competent with regard to the donor's residential address. If a minor attained 13 years of age, he or she is also entitled to give consent to the surgery. The introduction of such regulation manifests fuller respect for the autonomy of minor individuals[71]. It is also expressed in a possibility of raising effective objection regardless of the minors' statutory representative[72].

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70 *Ibidem*.
71 See: K.M. Zoń, Dopuszczalność, *op. cit.*
72 N. Kraszkiewicz, Małoletni…, *op. cit.*

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Consent to Deceased Donation in the American Transplant System

Abstract: According to the data, the deceased and living donor rates cannot keep pace with the growing need for organs in the United States. In three decades, the national waiting list has grown 8-fold. It is estimated that every 10 minutes another name is added to the national transplant waiting list. Approximately 22 people die every day waiting for a transplant. Most organs for transplants are recovered from deceased donors. The United States use the "donation model", a consent model for deceased organ recovery that prioritizes the rights of the individual (or the surrogate decision maker) over the needs of society, by requiring authorization or explicit consent prior to deceased organ recovery. Some transplant community members have advocated for shifting the current donation model of deceased donor organ recovery to a model that permits deceased organ recovery without explicit consent or authorization, in order to increase the number of organs available for transplant. This article aims at answering a question whether shifting to such a model in the United States could solve systemic problems, organs shortage in particular, and whether it would be ethically justified. The paper describes models of deceased organ recovery and presents the model currently used by the United States. It presents, from the American perspective, the analysis of the model of deceased organ recovery without explicit consent or authorization, as well as proposes alternative opportunities to increase deceased organ supply.
Keywords: transplantation, donation, deceased donor

1. Introduction

In the USA, a number of donors has increased over 2.5[1] times since 1988[2]. From 1 January 1988 to 31 March 2017, a total number of donors amounted to 341 033[3]. During this time, 695 096 transplantations[4] were performed.

1 From 5 909 in 1988 to 15 943 in 2016.
2 Data of the Organ Procurement and Transplantation Network – OPTN, collected from the 1 of October 1987, available at: www.optn.transplant.hrsa.gov/data (accessed: 26 April 2017).
3 Including 193 723 deceased donors and 147 310 active donors.
4 Including 548 002 *ex mortuo* i 147 094 *ex vivo*.

Most organs for transplantation come from the deceased. In the USA, a number of deceased donors has more than doubled since 1988 (from 4 080 donors in 1988 to 9 970 donors in 2016)[5]; apart from a few exceptions[6], the number has increased each year. From 1 January 1988 to 31 March 2017, a total number of deceased donors amounted to 193 723[7]. During this time, 548 002 *ex mortuo* transplants were performed. A number of *ex mortuo* transplants increased from 10 794 in 1988 to 27 630 in 2016[8].

Despite progress in medicine and the growth of technology and actions aimed at an increase of public awareness of donation of organs and transplantation, the relevant data imply that the number of *ex mortuo* and *ex vivo* donors is not sufficient to satisfy a growing demand for organs.

A list of individuals awaiting transplantation is continually increasing, in the past 30 years it has increased nearly eight times[9]. A total number of candidates for a recipient entered into the waiting list amounts to 118 173[10], including 75 952 active candidates[11]. Every ten minutes, a next candidate for a recipient is added to the above list. On average, 22 people die every day awaiting transplantation. In 2015 122 071 individuals[12] awaited transplantation; 30 975 transplantations were performed while organs were recovered from 15 068 donors[13].

Currently, the USA has implemented "a donation model", i.e. a consent model for deceased organ recovery that prioritizes the rights of the individual (or the surrogate decision maker) over the needs of society, by requiring authorization or explicit consent prior to deceased organ recovery. In order to increase the number of organs available for transplantation, some transplant community members have advocated for shifting the current donation model of deceased donor organ recovery to a model that permits deceased organ recovery without explicit consent or authorization.

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5 The number was respectively: 4 080 (1988), 4 011 (1989), 4 509 (1990), 4 526 (1991), 4 520 (1992), 4 861 (1993), 5 099 (1994), 5 363 (1995), 5 418 (1996), 5 479 (1997), 5 793 (1998), 5 824 (1999), 5 985 (2000), 6 080 (2001), 6 190 (2002), 6 457 (2003), 7 150 (2004), 7 593 (2005), 8 017 (2006), 8 085 (2007), 7 989 (2008), 8 022 (2009), 7 943 (2010), 8 126 (2011), 8 143 (2012), 8 268 (2013), 8 596 (2014), 9 079 (2015), 9 970 (2016.).

6 In 1989, 1992, 2008 and 2010.

7 Between the 1st of January 2017 and the 31st March 2017, the number of deceased donors was 2 547.

8 In other years: 11 222 (1989), 12 878 (1990), 13 329 (1991), 13 563 (1992), 14 732 (1993), 15 211 (1994), 15 921 (1995), 15 983 (1996), 16 266 (1997), 16 979 (1998), 17 010 (1999), 17 335 (2000), 17 641 (2001), 18 292 (2002), 18 659 (2003), 20 049 (2004), 21 213 (2005), 22 207 (2006), 22 053 (2007), 21 746 (2008), 21 850 (2009), 22 101 (2010), 22 518 (2011), 22 187 (2012), 22 967 (2013), 23 720 (2014), 24 985 (2015), 27 630 (2016).

9 From 15 029 people in 1988 to over 118 000 currently.

10 As of 15 April 2017, at 18:28 (the list is updated on an ongoing basis).

11 Candidates who are currently eligible for a transplant and are entitled to receive the organ.

12 As at the end of the year.

13 Data of the OPTN, available at: www.optn.transplant.hrsa.gov/data (accessed: 26 April 2017).

This article aims at answering a question whether the introduction of the above-mentioned model of organ recovery in the USA would solve systemic problems, and whether it would be ethically justified.

2. *Ex mortuo* organ donation models

Largely, legally binding solutions worldwide distinguish two general models of legally admissible *ex mortuo* organ recovery. The first one assumes that society has a legitimate interest in recovering organs from the deceased and may recover them without any form of permission or authorization from the interested individual (or the surrogate decision maker). In this model, social needs prevail over the rights of individuals[14]. It is defined as "deceased organ recovery without explicit consent or authorization"[15], "presumed consent"[16], or "opt-out"[17]. The Polish literature sometimes defines this model as the French one – requiring explicit exclusion of consent for organ recovery[18].

The second model assumes that organs belong to an individual and cannot be appropriated without his or her explicit consent or authorization (or authorization of the surrogate decision maker). This model, defined as "the donation model"[19], is currently binding in the USA. The domestic literature calls it the American-Canadian model[20] whereas the consent for organ recovery may be expressed in a written or spoken form in the presence of witnesses (opting in system) while presumed consent

14 Ethics…, *op. cit.*

15 In the opinion of the Ethics Committee OPTN / UNOS, this is the most appropriate term, see: Ethics of deceased organ donor recovery without requirement of explicit consent or authorization, White Paper, OPTN, available at: www.optn.transplant.hrsa.gov/data (accessed: 26 April 2017).

16 E.g. A. Rithalia, C. McDaid, S. Suekarran, Impact of presumed consent for organ donation on donation rates: a systematic review, "BMJ" 2009, No. 338, a3162; R. Veatch, L. Ross, Chapter 10: Routine Salvaging and Presumed Consent (in:) Transplantation Ethic, 2nd ed., Washington DC: Georgetown University Press 2015, p. 147 and following; A. Abadie, S. Gray, The impact of presumed consent legislation on cadaveric organ donation: A cross-country study, "Journal of Health Economics" 2006, No. 25 (4), p. 599 and following.

17 Eg. L. Shepherd, R. O'Carroll, E. Ferguson, An international comparison of deceased and living organ donation/transplant rates in opt-in and opt-out systems: a panel study, "BMC Medicine" 2014, No. 12 (131), p. 1 and following; C. Rudge, E. Buggins, How to increase organ donation: Does opting out have a role?, "Transplantation" 2012, No. 93 (2), p. 141 and following.

18 See eg.: E. Guzik-Makaruk, Transplantacja organów tkanek i komórek w ujęciu prawnym i kryminologicznym. Studium prawnoporównawcze, Białystok 2008, p. 34; G. Rejman, Zgoda na pobranie organu, narządu lub tkanek ze zwłok jako okoliczność uchylająca bezprawność czynu, "Studia Iuridica" 1991, t. 19, p. 167.

19 Ethics…, *op. cit.*

20 See eg.: E. Guzik-Makaruk, Transplantacja…, *op. cit.*, p. 34.

for organ recovery (opting out system) may be abolished determining that the deceased person objected to it before death[21].

3. *Ex mortuo* organ donation model in the USA

The US "donation model" is based on the moral priority of an individual[22] and a legal assumption according to which individuals have a "quasi-property right" to their bodies (including their organs). It gives them a right of certain kinds of control, without implying an ownership right to buy or sell body parts[23]. The society must respect the right of an individual to dispose of their own organs. An individual (or in some case their authorized agents) may donate (as a gift) their body or parts thereof[24].

Ex mortuo organ recovery is regulated by the Uniform Anatomical Gift Act – UAGA, amended in 2006[25]. The Act aims, among others, at establishing a system that honours and respects the right of an individual to donate their organs and strengthen the right of an individual to refuse to donate their organs by prohibiting others from overriding an individual's wish not to donate organs. The substantive and objective scope of the Act is limited to the recovery of tissue and organs from the deceased donors, consent for donation, changing a relevant declaration of will, and withholding or refusing donation.

Pursuant to Art. 4 of the Act, an anatomical gift of a donor's body or part[26] may be made during the life of the donor for the purpose of transplantation, therapy, research, or education. Such consent can be made by the donor (if he or she is an adult, emancipated minor[27], or a minor authorized under state law to apply for a driver's license), an agent of the donor (unless the power of attorney for health care or other record prohibits the agent from making an anatomical gift), a parent of the donor (if the donor is an unemancipated minor) and the donor's guardian.

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21 *Ibidem*, p. 34; E. Zielińska, Transplantacja w świetle prawa w Polsce i na świecie, "Państwo i Prawo" 1995, No. 6, p. 24.

22 P. Ramsey, The Patient as Person: Explorations in medical ethics, New Haven, Connecticut 1970.

23 Organ trade is forbidden by the National Organ Transplant Act – NOTA of 1984. According to. 301(a) it shall be unlawful for any person to knowingly acquire, receive, or otherwise transfer any human organ for valuable consideration for use in human transplantation if the transfer affects interstate commerce. According to art. 301(b) Any person who violates subsection (a) shall be fined not more than $50,000 or imprisoned not more than five years, or both. Organ trade is also forbidden according to art. 16 Uniform Anatomical Gift Act – UAGA of 2006.

24 Ethics…, *op. cit.*

25 See more: Anatomical Gift Act (2006) Summary, available at the web page of the *Uniform Law Commission* at: www.uniformlaws.org (accessed: 26 April 2017).

26 "Part" means an organ, an eye, or tissue of a human being (art. 2(18)).

27 Minors who are self-dependent and not under parental control; usually pursuant to a court order, B. Garner (ed.), Black's Law Dictionary, 10th ed., Thomson Reuters, 2014, p. 1147.

A donor may make an anatomical gift: by authorizing a statement or symbol indicating that the donor has made an anatomical gift to be imprinted on the donor's driver's license or identification card; in a will; during a terminal illness or injury of the donor, by any form of communication addressed to at least two adults, at least one of whom is a disinterested witness. A donor (or other person authorized to make an anatomical gift) may make a gift by a donor card or other record signed by the donor (or other person making the gift); or by authorizing that a statement or symbol indicating that the donor has made an anatomical gift be included on a donor registry (Art. 5). A donor (or other person authorized to make an anatomical gift) may amend or revoke an anatomical gift (Art. 6). An individual may refuse to make an anatomical gift of the individual's body or part by: a record signed by the individual (or another individual acting at the direction of the individual if the individual is physically unable to sign); the individual's will, whether or not the will is admitted to probate or invalidated after the individual's death; or any form of communication made by the individual during the individual's terminal illness or injury addressed to at least two adults, at least one of whom is a disinterested witness (Art. 7).

The Act envisages preclusive effect of anatomical gift, amendment, or revocation (Art. 8). In the absence of an express, contrary indication by the donor, a person other than the donor is barred from making, amending, or revoking an anatomical gift of a donor's body or part if the donor

made an anatomical gift of the donor's body or part or an amendment to an

anatomical gift of the donor's body or part. In the absence of an express, contrary indication by the donor (or other person authorized to make an anatomical gift), an anatomical gift of a part is neither a refusal to give another part nor a limitation on the making of an anatomical gift of another part at a later time by the donor or another person. However, if a donor who is an unemancipated minor dies, a parent of the donor who is reasonably available[28] may revoke or amend an anatomical gift of the donor's body or part. Similar to this, if an unemancipated minor who signed a refusal dies, a parent of the minor who is reasonably available may revoke the minor's refusal.

An anatomical gift of a decedent's body or part for purpose of transplantation, therapy, research, or education may be made by any member of the following classes of persons (who is reasonably available), in the order of priority listed: an agent of the decedent at the time of death; the spouse of the decedent; adult children of the decedent; parents of the decedent; an adult who exhibited special care and concern for the decedent; the persons who were acting as the guardians of the person of the decedent at the time of death; and any other person having the authority to dispose

28 "Reasonably available" means able to be contacted by a procurement organization without undue effort and willing and able to act in a timely manner consistent with existing medical criteria necessary for giving a whole or a part of a human body (anatomical gift), Legal Glossary, available at: www.oregonlaws.org (accessed: 26 April 2017).

of the decedent's body (Art. 9). A person authorized to make an anatomical gift may make an anatomical gift by a document of gift signed by the person making the gift or by that person's oral communication that is electronically recorded or is contemporaneously reduced to a record and signed by the individual receiving the oral communication (Art. 10).

4. The postulate to introduce the model of *ex mortuo* organ recovery without explicit consent or authorization

Dukeminier and Sanders first proposed the model of "deceased organ recovery without explicit consent or authorization" in the US as early as in 1968[29], and it currently remains under debate[30]. Some members of the transplant community are for the adoption of this model as it could increase a number of *ex mortuo* organs available for transplantation. In June 1993, Presumed Consent Sub-Committee of OPTN[31] Ethics Committee/UNOS[32] drafted White Paper containing ethical evaluation of presumed consent for organ recovery[33]. It expressed an opinion saying that the reform of the process of organ donation should not be based on the model of presumed consent because from the ethical perspective, presumed consent does not sufficiently protect individual autonomy of potential donors. However, in effect of the White Papers' revision commenced in 2014, the document of 1993 was found outdated. For this reason, in December 2016 a new White Paper was drafted titled Ethics of *Ex Mortuo* Organ Recovery without Required Explicit Consent or Authorization[34], which analyzed this model of organ donation and a potential possibility of its adoption in the USA.

29 J. Dukeminier, D. Sanders, Organ transplantation: a proposal for routine salvaging of cadaver organs, "The New England Journal of Medicine" 1968, No. 279 (8), p. 413 and following.

30 See e.g.: R. Veatch, L. Ross, *op. cit.*; K. Healy, Do presumed consent laws raise organ procurement rates?, "De-Paul Law Review" 2005-2006, No. 55, p. 1017 and following.

31 Organ Procurement and Transplantation Network – OPTN – established under NOTA of 1984; supports and monitors a fair organ allocation system for transplants; keeps a list of candidates for the recipient; combines candidates for the recipient with organ donors; enables effective and efficient placement of organs for transplantation; takes measures to increase organ donation; see more on the official web page at: www.optn.transplant.hrsa.gov (accessed: 26 April 2017).

32 United Network for Organ Sharing – UNOS – a private non-profit organization that manages the national transplant system on the basis of an agreement with the federal government; connects patients, donor families and transplant professionals to create a fair organ allocation system; see more on the official web page at: www.unos.org (accessed: 26 April 2017).

33 An Evaluation of the Ethics of Presumed Consent, A Report of the Presumed Consent Subcommittee of the Ethics Committee (June 1993), document available on the official web page of the OPTN at: www.optn.transplant.hrsa.gov (accessed: 26 April 2017).

34 Ethics, *op. cit.*

This model is usually justified either by supreme public interest (defined as common good) in relation to the individual's choice, or "presumed" consent of the deceased. Its proponents assume that the needs and rights of an individual are subordinated to public needs and interests (common good). The State is authorized to recover organs from the deceased without explicit consent or authorization just to benefit the overall needs of society and to prevent additional deaths due to organ failure. The law in many countries of South Europe, Scandinavia and Asia allow for the recovery of organs from the deceased that generally stand in this tradition.

In the USA, although this model is not allowed for deceased organ recovery, the ethical justification is applied to other practices in health care, e.g. medical examiners are authorized to carry out autopsy of the deceased who died in unexplained circumstances without requiring consent or permission by the deceased person's family. This practice is justified by the prevalence of public health and safety over the interests of a deceased individual.

The law of some countries, mainly South American, including Argentina, Chile, Ecuador, Uruguay, Panama and Venezuela as well as Wales, explicitly refers to a "presumption of consent" and allow *ex mortuo* organ recovery without explicit consent or authorization. Presumed consent means that the deceased would consent if asked. Ethical justification for this model is placed on respecting the rights of the individual while prioritizing public health.

Although many scholarly work and the laws in some of these countries use the terminology of "presumed consent" to represent the model of *ex mortuo* organ recovery, several members of the OPTN/UNOS Ethics Committee argue that this terminology is inaccurate[35]. Presuming consent rests on the moral premise that consent justifies an invasion of an individual to support the public's health that would otherwise be a violation of a moral right of the individual not to be touched. The ethical justification for this model requires empirical evidence demonstrating that most citizens of the particular country would consent if they were asked and had the ability to do so.

However, most countries with the presumed consent model have a significant minority of citizens who would not consent if asked[34]. The national rate of authorization for eligible donors in the United States is approximately 75%[36]. Therefore, justifying deceased organ and tissue recovery based on the "presumption of consent" appears to be flawed.

Furthermore, presumed consent is justified in other clinical contexts in the USA because some medical procedures rely on the presumption of informed consent, e.g. unconscious patients brought to an emergency room are treated without explicit

35 See: R. Veatch, L. Ross, *op. cit.*, p. 147 and following.

36 Data on Donation and Transplantation, Association of Organ Procurement Organizations, available at: www.aopo.org (accessed: 26 April 2017).

consent by relying on the legal notion of presuming consent, acknowledging that virtually everyone would consent to life saving treatment if they could be asked. Nevertheless, the concept of presumption remains morally controversial because if the presumption is wrong, an essential right of the patient is violated. In practice, however, only in rare cases patients brought to an emergency department would refuse treatment if only they could do so. This raises the question of how confident society must be in believing that the patient would consent if he or she could do so. Since a mistaken presumed consent involves violating an essential right of the patient, the ethical claim is that we must be very confident that the great majority of patients would consent. This is not empirically demonstrated when considering consent rates to organ donation[37].

Ex mortuo organ recovery without explicit consent or authorization may or may not include an opt-out option. The hard approach excludes an opt-out option, whereas the "soft" approach allows an individual (or the surrogate decision maker) to explicitly prohibit the state from recovering the individual's organs[38]. The majority of countries that have laws permitting deceased organ recovery without explicit consent or authorization allow the individual (or the surrogate decision maker) to opt-out in practice, even if the law does not explicitly describe the "opt-out" option[39].

Arguments contained in the White Paper supporting the adoption of the model without explicit consent or authorization *inter alia* depict that the USA adopt many regulations that restrict the rights of individuals in order to protect public health and safety (e.g. seatbelts and helmets laws). Furthermore, due to the fact that end-stage organ disease has become an epidemic (at least for kidneys), the rights of the individual could be restricted to fight this epidemic by increasing the number of organs for transplantation.

The literature demonstrates an association between higher organ recovery rates among countries that allow deceased organ recovery without explicit consent (by app. 25%-30%[40]) when compared with countries that require explicit consent or authorization[41]. However, the above data must be interpreted within the broader socio-cultural context of the transplant system as each country's government devotes

37 2012 National Survey of Organ Donation Attitudes and Behaviors, September 2013, U.S. Department of Health and Human Services, Health Resources and Services Administration, Healthcare Systems Bureau, Rockville, Maryland: U.S. Department of Health and Human Services.

38 C. Simillis, Do we need to change the legislation to a system of presumed consent to address organ shortage?, "Medicine, Science and the Law" 2010, No. 50 (2), p. 84 and following.

39 J. Fabre, Presumed consent for organ donation: a clinically unnecessary and corrupting influence in medicine and politics, "Clinical Medicine" 2014, No. 14 (6), p. 567 and following.

40 B. Boyarsky, E. Hall, N. Deshpande, Potential limitations of presumed consent legislation, "Transplantation" 2012, No. 93 (2), p. 136 and following.

41 See e.g.: A. Rithalia, C. McDaid, S. Suekarran, *op. cit.*, a3162; L. Shepherd, R. O'Carroll, E. Ferguson, *op. cit.*, p. 1 and following.

different resources and holds different cultural expectations of its citizens toward donation initiatives. Both models of *ex mortuo* organ recovery differ considerably in the practice of individual countries (e.g. some countries that do not require explicit consent or authorization require surrogate consent or allow for opt-out options while others do not)[42].

Arguments against the adoption of the model of organ recovery without explicit consent or authorization in the USA *inter alia* depict the existence of many barriers (including legal, empirical and cultural) as well as factors connected with the transplant system due to which it would be extremely difficult to change the present model of donation. Such a process would require legislative initiative in a federal level, which could lead to legal (or even constitutional) torts. What is more, from a US cultural perspective, individual rights are deeply embedded in values and beliefs. Individualism is a key feature of American culture. The model of *ex mortuo* organ recovery that does not require explicit consent would not gain sufficient support to justify its adoption[43]. Thus, in the USA, where individual rights are treated as a priority, organ recovery without explicit consent or authorization is unlikely to be embraced by the entire society.

Furthermore, it has been argued that if the adoption of the model of *ex mortuo* organ recovery without explicit consent or authorization causes a negative social attitude to organ donation (especially among individuals who would have previously agreed to donation), a number of organs recovered from the deceased might have increased only insignificantly (if at all).

It is argued that the introduction of an opt-out provision may reduce the risk of erroneously presumed consent. At the same time, any opt-out system that does not adequately inform US citizens of their right to opt out would be subject to legal challenge. It is alleged that the opt-out provision would not be sufficient to justify presumed consent. It would violate the rights of citizens to an unacceptable degree.

Ethnic minorities and socioeconomic groups that are underserved or marginalized have disproportionally lower rates of transplantation for all types of organs[44]. At the same time, many of those groups have higher rates of risk factors that generate the need for organ transplantation. Various factors contribute to this, which can be divided into three broad groups: biological (such as higher prevalence of obesity or of immunological factors common to them but less common in the majority population[45]); issues of the health care system (such as delayed average time before assessment for kidney transplantation for some minority patients or disparate

42 J. Fabre, *op. cit.*, p. 567 and following.

43 2012 National Survey of Organ Donation Attitudes and Behaviors, *op. cit.*

44 Data of the OPTN, available at: www.optn.transplant.hrsa.gov/data (accessed: 26 April 2017).

45 G. Switzer, J. Bruce, L. Myaskovsky, Race and ethnicity in decisions about unrelated hematopoietic stem cell donation, "Blood" 2013, No. 121 (8), p. 1469 and following.

rates of living kidney donation[46]); and issues related to lack of sufficient knowledge, and cultural values and behaviours of the groups themselves (such as a lower willingness to do living or deceased organ donation[47]).

Studies devoted to *ex mortuo* donation among ethnic minorities and marginalized socioeconomic groups revealed a high level of distrust of the health care system and organ donation itself[48]. Respondents of qualitative research frequently feared that if presumed consent existed, doctors will not do all they can to save them while donated organs will not be used to benefit them (e.g. people in the same minority group)[49]. Such beliefs are the effect of long histories of discrimination of those groups in the healthcare system whereas the adoption of a model not requiring explicit consent would most likely only strengthen the above convictions.

For this reason, instead of feeding mistrust in the transplant system by focusing on the adoption of a model of *ex mortuo* organs recovery without explicit consent, it is postulated to intensify informative actions targeted at diverse ethnic and socioeconomic groups, and highlight the value of donation and transplantation. Such actions may eventually decrease disparities and increase donation rates in these populations.

Even though it has been emphasized that an increase of a total number of organ transplantations remains a priority, it is uncertain whether a change of the current US donation model to a model that does not require explicit consent or authorization would actually improve rates of organ recovery and transplantation.

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46 C. Norris, L. Agodoa, Reducing Disparities in Assessment for Kidney Transplantation, "Clinical Journal of the American Society of Nephrology" 2012, No. 7 (9), p. 1378 and following; P. Reese, M. Nair, R. Bloom, Eliminating racial disparities in access to living donor kidney transplantation; how can centers do better?, "American Journal of Kidney Diseases 2012", No. 59 (6), p. 751 and following.

47 See e.g.: C. Breitkopf, Attitudes, beliefs and behaviors surrounding organ donation among Hispanic women, "Current Opinion in Organ Transplantation" 2009, No. 14 (2), p. 191-195; E. Gordon, Patients' decisions for treatment of end-stage renal disease and their implications for access to transplantation, "Social Science & Medicine" 2001, No. 53 (8), p. 971 and following; E. Gordon, J. Mullee, D. Ramirez, U.S. Hispanic/Latino concerns about living kidney donation: a focus group study, "Progress in Transplantation" 2014, No. 24 (2), p. 152 and following.

48 M. Irving, A. Tong, S. Jan, Factors that influence the decision to be an organ donor: a systematic review of the qualitative literature, "Nephrology Dialysis Transplantation" 2012, No. 27 (6), p. 2526 and following.

49 See more: S. Davison, S. Jhangri, Knowledge and attitudes of Canadian First Nations people toward organ donation and transplantation: a quantitative and qualitative analysis, "American Journal of Kidney Diseases" 2014, No. 64 (5) p. 781 and following: M. Morgan, C. Kenten, P. Deedat, Donate Programme Team. Attitudes to deceased organ donation and registration as a donor among minority ethnic groups in North America and the UK: a synthesis of quantitative and qualitative research, "Ethnicity & Health" 2013, No. 18 (4), p. 367 and following.

5. Alternative opportunities to increase deceased organ supply for transplantation

The OPTN/UNOS Ethics Committee[50] believes that there are alternative opportunities to increase number of organs recovered from the deceased. An actual number of recovered organs and successful transplantations could be increased by, e.g., the implementation of comprehensive strategies to improve the system of organ recovery and transplantation. It is postulated to increase public awareness and education, expand federal support, or develop advanced technologies and expertise in the field of organ recovery, preservation and transplantation.

It has been pointed out that strategies that may increase the rates of *ex mortuo* organ recovery encompass, among others, improvement of organizational aspects. People object to organ donation often in result of a lack of understanding, lack of trust, or concerns raised by the families about the process of organ recovery and transplantation. Currently in the USA 26 donors/million give their consent. Educational efforts targeted at specific populations (such as people in minority and lower socioeconomic status) brought ambiguous (mixed) results in increasing donation. While studies have shown the donation rate is not related to socioeconomic indicators, donation rates correlate with organizational improvements using culturally congruent in-hospital coordinators[51].

As pointed out, it is necessary to develop methods (techniques) of securing and preserving organs as well as resuscitation techniques in order to increase survival of organs coming from expanded criteria donors.

Since Spain has the highest rate of deceased organ donation in the world (33-35 donors per million population)[52], it is postulated to adopt some organizational factors of the Spanish system that could result in the increase of *ex mortuo* organ donation in the USA. They encompass, *inter alia*, increased political and legal support of transplant and organ procurement professionals, implementation of a comprehensive programme of education, improvement of public relations, and development of hospital reimbursement [53].

50 Ethics…, *op. cit.*

51 L. Siminoff, C. Saunders Sturm, African-American reluctance to donate: beliefs and attitudes about organ donation and implications for policy, "Kennedy Institute of Ethics Journal" 2000, No. 10 (1), p. 59 and following.

52 R. Metasanz, B. Domiguez-Gil, E. Coll, Spanish experience as a leading country: what kind of measures were taken?, "Transplant International" 2011, No. 24 (4), p. 333 and following; B. Borro-Escribano, I. Martinez-Alpuente, A. Blanco, Application of game-like simulations in the Spanish Transplant National Organization, "Transplantation Proceedings" 2013, No. 45 (1), p. 3564 and following.

53 D. Rodriguez Arias, L. Wright, D. Paredes, Success factors and ethical challenges of the Spanish Model of organ donation, "Lancet" 2010, No. 376, p. 1109 and following.

The Committee believes that transplantation medicine should invest in social education connected with the prevention of chronic illnesses and a decrease of end-stage organ disease.

Furthermore, attention has been drawn to the possibility of using social media to create a donor registry and increase communication with friends or families. Yet such efforts must be undertaken in a long-term perspective and they should be complementary to other promotional activities.

Some claim that financial and non-financial incentives for *ex mortuo* donation may significantly increase the rates of organ donation from the deceased. However, due to, e.g., a ban on organ trafficking, such a possibility remains ethically controversial[54].

6. Conclusion

The number of *ex vivo* and *ex mortuo* donors cannot keep pace with continuous growth of demand for organs in the USA. It is necessary to introduce changes in the current system of organ recovery and transplantation. Some members of the transplant community claim that a number of organs for transplantation may only increase in effect of the changed model of donation into the model of *ex mortuo* organ recovery without explicit consent or authorization. However, for many reasons, this argument is extensively debated.

According to the OPTN/UNOS Ethics Committee, shifting to a model of *ex mortuo* organ recovery without explicit consent or authorization in the USA is not ethically justified for the following reasons:

1) the donation model in the US is current public policy, embedded in a culture of individualism. Shifting this model would require extensive legal changes (and potentially constitutional) which would challenge fundamental deep-seated American cultural values;
2) it is highly probable that the change of a model into organ recovery without explicit consent would adversely affect the public's trust in the healthcare system, particularly by marginalized populations, potentially resulting in lower rates of organ recovery;
3) authorization rates for *ex mortuo* organ recovery in the USA are already high (75%). Particularly if an opt-out option is included, shifting the model would not necessarily increase the rates;

54 See e.g.: S. Satal, D. Cronin, Time to test incentives to increase organ donation, "JAMA Internal Medicine" 2015, No. 175 (8), pp.1329-1330; E. Gordon, C. Patel, M. Sohn, Does fi nancial compensation for living kidney donation change willingness to donate?, "American Journal of Transplantation" 2015, No. 15 (1), p. 265 and following.

4) although empirical data suggest an association between the rates of *ex mortuo* organ recovery and models that do not require explicit consent or authorization, as far as the increase of organ recovery rates is concerned, a substantial role therein may also be played by additional factors such as public education, federal support, or efficiencies in the organ preservation and transplantation system.

As pointed out, there are many alternative opportunities to increase the rates of *ex mortuo* organ recovery which do not violate individual rights and current public policy. They include, among others, the improvement of organizational aspects, increased efficiency and efficacy of organ recovery and transplantation system, increased public awareness of organ donation through mass media campaigns, social media and national donor registries and, finally, promoting scientific advancement in the area organ recovery, preservation and transplantation techniques.

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"Will of Life" as a Challenge for the Polish Legislator – Selected Problems

Abstract: Proposals to regulate life problems in Poland cause interest and are discussed both in the social and doctrinal level. The issue is controversial because it concerns a very delicate sphere of human life. This work is an attempt to define "the will of life". We state that this is a pro futuro statement, where each person can express his or her willingness to use specific medical procedures in anticipation of their future terminal condition. Then we will also discuss the form and scope of the will and we will try to determine the extent to which a doctor is bound by the patient's independent will expressed in the testament of life. In our work, we conducted an analysis of the Supreme Court case law in order to consider problematic issues. We also dealt with difficult questions of the topicality of will of life by referring to a patient in a particular medical situation since the will of man can change because of an illness. A healthy person judges the value of life well; his will can change over time. In conclusion, we presented arguments for and against the acceptance of wills of life. We discussed the need to regulate the above issues in Poland and pointed out which solutions adopted in other countries could be enacted in the field of domestic legislation.
Keywords: will of life, pro futuro statement, terminal state

1. Introduction

The debate on "the wills of life" (advanced decisions) is of a fundamental nature because it considers an extremely delicate sphere of human existence, i.e. a moment

of death and its dignity[1]. This issue arises immense interest and it is widely discussed both in the social and doctrinal level. The opponents claim that it is an attempt at introducing camouflage consent for euthanasia into the legal order. Yet the supporters believe that this regulation would confirm respect for human free will since a man can freely decide about the moment and manner to terminate his or her life[2].

In some foreign legislations, wills of life have already been regulated whereas Poland has not ratified the Oviedo Convention[3] yet, in consequence of which Polish legal provisions lack specific standards of procedure. Deontological norms do not mention anything about anticipated declarations that could be made by a patient who is not able to make a declaration of will. Hence, regulation of the above issue will positively affect both medical and legal science.

A purpose of this work is to explain the definition, form and conditions of making such types of *pro futuro* statements and attempt to specify *de lege ferenda* postulates thereon.

2. An attempt at defining "a will of life"

The Polish legal order lacks a uniform definition of a will of life. In order to explain this term, it is necessary to specify what *pro futuro* statements are because the science of medical law distinguishes many forms thereof. It is inappropriate to apply the term "a will of life" to all *pro futuro* statements[4].

According to M. Śliwka, a will of life is a patient's statement where she or he objects against specific medical interventions to be carried out in relation to him or her if they lose their capacity to express informed consent[5]. J. Haberko holds a similar opinion thereon – it is a patient's will derived from the statement that has been made earlier by the patient himself or herself in case of losing awareness[6]. We may talk about a will of life when a potential patient makes a statement for the future in a situation

1 E. Jachnik, Testament życia w świetle Europejskiej Konwencji Bioetycznej a możliwość składania oświadczeń pro futuro w prawie polskim, Zeszyt studencki Kół Naukowych Wydziału Prawa i Administracji UAM 2014, No. 4, p. 134.

2 B. Łabowicz, Testament życia, (in:) W cieniu czepka, Biuletyn informacyjny dolnośląskiej okręgowej izby pielęgniarek i położnych, 2014, No 2/268/ February, p. 9.

3 The convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine adopted on the 4 of April 1997 in Oviedo was signed by Poland in 1999, even though Poland has not ratified it.

4 M. Śliwka, Testament życia i inne oświadczenia pro futuro–przyczynek do dyskusji, www.ptb.org.pl/pdf/sliwka_testament_1.pdf (accessed: 30 March 2016).

5 A. Górski, Testament życia, (in:) A. Górski (ed.), Leksykon pojęć prawa medycznego, Warszawa 2012, p. 232.

6 J. Haberko, Realizacja standardów bioetycznych w prawie polskim w zakresie oświadczeń pro futuro, (in:) L. Kondratiewa-Bryzik, K. Sękowska-Kozłowska (eds.), Prawa człowieka wobec rozwoju biotechnologii, Warszawa 2013, p. 142.

when no threat has materialized yet[7]. We should also repeat after the doctrine representatives that it is a special manifestation of a patient's will made in case of a loss of awareness/consciousness concerning a manner of doctors' dealing with the patient[8]. M. Safian expands the above definition claiming that these statements refer to a wider catalogue of cases than only a loss of consciousness. Unconsciousness should be understood as a factual incapability of independent awareness (understanding) of the situation and making decisions[9]. On the other hand, M. Syska is more precise by saying that as far as wills of life are concerned, it would be an instruction in case of a loss of capacity referring solely to withholding therapy in a terminal condition, or euthanasia as well[10].

A will of life is to provide a person who made it with the control over acts and omission of acts which would be undertaken in relation to him or her in the future. A fully conscious patient determines his or her preferences on the acceptance of the course of treatment or its lack in case of a loss of competence to make such a decision in the future.

A will of life is sometimes mistaken for euthanasia, which actually involves helping another person to die upon his or her explicit request and under the influence of compassion (sympathy), which also implies active participation. In contrast, a will of life is passive respect for the patient's will by a doctor, mostly similar to withholding the so-called futile medical care.

3. A legal nature and form of the statement

Drawing a will of life, a person making this declaration should, above all, be fully informed about possible medical interventions that may be undertaken in relation to him or her. In the practice, it is difficult to inform a patient precisely because the statement refers to future and uncertain events[11]. It results from the research carried out in the 1990s that doctors are not duly prepared to talking to patients despite such an obligation imposed by the legislator[12].

A will of life should be classified as a unilateral legal action. It is effective in effect of a declaration of will itself made by a potential patient. According to the principle *voluntas aegroti suprema lex est*, a patient's will authorizes a doctor to undertake specific medical interventions or omit their launch in the future. B. Janiszewska poits

7 M. Śliwka, Testament życia i inne oświadczenia pro futuro…, *op. cit.*, p. 11.
8 M. Syska, Medyczne oświadczenia pro futuro, Warszawa 2013, p. 33.
9 M. Safjan, Prawo i medycyna. Ochrona praw jednostki a dylematy współczesnej medycyny, Warszawa 1998, p. 44.
10 M. Syska, Medyczne..., *op. cit.*, p. 41.
11 E. Jachnik, Testament życia…, *op. cit.*, p. 141.
12 W. Chańska, Ewolucja dyrektyw na przyszłość w amerykańskiej praktyce medycznej. "Prawo i Medycyna" 2015, No. 1, p. 38.

out that unilateral actions which, in accordance with case law, include declarations of will, are subject to the *numerus clausus* principle, pursuant to which only actions envisaged in the law are admissible. A lack of regulation of will declarations should result in their inadmissibility[13]. Thus, a lack of legal regulation leads to situations restricting patient autonomy. We may not deprive an individual capable of making decisions of this right only due to a loss of awareness (consciousness) or a lack of possibility of communicating their needs. M. Boratyńska notices the same: "… hence, we would have a group of adult patients who are mentally able and yet fully deprived of autonomy. The same patient would enjoy full autonomy as long as he or she is conscious. In other words, merely physical inability to communicate, express and receive an answer itself would entail abolition of autonomy while, at the same time, the patient would have no possibility of counteracting it in advance"[14]. The legislator should be obliged to construct provisions which will not limit autonomy and freedom of decision of individuals including their loss of consciousness.

According to M. Śliwka, regulation concerning *pro futuro* statements may, on no account, be merely limited to the objection raised by the patient; it should also embrace the individual's preferences. With the help of *pro futuro* declarations of will, a patient may not only specify which services he or she does not agree to, but they may also express a relevant wish as to the further treatment. Hence, a properly (duly) drafted will of life should contain a catalogue of acts that may not be performed in relation to the patient.

Therefore, we should apply a solution which will enable to make a declaration of will without a subsequent risk of errors or abuse. If the domestic legislator adopted a requirement of formulating statements in one of the special forms, health professionals would be exempted from the substantive analysis of such a statement. The burden connected with the statement's examination (review) with regard to its credibility and consistency with the patient's actual will should not be delegated into health professionals. Considering an example of withholding treatment in a terminal phase, it should be pointed out that such a decision is not exclusively a purely medical issue but it is also an ethical choice. Apparent and clear regulation specifying the principles of expressing and respecting a prior patient's will would allow to exempt doctors from the obligation to consider these intertwining and thus complicated issues.

Furthermore, we should discuss a relation of interdependence between doctor's actions and the attitude (position) of the incompetent patient's family. It does matter

13 B. Janiszewska, Dobro pacjenta czy wola pacjenta – dylemat prawa i medycyny (uwagi o odmowie zgody na leczenie oraz o dopuszczalności oświadczeń pro futuro), "Prawo i Medycyna" 2007, No. 2, p. 46.

14 M. Boratyńska, Niektóre aspekty świadomej zgody pacjenta na leczenie na tle orzecznictwa Sądu Najwyższego. Cześć 1. Sprzeciw pro futuro, "Prawo i Medycyna" 2007, No. 2, p. 25.

for a doctor whether the family actually cares about the patient's good, or whether family members are consistent in their opinion while this opinion is rational. Working out *modus vivendi* with the patient's family is not an easy task because it may generate a risk of delegating too serious responsibility for medical decisions onto the nearest and dearest. At the same time, it is also important show due respect for the doubts raised by the patient's family members[15].

In the Polish law there are no regulations indicating the need to respect prior declarations of will. However, the Supreme Court ruled in its judgment of 27 October 2005 that "a patient's declaration made in case of a loss of consciousness and specifying the will concerning doctor's action […] in medical situations that may occur in the future is binding if it has been made explicitly, unambiguously and undoubtedly"[16]. The Court further decided that "the principle of patient autonomy requires respect for his or her will regardless of the motives (confessional, ideological or medical, etc.). Hence, it should be assumed that a doctor is bound by a lack of patient's consent for a specific surgery (type of surgeries) while criminal or civil liability is excluded, and if the surgery is performed – it becomes legally invalid". For this reason, despite a lack of appropriate regulations, "a will of life" (advance decision) is admissible in our country – pursuant to the judicature's opinion.

4. Doubts concerning will of life's validity

We would like to discuss here a difficult issue of validity of a "will of life" with regard to the actual medical situation of a patient. Opponents of advanced decisions argue that in life threatening situations people behave different than they would if they were fully healthy; thus, human will may change in the face of an illness. A healthy individual assesses the value and quality of life differently. Drawing an advanced decision, an individual may wish not to continue living if found in a terminal condition, in particular when they were totally depended on others and requiring day and night incessant care.

As rightly noticed by M. Machinek, both experience and research prove that healthy individuals much more often reject certain medical interventions in their advanced decisions than those who draw such statements being aware of the unfavourable diagnosis[17].

15 J. Hartman, Bioetyka dla lekarzy, Warszawa 2012, p. 111.

16 The decision of the Supreme Court of 27 October 2005, III CK 155/05, OSNC 2006, No. 7-8, item 137.

17 M. Machinek, Etyczna problematyka testamentu życia i innych oświadczeń pro futuro. Głos w dyskusji. Debata wokół testamentu życia 23.11-30.11.2009, available at: www.ptb.org.pl/pdf/machinek_testament (accessed: 15 July 2016).

The case of a well-known German professor Walter Jens, a supporter of euthanasia, serves as an example thereof. He strongly advocated for a possibility of withholding any life supporting care. When he became ill, he did not recognize his family and required constant care. Significantly enough, he most frequently uttered the words "please do not kill me" when addressing his family at all. This situation confirms that a patient may change his or her mind. Has the will expressed in such a manner changed his earlier declaration of will made in full consciousness and autonomy[18]? The question is which advanced decision should be respected.

In our opinion, if there are doubts about the patient's prior will, which undeniably are his words uttered later, doctors should refrain from the fulfilment of the earlier statement. Moral intuition speaks against absolute respect for the patient's will autonomously expressed by him if he later changed this decision. According to T. Dukiet-Nagorska, "if there are no doubts as to the fact that a conscious patient has the right to refuse treatment, as long as there are no grounds to challenge authenticity of his statement or doubts as to whether he or she has not changed this decision, it should be respected"[19]. J. Hartman claims that if a doctor may not assume if the patient's will expressed before the dramatic situation he has encountered is the same as his current will, the doctor may reasonably doubt the validity of the advanced decision, or even more when it contains more reservations against medical interventions[20].

Due to the above considerations, we should remember that an individual may change his or her decision even if not facing death. Therefore, the Polish legislator intending to regulate the issue of advanced decisions should introduce time limits during which such statements are valid. It may be postulated that each person who made a *pro futuro* statement should update his or her decision after the lapse of a few or several years.

5. Selected legal regulations of other countries

Discussing the issue of advanced decisions, it is worth looking at the laws of other countries to examine their solutions thereto. We will present only some of them, i.e. those that, in our opinion, are worth considering with regard to regulating the above issue in Poland, in particular with regard to special types of agents.

Even though euthanasia is admissible in Belgium, there is an apparent distinction between this issue and *pro futuro* statements. Both issues have been regulated in distinct normative acts to prevent confusing these two institutions. As far as Belgium in concerned, we should approve of such Belgian principles as a binding nature of *pro*

18 J. Haberko, Realizacja standardów bioetycznych…, *op. cit.*, p. 144.

19 T. Dukiet-Nagórska, Autonomia pacjenta a polskie prawo karne, Warszawa 2008, p. 63.

20 J. Hartman, Bioetyka dla lekarzy, Warszawa 2012, p. 110.

futuro statements, comprehensiveness of regulations, and referral to different forms of such statements. As far as comprehensiveness of regulations is concerned, it is expressed, among others, in the Act on the Patient's Rights of 22 August 2002, which was to systemize the patient's rights and extend their protection[21]. The above quoted Act implements such institutions as advanced decisions, which are based on accurate information provided to the patient, person of trust and health agent. A person of trust shall act only when the patient is not conscious; if he or she loses consciousness, the Belgian law envisaged the institution of a health agent. This implies that the appointment of *personne de confiance* is not embraced by *pro futuro* statements. A role of this person is to support the patient in the process of providing information; a doctor conveys information to both the patient and person of trust. That is why he or she is appointed when the patient has problems with understanding information due to his or her health condition. A health agent shall act when the patient loses his or her consciousness and continues until the patient regains capacity to make conscious and autonomous decisions. A health agent is a kind of the patient's deputy because he or she enjoys a full scope of rights the patient is entitled to. Belgian solutions are based on respect for the right of an individual to decide about themselves with regard to the protection of human dignity. Relations between the patient and doctor rely on partnership, mutual respect and dialogue[22].

The Swiss legislator has also introduced the institution of a special agent/proxy. This agency is a special type of civil agency; it embraces comprehensive powers – apart from making medical decisions, the agent may also dispose of the principal's assets and represent him or her in legal relations with third parties. The agent's powers should be determined in the power of attorney whereas only a natural or legal person may be an agent and the document may be drafted in a holographic form or before a notary. The legislator envisaged a manner of the power of attorney's storage and a possibility of its registry in a special database. It should be remembered that the power of attorney is efficient solely if the principal is not capable of arranging his interests autonomously.

Switzerland has adopted an interesting solution assuming that the patient should be accompanied by someone who will be both a partner and counterweight for the doctor. This is a specific system of statutory agency in case of a loss of consciousness when the patient has neither made a *pro futuro* statement nor appointed a health agent. A person who may fulfil this role is a spouse or registered partner if they ran a common household or the partner who took care of the patient on a regular and continual basis. In this case, a doctor is obliged to include such a person in a decision-making process, and in particular provide him or her with all and necessary

21 Ustawa z 22 sierpnia 2008r. o prawach pacjenta (Moniteur Belge, MB z dnia 26 września 2002 r., No. 2002022737, p. 43719).

22 M. Syska, Medyczne…, *op. cit.*, pp. 151-153.

information about the patient's health condition. Doctors are bound by all types of *pro futuro* statements as well as decisions made by statutory representatives. The Swiss legislator has rightly assumed that if an unconscious or incompetent patient does not decide about his or her treatment any more, it would be better if the decisions are made by the patient's persons of trust rather than the court. Furthermore, the legislator has formulated criteria to be satisfied by such representatives. They reconstruct the patient's will based on their general knowledge about him or her. Such a decision should not only be consistent with the patient's will but it should also protect his or her interest.

The English law does not apply the institution of a person of trust but a specified person may be authorized to access medical documentation, yet without a possibility of deciding about the patient's treatment. Therefore, such a person is only authorized to access information about the patient's health condition and health services being provided[23]. In England, patient's autonomy is also protected by the institutions of binding advanced decisions and a possibility of appointing a health agent. The principal may authorize his or her agent (attorney) to decide about their personal and financial matters; he or she may also restrict the agent's rights to act in strictly determined factual situations, or limit his or her powers solely to specified actions. An advanced decision shall be invalid if the person making it withdrew it efficiently, or appointed a health agent and entrusted him or her with the right to decide about treatment whose scope has been indicated in the decision. A decision about making an advanced decision must be well thought because the person making it must specify precisely his or her medical situation therein. As far as the form thereof is concerned, there are no special requirements, which implies that the decisions may be made in any form, not only written. A medical power of attorney is applied when the principal is not capable of giving or refusing consent autonomously. If the principal drafts an advanced decision after appointing an agent, the advanced decision shall prevail and exclude the agent's powers to make decisions on treatment specified in the decision[24].

Interestingly enough, the guardian court competent to make a decision may appoint an agent of an incapable person in special situations. The English legislation envisages the obligation to act in the patient's interest when making a decision about the person incapable of self-determination. This obligation is both objective and subjective in nature, which means that attempts are made to embrace the patient by the decision-making process. The obligation to reconstruct the will of an incapable person based on their earlier wishes and opinions is very clear. If all efforts to specify the patient's wishes prove unsuccessful, the institution of a guardian or advisor

23 A. Sporczyk, Oświadczenia woli *pro futuro* w prawie francuskim i anglosaskim, "Prawo i Medycyna" 2015, No. 1 (58, vol. 17), p. 63 and following.

24 M. Syska, Medyczne…. *op. cit.*, p. 154 and following.

appointed for the person incapable of self-determination is applied to seek their opinion.

6. *De lege ferenda* conclusions and postulates

A heated debate on a will of life is still pending in Poland. Arguments raised by the supporters and opponents of wills of life mainly depend on their subjective beliefs and attitudes. Expressing their opinions, they mostly follow moral values and faith they have adopted. This shows that the debate will not end amicably in a compromise. It will be extremely hard to find a universal model of a will of life that both parties to the dispute would approve of.

Proponents of the will of life claim that it is an expression of respect for human free will providing people with the right to choose time and circumstances of their death. On the other hand, opponents strongly underline that such statements are attempts at implementation of legal consent for concealed euthanasia. Those who support the adoption of wills of life think that thanks to such decisions, they do not have to impose on their nearest and dearest a burden of care during a terminal illness. They also believe that wills of life prevent individuals from living indecently. On the other hand, others claim that this entails a risk of juggling human life.

We think that wills of life express attitudes of people living in contemporary times. We want to control all spheres of our lives, even those eternal (final), not accepting our lot. We should remember that we may not deprive individuals who categorically refuse to be kept alive in specific condition of the right to decide about themselves. Arguments of both parties to the debate are equivalent; therefore, it is so important to take into account both opinions when regulating the issue of a will of life. It is a formidable challenge for the legislator because institutions concerning subjective feelings of every person are always extremely difficult to be framed legally.

Life is believed to carry the highest value for the law. For this reason, no legal system should avoid making a stand on the arising need to regulate vital issues. Legislative procedure referring to the analyzed problem is not solely a matter between the legislator and a panel of experts. What is more, since it refers to the sensitive spheres of the entire society, society themselves should have a strong voice in the debate.

Now we would like to present our observations and solutions of other countries that should be taken into account while regulating wills of life:

- *pro futuro* statements in a positive and negative form, that is admitting not only the form of objection (opt out) but also consent specifying the individual's preferences;
- a requirement to draft wills of life in a special form, e.g. a written form on pain of invalidity, a type of holographic or notarial will;

- respect for the changes of prior wills of life even if the change was made in another psycho-physical condition;
- the need to introduce time limits and obligation of updating a will of life;
- the introduction of terminological transparency, which will prevent confusion of distinct institutions;
- the introduction of the institution of a statutory representative for patients who have not made a *pro futuro* statement.

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Situation of the Incapacitated in Granting Consent to Medical Treatment. Selected Issues

Abstract: A basic right of each patient is the right to grant consent to medical treatment. A doctor cannot act without the knowledge and will of a patient. Contrary behaviour is treated as illegal. A possibility of using the right of self-determination becomes complicated in the situation of incapacitated patients. The article presents the situation of the incapacitated in the process of granting consent to medical treatment. Particular attention has been paid to the situation of a partially incapacitated patient. The presented reflections lead us to conclude that under Polish legislation, the incapacitated patient is not completely deprived of the possibility of expressing his will. It is also important that the right of self-determination of an incapacitated patient should be respected by the physician throughout the entire treatment. The whole discussion aims at presenting the scope of autonomy of incapacitated patients in the context of substitute and double consent.
Keywords: autonomy, patient's consent, incapacitation

1. Introduction

Each patient enjoys a basic right to co-decide about his or her entire treatment. This right is manifested in a possibility of expressing consent to medical surgery by a patient. Thus, a doctor may not undertake any action if the patient has not expressed his or her will[1]. Conditioning the performance of medical surgery on the relevant consent obtained from the patient guarantees respect for his or her autonomy.

1 Subject to the exceptions provided for in the legislation on medical law.

Particular attention should be paid to the inexplicitly regulated legal situation of incapacitated persons. Problems connected with a possibility of giving relevantly legal consent by the incapacitated patient appear both in the Act of 5 December 996 on the Profession of a Physician and Dentist[2] and in the Act of 6 November 2008 on Patient's Rights and Patient Ombudsman[3].

In both Acts, i.e. on the Profession of a Physician and Dentist (hereinafter referred to as APP) and on Patient's Rights and Patient Ombudsman (hereinafter referred to as APR), the legislator uses the term of the "incapacitated person". Such a solution causes considerable interpretation problems. Under the interpretation of the provisions of Art. 32-34 of APP, the doctrine proposed to interpret the term "incapacitated" that does not specify precisely which incapacity it refers to as the one covering only fully incapacitated persons[4]. Such a statement does not seem right and apparently contains certain contradictions.

The article will analyze selected problems connected with the situation of incapacitated persons in the process of giving consent to medical treatment[5]. It will particularly present the issue of consent given by a statutory representative of the fully incapacitated person, consent or permission of the guardian court, and consent of a statutory representative and the incapacitated person.

2. Consent given by a statutory representative of the fully incapacitated person

Both simple and higher risk surgeries the fully incapacitated person is subject to require substitute consent of a statutory representative (Art. 32 par. 4 and Art. 34 par. 3 of APP). A statutory representative of the fully incapacitated person is his or

2 Consolidated text Journal of Laws 2017, item 125 as amended.

3 Consolidated text Journal of Laws 2016, item 186 as amended.

4 A. Zoll, Granice legalności zabiegu medycznego, "Prawo i Medycyna" 1999, No. 1, p. 37-38.

5 It should be pointed out that issues related to the nature of consent and to carring out the legal acts by the legally incapacitated persons require for separate treatment. Compare: M. Pazdan, Komantarz do art. 13 i 16., (in:) System Prawa Prywatnego, t. 1. Prawo cywilne – część ogólna, (ed.) M. Safjan, Warszawa 2012, pp. 1080-1105; K. Mularski, Czynności podobne do czynności prawnych, Warszawa 2011, p. 212 and following; P. Księżak, Komentarz do art. 13 i art. 16, (in:) K. Osajda (ed.), Kodeks cywilny. Komentarz. Przepisy wprowadzające. Część ogólna. Własność i inne prawa rzeczowe, Warszawa 2013, p. 356 and following; J. Strzebinczyk, Komentarz do art. 13 i art. 16, (in:) Kodeks cywilny. Komentarz (eds.) E. Gniewek, P. Machnikowski, Warszawa 2016, p. 42 and following; L. Kociucki, Zdolność do czynności prawnych osób dorosłych i jej ograniczenia, Warszawa 2011, pp. 107-249; A. Olejniczak, Z. Radwański, Prawo cywilne – część ogólna, Warszawa 2013, pp. 260-268; B. Janiszewska, Zgoda na udzielenie świadczenia zdrowotnego. Ujęcie wewnątrzsystemowe, Warszawa 2013, p. 82 and following. M. Tomaszewska, Charakter prawny decyzji o ubezwłasnowolnienie w sądowym stosowaniu prawa, Toruń 2008, pp. 67-96.

her guardian. Pursuant to Art. 175 of the Family and Guardianship Code[6], care/guardianship of the fully incapacitated person is subject to the appropriate provisions on minor persons. What is significant under this regulation is the fact that all comments (entries) on the scope of competence of a guardian and guardianship court supervision that regard consent of a statutory representative of a minor patient under 16 years of age shall be valid therein.

It should be added that no guardianship is appointed for the fully incapacitated person who attained 13 years of age and remains under parental authority[7]. In this case, substitute consent may be given by parents as statutory representatives of the fully incapacitated minor[8].

We should pay special attention here to the inexplicitly regulated legal situation of partially incapacitated persons. The analysis of Art. 32 par. 104 of APP does not entail any restrictions with regard to the autonomy of their will. Consequently, it should be assumed that a partially incapacitated person may decide himself or herself about undergoing a test or examination provided he or she is fully aware/conscious. This applies solely to simple medical surgeries (as it results from Art. 34 par. 1 and 3 of APP, a doctor may perform a surgery or apply a method of treatment or diagnosis posing a higher risk for the incapacitated person exclusively after obtaining substitute consent)[9]. According to M. Filar, a partially incapacitated patient is entitled to express consent if his or her health condition allows them to make a conscious decision[10]. T. Dukiet-Nagórska also claims that a partially incapacitated person may express their will efficiently if they understand the situation sufficiently[11]. It seems that the opinion presented by the doctrine is right. Taking into account the law-maker's axiological rationality, it should be assumed that if fully incapacitated persons have powers to express their will (Art. 342 par. 4 sent. 2 of APP), persons with greater mental capabilities should also be granted the same right. Doubts may arise when the

6 Consolidated text Journal of Laws 2017, item 683 as amended.

7 See: S. Kalus, (in:) K. Piasecki (ed.), Kodeks rodzinny i opiekuńczy. Komentarz, Warszawa 2011, p. 830.

8 See: M. Świderska, Zgoda pacjenta na zabieg medyczny, Toruń 2007, p. 52.

9 *Ibidem*, pp. 41-42.

10 M. Filar, Postępowanie lecznicze (świadczenie zdrowotne) w stosunku do pacjenta niezdolnego do wyrażenia zgody, "Prawo i Medycyna" 2003, No. 13, p. 43; M. Safjan, Prawo i medycyna. Ochrona praw jednostki a dylematy współczesnej medycyny, Warszawa 1998, p. 52; A. Suchocka, Zakres działań lekarskich w fazie sztucznego podtrzymywania życia w prawie polskim i międzynarodowym, Przegląd Prawa Europejskiego 2001, No. 1, p. 51; J. Kulesza, Brak zgody pacjenta na zabieg leczniczy a lekarski obowiązek udzielania pomocy, "Prawo i Medycyna" 2005, No. 19, p. 74 and following.; A. Kołodziej, Stopień autonomii pacjenta na tle ustawy o zawodzie lekarza i ustawy o ochronie zdrowia psychicznego, "Prawo i Medycyna" 2002, No. 11, p. 79; M. Świderska, Zgoda pacjenta na zabieg medyczny, Toruń 2007, p. 41.

11 T. Dukiet-Nagórska, Świadoma zgoda pacjenta w ustawodawstwie polskim, "Prawo i Medycyna" 2000, No. 6/7, p. 91.

court appoints a guardian for a partially incapacitated person due to irrational actions undertaken by him or her concerning healthcare.

Problems connected with a possibility of giving relevantly legal consent by a partially incapacitated patient appear together with the appropriate application of Art. 32 par. 6 of APP. To avoid inaccuracies connected with the legal situation of a partially incapacitated person, Art. 32 par. 6 of APP should be specified more precisely. As rightly proposed by M. Świderska, it is sufficient to specify in the content of the provision that it refers solely to fully incapacitated persons and not partially incapacitated persons by adding the word "fully"[12]. It seems that the author is right. The solution proposed by her would provide cohesion between the provisions of the Act, and it would lead to clear and consistent regulation of the legal situation of partially incapacitated persons by the legislator.

On the other hand, in the second case analyzed herein, consent of the guardian court shall be absolutely obligatory. It results directly from Art. 32 par. 6 of APP. Under this provision, if a patient refuses to undergo medical services, apart from consent given by his or her statutory representative or factual guardian, or if they do not give consent, it is necessary to obtain permission of the guardian court[13].

The situation of partially incapacitated persons becomes complicated also in connection with the content of Art. 17 and 18 of APR. Many problems arise in effect of the relation of the above quoted provisions to the Act on the Profession of a Physician and Dentist. According to R. Kubiak, it should be assumed that the Act on the Patient's Rights is *lex generalis* in relation to the Act on the Profession of a Physician and Dentist[14]. This postulate should be approved of because the Act on the Patient's Rights regards all medical services whereas the Act on the Profession of a Physician and Dentist regulates only surgeries performed by doctors. Therefore, in compliance with the principle *lex specialis derogat legi generali*, priority should be given to special provisions, that is the Act on the Profession of a Physician and Dentist[15].

The adoption of the above principle aims to resolve problems connected with the concurrent application of both Acts, which are not mutually coherent. Pursuant to Art. 17 par. 2 of APR, in the case of a fully incapacitated person, consent of a statutory representative shall be obligatory. This provision complies with Art. 32 par. 4 of APP. However, Art. 18 of APR, which deals with operations, stipulates in par. 1 that Art. 17 par. 2 of APR shall appropriately apply to giving consent to such surgeries.

12 *Ibidem*, pp. 41-42.

13 See: P. Dzienis, Zgoda pacjenta jako warunek legalności leczenia, "Przegląd Sądowy" 2001, No. 11/12, p. 78; J. Kulesza, Brak zgody pacjenta na zabieg leczniczy a lekarski obowiązek udzielania pomocy, "Prawo i Medycyna" 2005, No. 19, p. 77, M. Safjan, Prawo i medycyna, *op. cit.*, p. 52-53.

14 R. Kubiak, Prawo medyczne, Warszawa 2010, p. 349.

15 *Ibidem*, p. 349.

On the other hand, par. 3 orders to apply Art. 17 par. 2-4 of APR. The structure and mutual relations of the above quoted provisions are incoherent in relation to partially incapacitated persons. As far as simple surgeries are concerned, substitute consent is required solely toward fully incapacitated persons while these provisions also apply to operations, which means that partially incapacitated persons may decide themselves both about simple surgeries and operations. As stressed by R. Kubiak, such assumption contradicts Art. 34 par. 3 of APP, which orders the use of substitute consent regardless of the type of incapacitation/incapacity[16].

It results from the above that concurrent application of both Acts may lead to serious practical problems. For this reason, we should acknowledge priority of the Act on the Profession of a Physician and Dentist as *lex specialis* towards the Act on the Patient's Rights.

3. Consent given by a factual guardian

Considering the issue of substitute consent, it is worth mentioning the powers of the so-called factual guardian. Pursuant to the provisions of the Act, a factual guardian shall be a person who without a statutory obligation takes continuous care of the patient who, due to his or her age, health condition or mental state, requires such care (Art. 3 par. 1 point 1 of APR). The element of continuous care used in the above quoted definition eliminates all cases of temporary care provided to the patient. Therefore, in principle, a circle of entities that may be recognized as factual guardians is relatively narrow. A factual guardian may become, *inter alia*, a guardian of a partially incapacitated person who has not been granted the right of representation by the court.

The powers of a factual guardian are stipulated in Art. 32 par. 2 of APP. Under this provision, tests or examinations of a minor person or the person incapable of expressing consent require only consent of a factual guardian. According to the relevant literature, a factual guardian may give consent only to test or examination but not to further medical services[17]. Consequently, a guardian may give consent solely to routine and safe (not life and health threatening) medical services[18]. Interestingly, in other provisions the legislator envisaged a possibility of expressing consent to

16 R. Kubiak, Prawo medyczne, *op. cit.*, pp. 348-349.

17 See: M. Nesterowicz, Nowe ustawodawstwo medyczne, "Państwo i Prawo" 1997, No. 9, p. 6; R. Kubiak, Prawo medyczne, *op. cit.*, p. 350; R. Kędziora, Problematyka zgody pacjenta w świetle polskiego ustawodawstwa medycznego, "Państwo i Prawo" 2003, No. 7/8, p. 48; B Janiszewska, Zgoda na udzielenie świadczenia zdrowotnego. Ujęcie wewnątrzsystemowe, Warszawa 2013, p. 551.

18 M. Safjan, Prawo i medycyna…, *op. cit.*, p. 45. B. Janiszewska rightly points out that the factual carer decide on the medical examination if a minor patient, incapacitated or unable to give the informed consent or does not have a statutory representative or indeed he has such

medical acts (Art. 32 par. 6 of APP) as well as providing medical services (Art. 32 par. 8 and Art. 33 par. 1 of APP)[19] by a factual guardian.

It seems necessary to specify the scope of powers of a factual guardian more precisely. Another problem is the fact that his or her powers are considerably limited. Thus, the question arises here what to do when the parents of a child who has attained maturity definitely lose the right to decide about the child's life even if it is a matter of his or her life and health. According to M. Świderska, validity and existence of emotional ties that usually ensue from family or partner relations justify *prima facie* granting the so-called factual guardian more extensive powers[20]. At the same time, the postulate of expanding powers of a factual guardian cannot lower the level of protection of autonomy of patient's will enshrined by the Act[21]. For this reason, the extension of powers of a factual guardian must be justified by rational arguments resulting from the patient's situation.

4. Consent or authorization granted by the guardian court

The case shall be settled by the court when there is no entity entitled to express consent, or their will contradicts the patient's interest and may be withdrawn by the court's authorization[22]. Since cases requiring the court's permission have been discussed earlier, I will merely remind and summarize them here.

First of all, pursuant to Art. 32 par. 2 of APP, the guardian court's permission is necessary if a minor person or a person incapable of expressing his will consciously does not have a statutory representative, or if it is impossible to contact him or her. In other words, a lack of possibility to contact a statutory representative or its loss results in the situation when the court takes over a decision-making process. The court acts not only as the patient's surrogate decision maker but also statutory representative.

Moreover, the legislator has not regulated a legal situation of fully incapacitated persons when they do not have a statutory representative, or if it is impossible to contact them while it is necessary to undertake treatment. As it results from Art. 32

a representative, but it is not possible to communicate with him at the time when there is a need for an examination, B. Janiszewska, Zgoda na udzielenie...*op. cit.*, p. 559.

19 It should be noted that according to the art. 10b par. 1 of Act of 19 August 1994 r. on the protection of the sanity (consolidated text Journal of Laws 2017, item 882 as amended) the factual carer has the legal right to consent to see the medical documentation being reviewed by the Patient's Ombudsman for the Psychiatric Hospital. Interestingly, this provision, although contrary to the Act of 6 November 2008 on Patient's Rights and the Patient's Rights Ombudsman, is still in force.

20 M. Świderska, Zgoda pacjenta…, *op. cit.*, p. 59.

21 *Ibidem*, p. 59.

22 R. Kubiak, Prawo medyczne…, *op. cit.*, p. 355; B. Pawelczyk, Zasady wyrażania zgody oraz prawo do prywatności pacjentki ciężarnej, referat wygłoszony na konferencji naukowej: Podmiotowość pacjentki ciężarnej i rodzącej, Chełmża 10-11.11.2007 r., not published.

par. 4 of APP, a fully incapacitated person does not have a capacity to express consent himself or herself. The literature points out that this is a legal loophole and *legis* analogy should be applied appropriately[23]. In other words, it will be necessary to obtain the court's decision.

We deal with substitute consent also with regard to individuals having full capacity to perform legal acts but not capable of expressing informed consent. Such subjects do not have a statutory representative. That is why the guardian court should issue a relevant decision thereon.

Furthermore, we deal with the guardian court's intervention in the case of collision between the will of a patient and his or her statutory representative (factual guardian), or when the statutory representatives' refusal has been withdrawn. As rightly noticed by M. Świderska, the guardian court acts here as a mediator that must duly balance the parties' opinions and give them proper proportions[24]. The literature often postulates the amendment of Art. 36 par. 2 of APP. According to the doctrine representatives, this provision is too liberal and opens a possibility of ignoring both the patient's will and his or her statutory representative[25].

We do not hold the same opinion. Apparently, it is difficult not to agree that this provision arises considerable reservations; yet a doctor may also decide about the performance of a surgery in urgent cases without asking anyone about consent. That is why we agree with M. Świderska who rightly claims that it is difficult to refuse similar powers to the judiciary while indicating the rationale to be followed by the court in sentencing.

Pursuant to Art. 32 par. 10 of APP, the guardian court in the jurisdiction of which a medical act is to be performed shall be competent to issue permission. The proceedings to obtain substitute consent are conducted under Art. 579 of the Code of Civil Procedure. In urgent situations, the court may examine the case under a simplified procedure – without a hearing. We deal with an urgent situation when every moment of delay may lead to serious consequences for health and life and a doctor may then act even without the consent of the guardian court (Art. 32 par. 9 of APP and Art. 34 par. 7 of APP)[26]. Issued decisions become immediately enforceable.

23 M. Świderska, Zgoda pacjenta..., *op. cit.*, p. 54.

24 *Ibidem*, p. 55.

25 Zob. A. Kołodziej, Stopień autonomii woli…, *op. cit.*, p. 81; A. Liszewska, Zgoda pacjenta na zabieg leczniczy, "Państwo i Prawo" 1997, No.1, p. 89; M. Safjan, Prawo i medycyna…, *op. cit.*, p. 53.

26 Szerzej: M. Śliwka, Prawo pacjenta do świadczenia opieki zdrowotnej w stanie nagłym, "Prawo i Medycyna" 2008, No. 2, p. 44 and following; M. Filar, S. Krześ, E. Marszałkowska-Krześ, P. Zaborowski, Odpowiedzialność lekarzy i zakładów opieki zdrowotnej, Warszawa 2004, p. 193; M. Filar, Postępowanie lecznicze..., *op. cit.*, p. 44; J. Bujny, Prawa pacjenta..., *op. cit.*, p. 248 and following.; J. Kulesza, Brak zgody pacjenta..., *op. cit.*, pp. 70-71; A. Zoll, Stan wyższej konieczności jako okoliczność wyłączająca przestępczość w praktyce lekarskiej, "Prawo i Medycyna" 2005, No. 19, p. 13; M. Świderska, Zgoda pacjenta..., *op. cit.*, pp. 172-176; T. Dukiet-Nagórska, Stan wyższej konieczności w działalności lekarskiej, "Prawo i Medycyna" 2005, No. 2, p. 22; A. Zoll, Granice

5. Consent given by a statutory representative and incapacitated person

A statutory representative gives consent on behalf of the fully incapacitated person. However, if such a person is able to express his or her opinion consciously (understanding the situation sufficiently) about a medical test or examination, it is also necessary to obtain his or her consent[27]. The Act does not define the notion of the capacity to express consent. According to R. Kędziora, it should be assumed that it is the ability to express logical opinions about one's acts. The author notices that the restriction of this provision only to a test (examination) evokes justified doubts[28]. According to T. Dukiet-Nagórska, such a solution implies that pursuant to the principle of *argumentum a minori ad maius,* consent should be also obtained from the incapacitated person for health services other than a test (examination)[29]. We agree with the author. We believe that a person who is able to express his or her will consciously about a test (examination) is equally capable of deciding about other health services. As underlined by M. Świderska, such consent given by a person deprived of the capacity to perform legal acts shall maintain a sense of dignity by the awareness of impact on the preservation of one's own body integrity[30].

As far as the performance of operations or higher risk surgeries is concerned, the legislator has omitted a possibility of expressing consent by the fully incapacitated persons but sufficiently aware to be able to express their will (Art. 34 par. 4 of APP). In our opinion, they should not be deprived of their right of self-determination. The inclusion of the will of incapacitated persons is supported, *inter alia*, by the norm expressed in Art. 6 par. 3 of the Oviedo Convention. Pursuant to this provision, if an adult does not have the capacity to consent to an intervention because of a mental disability, a disease or for similar reasons, the intervention may only be carried out with the authorisation of his or her representative or an authority or a person or body

legalności zabiegu medycznego, "Prawo i Medycyna" 1999, No. 1, p. 29; R. Kędziora, Problematyka zgody pacjenta…, *op. cit.*, p. 41 and following.; K. Daszkiewicz, Uchylenie odpowiedzialności lekarza za wykonanie zabiegu leczniczego bez zgody pacjenta, "Palestra" 2002, No. 11/12, p. 37 and following; K. Sakowski, Komentarz do art. 34 ustawy o zawodach lekarza i lekarza dentysty, System Informacji Prawnej Lex.

27 See: J. Bujny, Prawa pacjenta – między autonomią a paternalizmem, Warszawa 2007, p. 241; K. Sakowski, Komentarz do art. 32 ustawy o zawodach lekarza i lekarza dentysty, System Informacji Prawnej Lex; J. Haberko, B. Pawelczyk, Poszanowanie autonomii pacjentki w zakresie udzielania przez nią zgody na zabiegi medyczne, "Ginekologia i Położnictwo – Medical Project" 2009, No. 1, pp. 42-43.

28 R. Kędziora, Problematyka zgody pacjenta, *op. cit.*, p. 49.

29 T. Dukiet-Nagórska, Świadoma zgoda pacjenta w ustawodawstwie polskim, *op. cit.*, p. 91.

30 M. Świderska, Zgoda pacjenta…, *op. cit.*, p. 64.

provided for by law. The individual concerned shall as far as possible take part in the authorisation procedure[31].

For the above reasons, we believe that the Polish legislator should guarantee the extension of the protection of autonomy of the patient who is actually able to express his or her will consciously, and allow him or her to exercise their right to decide about their body at least in the form of cumulative consent.

The introduction of the structure of cumulative consent may cause the collision of wills of the patient and his or her statutory representative or factual guardian as far as consent for a test (examination) is concerned. As it has been mentioned before with regard to the consent of a statutory representative and a minor over 16 years of age, if the opinions of these persons collide, it is obligatory to obtain the consent of the guardian court (Art. 32 oar. 6 and Art. 34 par. 5 of APP).

6. Conclusion

The Polish legislator does not treat an incapacitated patient as a person incapable *a priori* of expressing his or her will consciously. Just on the contrary, the legislation enshrines the principle of the need to obtain consent of such a patient – for instance in the case of a test (examination) performed by a doctor. Nevertheless, the scope of autonomy of the patient's will appears to be problematic. It seems that the scope of the patient's autonomy should depend on their ability to perceive and express will. Due to this, it is difficult to explicitly deprive not incapacitated persons suffering from recurring psychological disorders of the possibility to express their will. In the light of the currently binding provisions, such persons have a full capacity to perform legal acts, which entails that they may express consent for medical treatment.

The above considerations on incapacitated persons ensue the conclusion according to which Polish legislation does not fully deprive incapacitated patients of expressing their will. However, the authors believe the relevant restrictions are too far-reaching and undermining the right of self-determination. Essentially, the right of an incapacitated person to decide about themselves should be respected by a doctor throughout the entire treatment.

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31 The convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine adopted on the 4 of April 1997 in Oviedo.

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The Right to Demand to Withhold Information as an Expression of Patient's Autonomy

Abstract: The right to demand to withhold information is an expression of respect towards patient's will and his autonomy as well as denial of the paternalistic conception of a relation between an ill individual and his doctor. It is the patient who, as a disposer of the right to information, decides if and to what extent he wants to receive such information. Despite the fact that the right to information has been widely described in the medical law literature, the right to demand to withhold information, which is directly connected to it and ensuing from it, has not been thoroughly examined yet. Because of that, it seems right and reasonable to analyse the issue related to the boundaries of patient's autonomy. It should be emphasised that none of the current Laws pertaining to the obligation to inform have stated that the patient has the right to not be informed of his health condition. The institution of demanding to withhold information raises many concerns while in medical practice it very often occurs. The following paper examines the scope of the patient's right to demand to withhold information as well as the circumstances of excluding and restricting that right. Additionally, it widely describes the consequences caused by the right to resign from information. In particular, a part of the paper is devoted to the legal character of an expressed consent to treatment in accordance with the opinions expressed in the legal doctrine.
Keywords: patient's rights, the right to demand to withhold information, patient's autonomy

1. Introduction

The right to demand to withhold information expresses respect for the patient's will and autonomy[1], and contradicts the paternalistic perception of a relation between a patient and doctor[2]. The patient as a disposer of the right to information decides if and to what extent he wants to receive such information. Although the

1 E. Zielińska (ed.), Ustawa o zawodach lekarza i lekarza dentysty. Komentarz, Warszawa 2008, p. 450.

2 J. Bujny, Prawa pacjenta między autonomią a paternalizmem, Warszawa 2007, p. 148.

right to information has been widely discussed in the medical law literature, the right to demand to withhold information, which is directly connected to it and ensuing from it, has not been comprehensively analysed. For this reason, it seems right and reasonable to analyse the above issue, which is particularly related to the limits of patient's autonomy. It should be emphasized that none of the current Laws pertaining to the obligation to inform have stated that the patient has the right to not be informed of his health condition[3]. The institution of demanding to withhold information raises many concerns while in medical practice it very often occurs. Undeniably, the very nature of this right arises problems itself, as it is an exception[4] from the general principle of informing the patient and informed consent to therapy embedded in the doctrine and case law. This generates doubts related to the establishment of the scope of disclaimer of information and a potential restriction of the right to demand to withhold information – the exclusion of the right to not inform – and, in consequence of the above, the fulfilment of the request to not inform and its impact on the efficiency of consent expressed by the patient as well as ensuing ethical and legal dilemmas.

The right to demand to withhold information has been regulated in Art. 9 par. 4 of the Act on the Patient's Rights and Patient Ombudsman[5], which grants the patient the right to demand to withhold information about his health condition, diagnosis, proposed and possible methods of diagnosis and treatment, foreseeable consequences of their application or omission thereof, effects of treatment and forecast. A patient may resign fully or partially from the information he or she is entitled to receive by specifying clearly the scope of information he or she disclaims. Similar regulation has been contained in Art. 31 par. 3 of the Act on the Profession of a Physician and Dentist[6], under which a doctor is not obliged to inform the patient upon his or her request, and in Art. 16 of the Code of Medical Ethics[7,8]. Both provisions correspond to one another, similar to the right of the patient to not be informed and the exception

3 A. Górski, O obowiązku lekarza poinformowania pacjenta i zgodzie pacjenta na zabieg, "Studia Iuridica" No. 39, 2001, p. 85.

4 T. Dukiet- Nagórska, Stosowanie ustawy o zawodzie lekarza przez psychiatrów i ustawy o ochronie zdrowia psychicznego przez lekarzy innych specjalności, "Prawo i Medycyna" 2004, No. 4, p. 9.

5 Consolidated text Journal of Laws 2016, item 186 as amended [Tekst jedn. Dz.U. z 2016 r. poz. 186 ze zm.] in short u.p.p.

6 Consolidated text Journal of Laws 2017, item 125 as amended [Tekst jedn. Dz.U. z 2017 r. poz. 125 ze zm.] in short u.z.l.

7 Kodeks Etyki Lekarskiej, Announcement of the President of the Supreme Medical Council of 2 January, 2004 on the publication of a uniform text of the resolution on the Code of Medical Ethics [Obwieszczenie no 1/04/IV of Prezesa Naczelnej Rady Lekarskiej z dnia 2 stycznia 2004 r. w sprawie ogłoszenia jednolitego tekstu uchwały w sprawie Kodeksu Etyki Lekarskiej].

8 Even if the Code of Medical Ethics it is not a source of universally binding law due to art. 4 of u.z.l. is an important reference criterion for assessing the correctness of performing a medical profession.

from the obligation to inform the patient imposed on a doctor. The right to demand to withhold information has been regulated schematically. Due to this, in compliance with the statutory regulation, the doctrine also merely points out that the exemption of a doctor from the obligation to inform a patient is designated by the scope of request made the patient himself or herself[9]. Nevertheless, it should be underlined that such a statement is quite general and may be applied only in typical cases, which are relatively rare in the practice.

In order to systemize my article and assure its reliability, it is necessary to indicate a circle of subjects entitled to the discussed right. Even though patients themselves undeniably belong to this group, it is worth considering whether the patient's statutory representative is also entitled to the right not to inform. The doctrine has so far relied on the opinion according to which minor patients, including those who attained 16 years of age, may demand to withhold information whereas a statutory representative is denied this right[10]. The very form of the request itself is significant as it should be expressed directly, undoubtedly[11], clearly, decisively, indicating the patient's determination (omission to inform may not be based on presumed consent[12]) and, for evidence reasons, it should be recorded in medical documentation[13]. According to the opinion that has emerged in the doctrine[14], the very reading of the provision itself implies that consent may not be presumed and it must be a request verified according to severe criteria. A doctor may not cease to inform a patient based on his or her presumed behaviour, e.g. when the patient resigns from asking questions. As a disposer of the right to information, the patient may resume his willingness to be informed any time, and then he or she is informed upon general rules[15]. The doctrine emphasizes that the disclaimer must be active and explicitly expressed[16].

The causes of wavering the right to information may vary: a patient may be not interested in his or her health condition, he or she may not want to hear such information, or may feel disgust to such information[17], or the demand may be the

9 J. Bujny, Prawa pacjenta między…, *op. cit.*, p. 148.
10 D. Karkowska, Ustawa o prawach pacjenta i Rzeczniku Praw Pacjenta. Komentarz, Warszawa 2016, p. 237.
11 E. Zielińska (ed.), Ustawa o zawodach…, *op. cit.*, p. 450.
12 M. Boratyńska, P. Konieczniak, Prawa pacjenta, Warszawa 2011, p. 248.
13 L. Kubicki, Nowy rodzaj odpowiedzialności karnej lekarza (przestępstwo z art. 192 KK), 2000, No. 8, p. 31.
14 M. Świderska, Zgoda pacjenta na zabieg medyczny, Toruń 2007, p. 163.
15 A. Augustynowicz, A. Budziszewska- Makulska, Ustawa o prawach pacjenta i Rzeczniku Prawa Pacjenta. Komentarz, Warszawa 2010, p. 70.
16 *Ibidem,* p. 70.
17 M. Boratyńska, Autonomia a granice upoważnienia osoby bliskiej i zaufanej, "Prawo i Medycyna" 2014, No. 1 (54 vol.16), p. 68.

effect of full trust in the doctor[18]. The reasons for the waiver depend on the patient[19] and they are not subject to doctor's evaluation. In practice, the demand most often occurs when patients are in serious condition and they themselves suspect unfavourable forecast; then they do not want to be informed about their health condition by the doctor[20]. The doctrine indicates the supremacy of the so-called "right to the truth", which becomes restricted due to the fact that the patient may not want to know everything, particularly unfavourable forecast which may worsen his or her psychical and physical condition[21]. The demand to withhold information is not the disclaimer of the right in the civil law meaning because the subject of the right to information is the patient's personal interest – information autonomy[22].

2. The scope of the patient's right to demand to withhold information

The scope of the right to demand to withhold information is not specified in the binding legal provisions. Nevertheless, the doctrine points out that it depends on the patient because as a disposer of the right to information, he or she decides which information and to what extent thereof he or she disclaims. As a medical professional, who evaluates which information a patient may waive due to his and other persons' interest, a doctor affects the shape of information being conveyed as well. Moreover, it should be underlined that there are cases of exclusions of the application of Art. 9 par. 4 of APR and Art. 31 par. 3 of APP under the law itself.

Various ideas related to the scope of disclaimer of the right to information have emerged in the doctrine. The following opinions are the most common: the first one distinguishes a possibility of complete (full) disclaimer of information, where a doctor is exempted from the obligation to convey any information, and the second one – the concept of partial disclaimer – where medical professionals are exempted only from specific information[23]. A slightly different idea is presented by E. Zielińska, according to which a patient has the right to specify that he or she does not want to receive detailed information, or to be informed at all about some aspects of scheduled surgeries[24]. This scope of information not to be conveyed is determined more narrowly because it is limited to details and some aspects; what is more, it literally does not list a possibility of full disclaimer of the right to information. The

18 U. Drozdowska, W. Wojtal, Zgoda i informowanie, Warszawa 2010, p. 59.

19 D. Karkowska, Ustawa o prawach…, *op. cit.,* p. 234.

20 M. Grego, Podstawy i konsekwencje decyzji lekarza o ograniczeniu pacjentowi informacji o jego stanie zdrowia i rokowaniu, (in:) J. Hebrko, R.D. Kocyłowski, B. Pawelczyk (ed.), Lege Artis problemy prawa medycznego, Poznań 2008, p. 55.

21 M. Nesterowicz, Prawo medyczne, Toruń 2016, p. 189.

22 U. Drozdowska, Cywilnoprawna ochrona prawa pacjenta, Warszawa 2007, p. 148.

23 A. Augustynowicz, A. Budziszewska-Makulska, *op. cit.*, p. 70; D. Karkowska, *op. cit.,* p. 234.

24 E. Zielińska (ed.), Ustawa o zawodach…, *op. cit.*, p. 480.

right not to be informed is presented most narrowly by K. Michałowska, according to whom the admissible scope of disclaimer within the areas designated by Art. 31 par. 1 of APR is too wide – it is a full disclaimer of the obligation to inform – and it should be made narrower[25]. The information may be limited only to such data which would not adversely affect the patient's psychic because a doctor is not allowed not to fulfil the obligation to inform the patient[26]. An opposite opinion is held by J. Bujny, who believes that a patient disposes his right to information in any way while any attempts at limiting or disrespecting his will are manifestations of a lack of respect for the patient's will and interfere in his autonomy[27]. Under practical interpretation of the scope of disclaimer to exercise the right to information, it should be considered whether the patient may waive all information, including those connected with a risk posed by a surgery and forecast. Assuming that a patient is a disposer of his right and decides about its shape substantively (by authorizing other persons to inform) and objectively (about the type and scope of information), it should be acknowledged that the patient may request to restrict or withhold the information at his discretion[28].

3. Circumstances of exclusion or restriction of the right to demand to withhold information

Considering the scope of the right to demand to withhold information, it should be emphasized that it is not an absolute and unlimited right. Nevertheless, M. Boratyńska holds an opposite opinion thereon, claiming that the right to demand to withhold information specified in Art. 31 par. 3 of APP is explicitly stipulated and unlimited[29]. Although the reading of Art. 9 par. 4 of APR implies its absolute nature: "a patient has the right to demand", the regulation contained in Art. 31 par. 3 of APP is of a slightly more dispositive nature: "a doctor is not obliged to inform the patient". It is apparent that the provision exempts a doctor from the obligation to inform; yet it does not impose on him an absolute obligation not to inform upon the patient's request. Therefore, a situation when a patient has been provided with unwanted information should be admissible. The above interpretation is justified by the fact that the obligation of information (informing appropriately and within the proper scope) is treated as one of the most important obligations of a doctor. Hence, obliging doctors to consider patients' requests in an absolute and unlimited way without granting medical professionals a possibility of deciding *ad casu* would evoke doubts.

25 K. Michałowska, Charakter prawny i znaczenie zgody pacjenta na zabieg, Warszawa 2014, p. 160.
26 K. Michałowska, Informowanie pacjenta w polskim prawie medycznym, "Prawo i Medycyna" 2003, No. 13 (vol. 5) p. 115.
27 J. Bujny, Prawa pacjenta między…, *op. cit.*, p. 148.
28 U. Drozdowska, W. Wojtal, Zgoda…, *op. cit.*, p. 60.
29 M. Boratyńska, Autonomia a granice…, *op. cit.*, p. 68.

Despite recognition that a patient is a disposer of the right to information, a purpose of the discussed right (apart from the guarantee of the patient's substantive treatment) is also the guarantee of a due (appropriate) course of treatment, proper cooperation with the doctor, and, in some cases, the protection of the rights of third parties. There are two possibilities of excluding or restricting the right to demand to withhold information. The first one involves the restriction under the Act whereas the second one apparently results from the decision of the doctor himself who, due to the patient's good, will decide to inform the patient against his or her request taking into account the course of treatment and the importance of information for the patient's potential consent.

The statutory exclusion of the right to withhold information refers to patients suffering from infection and psychical disorders, or those undergoing medical experiments or transplantation, women deciding for abortion, female recipients of gametes (embryos) and male donors of sperm based on the Act on Infertility Treatment[30]. We should thoroughly consider situations when, under the law, a patient may not waive the right to be informed, which refers both to the information about "common" and higher risk (threat). It should be emphasized that there is no "compulsory information" in medicine except statutory prerequisites, which will be discussed[31].

The exclusion of the right to withhold information refers to infected patients not only due to their course of treatment but also in order to assure safety to third parties. Such use of the patient's right to no information could jeopardize other people[32]. A person likely to be sick, ill or exposed to infection is not only informed due to the specific nature of their condition but also hospitalized against their will (pursuant to Art. 35 par. 1 of the Act of 5 December 2008 on Counteracting and Fighting Human Infections and Infectious Diseases[33]). Moreover, an infected patient may not disclaim information due to safety of other people; here his or her autonomy expressed in the right to withhold information succumbs to the right of other people. Pursuant to Art. 39 of ACFH, in the case of diagnosing infection which may spread through sexual intercourse, a doctor or physician is obliged to inform the infected person about the need to contact the doctor of his sexual partner or partners – this obligation deprives the patient of the right to not be informed. Due to the content of Art. 26 of ACFH, strictly specified medical personnel – a doctor, physician, nurse or midwife – are obliged to instruct the infected patient, among others, about ways or measures to counteract spread of infection to other people, and in the case of diagnosing infection

30 D. Karkowska, Ustawa o prawach…, *op. cit.*, p. 237.
31 U. Drozdowska, W. Wojtal, Zgoda…, *op. cit.*, p. 59.
32 U. Drozdowska, Cywilnoprawna…, *op. cit.*, p. 148.
33 Consolidated text Journal of Laws 2016, item 1866, as amended [Tekst jedn. Dz.U. 2016 poz. 1866] in short u.z.z.ch.

which may spread through sexual intercourse, inform the infected person about the need to contact his sexual partner or partners' doctor. The provision does not allow the patient to resign from necessary information. The right to withhold information succumbs to the right of other people[34].

Furthermore, the situation of a psychiatric hospital patient is also specially regulated in the Act of 19 August 1994 on the Protection of Mental Health[35]. The provisions regulate mandatory treatment of a patient admitted without his consent with regard to whom a doctor is obliged to provide information about his scheduled treatment. Persons suffering from disorders are informed about the purpose of psychiatric hospitalization, health condition, proposed diagnostic and therapeutic action and their foreseeable effects. Due to special restrictions of the psychiatric hospital patient's autonomy, he or she may not be deprived of the right to the above-mentioned information.

The right to not inform is excluded with regard to persons undergoing medical experiments. Under the regulation contained in Art. 24 of APP, patients are informed about the purpose, methods and conditions of experiments, expected therapeutic or cognitive benefits, and a risk and possibility of withdrawing from the participation in the experiment at each stage thereof. The nature of such treatment is not medical and they always require complete information – the patient may not waive it[36]. Research and medical experiments as well as clinical tests have a lot in common, among others, the obligation to inform a person undergoing the experiment[37]. It should be indicated that a medical experiment is not always a medical action – due to this, the law prohibits experiments without voluntary consent; general provisions on consent for treatment do not apply in this case[38].

Individuals enjoying special information privileges are also candidates for living donors of tissue and organs as well as recipients thereof. Pursuant to Art. 12 par. 1 point 5 of the Act of 1 July 2005 on the Recovery, Preservation and Transplantation of Cells, Tissue and Organs[39], before giving consent, a donor is precisely and accurately informed in writing about a type of surgery, ensuing risk and foreseeable effects thereof for his or her health in the future. Similar to this, pursuant to Art. 12 par. 1 point 9 of ARPT, a candidate for a recipient is informed about a risk related to the

34 D. Karkowska, Ustawa o prawach…, *op. cit.*, p. 236.

35 Consolidated text Journal of Laws 2017, item 882 as amended [Tekst jedn. Dz.U. z 2017 r. poz. 882 ze zm.]

36 D. Karkowska, Ustawa o prawach…, *op. cit.*, p. 235.

37 W. Nowak, Prawne formy zgody pacjenta na eksperyment medyczny (zagadnienie cywilnoprawne), "Prawo i Medycyna" 2005, No. 3 (20, vol. 7), p. 47.

38 A. Górski, Leczyć czy nie leczyć? Dylematy podejmowania leczenia z punktu widzenia konfliktu dóbr, [in:] Czasopismo Prawa Karnego i Nauk Penalnych, Year XV: 2011, p. 160.

39 Consolidated text Journal of Laws 2017, item as amended 2017 [Tekst jedn. Dz.U. 2017 poz. 1000], in short u.p.p.p.

surgery of recovery of cells, tissues or organs and possible effects of the recovery for the donor's health.

Furthermore, pregnant women who have the right to obtain information about prenatal tests enjoy special information privileges, particularly if the embryo is at a higher risk of genetic and developmental defect, or incurable disease threatening the embryo's life[40] (Art. 2 par. 2a of the Act on Family Planning[41]). The right to demand to withhold information is excluded also with regard to women who want to terminate pregnancy (Art. 4a of AFP).

The last special regulation is the obligation to inform a woman as a recipient and a man as a donor, which is contained in the Act on Infertility Treatment[42]. It is the obligation to inform individuals with regard to whom actions related to *in vitro* conception have been undertaken. Gametes may solely be recovered from a donor if the absolute statutory condition is satisfied, i.e. the person being prepared for donation is clearly and precisely informed about the type of a surgery, its nature, laboratory tests conducted for this purpose and the right to receive the results of these tests, a manner of storing and protecting his personal data, medical secrecy, a risk related to the surgery of recovering gametes, foreseeable affects of its application in the future, security measures, etc. Analogical requirements have to be satisfied by a female recipient.

The second possibility of excluding or restricting the right to demand to withhold information results from dispositive reading of Art. 31 par. 3 of APP, according to which a doctor is not obliged to inform a patient. This interpretation results from the fact that the obligation to not inform, i.e. a peculiar ban on informing, may not be imposed on a doctor, as well as from the specificity of relations that are subject to the analysis. It is admissible (apart from the situations ensuing from the Act) that, due to the forecast, radicalism and irreparability of a given medical treatment, e.g. limb amputation or vasectomy, a doctor will inform the patient against his or her will[43]. The patient's request under such exceptional circumstances cannot abate (repeal) the doctor's obligation because the patient may not be deprived of the information about the purpose of the treatment related to, e.g., irreparable amputation of his body part[44]. Failure to inform would evoke more traumatic effects than a response to the information. What is more, non-medical treatments require full information.

40 D. Karkowska, Ustawa o prawach…, *op. cit.*, p. 221.

41 Consolidated text Journal of Laws of 1993, No. 17 item 78 as amended [Dz.U. 1993, Nr 17 ze zm., poz. 78], in short u.p.r.

42 Consolidated text Journal of Laws 2017, item 865 as amended [Tekst jedn. Dz.U. 2017 poz. 865].

43 D. Karkowska, Ustawa o prawach…, *op. cit.*, p. 235; M. Sośniak, Cywilna odpowiedzialność lekarza, Warszawa 1968, p. 47.

44 M. Świderska, Zgoda…, *op. cit.*, p. 169.

Their nature decides about informing the patient fully and excludes the protection of autonomy of the will of a patient refusing to be informed[45].

The doctrine also debates on the issue of disclaimer of the right to information related to higher risk surgeries. The doctrine relies on the opinion assuming that such a disclaimer is admissible also in this case due to referral to Art. 31 of APP contained in Art. 34 par. 2 of APP, according to which a doctor is obliged to inform the patient under Art. 31 of APP before the patient gives consent to operation or application of a therapeutic method or diagnosis posing a higher risk. Moreover, *ratio legis* of admissibility of the patient's disclaimer of information is the protection of autonomy of the patient's will[46]. M. Filar holds an opposite opinion believing that the reading of Art. 31 of APP supports absolute obligation of information with regard to operations and other surgeries posing a higher risk[47].

We think that the opinion reported in the doctrine saying that a doctor may not refrain from fulfilling the obligation of information he is burdened with and limit the scope of information to the information that would not negatively affect the patient's psychic when the patient does not want to be informed[48] is too far-reaching. However, due to the dispositiveness of Art. 31 par. 3 of APP and the right to inform the patient against his or her will in exceptional situations doctors are granted with, we will prevent concerns resulting from the potential effects that may be evoked by certain information during the treatment process. Nevertheless, it is argued that recommendations about the lifestyle or pharmacotherapy should not be identified with the information conveyed before the surgery which constitutes an element of consent[49]. In such situations, a doctor is obliged to talk to the patient and perhaps attempt to change the patient's decision not to be informed in order to satisfy the obligation of information *lege artis*. The postulate of defining the conditions of disclaimer in such a situation should be approved of[50].

4. Consent to treatment in the light of the demand to withhold information

The patient's right to demand to withhold information evokes consequences regarding the legal nature of the expressed consent to treatment while the doctrine presents various concepts thereof. The problem is extremely significant because properly expressed consent excludes a possibility of launching any therapy by medical

45 *Ibidem*, p. 169.
46 *Ibidem*, p. 163-164.
47 M. Filar, Lekarskie prawo karne, Kraków 2000, p. 264-265.
48 K. Michałowska, Informowanie…, *op. cit.*, p. 107.
49 M. Świderska, Zgoda…, *op. cit.,* p. 165.
50 M. Boratyńska, P. Konieczniak, Prawa…, *op. cit.*, p. 248.

personnel[51]. The problem results from the collision between the right to demand to withhold information disposed by the patient himself or herself on the one hand, and difficulty to assess consent expressed without informing the patient. A legal nature of consent expressed by the patient who waived the right to information results from the prerequisites of non-defectiveness of consent, pursuant to which a declaration of will may not be affected by defects of declarations of will – the fulfilment of the principle of informed consent[52]. However, it should be emphasized that due to statutorily admissible exception in the form of a possibility of not informing patients, on the one hand, they cannot consent to actions (acts) they do not know anything about while, on the other hand, they have the right to not be informed[53].

The demand to withhold information implies the expression of not-informed consent, called blanket consent, based on which a doctor has been generally authorized to act according to his expertise[54]. The doctrine argues that a patient has to the right to waive information and it is the only case of blanket consent which abates invalidity (unlawfulness) while the consent itself is not defective if it was demanded by the patient. Disclosure of information is not the only condition of validity of consent but patients cannot make a rational decision about treatment not knowing certain facts medical personnel is aware of[55]. Disclaimer of information may be connected with authorizing a person of trust, which is of a substitute nature, when the patient is informed "above his or her head". A person of trust is authorized due to the so-called prudence, e.g. in case of a medical error; in such situations, a person of trust is a sole recipient of information[56]. According to the above opinion, disclaimer of the right to information does not essentially mean disclaimer of the right to express consent to treatment as it is blanket consent. If effect of the demand to withhold information, our legal system contains only one case when consent for any treatment or consent for generally defined treatment may be applied[57].

According to the opposite concept, obtaining blanket consent from the patient is legally ineffective. Expressing consent, a patient must receive information while in the situation of withholding information upon the patient's request, doctor's actions shall be lawful but the consent itself shall be devoid of legal importance[58]. A similar

51 A. Górski, Leczyć, czy nie leczyć?, Dylematy… *op. cit.*, p. 153.
52 U. Drozdowska, W. Wojtal, Ustawa…, *op. cit.,* p. 16.
53 K. Michałowska, Charakter prawny…, *op. cit.,* p. 159.
54 *Ibidem*, p. 159.
55 M. Boratyńska, P. Konieczniak, Prawa…, *op. cit.,* p. 246.
56 M. Boratyńska, Autonomia…, *op. cit.,* p. 68.
57 M. Boratyńska, P. Konieczniak*,* Prawa…*, op. cit.,* p. 248.
58 *Ibidem*, p. 160.

assumption has been adopted by the doctrine; disclaimer of the right to information inhibits a possibility of expressing informed consent[59].

Absolutely distinct and apparently most acceptable opinion separates the concept of blanket consent from the demand to withhold information. A demand to withhold information entails abatement of one of the elements of the structure of effective consent because through his statement on the refusal to receive information, the patient overturns "the element of information". Blanket consent essentially involves acceptance of any medical interventions expressed by the uninformed patient who has not made a request to not be informed. Blanket consent, however, does not generate legal effects[60].

5. Doctor's conduct and the patient's right to demand to withhold information

Although a patient has the right to demand to withhold information, since the patient delegates responsibility and the right to make a decision onto a doctor, the doctor plays a significant role in the procedure of the demand to withhold information. For the above reason, it is necessary to discuss the conditions of disclaimer to information a doctor may provide.

The doctrine points out that satisfying the requirement of due diligence, a doctor should repeat the question whether the patient certainly waives the right to information including potential serious consequences, and ask about a possibility of appointing the authorized person to obtain information on the patient's behalf. In effect of the disclaimer, a doctor should inform about necessary requirements and consequences of the treatment, e.g. the need to follow a specific diet. What is more, the information before the treatment should not be identified with recommendations after the treatment concerning the patient's lifestyle; the patient's prior disclaimer does not matter here[61]. It should be emphasized that medical personnel must not put pressure on the patient in order to obtain his or her disclaimer, or suggest the patient may disclaim information for the sake of a free decision made by a doctor[62]. Continuing the thread of abuses committed thereon, we should point out a possibility of abuses related to omitting burdensome and time-consuming procedures of collecting informed consent, particularly in large centres admitting a lot of patients where there is a risk that doctors, with the approval of administrative authorities, will

59 T. Dukiet- Nagórska, Świadoma zgoda w ustawodawstwie polskim, "Prawo i Medycyna" 2000, No. 2, p. 80.

60 M. Świderska, Zgoda…, *op. cit.,* p. 164-165.

61 *Ibidem,* p. 165-166.

62 D. Karkowska, Ustawa…, *op. cit.,* p. 234.

persuade patients to disclaim this right[63]. What is more, a doctor may not suggest the patient uses the right to disclaim due to the patient's interest or failure to understand information[64].

The opinion reported in the doctrine saying that informing a patient about his or her health condition regardless of their wish not to do so, or conveying full information about their health condition even though they have not demanded it infringes the obligation of information[65] appears to be accurate. In consequence, we should consider whether a doctor provides a patient with excessive information when illegitimately informing him or her against their will. According to the definition proposed in the literature, excessive information is the information which may harm the patient. In the light of this definition, information conveyed against the request may constitute excessive information if it harms the patient. Nevertheless, the doctrine underlines that a doctor may not be held responsible for providing excessive information because the statutory structure of the information is defective and implies the provision of excessive information by doctors. What is more, this notion is difficult to define, which somehow excludes responsibility for its provision and entails difficulties in establishing precise limits of responsibility[66]. Consequently, a doctor may not be held responsible for the provision of excessive information.

Nevertheless, we should consider the situation when not respecting the demand to not inform, a doctor faces responsibility for the harm caused by this information. The patient informed against his or her will may, e.g., develop depression due to their health condition and mental state[67]. *Per analogiam*, we can invoke here the example of informing under the circumstances of a therapeutic privilege where, under the judgment of Higher Regional Court in Colonia, the court found the doctor liable for the harm when he straightforwardly told the patient about brain cancer and uncertainty of the future therapy. Receiving this information, the patient was shocked and had a mental breakdown to such an extent that he developed a heart disease and partial muteness. In the court's opinion, despite the doctor's right to inform, revealing the information in such a form violated this right[68]. The above problem is very delicate since the effects of information may appear irreparable[69], and it is difficult to balance the patient's right to information and not harming him or her[70].

63 This phenomenon is already present in the west on a large scale; M. Boratyńska, P. Konieczniak, Prawa..., *op. cit.,* p. 247.

64 M. Świderska, Zgoda…, *op. cit., p*. 166.

65 A. Górski, Leczyć…, *op. cit.,* p. 90-91.

66 R. Tymiński, Odpowiedzialność lekarza za udzielenie informacji nadmiernej, "Prawo i Medycyna" 2012, No. 1, p. 57.

67 A. Górski, Leczyć…, *op. cit.,* p. 92.

68 M. Nesterowicz, Prawo medyczne…, *op. cit.,* p. 190.

69 K. Michałowska, Zgodna…, *op. cit.,* p. 160.

70 M. Nesterowicz, Prawo medyczne…, *op. cit.,* p. 190.

The last problem concerns doctor's responsibility related to the abatement of unlawfulness of his or her action through the patient's informed consent – explicitly expressed patient's will exempts the doctor from responsibility[71]. Apart from autonomous contents, consent and information also provide security measures against depriving doctor's actions of the features of unlawfulness[72]. The conflict arises between the doctor's obligation to provide information, which restricts unlawfulness, and autonomy of the patient's will expressed in the demand to withhold information. The form of providing information which burdens a doctor serves, on the one hand, the patient's trust in the doctor and emphasizes the patient's autonomy and his or her right of self-determination but, on the other hand, it protects the doctor pursuant to Art. 6 of the Criminal Code[73]. It should be pointed out that the patient has the right to dispose of information and, trusting the doctor, he or she may waive the right to information. On the other hand, accepting this right, the doctor takes over the entire burden of not conveying information himself or herself, and in the face of not-informed consent, he or she makes a decision himself or herself. In order to secure the doctor's interest, the doctrine underlines that due to the effects evoked by the violation of the obligation of information contained in Art. 31 par. 1 of APP, the doctor should be able to prove that the patient demanded to withhold information directly and undoubtedly.

6. Conclusions *de lege ferenda*

Doubts discussed herein have been evoked by the quite schematically drafted regulation of the right to demand to withhold information. Due to the above, the following conclusions *de lege ferenda* may be drawn. We should approve of the determination of the scope of disclaimer and statutory prerequisite restricting or excluding the right to waive information. Moreover, we should attempt to define the conditions of the disclaimer and consequences thereof on the legal nature of consent for treatment. However, one of the most important postulates is to eradicate different readings of the provisions of the Act on the Patient's Rights and Patient Ombudsman and the Act on the Profession of a Physician and Dentist by combining them, which will effect in the patient's right to demand to withhold information and concurrently maintain certain authorization of the doctor to provide it, which results from the present reading of the latter Act.

71 M. Świderska, Zgoda…, *op. cit.,* p. 164.

72 K. Michałowska, Zgoda…, *op. cit.,* p. 160.

73 A. Dyszlewska-Tarnowska, (in:) L. Ogiegło (ed.), Ustawa o zawodach lekarza i lekarza dentysty. Komentarz, Warszawa 2015, p. 295.

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The Admissibility of 'Private Opinions' in Civil Medical Litigation Based on the Patient's Right to Medical Documentation

Abstract: A private opinion is a statement referring to the expertise not obtained from an expert appointed by the court. Consequently, in medical proceedings this opinion is not as important as expert evidence within the meaning of Article 278 § 1 of the Polish civil procedure. Nevertheless, the role of a private opinion in civil medical litigation is constantly increasing. This is primarily due to the crisis of the institution of an expert witness. The author focuses on the issue whether a private expert has the right to access information gathered in medical records. In the case of consent given by the patient himself as the holder of the right to access medical documentation, this issue does not raise any doubts. The situation is problematic when a medical entity acting as an opponent of the patient intends to use medical documentation to draft a private opinion. The medicinal entity may process sensitive data contained in medical records for purposes strictly defined by law. In view of this dilemma, the author presents the thesis that both the patient and the medical entity have the right to use this evidence if it is based on medical documentation. Her view is based on the content of Art. 27 par. 2 point 5 of the Data Protection Act, which allows to process data necessary to enforce the rights before a court as well as data referring to the principle of equal treatment in civil proceedings.
Keywords: private opinion, expert evidence, access to medical records, patient's consent, investigation and defence of rights before the court

1. Introduction

The term "medical litigation" means judicial proceedings to investigate compensatory claims made by patients due to the occurrence of harm during treatment[1]. Apart from classic cases where charges concern the commission of

1 The term "the medical process" is used less frequently than the term "doctor's process". Both terms are not concepts of legal but legal language (see e.g. M. Rogowski, Trudności związane

culpable medical error[2], there are cases where the source of civil liability is infection[3], or culpable violation of patient's rights[4]. The addressee of patient's claims in such cases is most often a medical entity, more seldom the doctor himself or herself.

All such proceedings are characterized by the complex factual state and the ensuing need to obtain an expert opinion. The claimant (a patient or potentially his or her family claiming liability[5]) must prove the incident (situation) and guilt as well as the chain of cause and effect between this incident and the harm (wrong) based on expertise. As a rule, the court obtains such expertise from judicially appointed expert witnesses, duly called "assistants of a procedural body"[6].

Pursuant to the provisions of the Act of 17 November 1964 – the Code of Civil Procedure[7], such proof is not basic evidence[8]. However, in case law practice, its importance is considerable while in medical litigation it often decides about adjudication or dismissal of the claim[9]. Nevertheless, before such evidence is admitted by the court, the party initiating a dispute must prepare for the trial. Pursuant to Art. 6 of the Act of 23 April 1964 – the Civil Code[10], a burden of proof (in this case

z przeprowadzeniem dowodu w procesach lekarskich, (in:) J. Haberko, R.D. Kocyłowski, B. Pawelczyk (ed), Lege artis. Problemy prawa medycznego, Poznań 2008, p. 86 i and following.; B. Janiszewska, Aktualne zagadnienia procesów lekarskich (przegląd orzecznictwa), "Prawo i Medycyna" 2004, No. 1, p. 39 and following).

2 See more on the notion of a medical error: K. Bączyk-Rozwadowska, Błąd lekarski w świetle doktryny i orzecznictwa sądowego, "Prawo i Medycyna" 2008, No. 3, p. 26 and following.

3 Cases relating to nosocomial infections compared to others are characterized by special features due to the use of factual presumptions, mainly in the area of proof of guilt and causation. See: B. Janiszewska, Dowodzenie w procesach lekarskich (domniemania faktyczne i dowód prima facie) "Prawo i Medycyna" 2004, No. 2, p. 104 and following.

4 Matters relating to the violation of patient rights are more and more common in courst. The most famous were the violation of the patient's right to information about the possibility of a prenatal examination,see eg.: the judgment of the Supreme Court of 13 October 2005 CK 161/05, OSP 2006, No. 6, item 71, with commentary of M. Nesterowicz; the Judgment of the Supreme Court of 12 June 2008, III CSK 16/08, OSNIC 2009, No. 3, item 48 [wyrok SN z dnia 12 czerwca 2008 r., III CSK 16/08, OSNIC 2009, nr 3, poz. 48].

5 The patient's relatives may raise their own claims for damages based on art. 446 of the Civil Code in the event of the patient's death.

6 See: the judgment of the Supreme Admnistrative Court of 20 August 1998 II SA 992/98. The literature also meets the terms "the assistant referee", "the scientific judge" or "the judge of facts", see: K. Piasecki, System dowodów i postępowanie dowodowe w sprawach cywilnych, Warszawa 2010, p. 196.

7 Consolidated text Journal of Laws 2016, item 1822 as amended [tekst jedn. z 2016 r. poz. 1822 ze zm.], in short kpc.

8 Formally, on the basis of the provisions of civil procedure, this evidence is assessed by the court under the same conditions as other evidence in the case. See: A. Klich, Dowód z opinii biegłego w postępowaniu cywilnym. Biegły lekarz, Warszawa 2016, p. 16 and following.

9 More on the role and meaning of the expert opinion see: A. Klich, Dowód, *op. cit.*, p. 71.

10 Consolidated text Journal of Laws 2017, item 459, as amended [Tekst jedn. z 2017 r. poz. 459 ze zm.], in short k.c.

the circumstances conditioning compensatory liability) shall rest on the person who draws legal effects from that fact[11]. On the other hand, Art. 232 of CCP stipulates that the parties shall be obliged to present evidence to confirm facts they draw legal effects from as well as present all facts and evidence without delay to assure efficient and prompt course of the proceedings (compare Art. 6 § 2 of CCP). Hence, the need to rely on the expert opinion, which will help the claimant prove the prerequisites of compensatory liability, may arise already during preparations for a trial. We deal here with a private opinion of an expert because it is drafted upon the party's and not the procedural body's request.

As pointed out in the literature, a private opinion plays a significant role as it allows to assess a probable success of the claim, facilitates estimation of potential profits and losses generated by the proceedings, and thus often decides whether a court struggle will be launched at all[12]. Furthermore, it may persuade the parties to conclude settlement (pre-court or out-of-court), due to which it may considerably shorten hearing of evidence and close the examination more quickly[13]. It is worth noticing here that a private opinion may be helpful not only for the claimant; the respondent more and more often relies on this type of evidence too, particularly if an unfavourable opinion drafted by the expert appointed by the court has been presented during the proceedings. The request to draft a private opinion may then constitute counter evidence and facilitate a substantive argument with the procedural opponent. Importantly enough, a private opinion is a tool considerably increasing a chance of finding out the truth, in particular in complex and ambiguous cases, that is in medical cases too[14].

11 It should be noted that the deviation from this rule is transferring the burden of proof from the patient to the doctor / medical entity to comply with the statutory obligation to provide the patient or his representative with accessible information, prior to consenting to the surgery, the Judgment of Supreme Court of 17 December 2004, II CK 303/04, OSP 2005, No. 11, issue. [Wyrok SN w wyroku z dnia17 grudnia 2004 r., II CK 303/04, OSP 2005, nr 11, poz. 131] with the commenatary of M. Świderska.

12 See: K. Knoppek, Prywatna opinia biegłego de lege lata i de lege ferenda, (in:) K. Flaga-Gieruszyńska, G. Jędrejek (ed.), Aequitas segitur legem. Księga Jubileuszowa z okazji 75-lecia urodzin profesora Andrzeja Zielińskiego, Warszawa 2014, p. 225 and following.; J. Misztal-Konecka, Znaczenie tzw. opinii prywatnej dla postępowania cywilnego, "Monitor Prawniczy" 2013, No. 2, p. 63 and following; A. Klich, Dowód, *op. cit.*, pp. 77-93; J. Budzowska, Opinia prywatna w sprawie o tzw. błąd medyczny, "Monitor Prawniczy" 2012, No. 5, p. 279 and following; D. Jagiełło, Dowód z opinii prywatnej w świetle procedury cywilnej oraz karnej, "Themis Polska Nova" 2015, No. 2 (9), pp. 153-157.

13 Compare J. Misztal-Konecka, Znaczenie, *op. cit.*, p. 66.

14 After P. Girdwoyń, T. Tomaszewski, Opinie biegłych w sprawach medycznych na tle zasady kontradyktoryjności, (in:) Prawo wobec problemów społecznych. Księga Jubileuszowa Profesor Eleonory Zielińskiej, Warszawa 2016, p. 627. It is true that the authors consider the problem in the context of criminal procedure provisions, but it seems that this view can be referred to the provisions of civil procedure that which admits the principle of the contradictionary dispute

Describing positive aspects of using a private opinion in civil proceedings, we cannot forget about a certain risk related to it[15]. Above all, it is pointed out that due to the operation of numerous insurance companies that are profit-oriented, a private expert is quite likely to issue an untrue (false) opinion. Money impacts an opinion-making process here; in some cases, a certain role may also be played by the expert's beliefs or attitudes, emotional involvement in the case, or even mechanical reproduction of the content of available information and documents by the expert[16]. Both lawyers and doctors are well aware of the phenomenon of information selection and conveying only such information which favours the person conveying it. What is more, as far as medical litigation is concerned, a private expert could not have access to all medical records the court will dispose of during a trial[17].

Due to the above, an interesting question arises here whether a private expert has the right to access information gathered in medical records. If the patient himself gives consent as a holder of the right to access medical records, this issue does not evoke major doubts. The expert is thus authorized to access patient's medical records. The situation is different when a medical entity as the patient's procedural opponent intends to use medical records at their disposal in order to draft a private opinion. A medical entity may process sensitive data contained in medical records for the purposes strictly specified by the law.

Taking the above into account, the issue of using experts' private opinions in medical civil litigation should be further analyzed. First of all, the legal nature of a private opinion compared to expert evidence in the meaning of Art. 278 et seq. of CCP will be explained. Next, the issue of using such evidence by both parties of a judicial dispute in the context of the patient's right to access medical records should be described.

2. The legal nature of private opinions in the light of opinions held by the doctrine of civil proceedings and court case law

According to the prevailing opinion of scholars, a private opinion is each statement invoking expertise not obtained from the expert appointed by the court[18]. In other words, it is a result of work carried out by an expert who drafts his or her

much stronger than the criminal procedure, but also it expresses the principle of striving for material truth.

15 See e.g.: A. Klich z punktu widzenia procesu cywilnego, A. Klich, Dowód, *op. cit.*, p. 91 and following.

16 Compare. A. Szymańska, Wykorzystanie prywatnej ekspertyzy w postępowaniu karnym, "Studenckie Zeszyty Naukowe" 2014, No. 25, p. 93.

17 J. Budzowska, Opinia prywatna, *op. cit.*, pp. 279-280.

18 See: J. Misztal-Konecka, Znaczenie, *op. cit.*, p. 64; K. Woźniewski, Tzw. prywatne opinie biegłych, "Gdańskie Studia Prawnicze – Przegląd Orzecznictwa" 2005, No. 3, p. 92 and following.

opinion upon request of the parties and not a procedural body; that is why it is known as extra-procedural, out of court or expert opinion[19].

The literature has been discussing the issue of the legal nature of a private opinion for a long time now since, in particular, in the light of the provisions of the Procedural Act, it may not be treated as expert evidence in the meaning of Art. 278 of CCP[20]. It should be underlined that expert evidence may occur in civil litigation solely upon the court's request when it is necessary to rely on expertise and, in principle, if an appropriate procedural motion has been submitted[21]. Hence, the prerequisites justifying drafting a court opinion and private opinion are different.

The position of an expert witness appointed by the court in civil litigation is exceptional[22]. A purpose of civil procedure provisions is to provide an expert witness with impartiality. This aim is achieved, among others, by the institution of expert witness's exclusion. Until an expert witness completes his actions, the party may request his exclusion for the same reasons as in the case of the judge exclusion[23]. Pursuant to Art. 281 sent. 2 of CCP, when the party submits a motion to exclude

19 Identical definitions regarding the private opinions are created on the basis of criminal proceedings; see: Z Kwiatkowski, Dopuszczalność wykorzystania "opinii prywatnej" w procesie karnym, (in:) A. Przyborowska-Klimczak, A. Taracha (ed.) Iudicum et scientia. Księga Jubileuszowa Profesora Romualda Kmieciaka, Warszawa 2001, p. 570; A. Podemska, Opinia biegłego w nowym modelu postępowania karnego, "Zeszyty Naukowe Towarzystwa Doktorantów UJ. Nauki Społeczne" 2014, No. 8, p. 39 and following.

20 See: szerzej J. Misztal-Konecka, Znaczenie, *op. cit.*, pp. 63-65.

21 The court accepts the evidence from an expert opinion after hearing the parties' requests on this subject (art. 293 § 1 of the Civil Procedure Code). It may admit evidence from an expert's opinion ex officio under art. 232 p. 2 kpc. when the proof is the only way to counteract the danger of obviously incorrect resolution of the case, undermining the function of civil proceedings: [the Judgment of Supreme Court of 15 January 2010, I CSK 199/09, Lex No. 570114, see also the judgment of the Supreme Court of 7 March 2013 II CSK 422/12, Lex No. where the court pointed out that the evidence from the expert's opinion due to the component in the form of special messages is evidence of such a kind that it cannot be replaced by any other evidential act, such as hearing a witness. The court allows violation of art. 232 second sentence of the kpc., since it ex officio does not provide evidence from an expert opinion, necessary for a proper assessment of the legitimacy of the action brought.

22 See: A. Klich, Dowód, *op. cit.*, p. 103 and following.

23 See: art. 48 and 49 kpc. The task of the trial body is to check whether there are circumstances excluding the expert from participation in the case. For this reason, the provisions of the kpc. which provide for prior to the appointment of an expert hearing the parties. The expert himself should also inform the court about the reason for his exclusion, e.g. when he has previously made a private opinion. See: J. Misztal-Konecka, *op. cit.*, pp. 67-68. One should agree with the author's argument that issuing a private opinion should be a reason to exclude from the opinion (similarly the Judgment of the Appeal Court in Wrocław of 16 April 2012, II AKA 67/12, OSAW 2013, No. 3, issue 294. The reason for the excluding is problematic if the patient had previously treated the patient. In the Judgment of 8 June 2010 (II UK 399/09) the Supreme Court decided that it does not consitute the circumstances that could raise doubts as to the impartiality of the expert. Critically against this judgment A. Klich, Dowód, *op. cit.*, p. 85.

an expert witness after he started his actions, the party shall be obliged to prove that the reason for the exclusion occurred later, or that the party was not aware of it before. Impartiality is further guaranteed by the oath taken by an expert. It reads as follows: *"Being aware of the meaning of my words and legal liability, I solemnly pledge that I will fulfil the duties of an expert witness I have been entrusted with reliably and impartially"*[24]. The oath is taken unless the parties (Art. 283 § 1 of CCP) or the court (Art. 515 of CCP) decide otherwise. The oath is taken by an expert witness appointed in a concrete case (*ad hoc* expert witness) while a permanent expert witness takes an oath after being appointed and entered into the register of expert witnesses. In the decision admitting expert evidence, the court determines an expert witness in person (possibly determines several expert witnesses), the scope of data subject to the opinion, and defines a substantive scope of the opinion, usually presenting certain theses that must be confirmed and assessed through the expertise[25].

A private opinion is devoid of the above-mentioned formal guarantees and, thus, it may not be equal to an expert opinion. It is worth pointing out that according to the opinion embedded in case law, grounding a judgment on an out-of-court statement of an expert witness infringes procedural law justifying a possibility of submitting an effective challenge[26]. Hence, expert evidence should not be replaced by a private opinion even if it has been drafted by a person registered as an expert witness[27]. Furthermore, the subject literature underlines that an expert witness plays an auxiliary role in the court and is entitled to use a title of an expert witness solely when drafting an opinion upon request of entities envisaged by the law (i.e. the court); any

24 It should be noted that in the content of promise there is no obligation to speak the truth (as in the promise relating to a witness in art. 268 of the k.c.p.), however, it is pointed out that the court can draw the attention to the expert, especially that before submitting a promise, an expert should be warned about criminal liability for submitting a false opinion (art. 233 § 4 k.k.).

25 In the judgment of 11 July 1969 (I CR 140/69, OSNP 1970, No. 5, issue. 85); the Supreme Court has stated that the task of the expert is not, however, to determine the facts of the case, but to expose and explain before the court the circumstances from the point of view of the special messages held by him, taking into account the material collected and made available to the expert.

26 See: the Judgment of 29 September 1956 III CR 121/56, OSN 1958, no1, issue 16. This view is still valid under the current provisions of civil procedure but a reservation should be made in accordance with art. 162 kpc. and the plea of appeal should be linked to art. 233 kpc. See: The judgment of 8 June of 2001, I PKN 458/00, OSNP 2003, no 11, issue. 112 where: "The expert's out-of-court expertise prepared at the request of the party is not subject to court review as evidence from an expert opinion (art. 278 kpc.)".

27 As Supreme Court in the cited judgment of 29 September 1956: "It cannot be treated as evidence in the proceedings by an expert opinion, even if it was a permanent court expert, drawn up in writing at the direction of the party and submitted to court files" See: the judgment of Supreme Court of 12 April 2002, I CKN 92/00, OSG 2003, no 11, issue 112: "Recognition of an expert opinion, even if it was an expert witness, being a private document, violates art. 233 kpc."

activity pursued by an expert witness beyond the scope of his powers may even result in deleting him from the registry of expert witnesses[28].

Nevertheless, the above opinions do not efface the importance of private opinions. The Supreme Court ruled in the judgment of 8 June 2001[29] that an out-of-court expert opinion may be treated as a part of the party's reasoning. It occurs when the party explicitly requests to treat the expert opinion as a part of their own factual and legal reasoning. However, if the party submits an out-of-court expert opinion with a clear intention to treat it as evidence in the case, there are grounds to attribute it the status of private document evidence[30].

Pursuant to Art. 245 of CCP, a private document proves that a person who signed it made statements contained therein. The content of the expert's statement contained in a private document is not subject to the presumption of truth, which means that a person having a legal interest in it may confirm/prove that the content of such statement is not true[31]. This way the parties get involved in a substantive dispute about the claims and theses included in the opinion (comp. Art. 253 of CCP[32]). It should be emphasized that in the Polish civil trial, the collection of trial evidence, i.e. factual statements and evidence to verify them, burdens the parties thereto (the principle of adversarial litigation). Adversarial proceedings are characterized by litigation burden categories, in particular a burden of statement and burden of proof. Despite the fact that we are far from the model of proceedings where "the party's expert" is a typical element of adversarial litigation, it can be said that treating a private opinion as a private document is a step increasing an adversarial nature of litigation. Nevertheless, the problem is that a private expert may not be heard as an expert witness because he or she is not an expert witness.

In the judgment of 8 November 1976[33], the Supreme Court decided that a person who, due to his or her expertise, has observations unavailable to others (e.g. a doctor treating a patient), should generally be heard as a witness while another person, who has not previously encountered facts vital for the case's resolution, should be entrusted

28 See. A. Klich, Dowód, *op. cit.*, p. 81, 217. As it seems, this is not a matter of prohibiting the preparation of private opinions by experts entered on the list, but not to use the title "forensic expert" in the event of preparing such opinions, so as not to mislead the parties to the proceedings as to their importance (rank) opinion issued in this way.

29 I PKN 468/00, OSNP 2003, No. 8, issue 197. Lex No. 50484.

30 Similarly: the judgment of Supreme Court of 15 January 2010, I CSK 199/09, Lex No. 570114; the judgment of 8 June 2010., I PKN 468/00, Lex No. 50484; the Judgment of Supreme Court of 25 February 2015, IV CSK 312/14, Legalis.

31 See: the judgment of Supreme Court of 2 July 2009, V CSK 4/09, Lex No. 527176 [wyrok SN z dnia 2 lipca 2009 r., V CSK 4/09, Lex nr 527176].

32 See: the judgment of Supreme Court of 2 February 2011, II CSK 323/10, Lex No. 738542. For the private opinion presented by the party in the course of the process, art. 253 kpc."

33 [I CR 374/76, OSN 1977, No. 10, issue 187.

with the function of an expert witness[34]. Thus, assuming that a private expert may be heard as a witness, differences between expert witness evidence and witness evidence should be emphasized. A basic difference is that witnesses convey information about the facts and state of affairs while expert witnesses express their judgment of the facts, i.e. opinions. Facts may only exceptionally be the subject of expert witness evidence[35]. For the above reasons, requesting admissibility of witness evidence, i.e. private expert, we must prove that our expert will present before the court factual information observed just thanks to his or her professional experience and will not merely express his or her opinion (which is already contained in the case files). Hence, there is a risk that the court will not accept our request and the arguments could only be raised in pleadings. Nevertheless, the judicature expressed an accurate opinion that a private expert opinion may be a prerequisite of the necessity to admit another expert witness evidence or supplementary opinion by the court[36]. Furthermore, if an expert witness appointed by the court questions the out-of-court opinion, the court must critically consider arguments contained in both opinions[37].

In the judgment of 2 February 2011[38], the Supreme Court acknowledged that the parties more and more often present private opinions in a trial. They are an element of trial evidence and as such they should be made available to the opposite party. In the judgment of 30 June 2004[39], the Supreme Court decided that private document evidence is independent evidence whose force is assessed by the court according to the principle of free evaluation of evidence expressed in Art. 233 § 1 of CCP, i.e. at the court's discretion based on the comprehensive examination of evidence collected in the case. For this reason, the same as in case of other evidence, it is assessed whether a private opinion should be recognized. In effect thereof, the court may evaluate if private document evidence may be accepted or refused with regard to its credibility.

In the case heard by the Court of Appeal in Szczecin[40], the courts refused to recognize credibility of private medical expert opinions because they had been drafted by doctors of completely different specialization with regard to the object of

34 Polskie prawo procesowe nie przewiduje instytucji "świadków-biegłych" znanej prawu niemieckiemu i austriackiemu, see: K. Gajda-Roszczynialska, (in:) Ł. Błaszczyk, K. Markiewicz (eds.), Dowody i postępowanie dowodowe w sprawach cywilnych. Komentarz praktyczny z orzecznictwem, Warszawa 2015, pp. 646-647.

35 *Ibidem*, p. 646, see also: A. Klich, Lekarz jako osobowe źródło dowodowe w postępowaniu cywilnym (część I – lekarz jako świadek), "Prawo i Medycyna" 2013, No. 3-4, p. 120-136.

36 See the Judgment of Supreme Court of 21 August 2008, IV CSK 168/2008 [wyrok SN z dnia 21 sierpnia 2008 r. IV CSK 168/2008].

37 See the Judgment of Supreme Court of 8 November 1988 II CR 312/88, Legalis [Wyrok SN z dnia 8 listopada 1988 r., II CR 312/88, Legalis].

38 II CSK 323/10, Lex No. 738542 [II CSK 323/10, Lex No. 738542].

39 IV CK 474/03, OSNC 2005, no ,6, issue 113 [IV CK 474/03, OSNC 2005, nr 6, poz. 113]; the Judgment of Supreme Court of 10 October 2012 2012, I UK 210/12, Lex No. 128472.

40 The Judgment of Appeal Court in Szczecin of 4 December 2012, I ACa 119/12, Lex No. 1246842.

expertise, which in itself deprived it of any value to the evaluation of circumstances essential for the resolution of the case. What is more, the authors of this opinion did not dispose of full documentation gathered during the trial. Due to the above, the Court of Appeal decided that these opinions did not contribute much to the case because their content did not univocally allow to evaluate the claimant's health condition because of incomplete medical documentation disposed by their author.

On the other hand, in the case heard by the Court of Appeal in Katowice[41], the first instance court (Regional Court) admitted private expert evidence presented by the defendant. Hence, the challenge raised by the opposite party of breaching Art. 278 § 1 of CCP by the court proved to be accurate. Nevertheless, according to the Court of Appeal, this breach did not impact the manner of the case's resolution because the private opinion corresponded to the findings made by the court expert witnesses.

3. Admissibility of using private opinions in the light of the patient's right to medical records

Pursuant to Art. 24 par. 1 of the Act of 6 November 2008 on the Patient's Right and Patient Ombudsman[42], the entity providing medical services shall be obliged to keep, preserve and provide access to medical records in a manner specified in this Act and the Act of 28 April 2011 on the System of Information in Healthcare[43], and protect data contained therein. The right to access medical records is a part of widely understood patient's information autonomy. For this reason, the legislator first enlists a patient himself as an authorized entity, to be followed by his statutory representative as well as individuals authorized by them (see Art. 26 par. 1 of APR). It does not mean, however, that other entities do not have the right to access medical records without the patient's consent[44]. Pursuant to Art. 26 par. 3 of APR, these are, among others, entities providing health services if such records are necessary to assure continuity of health services, public authorities bodies, NFZ (National Health Fund), medical professions self-government bodies, and national and provincial consultants within the scope necessary to fulfil their tasks, in particular monitoring and supervising; entities mentioned in Art. 119 par. 1 and 2 of the Act of 15 April 2011 on Therapeutic

41 I ACa 676/12, Lex No. 1236712.

42 Consolidated text Journal of Laws 2016, item 186 as amended [Tekst jedn. Dz.U. z 2016 r. poz. 186 ze zm.], in shoirt u.p.p.

43 Consolidated text Journal of Laws 2015, item 636 as amended [Tekst jedn. Dz.U. z 2015 r. poz. 636 ze zm.].

44 The problem of who is the administrator of information gathered in the documentation has been solved by the legislator in a specific way. Because the medical documentation is not only for the treatment of the patient, but is subject to public law regulation, i.e. control and supervision, therefore the entity administering the documentation is its dispatcher.

Activity[45] within the scope necessary to carry out control upon the request of a competent Health Minister, etc. In every above mentioned case of providing access to medical records the legislator specified the reason for processing information contained in the records; the only exception thereto are insurance companies that have access to medical records based on the insured patient's consent (comp. Art. 26 par. 3 point 7 of APR[46]). This manner of regulation results from the need to protect sensitive data that the data contained in medical records undeniable are. Pursuant to Art. 27 par. 1 of the Act of 29 August 1997 on Personal Data Protection[47], processing sensitive data is forbidden while exceptions thereto specified in par. 2 of Art. 27 should be strictly interpreted.

The above quoted case of access to medical records given to other entities providing services is specified more precisely in the Act on the Patient's Rights in the purpose of assuring continuity of provided services. The medical law literature points out that this solution corresponds to other provisions of medical law that envisage analogical exemption from medical secret (comp., for instance, Art. 14 par. 2 point 4 of APR), and it aims at the protection of the patient's interest[48]. To assure proper performance of therapeutic activities, the entity providing such services should dispose of specific medical information. Due to the protection of patient's privacy, the interpretation of this provision should be rigorous, which means that a medical professional requesting access to medical records should justify circumstances indicating the need and scope of expected data[49]. For this reason, claiming that the above quoted norm cannot be treated as an excuse (justification) to provide access to medical records to a specialist doctor who drafts a private opinion for the needs of one of the parties to civil litigation should not arise any doubts.

The problem of processing medical records by their administrator is perceived in the practice of law application. In his study addressed at entities performing therapeutic activity, A. Sieńko points out that in case of a claim submitted by the patient, a therapeutic entity is obliged to inform the insurer providing insurance

45 Consolidated text Journal of Laws 2016, item 1638 as amended [Tekst jedn. Dz.U. z 2016, poz. 1638 ze zm.].

46 Nevertheless, the legislator in the act of 11 September 2015 on insurance and reinsurance activity Journal of Laws 2015, item 1844 as amended] [Ustawa z dnia 11 września 2015 r. o działalności ubezpieczeniowej i reasekuracyjnej (Dz.U. z 2015 r., poz. 1844 ze zm.)] predicted stricter conditions related to the use of the insured's medical records by the insured

47 Consolidated text Journal of Laws 2015, item 2135 as amended [Tekst jedn. Dz.U. z 2015, poz. 2135 ze zm.], in short u.o.d.o.

48 See: R. Kubiak, Tajemnica medyczna, Warszawa 2016, p. 224; U. Drozdowska, (in:) Taż (ed.), Dokumentacja medyczna, Warszawa 2012, p. 67.

49 The issue of protecting the patient's privacy in dealing with many healthcare representatives will be of fundamental importance when the obligation to maintain electronic medical records and the obligation to send unit medical data to specific platforms created within the medical information system becomes effective.

protection for the period when the service covered by the claim was provided[50]. Launching the so-called liquidation proceedings, the Insurance Company evaluates the patient's claim through their own medical consultant; therefore, the Company requests the entity performing therapeutic activity (insured against civil liability) to provide explanations. Hence, already at this point, it is essential, or even necessary to provide the insurer with the access to the patient's medical records[51]. Yet, the entity providing services may not do so without the patient's consent. Even though at this point patients usually give consent to make their medical records available (probably expecting the therapeutic entity's civil liability insurer to pay them requested allowance without launching civil litigation), already during the proceedings, they frequently refuse to give their consent believing that the insurer or private medical consultant act on behalf of the defendant (i.e. litigation adversary).

For the above reasons, the grounds for making medical records available (without the patient's consent) are sought in the content of previously quoted Art. 27 par. 2, which in point 5 envisages a possibility of processing data if they are necessary to claim one's rights before the court. According to P. Barta and P. Litwiński, this prerequisite legitimizes processing sensitive data within the scope of activities related to claiming all rights (private and public) which are implemented by courts, parties and their attorneys regardless of the type and course of proceedings[52].

The Court of Appeal in Krakow expressed an opinion on the admissibility of application of the above mentioned regulation in civil litigation in the judgment of 3 September 2015[53]. The circumstances of the case were as follows. Due to the pending trial for compensation and damages for medical error, the defendant (a therapeutic entity) requested the issue of a private opinion on the actions undertaken by medical personnel during the claimant's stay in hospital related to her pregnancy and child delivery. Therefore, the hospital made the claimant's medical records available for the purpose of consultation. It is worth adding that the expert witness appointed by the court issued an unfavourable opinion for the defendant while the court dismissed the defendant's request to admit a supplementary opinion of another expert witness evidence to explain vital circumstances of the case. The claimant launched another trial against the defendant claiming apology and compensation on her own and her child's behalf for the infringement of personal interests. When she found out that her and her son's medical records were made available to the doctor drafting an opinion upon the request of the hospital (the defendant), she said she was offended. She felt

50 A. Sieńko, Błędy medyczne, odpowiedzialność lekarza i placówki medycznej. Jak uniknąć kosztownych pułapek, Warszawa 2013, p. 70.

51 *Ibidem*.

52 P. Barta, P. Litwiński, Ustawa o ochronie danych osobowych. Komentarz, Warszawa 2015, p. 315.

53 I ACa 679/15. Lex No. 1927548.

discomfort knowing that intimate information about her and her newborn child's health conditions was "leaked".

Although the courts hearing this case adopted distinct reasoning, the claimants' claims were found unreasonable in both judgments[54]. The Regional Court as the first instance court dismissed the claim under Art. 27 par. 2 point 5 of APDP. The Court decided that the above quoted provision should refer to all litigants; it involves both claiming, prosecuting and defending rights. For this reason, the therapeutic entity was authorized to process data contained in medical records. The Court underlined that the defendant was burdened with the obligation to prove that their action was not unlawful and this duty was fulfilled in compliance with the content of Art. 24 of the Civil Code. The scope of data handed over to the specialist was justified by the opinion to be issued; thus, it was adequate to the purpose thereof. It is difficult to require to remove data concerning the claimants' health condition from the records if the object of the opinion was regularity and accuracy of actions undertaken by medical personnel corresponding to the condition of the claimant before and during the child delivery. These circumstances were vital for the resolution of the case between the parties for damages and determination of liability for the future. Moreover, the defendant undertook steps to assure anonymity of records to be given out[55].

The Court of Appeal ruled distinctly; the Court assumed that making medical records available to another doctor for consultation infringes the claimants' personal goods. The Court argued that the provisions of medical law prevail over the provisions of APDP as they guarantee farther-reaching protection. The Court decided that the argument raised by the therapeutic entity about fulfilling its own right to defence was not relevant because a private opinion does not have an attribute of evidence, being merely development of the claims and challenges of the party in the pending trial. Therefore, the Court decided there was no exclusion of unlawfulness because medical records may only be made available under the judicial decision admitting expert evidence, and medical records may be made available solely for this purpose. The party may submit such evidence while medical records may not be freely processed.

Referring to the reasoning contained in the above presented judgments, two issues are worth paying attention to. The first one is connected with the relation between the provisions of APDP and the so-called sector Acts, i.e. here the Act on

54 The district court The SO dismissed the claims due to the indication of the legal basis for action by the healthcare entity, and Apeal Court refused to adjudicate because the infringement of the claimant's personal rights was not commonly associated with breaking the medical secret in a way that harmed her personal rights. See. justification of the cited judgment.

55 As Apeal Court explainedp these activities were not complete, in many places data anonymization did not take place. This issue does not matter, however, from the point of view of the interpretation of the quoted provisions.

the Patient's Rights, while the second one regards directly a private opinion treated as evidence in medical proceedings.

The first issue is a source of many doctrinal doubts[56] because Art. 5 of APDP which sets forth mutual relations between APDP and the provisions of the so-called Sector Acts is not a typical conflicting norm[57]. Under this provision, if the provisions of separate Acts that refer to data processing envisage farther-reaching protection than it ensues from this Act, the provisions of those Acts shall apply. For this reason, APDP is of a subsidiary nature while its regulations should be taken into account to assure the so-called minimum protection[58].

It is worth noticing that it is assumed that special Acts referring to data processing will supplement or develop obligations within the scope of assuring data security. However, special Acts often either omit or regulate separately specific issues due to their specificity, which makes it difficult to evaluate whether given regulation lowers or increases this protection standard. Referring to the presented issue, it should be indicated that the provision of Art. 26 par. 3 of APR envisaging access to medical records by various legal entities is of a structuring nature[59]. Entities enlisted in the provision are generally authorized to process medical data based on separate legal acts. Requesting access to medical records, they must indicate legal grounds which usually justify the fulfilment of the so called essential public interest[60]. Because a therapeutic entity administers personal data and makes it available itself, the above-mentioned regulation could not embrace the discussed case as the legislator regulated the purposes of data processing by their administrator separately, both in the Act on the Patient's Rights (comp. Art. 23-24 of APR) and the Act on Personal Data Protection (comp. Art. 27 par. 2 point 7 of APDP). That is why the Administrative Court's reasoning based on the application of the rule *lex specialis derogat legi generali*

56 J. Barta, P. Fajgielski, R. Markiewicz, Ochrona danych osobowych, Komentarz, Kraków 2004, p. 364; U. Drozdowska, (in:) Dokumentacja medyczna…, *op. cit.*, pp. 32-33; J. Byrski, Wybrane tajemnice zawodowe a prawna ochrona danych osobowych, (in:) G. Sibiga, X. Konarski (ed.), Ochrona danych osobowych. Aktualne problemy i nowe wyzwania, Warszawa 2007, p. 191 and following.

57 Compare: P. Barta, P. Litwiński, Ustawa…, *op. cit.*, pp. 62-63.

58 See: U. Drozdowska (in:) Dokumentacja medyczna…, *op. cit.*, pp. 32-33.

59 D. Karkowska, Ustawa o prawach pacjenta i Rzeczniku Praw Pacjenta. Komentarz, Warszawa 2012, p. 372.

60 The so-called premise important public interest is expressed, among others in art. 8 par. 2 of European Convention for the Protection of Human Rights and Fundamental Freedoms of 4 November 1950 Consolidated text Journal of Laws 1993, item 61 as amended (Dz.U. z 1993 r., Nr 61, poz. 284) ratified by Poland. Against the background of this provision, the ECHR's jurisprudence sets out the limits of the right to the protection of medical data in the situation in national law in situations such as: the need to ensure public safety, economic prosperity of the country, order protection and prevention of crimes, protection of health and morality, protection of the rights and freedoms of persons. See also the art. 31 par. 3 of the Constitution of the Republic of Poland, concerning restrictions on rights and freedoms.

is inaccurate. The special norm does not describe the situation of making medical records available to protect the rights of the entity processing the records.

It is worth invoking here arguments presented in the situation of conflict between the protection of the patient's secret and doctor's interest. It is pointed out that the above conflict occurs if a doctor claims due remuneration from the patient, or defends himself against charges jeopardizing his professional reputation[61]. In such cases, exclusion of the doctor's right to defence cannot be accepted as it would be the abuse of the law committed by the party requiring respect for the secret[62]. It seems that this argument may be referred to the discussed conflict between the protection of data contained in medical records and the need to use these data to defend a therapeutic entity. Deprivation of a possibility of using medical records in defence against liability for damages should be recognized as the abuse of law. In such a situation, a therapeutic entity should not be charged with unlawful conduct.

It is worth adding that this problem has been discerned by the EU legislator who, in Art. 9 par. 2 point f) of the Regulation of the EU Parliament and of the Council of 27 April 2016 (2016/679) on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC[63], decided that processing sensitive data is admissible if it is necessary for the establishment, exercise or defence of legal claims or whenever courts are acting in their judicial capacity.

Moving on to the argument of the Court of Appeal saying that a private opinion does not have a value of evidence because the party is entitled to submit a motion to admit expert evidence, it should be acknowledged that it contradicts case law presented in point two. The evidence value of a private opinion should be sought in the fact it may become a private document while the court should take into account arguments presented therein and confront them with the reasoning presented by the expert witness. The attitude of the Court of Appeal in Krakow leads to the infringement of the principle of "equality of arms" in civil litigation since the patient may use a private opinion while the therapeutic entity may not. In the context of the procedural principle assuring equality of procedural measures for each litigant[64],

61 M. Safjan, Prawo i medycyna. Ochrona praw jednostki a dylematy współczesnej medycyny, Warszawa 1998, p. 147.

62 *Ibidem*.

63 Dz.U. UE L. 119/1. http://eur-lex.europa.eu/legal-content/PL/TXT/?uri=CELex:32016R0679 (so-called general regulation on data protection). The regulation introduces uniform legal regulations regarding the protection of personal data at EU level. This regulation will apply directly in the EU countries (without the need for implementation) from 25 May 2018.

64 See: A. Góra-Błaszczykowska, Zasada równości stron w procesie cywilnym, Warszawa 2008, p. 90 and following.

we may notice the need to regulate issues related to the application of a private opinion in the Procedural Act[65].

Additionally, it is worth pointing out that administrative courts do not hold such a rigorous opinion as civil courts with regard to the use of documentation for the purpose of pending proceedings[66]. The Supreme Administrative Court decided in the judgment of 25 August 2011[67] that the content of medical records is the ground for establishing an essential circumstance of the case (in this case it was the establishment of a vocational disease), and the party's position on a lack of possibility of finding out its content (by the administrative body) cannot be approved of. This would entail issuing a decision which would not be subject to any control since the only evidence it would be based on could be a verdict of a competent court or tribunal that could not be verified and compared with the source evidence it was grounded upon. It is similar to the case resolved by the Provincial Administrative Court in Warsaw in the judgment of 5 August 2005[68]. The entity who had access to the victim's medical records in preparatory proceedings was the defendant's attorney, who also handed it over to the doctor issuing a private opinion. In this situation, the PAC accepted a possibility of application of Art. 27 par. 2 point 5 of APDP and decided that the right had not been infringed.

4. Conclusion

A private opinion in medical proceedings does not bear the same importance as expert evidence in the meaning of Art. 278 § 1 of CCP. Such expert opinions are usually refuted by the opposite party who raise objections as to their credibility and objectivism, and most of all, the fact they must be paid for. Nevertheless, their role in civil litigation is continually increasing. It is caused, above all, by the crisis of the institution of expert witnesses. Courts wait for the expert witness opinions from several months to several years[69]. What is more, there are shortages of expert witnesses in many specializations while some of them, due to numerous professional

65 The solution is to introduce an expert-side institution, which is part of the adversarial principle of the dispute, or the institution of a witness – expert. Also it is possible try to create additional legal mechanisms to control the reliability of the private opinions presented. However, there is no room for a wider presentation of these proposals. See: A. Klich, Dowód, *op. cit.*, p. 89-93.

66 See: the judgment of Regional Administrative Court in Warsaw of 5 August 2005 II SA/Wa 564/05 Legalis; the judgment of Regional Administrative Court in Rzeszów of 22 February 2011, II SA/Rz 981/10, Legalis; the Judgment of Regional Court in Wrocław of 28 February 2013, IV SA/Wr 695/12, Legalis; the Judgment of Regional Administrative Court in Warsaw of 18 December 2013, II SA/Wa 1449/13, Lex No. 1542378. The decisive factor for this ruling line is the principle of internal transparency of the proceedings.

67 II OSK 991/11. Legalis. See also: R. Kubiak, Tajemnica medyczna…, *op. cit.*, pp. 228-229.

68 II SA/Wa 564/05, Legalis.

69 See: J. Budzowska, Opinia prywatna…, *op. cit.*, p. 279.

responsibilities, refuse to draft an opinion for the court's use. The opinions of science and research institutions are not an alternative because they set very long time limits to drafting them too[70]. Existing legal solutions allow to use private expert opinions for the sake of the justice system only partially because they may not compete with expert evidence.

The interpretation of the provisions of substantive law within the scope of personal data protection should not lead to the creation of additional barriers hampering the use of such evidence in civil litigation as it entails the so-called legal exclusion. According to K. Flaga-Gieruszyńska, the essence of such exclusion is full or considerable deprivation of a possibility of exercising rights and freedoms as well as competence by specific individuals or entire groups of individuals they are entitled to[71]. We got used to the fact that such exclusion refers to the patient who is a weaker party (by the definition) in the professional relations, particularly in the relation between the patient and organized medical institution. However, reality could be different; there are therapeutic entities in a very bad financial situation that may face problems with not only paying allowances but also paying costs of long litigation. Civil liability insurance does not solve this problem because insurers usually do not want to pay allowance before the court's judgment. Hence, under the principle of equal arms, each party should be equipped with a possibility of reliable presentation of their position, including submission of evidence motions and presentation of evidence in the circumstances that do not place them in a worse situation than their procedural opponent[72].

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70 See: A. Przybycień, P. Szewczyk, Terra incognita, czyli o alternatywnym sposobie kompensacji szkód medycznych, "Edukacja Prawnicza" 2012, No. 1, dodatek specjalny, p. VIII.

71 K. Flaga-Gieruszyńska, The problem of legal exclusion on the example of access to justice in civil cases, (in:) M. Sitek, G. Damacco, A. Ukleja, M. Wójcicka (ed.), Europe and Founding Fathers. Investment in common future, Olsztyn 2013, p. 125.

72 A. Góra-Błaszczykowska, Zasada równości stron…, *op. cit.*, p. 90.

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Administrative Limitations of Patient's Autonomy – Remarks on Involuntary Treatment

Abstract: Public administration operates under a wide variety of legal forms as well as regulates a broad scope of citizens' day-to-day activities. Disease surveillance conducted by specialized organs called 'administrative police' is one of many subjects of state interest that is also vital for individuals' self-determination. Under the competences of epidemic intelligence, public authorities may also interfere within the scope of patients' autonomy, e.g. compulsory vaccination. However, the given procedural standard is not sufficient, i.e. procedural guaranties which are optimal for mere adjudicative, '*court-room*', adversarial process of decision-making seems to lessen the right to fair administrative trial and as such may be recognized as unconstitutional one. This is to say administrative proceedings are not coherent with the essence of patient's autonomy doctrine (concept). In this study authors address several issues connected both with the legal framework of proceedings before 'administrative police' and judicial review of public authorities' actions which affect the individual's right of self-determination.
Keywords: regulatory power, administrative proceedings, involuntary treatment, disease surveillance

1. Introduction

From the perspective of medical ethics, the principle of patient's autonomy is limited to the regularity according to which medical surgeries may be performed on an autonomous person solely upon his or her consent[1]. The structure of many vital institutions of medical law such as, e.g. medical secret, apparently embraces respect

1 See: W. Załuski, Autonomia, (in:) A. Górski (ed.) Leksykon prawa medycznego – 100 podstawowych pojęć, Warszawa 2012, p. 3.

for the patient's autonomy[2]. A concern for the patient's autonomy in a therapeutic process vividly depicts tensions between paternalism[3] and individualism (autonomy)[4] within the operation of the healthcare system *in genere*. Hence, it indicates conflicts of interest in medicine[5] that are an immanent part of a therapeutic activity, or even notorious contestability of ensuing legal interpretative issues[6].

The issue of a restrictive role of administrative measures interfering in the patient's autonomy has already been discussed in the literature[7]. However, previous studies have focused on the analysis of inherent systemic features referring to the practice of public administration operation to a lesser degree. For this reason, our article may be treated as systemization of the issues that have already been signalled in earlier studies. It seems that a special position of a patient as an addressee of actions undertaken by public authorities requires the revision of available forms of impact thereon as well as verification of actions launched in order to enforce obligations imposed on public administration. Pending debate on the procedural framework of public administration operation towards individuals[8] has considerably affected the choice of the topic herein. Thus, the issue of adequacy of administrative regulatory powers used by the legislator remains up-to-date. It should also be mentioned in the introduction that our further considerations refer solely to procedural aspects

2 See: K. Michalak, "Tajemnica lekarska jako gwarancja autonomii pacjenta – krytyczna analiza dogmatyki". Selected the theses referred to in this study thesis were delivered during the II National Conference of the Law of Patients "Limits of patient's autonomy". The text takes into account and developed the results of the discussion held during the conference.

3 As to the concept under medical law see: W. Załuski, (in:) A. Górski (ed.), *op. cit.*, p. 145. See also H.R. Wulff, S.A. Pedersen, R. Rosenborg (transl. Z. Szarawarski), Filozofia medycyny – wprowadzenie, Warszawa 1993, p. 237 (in:) Compare also: B. Gert, C.M. Culver, K.D. Clouser, Paternalism and Its Justification, (in:) Bioethics: A systematic approach, Oxford 2006.

4 As to the concept under medical law see: W. Załuski (in:) A. Górski (red.), *op. cit.*, p. 1.

5 Widely on the conflicts of goods in medicine see: A. Górski, Leczyć czy nie leczyć? Dylematy podejmowania leczenia z punktu widzenia konfl iktu dóbr, "Czasopismo Prawa Karnego i Nauk Penalnych" 2011, special issue, p. 151-160. Also: A. Górski, Lekarz w procesie karnym (wybrane zagadnienia), (in:) P. Kardas, T. Sroka, W. Wróbel (co-ed.), Państwo prawa i prawo karne. Księga jubileuszowa Profesora Andrzeja Zolla, t. 2, Warszawa 2012, p. 1597 and following.

6 Similarly: K. Gromek, Ustawa o ochronie zdrowia psychicznego. Komentarz, Warszawa 2004, p. 9., J.C. Joerden, Medizinstrafrecht – Einführung, (in:) J.C. Joerden, A.J. Szwarc, K. Yamanaka (ed.) Das vierte deutsch – japanisch – polnische Strafrechtskolloqium der Alexander von Humboldt – Stiftung, Poznań 2011, p. 145.

7 Por. M. Boratyńska, Szczepienia ochronne małoletnich a wykonywanie władzy rodzicielskiej. Uwagi na tle wyroku NSA, "Prawo i Medycyna" 2013, No. 3-4, p. 88; T. Dukiet-Nagórska, Uwagi na temat Ustawy z dnia 6 września 2001 r. o chorobach zakaźnych i zakażeniach, "Prawo i Medycyna" 2002, No. 11, p. 26.

8 Compare: Reforma prawa o postępowaniu administracyjnym. Raport zespołu eksperckiego, Warszawa 2016, passim; accessible at: http://www.nsa.gov.pl/wydarzenia-wizyty-konferencje/uzupelniony-raport-ekspercki-nt-reforma-prawa-o--postepowaniu-administracyjnym,news,24,327.php.

of proceedings involving patients with particular focus on the legal framework of public authorities' actions[9].

The sphere of patient's rights[10] in the systemic approach is potentially restricted in the effect of the application of administrative measures of impact exerted upon an individual in many cases[11]. Nevertheless, one level of this interference that may be analyzed appears particularly vital for the protection of patient's rights. It is administrative involuntary treatment in the consequence of a decision-making process[12] of administrative authorities. The right to consent to medical interventions[13] undeniably belongs to the canon of patient's rights. On the one hand, it is a declaration of the state's respect for each individual's dignity and physical integrity[14] as well as privacy[15], while on the other hand, it creates an element of special bond based on trust between a patient and doctor[16]. Fulfilling its regulatory powers, the State takes advantage of proper measures of impact, among others to maintain order, security or public health. The activity of administrative authorities

9 In particular, the disputed issues related to the possibility of establishing the affiliation of a specific regulation formula to one of the classically separated branches of law are disregarded; see the classification of procedures in the Act of 19 August 1994 on the protection of mental health. Compare: P. Wszołek, Kryteria wyodrębniania prawa administracyjnego, Warszawa 2016, *passim*.

10 Therefore, it is too too narrow to treat the view expressed in the literature that the obligation to vaccinate is only a "restriction of civil rights and freedoms"; see: I. Jaworska, Odmowa zaczepienia dziecka i jej konsekwencje prawne, "Przegląd Prawa Publicznego" 2017, No. 3, p. 60-62. Although it is notorious that the right to self-determination has law-constitutional provenance, the analysis of administrative means of influencing the sphere of patient's rights is characterized by a series of peculiarities which cannot be *prima facie* overlooked. Thus, the limitation of the administrative analysis of coercion of treatment and only to the problems of constitutional rights and freedoms is a simplified exponential formula.

11 It is enough to indicate here, strictly for administrative and legal regulation of the patient's relation within the administrative facility, which is an independent public health care facility; see about it: A. Zemke-Górecka, Status prawny samodzielnego publicznego zakładu opieki zdrowotnej i jego prywatyzacja, Warszawa 2010, passim.

12 The use of imprecise expression referring to one of the legal forms of public administration activity, which is an administrative decision, is a necessary simplification. Through the decision-making process we will understand all the cases in which the public administration body in a formal way interferes directly with the sphere of patient's rights. This concept will cover administrative decisions as well as administrative performance titles for the purposes of this article.

13 Compare: A. Augustynowicz, A. Czerw, Stosowanie środków przymusu bezpośredniego przez personel medyczny w procesie diagnostyczno-terapeutycznym w podmiotach leczniczych innych niż szpitale psychiatryczne – zagadnienia wybrane, "Prawo i Medycyna" 2013, No. 1-2, p. 35.

14 Compare: D. Karkowska, Prawa pacjenta, Warszawa 2009, p. 126, 385.

15 Compare: M. Świderska, Przymus leczenia i innych zabiegów medycznych, "Prawo i Medycyna" 2004, No. 3, p. 27-29.

16 W literaturze wskazuje się, iż wymóg zgody kreuje partnerską relację pomiędzy pacjentem a lekarzem; por. M. Filar, Postępowanie lecznicze (świadczenie zdrowotne) w stosunku do pacjenta niezdolnego do zgody, "Prawo i Medycyna" 2003, No. 5, p. 41.

involving the above-mentioned objective is defined as policing[17]. Implementation of powers inherent to police may *in concreto* imply interference in the sphere of individual's rights and freedoms. The example of such impact is admissibility of restricting individual's self-determination in the face of socially desirable[18] medical intervention. This subject matter is closely related to the forms of coercive fulfilment of duties inherent to the bodies of public authorities.

Two hypothetical factual states are in particular indicated as potential sources of involuntary treatment justifying its revision. These embrace widely understood mental health and epidemic threat[19]. The first of the above-mentioned spheres of interference is characterized by a complex nature and strong judicial protection of individual's rights. The protection of patient's rights seems optimal[20] in this case. A special role of the court, in particular, and procedural guarantees allow to presume[21] that despite intensive restriction of the individual's right of self-determination, a minimal standard enshrined both by domestic and international law[22] is preserved. For these reasons as well as rich literature on the control over legality of measures applied under the Psychiatric Law, this issue does not require additional analysis entailing unnecessary repetitions. What is more, qualifying treatments referring to the subject course of proceedings arise doubts. Not without a reason, we could seek administrative law elements[23] in the activities pursued by

17 Compare: J. Dobkowski, Policja administracyjna. Zagadnienia doktrynalno-instytucjonalne, "Samorząd Terytorialny" 2004, No. 7-8, p. 9-11.

18 The consent of the patient as a category remaining in connection with the social interest was already analyzed in literature; see: M. Sośniak, Z problematyki zgody chorego na poddanie się zabiegowi leczniczemu, "Polski Tygodnik Lekarski" 1960, No. 46, p. 1784.

19 Compare. L.K. Paprzycki, Stosowanie przymusu w postępowaniu psychiatrycznym (w świetle obowiązującego prawa oraz projektu ustawy o ochronie zdrowia psychicznego), "Postępy Psychiatrii i Neurologii" 1993, No. 2, p. 311; A. Augustynowicz, A. Czerw, Stosowanie środków…, p. 36; M. Filar, Postępowanie lecznicze…, *op. cit.*, p. 44. Kwestie definicyjne zdrowia psychicznego, zaburzeń o raz innych stanów wymagających asystencji lekarskiej por. Por. K. Dąbrowski, (in:) K. Dąbrowski (ed.), Zdrowie psychiczne, Warszawa 1985, p. 8 and following.

20 Nevertheless, from a procedural point of view, judicial control over the use of psychiatric constraints may raise doubts. The literature indicates inefficiency and limited effectiveness of judicial protection instruments in this regard; see. one instead of many K. Michalak, J.G. Firlus, Wybrane aspekty sądowej kontroli stosowania przymusu leczenia – przegląd zagadnień ze szczególnym uwzględnieniem szybkości postępowania, "Jurysta" 2016, No. 9, p. 16-17.

21 Although in the scope of individual systemic and procedural solutions relating to the proceedings before the guardianship court, criticism was formulated in the literature. See: J. Nelken, O konieczności kontroli sądowej nad przymusowym umieszczeniem w szpitalu psychiatrycznym, "Nowe Prawo" 1983, No. 3, p. 77-78.

22 M. Balicki, Przymus w psychiatrii – regulacje i praktyka, "Prawo i Medycyna" 1999, No. 1, p. 42; K. Korzan, Postępowanie w sprawach ochrony zdrowia psychicznego, "Rejent" 1996, No. 6, p. 23-24.

23 Literature analysis seems to justify this thesis in part. Let us note, therefore, that the role of the court and the judge on the basis of the psychiatric act remains undetermined, and the nature

legitimate and official entities initiating individual proceedings. Nevertheless, this issue may merely be signalled here as it exceeds the framework of this study.

A basic part of the study will be devoted to the second group of proceedings, i.e. those connected to the prevention and counteraction of infectious diseases[24]. It is undeniable that legal measures of interference into the sphere of the patient's autonomy are of administrative law nature in this case. A basic question arises here whether the legislator has effected normative correlation of the *stricte* administrative proceedings with the complicated issue of patient's rights. In other words, whether Acts regulating proceedings before the bodies of sanitary police and the provisions of general administrative procedure[25] that are additionally applied[26] fulfil the standard of respect for patient's rights[27].

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of some activities seems to be borderline. Compare with the legal form of the judge who visits the psychiatric hospital: M. Sychowicz, Postępowanie sądowe w sprawach z ustawy o ochronie zdrowia psychicznego, "Przegląd Sądowy" 1995, No. 1, p. 7.

24 The proceedings in this category of cases are primarily regulated by the Act of 5 December 2008 (Consolidated text Journal of Laws, item, 2013, issue 947) [Ustawa z dnia 5 grudnia 2008 r. o zapobieganiu i zwalczaniu zakażeń i chorób zakaźnych u ludzi (tekst jedn. z 2013 r. poz. 947), in short "Epidemiological act"]. However, up-to-date rest the references for Act of 14 March 1985 on the State Sanitary Inspection (Consolidated text Journal of Laws 2015, issue: 1412, in short: uPIS) [Ustawa z dnia 14 marca 1985 r. o Państwowej Inspekcji Sanitarnej [Tekst jedn. z 2015 r. poz. 1412, in short uPIS] at least for two reasons. First of all, it is the basic source that creates task-oriented scope of activities of the sanitary police. Secondly, in the face of still-present doubts in the scope of determining the appropriate legal form of imposing selected duties, a subsidiary reference to these cases in the uPIS is appearing, where the legislator speaks explicitly about the decisions of the forms of communicating the will of the administrative organ.

25 The basic act regulating the general administrative (jurisdictional) proceedings is the Act of 14 June 1960 – The Code of Administrative Procedure [ustawa z dnia 14 czerwca 1960 r. Kodeks postępowania administracyjnego, (tekst jedn. Dz.U. z 2016 r., poz. 23)], in short k.p.a."].

26 In the face of the phenomenon of the "decodification" of administrative procedure, there are no doubts that the procedure of compulsory treatment and research aimed at preventing epidemiological threat belongs to the group of separate (specific) administrative proceedings; see about the issue of the system of administrative proceedings T. Woś, (in:) T. Woś (ed.), H. Knysiak-Molczyk, A. Krawiec, M. Kamiński, T. Kiełkowski, Postępowanie administracyjne, Warszawa 2013, p. 85-88; Z. Kmieciak, Zarys teorii postępowania administracyjnego, Warszawa 2014, p. 69 and following.

27 This question remains valid only in those cases where k.p.a is applicable in other cases – in the absence of formalized proceedings aimed at concretising substantive law standards – the protection of individual rights will be exhausted in the judicial control of public administration performed by administrative courts and in the intra-administrative control procedures prescribed in the enforcement proceedings.

2. Legal forms of "specification" of obligations restricting patient's autonomy in administrative law

Considerations on the scope and degree of intensified interference of public authorities towards an individual seem incomplete without the assessment of the normative model of legal forms of communicating the authority's will[28]. This issue appears to be limited to an attempt at answering the question about the optimal legal form of public authorities'[29] (sanitary police) operation in the discussed cases. It is not possible to provide an unambiguous answer to the above *de lege lata* question since the legislator distinguishes a legal procedural form depending on the content and type of obligation[30] imposed on the individual. On the one hand, the competence norm obliging a body to issue an administrative decision to update (revise) a factual administrative legal state has been contained in cases described in Art. 33 of the Epidemic Act. Nevertheless, it is difficult to acknowledge that in the discussed cases we can presumably talk about an alleged legal form of an administrative decision[31] that is appropriate for involuntary treatment. The statutory catalogue is of a closed nature[32], *ergo* it may not be subject to extensive interpretation. On the other hand, there is also the issue of preventive vaccination mentioned in Art. 17 of the Epidemic

28 Compare: J. Boć, Obywatel wobec ingerencji współczesnej administracji, Wrocław 1985, p. 115.

29 Compare on the subject of determining the designate of the legal concepts, the form of public administration activities, as well as their functions: J. Starościak, Prawne formy i metody działania administracji, (in:) System prawa administracyjnego, t. 3, Wrocław-Warszawa-Kraków-Gdańsk 1978, p. 39-41. The review of legal forms of operation of the sanitary police is made: M. Janik, Policja sanitarna, Warszawa 2012, p. 172 and following.

30 he literature indicates that one of the axioms (peculiarities and specificity) of administrative law is the duality of its norms assuming a dichotomous division of them, taking into account the criterion of influencing the sphere of rights and obligations of the individual; see. J. Zimmermann, Aksjomaty prawa administracyjnego, Warszawa 2013, p. 135-136. It is notorious, because not all norms constituting the duties of administrative law provenance require authoritative concretization.

31 The doctrine has repeatedly praised the thesis that there exists a presumption of the form of an administrative decision for those cases when the public administration body imposes obligations on the individual or deprives it of its rights: see: M. Romańska, Komentarz do art. 104 Kodeksu postępowania administracyjnego, in: H. Knysiak-Molczyk (ed.) Kodeks postępowania administracyjnego. Komentarz, Teza 5, Lex Omega; J. Jendrośka, Potrzeba nowego modelu procedury prawnej w administracji, "Państwo i Prawo" 2003, No. 3, p. 30. Nevertheless, even with respect to specific rules of enforcing administrative treatment, it is impossible to demonstrate that the body had to necessarily concretize its obligations in the form of an administrative decision. Art. 33 of the epidemiological act explicitly indicates the elements of the administrative factual state which authorize and at the same time oblige the body of the sanitary police to issue an individual administrative act. The purposefulness of using this legal form of communicating the will of the organ remains a separate issue.

32 Compare: based on the previously binding legal status M. Świderska, Zgoda Pacjenta na zabieg medyczny, Toruń 2007, p. 289; T. Dukiet-Nagórska, *op. cit.*, p. 25.

Act. It is *de lege lata* consistently assumed that the obligation to fulfil this duty results directly from the provisions of law[33], therefore, the issue of an administrative decision thereon is inadmissible[34]. Substantive accuracy and purposefulness of the division introduced by the legislator evoke justified doubts. The normative distinction of methods of "specification"[35] of obligations related to the elimination of epidemic threat inevitably results in further modifications referred to the course of verification of sanitary police actions undertaken towards an individual.

Hence, let us briefly consider procedural aspects of the fulfilment of the duty to undergo obligatory preventive vaccination. The structure of this obligation adopted by the legislator is special for at least two reasons. First of all, specification of the norm of substantive law[36] (non-specified norms, directly effective)[37] is unnecessary here. In other words, a formalized administrative act specifying the content and addressee of the obligation does not exist here. *Sui generis* only the administrative executive deed provides more precise specification of both relevant elements of the obligation. Public administrative authority does not undertake any prior action constituting a procedural act[38]. Secondly, sanitary police should fulfil the obligation entrusted by

33 Compare I. Jaworska, *op. cit.*, p. 62.

34 Compare: P. Daniel, Egzekucja obowiązku poddania małoletniego dziecka szczepieniu ochronnemu w orzecznictwie sądów administracyjnych, "Przegląd Prawa Publicznego" 2014, No. 4, p. 48; the Judgment of Regional Administrative Court in Bydgoszcz of 4 November 2015, II SA/Bd 871/15, Lex No. 1948739. Therefore, M. Janik's arguments should be considered incorrect, as it states that the obligation to undergo protective vaccinations suffers from concrete formulation in the administrative decision; see: M. Janik, *op. cit.*, p. 186-187.

35 Establishing a "concrete" obligation here is a simplification. This formula cannot be equated with the stages of applying the law by public administration bodies. This different formula for concretizing the obligation is usually reduced to individualizing the addressee of a statutory order.

36 Compare: D.R. Kijowski, (in:) D.R. Kijowski (ed.), Ustawa o postępowaniu egzekucyjnym w administracji, Warszawa 2015, p. 163.

37 Compare T. Woś, (in:) T. Woś (ed.), H. Knysiak-Molczyk, A. Krawiec, M. Kamiński, T. Kiełkowski, *op. cit.*, p. 45. This method of imposing obligations on individuals should be distinguished from the situation when the order of a particular procedure results from the so-called material and technical activities of organs. The latter are also referred to as acts creating duties in a special way; por. K.M. Ziemski, Ogólna charakterystyka działań (czynności) materialno-technicznych, (in:) R. Hauser, Z. Niewiadomski, A. Wróbel (co-ed., System prawa administracyjnego, t. 5, Warszawa 2013, p. 71-72.

38 It is necessary to bear in mind a specific category of other public administration acts and activities that are also issued outside formalized administrative proceedings. Nevertheless, it is impossible to include in this category the legal forms of public administration activity; see about other acts and activities A. Kisielewicz, Akty i czynności, o których mowa w art. 3 § 2 pkt 4 ustawy z 30 sierpnia 2002 r. – Prawo o postępowaniu przed sądami administracyjnymi, (in:) J. Posłuszny, Z. Czarnik, R. Sawuła (współred.), Instytucje procesu administracyjnego i sądowoadministracyjnego, Przemyśl-Rzeszów 2009.

the legislator with due diligence, i.e. monitor its proper fulfilment by the individual[39]. In effect thereof, as far as the obligation ensuing directly from the statutory provisions is concerned, an employer shall unambiguously resolve a conflict between the values implied by the potential threat for public health and the individual's right of self-determination. The statutory obligation to undergo preventive vaccination is secured in the course of administrative executive proceedings[40]. Nevertheless, failure to follow a formalized course of the specified obligation to undergo medical treatment does not mean that the individual is deprived of the right to defend their rights[41]. A further part of the article will be limited to the analysis of measures applied to fulfil the obligation of preventive vaccination of minors[42]. This analysis will allow to formulate *lex ferenda* postulates thereon.

3. Obligatory preventive vaccination – the fulfilment of administrative law norms (administrative law obligation *ipso iure*)

Failure to undergo the statutory obligation mentioned in Art. 17 of the Epidemic Act in due time obliges the administrative obligee to undertake actions envisaged by the law to apply executive measures[43]. The fulfilment of obligations of both the obligee and executive authority has been normatively secured by a possibility of challenging their inactivity[44]. At the same time, it should be pointed out that the legislator quite peculiarly structured legitimacy of submitting a complaint to question protraction of involuntary administrative proceedings. It should be underlined that the entity whose legitimacy is based solely on the request to secure factual interest is also entitled to submit a legal measure under Art. 6 § 1a of the Executive Act. It is a special situation insofar as, in principle, objective legal order, general administrative proceedings

39 See: T. Woś, (in:) T. Woś (ed.), H. Knysiak-Molczyk, A. Krawiec, M. Kamiński, T. Kiełkowski, *op. cit.*, p. 45; J. Boć, *op. cit.*,p. 60-61.

40 Ie. in the mode and on terms specified in Act of 17 June 1966 on enforcement proceedings in administration (Consolidated text Journal of Laws 2014 , item 1619 , as amended) [Ustawa z 17 czerwca 1966 r. o postępowaniu egzekucyjnym w administracji (tekst jedn. Dz.U. z 2014 r., poz. 1619 ze zm)], in short: enforcement law.

41 The administrative enforcement procedure itself is intended to protect the rights of the individual.

42 n order to simplify the argument, we make the assumption that a minor who is an indirect addressee of the activities of the sanitary police body is under the age of 6.

43 Organ administracji publicznej występujący w roli wierzyciela ma obowiązek doprowadzenia do przekształcenia stanu rzeczywistego (zastanego) do stanu określonego treścią zakazu ustawowego; por. co do znaczenia sformułowanej w art. 6 § 1 ustawy egzekucyjnej dyrektywy postępowania wyrok WSA w Gliwicach z 29 maja 2013 r., I SA/Gl 146/13, Lex No. 1346882.

44 Compare on the importance of the legal remedy referred to in art. 6 § 1a of the act on enforcement, M. Mikosz, Konstrukcja i rozpoznawanie środków zaskarżenia bezczynności w ustawie o postępowaniu egzekucyjnym w administracji, "Samorząd Terytorialny" 2007, No. 7-8, p. 129-132.

in particular, create measures to protect the individual's[45] justified legal interest[46]. We should remember that with regard to the monitored fulfilment of obligatory preventive vaccination of minors, the catalogue of entities potentially legitimate to submit a complaint about inactivity may be quite wide. It seems that the subject scope of legitimacy to submit the discussed legal measure may embrace a head (manager) of an administrative facility the minor attends, e.g. a kindergarten[47].

Apart from the practical aspect of secured efficiency of executive proceedings, we should pay attention to a crucial element of legal provenance ensuing from the content of Art. 6 § 1a of Executive Act. A complaint about the obligee's inactivity allows to carry out a preliminary review of admissibility of initiated and pending executive proceedings. Notoriously, a negative prerequisite of the fulfilment of the statutory obligation, including executive proceedings due to order non-enforceability, are long-term medical contraindications to vaccinate the child[48]. The submission of a complaint about the obligee's inactivity also allowed to verify this circumstance. The obligee is not inactive if the enforcement of the obligation is inadmissible. Significantly enough, the entity questioning the administrative obligee's inertia, may also initiate a judicial review of the legality of conduct of the body responsible for the fulfilment of obligatory preventive vaccination.

Hence, in case of no medical contraindications and assumed fulfilment of the obligation of information by a doctor[49] ensuing substantive and technical action

45 Compare: K. Jadny-Jednrośka, J. Jendrośka, System jurysdykcyjnego postępowania administracyjnego, (in:) System prawa…, t. 3, p. 189: "The Code based the concept of the page on two equivalent tests – on the legal obligation and legally protected interest (...)".

46 Compare regarding the way of understanding and sources of legal interest on the basis of general administrative proceedings of R. Kędziora, Kodeks postępowania administracyjnego. Komentarz, Warszawa 2014, pp. 248-249.

47 In the context of a problematic issue related to the admissibility of refusal to admit a minor to an administrative establishment in the event of a failure to fulfill the obligation to vaccinate, the legal measure provided for in art. 6 § 1a of the act on enforcement, it appears to be particularly useful. See: on the correlation of the obligation under art. 17 of the epidemiological act and admissibility of refusal to enter kindergarten Information on the activities of the Children's Ombudsman for 2015 and remarks on the state of observance of children's rights, Warszawa 2016, p. 145; M. Boratyńska, *op. cit.*, p. 79.

48 See: P. Daniel, *op. cit.*, p. 52; M. Boratyńska, *op. cit.*, p. 75, here the equivalence of both duties was indicated. A medical qualification test can be regarded as a complementary component of the general statutory obligation to undergo protective vaccinations. On the marginal note, medical contraindications are a negative premise of coercion in general; compare: J. Sawicki, Przymus leczenia, eksperyment, udzielenie pomocy i przeszczep w świetle prawa, Warszawa 1966, p. 82.

49 Information and explanation of therapeutic activities remain in correlation with each other; A. Górski, O obowiązku lekarza poinformowania pacjenta o zgodzie pacjenta za zabieg, "Studia Iuridica" 2001, t. XXXIX, p. 85; A. Górski,czynność lecznicza i czynność nielecznicza (in:) A. Górski (ed.), *op. cit.*, p. 13-18.Also: R. Kędziora, Problematyka zgody pacjenta w świetle polskiego ustawodawstwa medycznego, "Prokuratura i Prawo" 2003, no 7-8, p. 57. The literature indicates that the legislator, in the case of an obligation to submit to the obligation of protective

undertaken by him or her[50] in the form of summoning for a qualifying examination due to a notified lack of consent of the entity[51] mentioned in Art. 5 par. 2 of the Epidemic Act for preventive vaccination, sanitary police is obliged to undertake first actions regulated by the Epidemic Act. Most of all, in accordance with the principle of a threat, the authority should provide the fulfilment of the obligation without the need to apply executive measures[52]. A possibility of withdrawing from the need to apply state coercion appears to be particularly desirable in the discussed case[53]. This issue is also related to the forecast efficiency of measures of impact applied by executive authorities upon entities responsible for the fulfilment of the obligation of preventive vaccination of minors.

Among two potentially available executive measures (a coercive fine and indirect coercion[54]), prior futility of their application may be reasonably assumed[55]. The above expressed thesis seems to be confirmed by the normative shape of both manners of execution. The legislator orders an executive authority to apply such measures which, on the one hand, will prove efficient and, on the other hand, least burdensome for their addressee. Indeed, the person responsible for the fulfilment of the obligation should first be fined so that this measure of impact could enforce him or her to exercise the duty. However, it does not seem to be the only available means to enforce the obligation[56]. Selecting and applying means of its activity, the

vaccination, pays special attention to the obligation to inform the patient about the existence and content of the obligation; see. A. Augustynowicz, A. Czerw, *op. cit.*, p. 37. A separate and very controversial issue is the issue of the subjective scope of this information obligation related to the presence of a parent when vaccinating a minor, por. R. Kubiak, Szczepienie dziecka bez obecności rodziców, "Medycyna Praktyczna", accessible at: http://www.mp.pl/szczepienia/prawo/zapytajprawnika/71977,szczepienie-dziecka-bez-obecnosci-rodzicow (accessed: 15 September 2016).

50 See: I. Jaworska, *op. cit.*, p. 64.

51 The singular used in this case is a simplification. It is obvious that both the warning as well as the enforcement title and active participation in the enforcement proceedings concern both legal guardians of the minor. So for parents: the Judgment of Regional Administrative Court in Cracow od 25 October 2012 III SA/Kr 1532/11, Lex No. 1235560.

52 See: T. Lewandowski, Glosa do wyroku NSA z dnia 8 lipca 2009 r., II FSK 618/08, Thesis No. 3, Lex/el 2011.

53 In the case of non-compliance with the obligation of protective vaccination we deal with the so-called indirect coercion. Its essence boils down to the possibility of applying sanctions of an administrative nature for the purposes of enforcing the order while excluding the possibility of the use of force in the form of physical strength and other forms of direct impact on the patient; see. as to the definition: M. Świderska, Zgoda Pacjenta…, p. 248. Although administrative sanctions seem to be too narrowly understood here. It is impossible to accept, because direct coercion of the enforcement law in the administration is not a legal and administrative sanction.

54 Compare: I. Jaworska, *op. cit.*, p. 70.

55 Regarding the limited effectiveness of direct administrative and legal coercion compare: A. Augustynowicz, A. Czerw, *op. cit.*, p. 39-40.

56 art of the literature assumes that enforcement measures are only to be used to discipline legal guardians, for example. P. Daniel, *op. cit.*, p. 49; M. Świderska, Przymus leczenia…, *op. cit.*,

executive authority should take into account the relevant directive, i.e. a purpose of executive proceedings, that is involuntary fulfilment of the obligation[57]. Insofar as the application of direct coercion envisaged in Art. 36 of Epidemic Act[58] is excluded in the discussed case, the executive authority may enforce compulsory appearance of both the person responsible for the fulfilment of the obligation as well as the minor at the facility providing medical service[59].

Nevertheless, there are no *de lege lata* legal possibilities of applying direct coercion to the act of performing preventive vaccination itself. Hence, it is particularly desirable to search alternative and conciliatory forms of persuading the obliged person to voluntarily obey the norm of substantive administrative law. The obligation to admonish the obliged individual, which is mentioned in Art. 15 of the Executive Act, is the only necessary formal element allowing to proceed to the next stage of the proceedings. Notifying the obliged individual[60], which is a peculiar normative *novum*, does not seem to be an optimal formula assuring conceivably prompt achievement of the purpose in the form of the fulfilment of the obligation mentioned in Art. 17 of Epidemic Act. For this reason, we may postulate the introduction of a mediatory[61]

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p. 26. Thus, they exclude prima facie the use of coercive measures available in the enforcement proceedings. It seems that in this case the difference between the application of the two different ways of coercion is not taken into account. It is something else, because bringing the obligation to coercion into force, and something else, for example, bringing the parent and the child to the place of fulfillment of duty. See. also general considerations regarding "compelling for research" through the use of direct coercion M. Świderska, Zgoda Pacjenta…, *op. cit.*, p. 289. T. Dukiet-Nagórska also emphasizes this difference and indicates that the administrative enforcer has the legal right to bring the obligee to the place of examination or treatment; see: T. Dukiet-Nagórska, *op. cit.*, p. 26-27. Although the author excludes the admissibility of the use of coercive measures in the event of enforcement of the order to undergo preventive vaccination; por. *ibidem*, p. 29.

57 Compare: M. Król, Szukanie złotego środka – o zasadzie stosowania egzekucji najmniej uciążliwej dla zobowiązanego, "Przegląd Podatkowy" 2015, No. 8, p. 42.

58 See: A. Augustynowicz, I. Wrześniewska-Wal, Aspekty prawne obowiązkowych szczepień ochronnych u dzieci, "Pediatria Polska" 2013, No. 88, p. 124. Although the authors exclude *in genere* the use of coercion in the discussed area both from the epidemiological act, as well as coercion as a means of enforcing the duties by the enforcer; *ibidem*, p. 125.

59 The use of coercion against a minor is possible taking into account the content of art. 152 of the enforcement act. It should be borne in mind that parents (statutory representatives) are obliged in the enforcement proceedings, whereas the executive entity is a minor. Hence, it is also possible to bring parents to the place where the qualifying examination is carried out together with the child. The last thesis is justified with the assumption of complementarity of the vaccination obligation and qualifying tests – as well as above.

60 See: art. 6 § 1b of the act on enforcement. Only the prior uselessness of this mode is marked, taking into account the location and systemic links to the enforcement of financial obligations.

61 The issues of the so-called administrative mediation belongs to the contentious issues in the Polish literature; see. on this topic: A. Szpor, Mediacja w prawie administracyjnym, (in:) E. Gmurzyńska, R. Morek (współred.), Mediacje. Teoria i praktyka, Warszawa 2014, p. 397 and following.; J. Wegner-Kowalska, Idea mediacji w postępowaniu administracyjnym, "Przegląd Prawa Publicznego" 2016, No. 10, p. 90-92. Nevertheless, the recent modification of the procedural

pre-executive[62] way of resolving the dispute. Undoubtedly, the obliged individual is many a time informed about the need to fulfil the statutory obligation, among others by a doctor[63]. Yet, perhaps only the participation of the third person (a mediator) will cause voluntary fulfilment of the obligation[64]. The need to introduce efficient and flexible procedural measures is particularly desirable because of restricted efficiency of administrative execution and the special sphere of impact exerted by administrative authorities, which is patient's autonomy. Mediation appears as an informal and flexible procedure, which is not subject to detailed regulatory power[65]. Thus, it creates appropriate conditions for a settlement[66]. Obviously, specificity of administrative law norms (*ius cogens*) and explicitly jurisdictional, or relatively unilateral, nature of interference in the sphere of the rights and freedoms seem not to adjust to the procedure involving negotiating and persuading the order's addressee to voluntary performance thereof[67]. Hence, the above invoked peculiarities *prima facie* exclude admissibility of informal "persuasions" within this scope[68].

framework of administrative jurisdiction seems to close this chapter of scientific discourse. The legislator, driven by the need to make public administration more flexible and to provide a client friendly and informal approach to external entities (individuals), introduced in art. 96a and n. k.p.a. institution of mediation for administrative proceedings. Parallel, the review of the general administrative procedure enacted in art. 13 k.p.a. making the body conducting the administrative proceedings responsible not only (as it was in the legal system until 1 June 2017) for seeking an amicable resolution of the case, but first of all creating an appropriate framework for dialogue between the individual and the public administration.

62 Some doubts may be attributed to the proper legal basis for authorizing the executive to mediate. It seems – with some precaution – that in the present case, art. 18 of the Act on Enforcement containing a clause of subsidiary application of the provisions of the code of At the same time, it should be emphasized that the mutative application of the provisions regulating the administrative mediation procedure allows for the necessary modifications to be introduced. Above all, it is desirable to limit the formalism of this incident mode to speed up the procedure.

63 Regarding the doctor's information duties and binding the providers of medical services with a communication on a preventive vaccination program compare: I. Jaworska, *op. cit.*, p. 63.

64 See. arguments for the need to incorporate the mediation institution into general administrative proceedings: J. Wegner-Kowalska, Mediacja (art. 13, art. 96a-96g), in: Raport…, pp. 96-97.

65 See: Z. Kmieciak, Mediacja i koncyliacja w prawie administracyjnym, Kraków 2004, p. 56.

66 The basic function of the mediator as an impartial participant in the dialogue of entities participating in the proceedings aimed at removing the actual dispute is inter alia the facilitation and improvement of bilateral communication, see: C.H. Moore, Mediacje. Praktyczne strategie rozwiązywania konfliktów, Warszawa 2012, p. 33-34.

67 Although the administrative procedure was not based on the construction of a legal dispute, and thus does not have an adversarial character, its adversarial character does not raise fundamental doubts. The dependence seems to be perceived by foreign literature, in particular those related to American administrative practice; see: E. Rubin, It's time to Make the Administrative Procedure Act Administrative, "Cornel Law Review" 2003, vol. 89, pp. 102-103.

68 See. critical remarks about the institution of mediation in court-administrative proceedings: T. Woś, Postępowanie mediacyjne w ustawie – Prawo o postępowaniu przed sądami administracyjnymi, (in:) Podmioty administracji publicznej i prawne formy ich działania, Toruń 2005.

Nevertheless, due to restricted efficiency of available measures *de lege lata* without the need to evoke *contra legem* interpretation[69] and concurrent respect for the right of self-determination, it is necessary to search alternative forms of enforcing statutory obligations. What is more, a dialogue between the addressee of the statutory order and administrative authority responsible for its performance is conducted solely in formalized internal administrative monitoring proceedings, i.e. complaint proceedings and charges procedure. These incidental proceedings cannot be treated as forms of hearing the addressee of jurisdictional administrative actions[70].

The praxeological and purposeful directive of withdrawing from the application of a certain means of execution is a separate issue. In the discussed case, although an administrative executive body is normatively allowed to apply a concrete executive measure, social values may justify a negative assessment of the fulfilment of the obligation carried out in a certain manner, i.e. using a specific executive measure. Nevertheless, these considerations regard the sphere of withdrawing from (selecting) an executive measure by the authority rather than legality of its application. Hence, they refer to the sphere of facts rather than the law. The literature often depicts a wrong approach thereto grounded on the improper presumption where those two above-mentioned levels, i.e. axiological evaluation and legal admissibility, overlap[71].

4. Searching the standard of due process in administrative proceedings affecting the sphere of the patient's rights – comments *de lege ferenda*

The above-mentioned shortcomings ensuing from the adopted model enforcement of the obligation under Art. 17 of Epidemic Act imply the need to consider its change. Most of all, the very manner of "specifying" the addressee and partially the content of the obligation may evoke doubts[72]. The adopted method of

69 See: A. Augustynowicz, A. Czerw, *op. cit.*, p. 45, 48.

70 Wysłuchanie adresata działań administracji publicznej traktowane jest, jako minimalny standard, jaki powinno zapewniać postępowanie administracyjne; see: Z. Kmieciak, Zarys systemu…, p. 86.

71 It seems that the part of the literature eludes the circumstance that there is no clear legal basis that creates a negative condition for applying a given method of execution to the obligee-patient. Regardless of the doubts caused above all by the purposeful level of evaluations, it cannot be regarded as a correct approach according to which the negative assessment of the application of the enforcement measure – eg taking into account the aspect of non-purpose application – has the whole system-wide effect of its inadmissibility by law.

72 In the literature, it was pointed out that there were shortcomings in the specification of the content of the order to undergo obligatory vaccinations. This issue also shows the connection with the issue of the rank of a legal act containing a subsidiary element co-shaping the content of the obligation forming the basis for the use of administrative coercion; see: A. Augustynowicz, I. Wrześniewska-Wal, Aspekty prawne…, p. 121. In the light of the requirement of a high degree of precision of the obligation arising from ex lege, and subject to enforcement, this issue seems to be highly disputable, see: D.R. Kijowski, in: D.R. Kijowski (ed.), *op. cit.*, p. 163 where it was pointed

regulation does not appear appropriate. Hence, we should consider a possibility of entrusting State Sanitary Inspection bodies with the powers to impose[73] any obligations interfering in the sphere of the patient's rights through the issue of an administrative decision. There are no sufficient arguments to justify the abandonment of a *stricte* legal administrative form limiting patient's rights. In particular, taking into account the directives optimizing the length of proceedings with the participation of an individual, handing over *stricte* police powers to common courts appears useless[74].

Apart from the need to unify legal forms of administrative authorities' operation, it is necessary to carry out statutory adaptive measures within the scope of the course of proceedings. It seems that the form of general administrative proceedings in this case is considerably inappropriate. Therefore, it is necessary to implement the idea of hybrid proceedings into the Epidemic Act[75]. This formula allows to correlate *stricte* public law issues (care for public health) with those whose provenance resembles private law[76]. Moreover, the proposed solution would be a rational compromise between a desirable standard of protection of individuals participating in proceedings before sanitary police bodies and the need to assure effective measures of enforcing obligations imposed upon individuals[77] (optimization of individual interest and valid public interest).

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out that there was a need for unquestionable determination based on the provision creating the order of the addressee as well as the content of the obligation itself. Therefore, even the very existence of a duty, ie issuing a declaratory decision, would eliminate the doubts mentioned above.

73 n this way, there is no transformation of the nature of the obligation to undergo obligatory vaccinations. We should bear in mind that the legal form of the administrative decision may appear to be optimal also in the event of confirmation of the order, i.e. the need to demonstrate the obedience to the administrative legal obligation. In such a case, the body only states that a given obligation binds the entity while creating it. J. Zimmermann, Polska jurysdykcja administracyjna, Warszawa 1996, p. 141; J. Jendrośka, *op. cit.*, p. 30.

74 The formula of coercion adopted in the epidemiological act does not require such far-reaching procedural guarantees of a systemic nature. Cf. regarding the necessity of introducing a judicial review of the legality of coercion of psychiatric treatment; J. Nelken, *op. cit.*, p. 74-75. As it seems in this case, the danger of abuse by sanitary police authorities is not updated.

75 Compare in terms of the idea and model of this process formula: Z. Kmieciak, Zarys systemu…, *op. cit.*, p. 78.

76 Dyskutowane zagadnienia odnoszą się do braku zgody względnie wyrażenia sprzeciwu dla wykonania świadczenia medycznego. Nie sposób nie dostrzec dyskutowanej w orzecznictwie i literaturze złożonej i na poły mieszanej naturze tego uprawnienia pacjenta; por. rozważania na ten temat. J. Ciechorski, Glosa do wyroku Sądu Apelacyjnego w Katowicach z dnia 15 stycznia 2014 r., I ACa 922/13, "Orzecznictwo Sądów Polskich" 2016, No. 6, p. 781-784. The reference to the voted judicature is not accidental. The court, as it inter alia indicates a special and unconditional legal character of the patient's consent. Therefore, with the postulated change of the formula of conduct, one should bear in mind the specificity of the sphere in which public administration intends to interfere with its activities.

77 The normative method of modifying the course of proceedings (so-called special administrative proceedings) before the public administration authority does not always take into account the

This result may be achieved by introducing changes[78] to several aspects. Firstly, the legislator should prescribe possibly short terms to resolve matters. The category of legal interests considered in the proceedings requires the principle of prompt proceedings to be fulfilled as fully as possible[79]. Secondly, statutory law should specify the manner of initiating proceedings for involuntary treatment more precisely. It appears *de lege lata* that proceedings in result of which an administrative decision mentioned in Art. 33 par. 1 of Epidemic Act may be issued are initiated upon a request[80]. However, contrary arguments may also be applied here. The literature points out that as far as initiation of administrative proceedings is concerned, contrary to the literal meaning of Art. 61 § 1 of the Code of Administrative Procedure, there is no normative alternation. In other words, the provisions of substantive law should specify the manner of launching proceedings (upon a request or ex officio)[81]. In particular, the issue of binding the authority by a report made by a doctor remains *explicite* unresolved in the Act. Fourthly, since general administrative proceedings lack the right of assistance for the needs of such proceedings, it is necessary to assure the participation of a professional attorney ex officio therein[82]. It is justified

interests of the recipients of state interference in the sphere of individual rights and freedoms in a holistic way. Let us note, for the order of reflection, that the justification for innovative process solutions is the need to improve and operationalize the operation of public administration bodies; see e.g. H. Knysiak-Sudyka, L. Klat-Wertelecka, Model administracyjnego postępowania uproszczonego, "Państwo i Prawo" 2016, No. 7, p. 93. Thus, the legislative directive includes in this case not strictly the interests of the parties to the proceedings, but the need to globally improve the functioning of the state apparatus, which only in the aspect of indirect influence can positively affect the protection of the parties' rights.

78 The demand for appropriate statutory changes as regards the order to undergo obligatory vaccinations has already been publicized in the literature; see: A. Augustynowicz, I. Wrześniewska-Wal, Aspekty prawne…., *op. cit.*, p. 125.

79 On the basis of the psychiatric act, the legislator introduces an instructional 14-day period for conducting the trial. Literature seems to dominate the view of the optimal temporal formula in this respect; see: L.K. Paprzycki, Ochrona praw człowieka w świetle projektu ustawy o ochronie zdrowia psychicznego (część II), "Palestra" 1993, No. 11, p. 27, which indicated that the monthly term is too long. Differently Nelken, *op. cit.*, s. 77. At the same time, the emphasis here must be placed on the fact that in the case of proceedings before public administration bodies, the legislator should prescribe the time limit for settling the matter, rather than taking specific actions in the course of the proceedings.

80 As to the obligation of notification (notification) imposed on the doctor, referred to in art. 27 of the epidemiological act compare: A. Augustynowicz, I. Wrześniewska-Wal, Ograniczenie autonomii pacjenta w diagnozowaniu i leczeniu gruźlicy, "Pneumologia i Alergologia Polska" 2013, No. 81, pp. 131-132.

81 See: H. Knysiak-Molczyk, (in:) T. Woś (ed.), H. Knysiak-Molczyk, A. Krawiec, M. Kamiński, T. Kiełkowski, *op. cit.*, p. 245.

82 See: P. Dobosz, Procedury administracyjne, model sądownictwa administracyjnego a "prawo pomocy", (in:) J. Stelmasiak, J. Niczyporuk, S. Fundowicz, Polski model sądownictwa administracyjnego, Lublin 2003, pp. 125-126; see: as to the right to help in proceedings related to psychiatric coercion: M. Sychowicz, *op. cit.*, p. 12.

not only by particular individual interests but also economical reasons. Fifthly, we should consider admissibility of participation of the Patient's Ombudsman in the proceedings as a party thereto.

Of course, changes in the course of proceedings before sanitary police bodies ensue the need to consider a more precise specification of the course of the obligations' enforcement. Restricted admissibility of repeated coercive fines is a highly desirable solution. It is equally important to consider changes in the course of execution of obligations that are *stricte* related to the patient's autonomy. In particular, it is necessary to change the scope of participation of assisting bodies by the extension of the subjective catalogue to encompass a doctor therein[83]. Then, being an entity actively participating in executive proceedings, a doctor would perform actions within the scope of public administration which would take a form of direct executive measures (*verwaltungsbehördlicher Befehls*), which are applied in the Austrian system practice[84]. Furthermore, taking into account controversies related to the application of direct coercion under administrative law, the legislator should decide about admissibility of taking the obligor to the venue where the obligation is fulfilled in effect of the failure to obey a prior administrative decision.

The authors explicitly intended to propose the optimized model of proceedings before sanitary police authorities including experiences connected with involuntary psychiatric treatment. Judicialization of proceedings[85] and higher protection for the individual's rights also affect the scope of exercise of the right to a trial[86] in matters related to involuntary treatment under administrative law. Due to the fact that the legislator abandoned the implementation of the judicial method to impose the

83 And this is due to the lack of legal as well as the actual ability to enforce the order by an administrative enforcer; see: T. Dukiet-Nagórska, *op. cit.*, p. 26; regarding the role of the bodies assisting in the use of direct coercion compare: J. Radwanowicz, Przymus bezpośredni w egzekucji administracyjnej, w: J. Niczyporuk, S. Fundowicz, J. Radwanowicz, System egzekucji administracyjnej, Warszawa 2004, p. 492-493. As to the division of duties between the police using direct coercion and the doctor see in: Prawne problemy pobrania krwi od osoby podejrzanej o popełnienie przestępstwa lub wykroczenia po użyciu alkoholu, "Prawo i Medycyna" 2003, No. 13, p. 52-53.

84 See: D.R. Kijowski, Austria, (in:) Z. Kmieciak (ed.), Postępowanie administracyjne w Europie, Warszawa 2010, p. 70; A. Krawczyk, Merytoryczne orzekanie przez sądy administracyjne w Austrii w świetle założeń reformy sądownictwa administracyjnego (Verwaltungsgerichtsbarkeits-Novelle 2012, (in:) I. Lipowicz, Z. Kmieciak (co-ed.), Przyszłość sądownictwa administracyjnego w Polsce z uwzględnieniem tendencji europejskich, Warszawa 2012, p. 265; Z. Kmieciak, P. Florjanowicz-Błachut, Austria – reforma sądownictwa administracyjnego. Wybór przepisów znowelizowanych 51. Ustawą federalną, erwaltungsgerichtsbarkeits-Novelle 2012, "Zeszyty Naukowe Sądownictwa Administracyjnego" 2013, No. 4, p. 191.

85 See: Z. Kmieciak, Zarys systemu…, p. 101 and following.;

86 There is no doubt about the importance of judicial control – at least the legality – of administering lawful and compulsory treatment; see. T. Dukiet-Nagórska, *op. cit.*, p. 28-29; M. Świderska, Zgoda Pacjenta..., p. 279, which determines the use of coercion from judicial control.

obligation interfering in the patient's autonomy upon an individual, it is necessary to correlate both proceedings, i.e. administrative (or executive) proceedings and judicial monitoring (revision) proceedings[87]. *De lega lata,* encompassing shortcomings of the proceedings before sanitary police authorities, the right to a trial is not sufficiently fulfilled in the discussed cases. Due to the limited framework of this study, we may only signal selected aspects of the subject issue. Firstly, judicial monitoring (review) of public administration merely involves verification while judicial adjudicatory capabilities are limited to admissible elimination of an act or action undertaken by public administration from legal transactions[88]. Secondly, the Polish model of administrative justice system is characterized by normatively implied protraction caused by, among others, the complainants abusing their procedural rights[89]. This tendency is particularly apparent in case of an unlimited possibility to question actions undertaken in administrative executive proceedings, which leads to their global protraction and, in consequence, more often than not efficiently prevents the obligation's enforcement[90].

In the light of the above considerations, it should be underlined that the existing *de lege lata* model of applicable administrative involuntary treatment cannot be retained. Restriction of the right to a trial by the exclusion of a possibility to carry out *de novo* control is justified only if the standard of due process is fully applied in administrative proceedings. Then, in compliance with the nature of a monitoring activity, the role of administrative judicature may be limited merely to the protection

87 There are no fundamental doubts that both legal protection modes remain in close correlation. Thus, it seems legitimate to determine the dependence according to which the greater the scope of the guarantee in the administrative procedure, the lower the possibility of court interference in the sphere of public administration activities; see: M. Bernatt, Konstytucyjne aspekty sądowej kontroli działalności administracji (między efektywnością a powściągliwością), "Państwo i Prawo" 2017, No. 1, p. 34. By slightly modifying the content of the article outlined in the literature, one can assume that the degree of implementation of rights guaranteeing the protection of individual rights in administrative proceedings determines the mode of court proceedings and the way of adjudication by them (e.g. de novo control determined by the minimum standard of protection of individual rights in proceedings before a public administration authority)

88 See e.g. T. Woś, Komentarz do art. 1 ustawy – Prawo o postępowaniu przed sądami administracyjnymi, (in:) T. Woś (ed.), H. Knysiak-Sudyka, M. Romańska, Prawo o postępowaniu przed sądami administracyjnymi, Komentarz, Teza 6-8, Lex Omega.

89 See: Judgment of Higher Administrative Court of 16 October 2015, I OSK 1992/14, Lex No. 1975884; H. Knysiak-Molczyk, Czy sądy administracyjne realizują prawo do sądu w aspekcie rozpatrzenia i rozstrzygnięcia sprawy w rozsądnym terminie?, (in:) I. Lipowicz, Z. Kmieciak (co-eds.), *op. cit.*, Warszawa 2012.

90 See: T. Woś, Komentarz do art. 3 ustawy – Prawo o postępowaniu przed sądami administracyjnymi, (in:) T. Woś (ed.), H. Knysiak-Sudyka, M. Romańska, Prawo o postępowaniu…, Teza 41. See also the critique of the effectiveness of compulsory administrative proceedings in the context of the right to court, the judgment of the ECHR of 3 May 2011 in the case of *Apanasewicz v. Poland* (No. 35630/02).

of the objective legal order. The implementation of this approach relies on the assumption that the legislator includes systemic effects of selected legal protection in a specific category of cases. The abandonment of the judicial form of application (confirmation) of involuntary treatment should embrace the need to change the manner of proceedings in cases resolved before public administrative authorities.

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Limitations of Patient's Right to Self-Determination Due to Hospitalization for Tuberculosis

Abstract: The subject of the article is a discussion of issues related to the limitation of patients' rights provided for in the law in the prevention and control of one of the infectious diseases – tuberculosis. The above restrictions result from the treatment of public health as a merit of higher protection than individual human rights. They are manifested in specific responsibilities of patients suffering from tuberculosis such as forced treatment and hospitalization and, therefore, despite the lack of consent or against the objection, in compliance with the injunctions and prohibitions of the State Sanitary Inspection prevents and combats infectious diseases. In this article, I present legal solutions limiting the patient's right to decide on treatment, consent or objection to health services related to the implementation of tuberculosis prevention and control tasks, thus limiting the patient's autonomy in relation to this disease. Moreover, I point to the problems arising in connection with the fulfilment of obligations in this respect.
Keywords: patient's rights, restriction of patient's autonomy, tuberculosis, obligatory hospitalization

1. Introduction

One of the fundamental constitutional rights is each individual's right to personal freedom (Art. 41 par. 1 of the Polish Constitution). However, there are exceptions thereto. The Polish Constitution admits limitations within the above scope saying that any deprivation or limitation of liberty may be imposed only in accordance with principles and under procedures specified by statute. This regulation is completed by the principle of proportionality set forth in Art. 31 par. 3 of the Polish Constitution, which specifies precisely the prerequisites thereof. Namely, the above limitations may be enacted solely by statute and only if they are necessary in a democratic state to provide its security or public order, or to protect natural environment, public health and morality, or freedoms and rights of third parties. These restrictions may not infringe the essence of freedoms and rights.

In the light of Art. 31 par. 3 of the Polish Constitution, public health is the admissible ground of restricting constitutional rights and freedoms. Currently binding provisions of law envisage several limitations of patient's rights for the above reason. Such limitations are manifested, *inter alia*, in special obligations of patients who are at a risk of developing tuberculosis as well as other people who contact them that are contained in the Act on Prevention and Counteraction of Human Infections and Infectious Diseases[1].

Art. 16 of the Act on the Patient's Rights and Patient Ombudsman[2] contained in Chapter 5 stipulates that the patient has the right to give consent for specified health services, or refuse to give such consent after obtaining information within the scope laid down in Art. 9. Pursuant to Art. 15 of the above Act, provisions of Chapter 5 are applied to consent given for the provision of health services or refusal to give such consent unless the provisions of separate Acts stipulate otherwise. Hence, a refusal to give consent for the provision of specified health services is possible solely if the exceptions set forth in other Acts do not occur. Such exceptions occur under APCHI.

2. The catalogue of obligations

The catalogue of obligations referring to individuals staying in the territory of the Republic of Poland and related to the prevention and counteraction of infections and infectious diseases has been specified in Art. 5 par. 1of APCHI. Such individuals are obliged to undergo sanitary treatment, preventive vaccination, post-exposal prophylactic use of medicaments, sanitary and epidemic examination including activities to collect or supply material to such tests, disease surveillance, quarantine, treatment, hospitalization, and isolation.

Pursuant to Art. 33 par. 1 of APCHI, in the wake of suspected or diagnosed infection or infectious disease, Poviat or Border State Sanitary Inspector is entitled to order a person at a risk of developing infectious disease, or diagnosed with infection or infectious disease, or a person who had contact with the source of biological infection agent to carry out obligations resulting from Art. 5 par. 1 of APCHI by issuing a relevant decision.

1 Act of 5 December 2008 r. on preventing and combating infections and infectious diseases in humans (consolidated text Journal of Laws 2016, item 1866, as amended (tekst jedn. Dz.U. z 2016 r., poz. 1866 ze zm.) [Ustawa z dnia 5 grudnia 2008 r. o zapobieganiu oraz zwalczaniu zakażeń i chorób zakaźnych u ludzi (tekst jedn. Dz.U. z 2016 r., poz. 1866 ze zm.)], in short u.z.c.z.l.

2 The Act of 6 November 2008 on patient rights and the patient's rights ombudsman (consolidated text Journal of Laws 2016, item 186, as amended 2016) [Ustawa z dnia 6 listopada 2008 roku o prawach pacjenta i Rzeczniku Praw Pacjenta (tekst jedn. Dz.U. z 2016 r., poz. 186 ze zm.)], in short: u.p.p.

3. Involuntary hospitalization

The most severe restriction of the patient's right of self-determination related to the prevention and treatment of tuberculosis interfering his rights and resulting in temporary deprivation of liberty is obligatory hospitalization. In case of tuberculosis, two categories of individuals are subject to obligatory hospitalization, i.e. persons developing active tuberculosis (spreading germs) and those who are reasonably suspected of lenient TB. It should be emphasized that it does not refer solely to pneumonic tuberculosis but other forms thereof too. Individuals suffering from pneumonic tuberculosis after active TB phase are not subject to this obligation (*a contrario* Art. 40 par. 1 point 1 of APCHI). Such persons are treated in open clinics, i.e. as outpatients.

As far as the first group is concerned, determination of temporary limits of obligatory hospitalization may appear problematic in practice. Although APCHI indicates that this obligation covers active TB period, unambiguous determination of this period may prove difficult[3]. Medicine points out that active TB period lasts app. two weeks. Spread of TB germs may be credibly confirmed by a microbiological test. Depending on the test method, the results may be known even after ten weeks[4]. Hence, it may be difficult to determine time limits of obligatory hospitalization in a reliable way. Since precise determination thereof is not possible, and due to the necessity of waiting for the test results and the ensuing time of waiting, actual period of hospitalization of a given individual may be longer than the duration of active TB period. However, the issue of waiting for test results depends on the present medical knowledge, which may not be contained within fixed legal framework. To improve the patient's situation, the provisions should indicate the obligation of immediate patient's discharge when the result of a microbiological test does not confirm active TB.

As far as the second group of individuals is concerned, the provision does not determine time limit of obligatory hospitalization. Nevertheless, it seems that this obligation expires when active TB is excluded. Yet, in order to determine this, it is necessary to carry out a microbiological test, which evokes the above-mentioned problems. What is more, with regard to this group of individuals, the legislator

3 Determining the infectious period of the patient was described by M. Korzeniewska-Koseła, Postępowanie wobec osób z kontaktu z chorym na gruźlicę, "Medycyna Praktyczna" 2011, No. 6, p. 34 and following.

4 E. Augustynowicz-Kopeć, Z. Zwolska, Mikrobiologiczna diagnostyka gruźlicy oraz zasady ochrony pacjentów i pracowników przed zakażeniami wywołanymi prątkami gruźlicy. Rekomendacje Polskiego Towarzystwa Chorób Płuc i Krajowej Izby Diagnostów Laboratoryjnych, Warszawa 2014 r., p. 9, http://kidl.org.pl/uploads/Rekomendacje_ Gruzlica.pdf (accessed: 2 May 2017).; Zalecenia Polskiego Towarzystwa Chorób Płuc dotyczące rozpoznawania, leczenia i zapobiegania gruźlicy u dorosłych i dzieci, "Pneumonologia i Alergologia Polska" 2013, t. 81, No. 4, p. 339.

requires that the suspicion of active TB be justified. It is not required with reference to individuals suspected of developing other diseases such as, e.g., diphtheria, cholera or typhoid, who are also subject to obligatory hospitalization (Art. 34 par. 1 point 2 of APCHI). The doctrine has accurately noticed that such distinction is not reasonable[5].

The above patients are admitted to hospital following different procedures; that is:

1) on the basis of a doctor's referral or without a referral if the patient's health or life is endangered, or
2) on the basis of an administrative decision issued by a sanitary inspector.

In order to fulfil the discussed obligation, when tuberculosis is suspected or diagnosed, a doctor or physician are obliged to instruct the patient about obligatory hospitalization and refer him or her to hospital, and inform State Poviat Sanitary Inspector competent for the place where infection or infectious disease have been diagnosed, who is authorized to undertake action to make the patient undergo treatment. Voluntary hospitalization does not arise complications connected with the fulfilment of the above obligation in the discussed situations. The problems arise when this obligation is fulfilled against the patient's will.

Then, not only the patient's right to consent to medical treatment is restricted but also his or her right to choose the hospital resulting from Art. 30 of the Act of 27 August 2004 on Healthcare Services Financed from Public Funds[6] as these persons should be admitted to the hospital assuring efficient isolation. In practice, these will mostly be specialist hospitals treating tuberculosis. Such restriction does not ensue from the above provision unambiguously. Nevertheless, it is more important here to guarantee efficient isolation and proper treatment taking into account public interest rather than individual's right and patient's right to choose the hospital. However, it is difficult to approve of the opinion presented in the literature[7] saying that "a doctor should arrange the place of patient's hospitalization and organize his or her transport to the proper medical facility"[8]. According to the definition contained in Art. 5 point 38 of AHSF, sanitary transport is an accompanying service that may be used solely in cases specified in the Act. These cases are set forth in Art. 41 of the above mentioned Act. The discussed case is not one of them. Undoubtedly, however, it does not help to achieve the purpose, i.e. protection of public health. The

5 A. Augustynowicz, I. Wrześniewska-Wal, Ograniczenie autonomii pacjenta w diagnozowaniu i leczeniu gruźlicy, "Pneumonologia i Alergologia Polska" 2013, t. 81, No. 2, p. 132.

6 Act of 27 August 2004 on health care services financed from public funds (Consolidated text Journal of Laws 2016, item 1793, as amended [Ustawa z dnia 27 sierpnia 2004 r. o świadczeniach opieki zdrowotnej finansowanej ze środków publicznych (tekst jedn. Dz.U. z 2016 r., poz. 1793 ze zm.)], in short u.ś.o.z.

7 As rightly see: T. M. Zielonka, Prawne aspekty diagnostyki i leczenia gruźlicy, "Pneumonologia i Alergologia Polska" 2013, t. 81, No. 2, p. 90-91.

8 A. Augustynowicz, I. Wrześniewska-Wal, Ograniczenie …, *op. cit.*, p. 133.

law, however, does not impose such obligations on doctors and therapeutic entities while the nature of a disease may not justify the extension of their obligations beyond statutory regulations. Nevertheless, it is hard not to agree with the statement saying that it is difficult to accept the situation when an active TB patient, or the one who is credibly suspected of it should decide himself or herself in which hospital they are going to undergo obligatory treatment and arrange transport thereto themselves. It does not help to achieve the purpose of the fulfilment of the obligation to undergo hospitalization and restrict contacts between active TB carriers and others as much as possible (as this person could use public transport to get to the hospital, which should not take place). Hence, valid provisions within the above scope need to be improved. It is necessary to introduce such obligations which will embrace the above situation in the list of cases when a patient is entitled to free sanitary transport.

4. The right to appeal to the court

The fulfilment of obligatory hospitalization *de facto* leads to the infringement of Art. 41 of the Polish Constitution resulting from Art. 31 thereof and being *lex specialis* thereto, i.e. the right of every human to freedom. Although Art. 41 par. 1 of the Polish Constitution enshrines a possibility of deprivation or limitation of liberty, but solely upon the principles and under the course envisaged by the statute. This regulation is completed by previously mentioned (in the introduction) Art. 31 par. 3 of the Polish Constitution. Obligatory hospitalization leads to the deprivation of human personal freedom[9]. Deprivation of liberty related to obligatory hospitalization must satisfy the test of proportionality mentioned in Art. 31 par. 3 of the Polish Constitution[10].

Furthermore, the Constitution enshrines that every person deprived of liberty not on the basis of a judicial ruling has the right to appeal to a court in order to promptly determine the legality of this deprivation. This right does not imply any specific measure or legal institution but only a mechanism which must be implemented each time[11].

9 P. Wiliński i P. Karlik wskazują na podobny, szczególny rodzaj pozbawienia wolności, jakim jest przymusowe umieszczenie osoby w szpitalu psychiatrycznym bez jej zgody na podstawie art. 23 ustawy o ochronie zdrowia psychicznego, P. Wiliński/P. Karlik (in:) M. Safjan, L. Bosek (ed.), Konstytucja RP. T. I, Komentarz, Warszawa 2016, p. 998; podobnie L. Garlicki, Polskie prawo konstytucyjne. Zarys wykładu, Warszawa 2014, p.108; see also the verdict of the European Court of Human Rights of October 16 2012 in the case *Kędzior v. Polska*, no .45026/07.

10 A. Ławniczak, Zasada poszanowania wolności i jej ograniczenia, (in:) M. Jabłoński (ed.), Wolności i prawa jednostki w Konstytucji RP. Idee i zasady przewodnie konstytucyjnej regulacji wolności i praw jednostki w RP, Warszawa 2010, T. I, p. 392 and following.

11 See: P. Wiliński nP. Karlik. (in:) Konstytucja…, *op. cit.*, p. 1001; P. Sarnecki indicates that the appeal is not a descriptive term, it does not have to be so titled and does not even have to be in written form, (in:) L. Garlicki, M. Zubik (ed.), Konstytucja Rzeczypospolitej Polskiej. Komentarz, t. II, Warszawa 2016, p. 217.

This issue is also related to the right to a trial envisaged in Art. 45 of the Polish Constitution[12] which, as explained in the Constitutional Tribunal's case law, encompasses in particular:

1) the right to a trial, i.e. the right to initiate litigation before the court;
2) the right to a proper course of judicial procedure in compliance with the requirements of justice and openness;
3) the right to a ruling, i.e. the right to obtain binding resolution of the case by the court[13].

It results from Art. 37 par. 1 of APCHI that a person subject to hospitalization is not deprived of the right to refuse to consent to undergo health services. The refusal to give consent, however, does not effect in the withdrawal from hospital treatment but merely ensues the obligation to inform the patient about measures of appeal he or she is entitled to (Art. 39 par. 2 of APCHI). If a patient does not give consent to hospitalization, APCHI obliges the head of a therapeutic entity where the patient is placed to inform him or her about measures of appeal he or she is entitled to. However, APCHI provisions do not determine what these measures of appeal are and do not regulate appellate proceedings in this case, in particular litigation before a court. Thus, they do not protect the right of the patient subject to obligatory hospitalization in discussed circumstances required by Art. 41 par. 2 of the Polish Constitution. This regulation arises reservations.

If hospital treatment is grounded upon an administrative decision issued by a sanitary inspector, it seems that the patient should be additionally instructed about the right and manner of appeal against this decision (the instruction is also contained in the administrative decision). The proceedings themselves connected with the examination of appeal would be carried out pursuant to the provisions of the Act of 14 June 1960 – the Code of Administrative Procedure[14]. However, it is not an appeal that may be submitted with a court. Meanwhile, the requirement to provide such a guarantee ensues from the Polish Constitution and, as pointed out by the Constitutional Tribunal in the judgment of 10 July 20017 (SK 50/06)[15], statutory regulations that may be the grounds of deprivation of liberty must be precise and

12 B. Banaszak, Konstytucja Rzeczypospolitej Polskiej. Komentarz, Warszawa 2009, p. 224.

13 Judgment of the Constitutional Tribunal of 11 June 2002, SK 5/02 (Journal of Laws 2002, No. 84, item 763) [Wyrok TK z dnia 11 czerwca 2002 r., SK 5/02, Dz.U. 2002, nr 84, poz. 763].

14 The Act of 14 June 14 1960 - Code of Administrative Procedure (consolided text Journal of Laws of 2016, item 23, as amended), [Ustawa z 14 czerwca 1960 r. – Kodeks postępowania administracyjnego (tekst jednolity Dz.U. z 2016 r., poz. 23 ze zm.)], in short k.p.a.

15 The Judgment of 10 July 2007 SK 50/06, Dz.U. Nr 128, poz. 903 [Wyrok z 10 lipca 2007 r., SK 50/06, Dz.U. Nr 128, poz. 903] with justification available at otk.trybunal.gov.pl/orzeczenia/teksty/otk/2007/SK_50_06.doc (accessed: 2 May 2017).

protective against excessive limitation of liberty. Current regulations are far from satisfying these requirements.

It is worth considering the regulation which was contained in the previously binding Act of 6 September 2001 on Infectious Diseases and Infections[16]. In the discussed situation, Art. 30 par. 3 thereof obliged a head of a unit to inform the patient about his or her right to appeal to a court in order to promptly determine the legality of deprivation of liberty and enable him or her to appeal to a court. Although this Act lacked procedural provisions regulating the procedure of litigation, for the reasons not revealed in the justification to the new Act on Preventing and Counteracting Human Infections and Infectious Diseases, this provision has a different reading.

Moreover, binding APCHI does not contain solutions similar to those included in the Act of 19 August 1994 on Mental Health Protection[17], i.e. regulation imposing the obligation of obtaining patient's consent for admission to hospital and determining a manner of controlling the legality of such admission in litigation. The guardianship court's control performed in effect of an individual having been admitted to psychiatric hospital under Art. 25 of the Act on Mental Health Protection is presented as a special case of just such control. In this case, the court assesses the grounds for the admission of an individual to psychiatric hospital and orders his or her immediate discharge if they are not found[18].

It should also be noticed that binding provisions of APR and the Act of 5 December 1996 on the Profession of a Physician and Dentist[19] do not introduce the obligation of obtaining patient's consent for hospitalization (except psychiatric hospital) but for the provision of health services. Admission to hospital itself is not the provision of health services but it occurs just for this purpose. It is sometimes preceded by the provision of health services in hospital and in some cases (scheduled admissions) it is not related to prior information about health condition conveyed by a doctor in hospital at admission but earlier, in a manner and scope required by the law.

Legal regulations should determine instruments allowing to pursue prompt control (review) of the legality of deprivation of liberty. Time is of considerable importance here from the perspective of individual's rights, and it should be short. Time limits to examine cases provided in the Code of Administrative Procedure do not guarantee fast pursuit of such control, and they refer to treatment undergone on

16 Ustawa z dnia 6 września 2001 r. o chorobach zakaźnych i zakażeniach (Dz.U. Nr 126, poz. 1384).

17 Act of 19 August 1994 on the protection of mental health (Consolidated text Journal of Laws 2016, item 546, as amended)[Ustawa z dnia 19 sierpnia 1994 r. o ochronie zdrowia psychicznego (tekst jedn. Dz.U. z 2016 r., poz. 546 ze zm.)].

18 P. Wiliński, P. Karlik, (in:) Konstytucja…, *op. cit.*, p. 1001.

19 Act of 5 December 1996 on the professions of a doctor and a dentist (consolidated text Journal of Laws 2017, item 125 as amended) [Ustawa z dnia 5 grudnia 1996 r. o zawodach lekarza i lekarza dentysty (tekst jedn. Dz.U. z 2017 r., poz. 125 ze zm.].

the basis of an administrative decision. Even though pursuant to Art. 35 § 1 of CAP, public administrative authorities are obliged to examine cases without unnecessary delay while Art. 35 § 2 of CAP sets a maximum monthly limit to examine a case, this time limit should be recognized as absolutely too long to guarantee patients the right to control the legality of deprivation of liberty. What is more, it is not judicial but administrative control. In the judgment of 2 June 1999, the Constitutional Tribunal[20] ruled that the right to a trial is preserved under such regulations which assure judicial control of a ruling, decision or other individual act shaping the subject's legal situation through the initiation of proceedings before a common or administrative court. Despite this, remoteness of control of the decision of a sanitary inspector by an administrative court makes the objectives of such control impossible to achieve.

Binding regulations do not determine mechanisms of judicial protection against unreasonable hospitalization and thus ensuing unreasonable deprivation of personal liberty. The need to provide protection in case of deprivation of liberty results directly from the Polish Constitution, which was further underlined by the Constitutional Tribunal in the judgment of 10 July 2007 (SK 50/06)[21]. The Constitutional Tribunal's case law has also pointed out that statutory regulations which may be the grounds of deprivation of liberty must satisfy the highest requirements, in particular with regard to their preciseness[22]. Binding regulations must be improved within this scope by the introduction of precise mechanisms of fast and efficient judicial control over the fulfilment of obligations related to obligatory hospital treatment and the legality of deprivation of liberty in such cases.

Hence, biding APCHI must be amended by the introduction of a possibility of appealing (regardless of its name) and specification of the procedure (referral to the provisions of out-of-court proceedings) connected with its initiation and examination. Actual protection would be guaranteed if such an appeal measure could be lodged through the entity where the patient is staying if a real possibility of serving correspondence directly to the patient in hospital was assured (upon which the entity providing the patient with health services is allowed to give information about him or her). Furthermore, an essential element of such protection is assuring the patient's right to be heard. Taking into account the grounds of obligatory hospitalization and the need to isolate the patient from other individuals who could be infected by him or her, the patient should be obligatorily heard in the place of his or her stay. Transporting him or her to a court for this purpose should also be out of the question.

20 The judgment of Constitutional Court of 2 June 1999, K 34/98, Journal of Laws No. 86, item 964 [Dz.U. Nr 86, poz. 964].

21 The judgment of Constitutional Court of 10 July 2007, SK 50/06, Journal of Laws No.128, item. 903 [Wyrok TK z 10 lipca 2007 r., SK 50/06, Dz.U. Nr 128, poz. 903], otk.trybunal.gov.pl/orzeczenia/teksty/otk/2007/SK_50_06.doc (accessed: 2 May 2017).

22 The judgment of Constitutional Court of 24 July 2006, Journal of Laws No. 141, item 1009 [Dz.U. Nr 141, poz. 1009].

It is also important to determine a group of people, apart from the patient, who also participate in this procedure. Participation of a prosecutor representing public interest seems reasonable here. It also appears reasonable for the entity admitting the patient to hospital to participate in the proceedings as they will also control the manner of this entity's conduct.

However, we should also pay attention to the fact that the introduction of appellate procedure to APCHI, as required by the Polish Constitution, could entail a double nature of review (control) proceedings under currently adopted solutions with regard to hospitalization based on a sanitary inspector's decision. This could lead to the situation when in effect of the appeal, a common court would decide that deprivation of liberty was unlawful and thus would order the patient's discharge from hospital. Meanwhile, the sanitary inspector's decision on obligatory hospitalization would become final and binding (due to the lack of challenge, or rejected appeal). Despite the common court's ruling on the hospitalization unlawfulness, the administrative decision would be enforceable under administrative execution proceedings. The court ruling and administrative decision would be contradictory, which cannot occur. This problem could be solved by the introduction of one judicial appellate procedure and a limited possibility of applying measures of challenge under administrative proceedings. However, this issue is debatable due to the right to challenge decisions and rulings enshrined in Art. 78 of the Polish Constitution as well as limited possibilities of implementing exceptions thereto. It seems that the best solution preventing the occurrence of such collision and concurrently assuring the above-mentioned guarantees is depriving a sanitary inspector of the power to impose obligatory hospitalization on a specific individual by the issue of an administrative decision. Instead, a sanitary inspector would be obliged to apply to a guardianship court for the issue of a ruling ordering such a person to undergo treatment. The grounds justifying obligatory hospitalization of a specific person could be verified already at this stage. Such a ruling should be immediately enforceable. However, the patient should be entitled to challenge it. Thus, judicial control of the legality of deprivation of liberty would be assured and legal transactions would not contain contrary resolutions of administrative authorities or administrative courts and common courts.

5. Conclusion

Valid legal regulations considerably limit the patient's right to decide about his own health and personal freedom in specific situations. They focus more on public health protection and the need to prevent and counteract infectious diseases. This assumption is right but individual rights cannot be ignored too. Restricting the patient's personal freedom, it is particularly important to concurrently provide

him or her with appropriate measures (instruments) to control regularity of applied restrictions in compliance with the requirements enshrined by the Polish Constitution. Regulations contained in APCHI should, by all means, introduce such guarantees within the scope of obligatory hospitalization.

One of the weaknesses of current regulations is a failure to regulate issues connected with providing patients subject to the discussed obligatory hospitalization with sanitary transport to the competent hospital and restriction of the patient's right to choose a medical service provider. In order to assure proper regulation thereof, it is necessary to oblige the entity referring the patient to hospital to find appropriate facility guaranteeing efficient isolation, provide sanitary transport there and oblige the patient to use this transport while explicitly limiting the right to choose the hospital to carry out the treatment. At the same time, the entity referring the patient to hospital should be obliged to search the hospital located as close to the patient's place of residence as possible.

Practical problems may arise with regard to the time of waiting for the result of a microbiological test confirming or not the fact of active TB period, which affects duration of hospitalization. These problems will concern individual cases and they are connected with the choice of microbiological methods of diagnosing tuberculosis, therefore they are related to the sphere of medical knowledge. Nevertheless, intending to improve the patient's situation, it would be purposeful to formulate an explicit order upon which the patient shall be immediately discharged from hospital if active TB is not confirmed.

However, the most essential point of the analyzed issue is the introduction of mechanisms of judicial control of the legality of deprivation of liberty. This control must concern not only the legality of a decision on deprivation of liberty itself but its prerequisites and the course of issuing it including a manner of its implementation, and in particular duration of deprivation of liberty[23]. Administrative control which may be currently launched upon the patient's initiative regards only hospitalization based on an administrative decision. It is merely limited to a possibility of appealing against this decision. A drawback of this solution, however, is the fact that the time of examining the appeal against this decision may appear too long to assume that the right to personal freedom is sufficiently protected. It is not judicial control enshrined by the Polish Constitution too.

It is particularly important to develop the course of proceedings connected with the launch and examination of such an appeal (regardless of the name adopted for this measure) that would actually provide the patient with a possibility of taking advantage of the protection he or she is entitled to despite his or her factual isolation. Such regulations should also oblige the court to examine the appeal within strictly

23 The judgment of the Constitutional Tribunal of 11 June 2002, SK 5/02, Journal of Laws 2002, No. 84, item 763 [Dz.U. 2002, nr 84, poz. 763].

specified and short time (the Constitutional Tribunal has depicted the need to assure such guarantees in the above mentioned case law), and thus ensure the guarantee of the court's prompt response through ordering immediate discharge of the patient if his or her hospitalization has been proved unreasonable (unjustified).

In conclusion of the above considerations, currently binding provisions should be completed by adding regulations concerning several issues vital for the assurance of proper protection of personal freedom of the patient obliged in above mentioned cases to undergo treatment in closed medical facilities. Nevertheless, such regulations should concurrently encompass the need to prevent spreading of such a dangerous infectious disease as tuberculosis.

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Commentary on the Judgement of the Court of Appeal in Krakow of 12 May 2015 (File No. I ACa 204/15)

Thesis: The right to plan a family and the ensuing right to legal termination of pregnancy under conditions specified in Art. 4a of the Act of 1993 on Planning Family, Human Foetus Protection and Conditions of Pregnancy Termination is a personal interest.

1. The judgment of the Court of Appeal in Krakow of 12 May 2015 in the case I ACa 204/15, which is a subject of this gloss, considers a significant problem of the case referred to in the subject literature as wrongful birth. The glossed case concerned a wrongful birth action launched by the mother of the child against the hospital for financial and non-financial damage caused by the doctors employed by the defendant who carried out the foetus examination, which, according to the claimant, prevented a discovery of the foetus impairment mentioned in Art. 4a par. 1 point 2 of the Act of 7 January 1993 on Planning Family, Human Foetus Protection and Conditions of Pregnancy Termination[1]. According to the claimant, in consequence of the above action, she was denied information about the foetus health condition and, in effect thereof, she was deprived of the right to make a decision on lawful termination of pregnancy, which eventually led to the infringement of her personal interest in the form of the right to decide about giving birth to a child.

1 Consolidated text Journal of Laws 1993, No. 17, item 78 as amended [Tekst jedn. Dz.U. z 1993 r. Nr 17, poz. 78 ze zm]. According to the cited provision: "An abortion may only be carried out by a physician if: (...) 2) prenatal tests or other medical conditions indicate a high probability of severe and irreversible impairment of the fetus or an incurable disease threatening his life"

To begin with, it should be clearly emphasised that the subject of the glossed judgment was the issue of liability for the admissibility of delivery of the child with genetic defects and other serious impairments against a potential will of her parents despite the occurrence of circumstances admitting lawful termination of pregnancy. Moreover, another issue that emerged therein was the exclusion of claim limitation due to exceptional and special circumstances grounded in the general clause of the "principles of community life" originating from Art. 5 of the Civil Code. Nevertheless, it should be noticed that quite other and yet important reasons decided about an unprecedented nature of this judgment in the light of the previously adopted case law[2]. Hearing the case, both instances courts focused on the axiological nature of general clauses in the context of the principle of equity and community life while somehow omitting the essence of the nature of contractual relationship that the relation within the scope of liability for damages for torts undeniably is. It should be pointed out here that the decision of the Regional Court that was upheld by the Court of Appeal evokes numerous controversies due to considerable substantive law defects. Generally, however, in order to discuss and understand the issues considered herein profoundly, it is necessary to analyze the facts of the case that were the grounds of the invoked judgment.

2. On 5 September 2005 the claimant came to SPZOZ[3] in S. After performing the USG test, doctor M.N., a specialist gynaecologist, confirmed the claimant's pregnancy as six weeks and two days. Next appointment was scheduled for 14 October 2005. The USG test was also performed on this day by doctor M.N. in the fourteenth week and second day of the pregnancy, in effect of which no abnormalities were found in the foetus. Next appointment took place on 12 December 2005 during which the claimant was examined by another doctor – P.S. – a specialist in gynaecology and obstetrics. After performing the USG test, the pregnancy length was confirmed as 22 weeks and 5 days while the registered results of the test were correct. Concurrently, on the same day, the claimant's foetus was X-rayed by the apparatus from the X-ray laboratory but the scan was not assessed by doctor P.S.. According to the description of the factual condition contained in the judgment, the scan disclosed changes in the foetus's spine and flatten skull bones.

Next appointment took place on 20 February 2006. After performing the USG test, the pregnancy length was recorded as 32 weeks and 3 days. Apart from the

2 See: the judgment of the Supreme Court of 13 October 2005, IV CK 161/05, Legalis No. 75250; the Supreme Court judgment of 6 May 2010, No. 248326] and the judgment of Supreme Court III CSK 16/08, Legalis No. 108175 and the judgment of Supreme Court of 12 June 2008, Legalis No. 108175, the judgment of the Supreme Court of 21 November 21 2003 V CK 16/03, Legalis No. 62304.

3 The Independent Public Health Care Institution, in accordance with the accepted views of doctrine and jurisprudence, has the status of an independent legal entity.

previously recorded results, a slight extension of one of the brain's side ventricle was noticed. It was the reason for referring the claimant to the superior referential centre, i.e. (...) Centre (...) in K., where on 22 February 2006 during the test a doctor diagnosed the foetus with hydrocephalus and recommended the claimant consult Dr D. in Ł.

After another consultation, the claimant was referred to the Institute Centre (…). On 28 February 2006 genetic USG and echo tests were carried out there in result of which the foetus was diagnosed with: "*spina bifida (split spine) of the lower back, a potentially incorrect structure between the neck and the chest as well as the backbone, functionally extended side ventricles of the brain, a potential development of microcephaly (to be further observed), and clubfeet*"[4]. Eventually, on 5 April 2006 the claimant gave birth to the girl who soon afterwards was diagnosed with meningocele of the thoracic and lumbar spine, paralysis and deformation of lower limbs as well as extended brain ventricles while the kidneys' USG test confirmed extended renal calyxes[5]. Soon after her birth, the child underwent neurosurgery involving hernioplasty and implantation of ventriculi-abdominal shunt, and started rehabilitation. Since her birth, the child is under permanent care of an orthopaedist, nephrologist, neurosurgeon and rehabilitation specialist.

For the above reasons, the claimant brought a suit against SPZOZ in S. on 9 November 2011 claiming PLN 500.000 compensation and PLN 43.513,29 damages from the defendant together with statutory interest from the day on which the suit was served, and determining the defendant's future liability for the effects of the incident (event) embraced by the suit.

According to the claimant, the defendant infringed her personal interest in result of unlawful action, in effect of which she suffered harm and damage. The claimant specified harm as all pain she suffered whereas damage as a total amount of expenses she incurred from the day on which the foetus was able to live independently outside the mother's body. At the same time, the claimant pointed out that the harm and damage were adequately caused by the defendant's unlawful action. The claimant also estimated that the claim for damages contained costs paid for the daughter's treatment.

The defendant applied for the dismissal of the claim on the ground of claim limitation. Additionally, he denied the claimant's arguments provided as the grounds of the suit.

Under the judgment of 4 November 2014, the Regional Court in K. awarded the claimant M.T. PLN 250.000 compensation from the defendant SPZOZ in S. together with statutory interest from 20 March 2012 until the day of payment, and PLN

4 Justification of the judgment of the Court of Appeal in Krakow of 12 May 2015 I ACa 204/15, Legalis No. 1315349.

5 *Ibidem.*

30.917,79 damages together with statutory interest from 20 March 2012 until the day of payment. The Court dismissed the claim in other parts and determined the cost of proceedings. Both parties appealed against this judgment.

Hearing the appeal of both parties against the judgment of the Regional Court on 28 April 2015, the Court of Appeal in Krakow, I Civil Department, dismissed both appeals as unreasonable (unjustified). At the same time, in accordance with the thesis quoted in the introduction to the article, the Court of Appeal ruled that the right to lawful termination of pregnancy under conditions specified in Art. 4a of the above quoted Act is a personal interest.

3. Referring to the most crucial arguments and theses related to the subject matter of this gloss that were contained in the reasoning to the discussed judgment, it should be pointed out that the Court of Appeal in Krakow treated the facts established by the Regional Court as its own. The Court of Appeal decided that they were established and examined correctly and complied with the current opinions of the judicature while satisfying all criteria indicated in Art. 233 § 1 of the Code of Civil Procedure. What is more, the Court decided that substantive law was not infringed in this case, which was the subject of appeal of both parties.

The Court decided that the right to plan a family and the ensuing right to lawful termination of pregnancy under conditions specified in Art. 4a of the Act of 7 January 1993 on Planning Family, Human Foetus Protection and Conditions of Pregnancy Termination is a personal interest. Furthermore, the Court approved of the opinion expressed by the first instance court according to which the right to decide about raising a disabled child is a personal interest of "the highest value". This opinion of the court was supported by the Supreme Court's case law expressed, *inter alia*, in the judgment of 21 November 2003[6]. In the discussed case, unlawfulness of doctor's conduct resulted from his violation of Art. 19 par. 1 point 1 of the Act of 30 August 1991 on Healthcare Facilities[7] as well as infringement of Art. 4 of the Act of 5 December 1996 on the Profession of a Physician and Dentist[8] saying that: *A doctor shall be obliged to perform his profession in accordance with the current state of medical science, using available methods and measures of preventing, diagnosing and treating illnesses in compliance with the rules of professional ethics and with due diligence*. The

6 V CK 16/03, OSNC No. 6, issue 104 [V CK 16/03, OSNC Nr 6, poz. 104].

7 Consolidated text Journal of Laws No. 91 item 468, as amended [Dz.U. Nr 91, poz. 468 ze zm.] The act has been repealed by the provisions of the Act of 15 pril 2011 on medical activity. Currently, the content of the provision of art. 19a of the Act on health care institutions, we find in the provision of art. 4 act of 28 January 2016 on patients' rights and the patient rights ombudsman [ustawa z dnia 28 stycznia 2016 r. o prawach pacjenta i Rzeczniku Praw Pacjenta] (tekst jedn. Dz.U. z 2016 r. poz. 186 ze zm.) Consolidated text Journal of Laws 2016, item 186 as amended]

8 Consolidated text Journal of Laws 2005, No. 226, item 1943, as amended [Dz.U. z 2005 r. Nr 226, poz. 1943 ze zm.].

Court believed that the violation of the above quoted provisions was the effect of a failure to provide due diligence by the doctor employed by the defendant while performing the USG tests, and then a failure to inform the claimant about the foetus's defects, which prevented her from making an informed decision about the pregnancy.

Moreover, it should be pointed out that according to the Court of Appeal, awarding the claimant PLN 30.917,79 from the defendant, the Regional Court violated neither Art. 361 § 1 of the Civil Code nor § 2 thereof. The Court noticed that the redress of damage embraces the loss while in this case the losses suffered by the claimant are extraordinary expenses ensuing from the fact that the needs of the disabled child generate more costs than those of a healthy child.

Furthermore, the Court of Appeal agreed with the opinion of the Regional Court on the grounds to apply Art. 5 of the Civil Code in the context of the limitation of claim raised by the defendant. The Court of Appeal believed that the limitation period had rightly begun to run at the moment of the child's birth. The Court also agreed that setting up the statute of limitation in this case is contrary to the principles of community life. The Court believed that even though the claimant was late with initiating the subject suit in effect of the violation of her personal interest by the defendant, the reasons for this delay ensued from the necessity to commit herself to taking care of the ill child.

What is more, the Court ruled in the discussed judgment that both parties' reasons for the appeal concerning violation of Art. 448 of the Civil Code are wrong. The Court decided that according to the facts of the case, personal interest of the highest value was indeed infringed while the awarded amount of PLN 250.000 was adequate in the meaning of the above quoted provision and absolutely satisfied its compensatory role.

4. To start with, it should be emphasized that the relevant case law is not totally uniform even though it is clearly predominated by the opinion expressed in the judgment of the Court of Appeal in Krakow in the case I ACa 204/15. It may even be said that a certain tendency becomes apparent, which somehow entails departure from elementary assumptions of substantive law regulating liability for harm or damage consistently or rigorously.

Nevertheless, as far as the described facts of the case are concerned, it is essential to focus on the content of Art. 361 of the Civil Code in connection with Art. 6 of the Civil Code containing a fundamental ground for the resolution of the occurrence of prerequisites of liability for damages, i.e. most of all, the adequate chain of cause and effect[9]. (Based solely on the data contained in the reasoning to the analyzed judgment) it seems that both first and second instance courts carried out hearing of

9 P. Sobolewski, Komentarz do art. 361 kc. (in:) K. Osajda (ed.), Kodeks cywilny. Komentarz, Warszawa 2017.

evidence relying only on the formal aspect based on the established infringement of the above specified provisions of law separating the proceedings from the substantive requirements set forth in the Civil Code. What should be considered here is the fact that even unquestionable acceptance of the expert evidence on a possibility of detecting the foetus defects already on 12 December 2005 (after analyzing three results of the USG tests), and the fact that at that time the foetus was not able to live independently outside the pregnant woman's body yet, do not decide about the liability of the doctor or SPZOZ employing him/her in relation to the pregnant woman who, not knowing about these defects, was deprived of the possibility to exercise the right to lawful termination of pregnancy. What is more, this is not decided even by the proved prerequisite of guilt of these entities[10].

The above and similar cases concern an extremely difficult problem of determining a peculiar counterpart of the so-called potential damage, i.e. the situation where a certain already specified event could affect another equally specified event which still has not occurred[11]. In other words, assuming that all evidence has been proved, the Court should examine whether the claimant would have exercised the so called right to abortion at all, that is if the pregnancy would have been terminated[12]. According to the norm expressed in Art. 6 of the Civil Code, the burden to prove this fact lies solely with her, and only if this circumstance had been confirmed, it would be admissible to consider the occurrence of the adequate chain of cause and effect[13]. However, neither first nor second instance court considered this while hearing evidence.

Obviously, it cannot be absolutely certainly determined whether the claimant would have undoubtedly decided to abort the child if the doctors had acted properly. Finally, it is not possible to prove beyond reasonable doubt that specific effects expected by a given entity (not giving birth to the child) would have happened if it had not been for the interference or unintentional change of conditions caused by undue performance of the obligation or tort. For example, the defendant could have argued

10 Particularly noteworthy are considerations regarding the fault and the degree of doctor's diligence, made by M. Sośniaka, Cywilna odpowiedzialność lekarza, Warszawa 1989, p. 103 and following. Z nowszej literatury zob. M. Nesterowicz, Prawo medyczne. Komentarze i glosy do orzeczeń sądowych, Warszawa 2017, p. 112 and following.

11 See: judgment of the Court of Appeals in Katowice of 15 November 2011 in case I ACa 689/11, Legalis No.1049546.

12 He seems to be right: E. Gniewek, iż dyspozycja art. 6 of Civil Code. it can also be a norm directed not only to the string, which for natural reasons depends on the proper determination of certain facts, but also to the court, see: E. Gniewek, Kodeks Cywilny. Komentarz, Warszawa 2016, p. 24.

13 The justification of the judgment of the Court of Appeal in Warsaw of 23 June 2015 issued in the case VI ACa 1167/14, Legalis No. 1338016. Analyzed in its pages, the actual situation differs from the case described in the vote, but also reflects the sense and perspective of circumstances that cannot be derived in a complete and direct way, and above all puts possible reasons for evidence, from which it does not absolve them current, even different ruling line.

that one should leave some space for natural human reflections emerging from fear or moral concerns that would have finally qualified the claimant's conduct as a future and uncertain event which, in consequence, would have led to the elimination of the reasons for litigation and its dismissal.

Nevertheless, this sphere should be understood slightly differently. As far as the discussed facts of the case are concerned, it should have been established that the claimant actually undertook important decisive and consistent steps in order to terminate pregnancy, and that her attitude fit a logical chain of actions whose natural aim and consequence was to exercise the rights guaranteed by the Act on Planning Family, Human Foetus Protection and Conditions of Pregnancy Termination[14]. To put it simply, it can be presented in the following way: if the claimant had known about the defects, she would have exercised the right to terminate pregnancy because her intention explicitly ensued from the witnesses' evidence, claimant's deposition and entries in medical records. Yet, the analyzed proceedings did not explain this.

The Court's decision saying that the doctors' conduct prevented the claimant from considering a possibility of terminating pregnancy is merely an extended chain of imprecise alternatives in effect of which almost everything is recognized as inherent personal interest that may not be infringed by any conduct not satisfying the expected norm. Such an attitude is in absolute opposition to the adequate cause and effect chain. Depriving someone of a possibility of considering something is merely stripping him or her of the right to reflect rather than the right to choose[15]. It makes his or her individual circumstances lack a possibility of reflecting on some issue and devoting some time to it with the concurrent "blessing" of not using this right. If in effect of such circumstances a congenitally diseased child is born, the claimant and then the court hearing the case should establish, step by step, effect after effect, what has led to such negative consequences[16]. A possibility of reflection would have caused that the claimant could have acted completely different. First of all, she might have not taken advantage of the very possibility itself at all, that is she might have not even analyzed her situation. Secondly, this consideration could have made her decide to terminate as well as continue pregnancy. All such doubts distort the adequacy of the cause and effect chain and should result in the dismissal of litigation[17].

14 The issues touched upon perfectly illustrate the case of the so-called "Łomża case" in the case being the subject of the decision of the Białystok Court of Appeal of 4 July 2008 I ACa 278/08, Legalis No. 158117. Nie zachodziły w niej wątpliwości, co do poczynań powódki i jej zamiaru wobec poddania się procedurze terminacji ciąży.

15 See: the Judgment of the Court of Appeals in Katowice of 15 November 2011 I ACa 689/1, Legalis No. 1049546.

16 On the issue of the adequacy of the causal relationship and the obligation to prove it see: the judgment of the Łódź Court of Appeal of 23 July 2013 I ACa 1160/12, Legalis No. 736121.

17 Compare the justification of the judgment of the Court of Appeal in Lublin of 21 April 2015, I ACa 894/14, Legalis No. 1249618.

The consequence of the Court's decisions is the need to award compensation also when the claimant unambiguously claims that she would have never exercised the right to terminate pregnancy as it is against her moral beliefs. Since the doctor failed to fulfil the obligation of informing the claimant, in result of which she did not have relevant knowledge, regardless of her attitude to the right to abortion, she was deprived of the possibility of considering the issue, which is to decide about the violation of personal interest. It is essentially *per absurdum* reasoning.

Furthermore, the Court of Appeal did not uphold the defendant's reason for appeal concerning violation of Art. 5 of the Civil Code with regard to limitation (which will be referred to later on). Nevertheless, this Article was actually violated – in the context of the analyses pursued above. The Bench has apparently disregarded the fact that even though the previous, dismissed suit in the case I C 1951/08 initiated by the statutory representative (now the claimant) did not satisfy the *rei iudicatae* directive but it somehow disclosed her reasoning and intentions. In the previous suit filed on her daughter's behalf, she claimed PLN 150.000 compensation from the same defendant for the doctor's negligence leading to the wrong forecast and diagnosis, failure to recognize prenatal disorders of the minor, in result of which she was deprived of undertaking possible preventive measure, i.e. commencing appropriate treatment, in particular operating the foetus before her birth[18].

Hence, it should be noticed that *nasciturus* is not a disposer of her rights. Therefore, decisions about specific invasive surgeries would have been made by her statutory representatives on her behalf. Whereas the representative believed that deprivation of a possibility of treatment and prenatal operation was harm. For this reason, the discussed lack of possibility of terminating the same pregnancy cannot be harm any more[19].

It is obvious that the previous suit in the case I C 1951/08 examined the harm suffered by the daughter of the current claimant. However, due to the child's young age (she was 2 years old at that time), the whole logical process was conducted by her statutory representatives and it directly illustrates their point of view. Therefore, the suit in the case I C 2892/11 became merely a different way, mechanism or path to win substantial compensation and damages.

Additionally, it should be noticed that in the light of the above court's arguments, insofar as harm suffered in result of the violation of the right to information may be actually established, proving financial harm becomes problematic. If the Court

18 In the context of the plea of limitation raised by the defendant in connection with improperly stated in the appeal allegation of violation of the principle of res judicata, it is worth reviewing the position of the Supreme Court in the judgment of 24 September 2009 IV CSK 43/09, Legalis No. 265790.

19 The abuse of law with regard to the protection of personal rights – commentary to art. 24 Civil Code.: E. Łętowska, K. Osajda, (in:) M. Safjan (ed.), Prawo cywilne – część ogólna. System Prawa Prywatnego, t. 1, Warszawa 2012/Legalis.

resolving the request decided that the infringed provisions of law violate the claimant's personal interest, the harm should remain in the adequate cause and effect chain with regard to the violated interest exclusively. In other words, if the claimant was not informed about the foetus's defects, in effect of which she suffered harm of infringed personal interest, then funds necessary for treatment, care or rehabilitation of her born child are not related at all to the infringement of her personal interest. They are certainly not adequately related in the meaning that has been previously adopted by the Polish doctrine of civil law.

The judgment is logically incoherent in this respect too. If the Court of Appeal did not uphold the alleged infringement of Art. 316 § 1, Art. 328 § 2 and Art. 233 of the Code of Civil Procedure finding the facts of the case established by the Regional Court as its own, it also approved of the opinion held by the Regional Court in Krakow, expressed in the following conviction: *according to the Regional Court, claiming PLN 700.000 compensation and arguing that this amount was to, at least partially, help to recover the minor O.'s health, the claimant appears to confuse the individuals entitled to compensation. Of course, improved health condition of the claimant's daughter will affect the intensity of suffered harm, nevertheless, the claimant is a person entitled to compensation because her personal interest has been infringed*. In consequence, the Court of Appeal decided that *the claimant has not demonstrated some costs*. The Court did not accept the request for *sensu stricte* procedural reasons and not due to those ensuing from substantial law. Meanwhile, under Art. 24 § 2 of the Civil Code, *if the infringement of a personal interest resulted in financial harm, the victim may demand redress thereof under general rules*. According to the Court, in effect of infringed personal interest, *the claimant was deprived of a possibility to consider*, but not deprived of her right to terminate pregnancy, which only then (as in the Łomża case[20]) could justify the recognition of the costs of treatment, rehabilitation and general care of the child as financial harm. Otherwise, there is no "bridge" spanning the infringement of personal interest and the costs claimed in the litigation to decide about the adequate cause and effect relation because we do not know if the claimant would have exercised the right to abortion. In brief, if the claimant had not sufficiently proved that she had intended to exercise the right to terminate pregnancy, it is not legitimate to assume that both financial and factual impediments resulting from the child's disability constitute harm suffered by her mother. Constructing a specific "chain" of interconnected dependencies joined by absolutely uncertain and improperly established circumstances does not permit to find them as regular, adequate and commonly known consequences of specified events. This way, the common court relocated the burden of maintenance of the disabled individuals from public funds into therapeutic entities, which does not appear to be justified.

20 See: the judgment of the Appeal Court in Białystok of 4 July 2008, I ACa 278/08, and Legalis No. 158117.

5. Finally, we should consider the issue connected with the limitation of claim duly raised by the defendant. We should think about the sense of existence of the institution of limitation if its duration is not categorically fixed and, generally, due to non-uniform case law, there is always a risk that the court hearing a case will decide to apply extensive interpretation of Art. 5 of the Civil Code. It is true that the Supreme Court's case law contains peculiar instructions (recommendations) permitting to withdraw from the prevailing limitation rule, but the courts hearing the discussed case have not applied it[21]. The problem is that the court hearing an individual case may find nearly any danger in the so-called principle of abuse of law. Relying solely on the analyzed facts of the case, it may be reasonably stated that there were no grounds to refer to Art. 5 of the Civil Code. Considering the reasons to the judgment, there are absolutely no doubts as to the fact when the claimant learnt about harm or damage, or when she literally experienced it. Finally, it is also undeniable that the claimant was physically and intellectually capable of suing much earlier as she had done it first time already on 31 July 2006. The claimant was over two years late. Therefore, in compliance with the prevailing opinion, this period is too long to justify talking about the abuse of law or harm suffered in effect of the application of this law[22]. Taking into account special and exceptional circumstances cannot directly lead to disrespect for substantive law preceded by reference to the allegedly higher principles. Hence, considering the complexity of the problem and the claimant's awareness of the harm she suffered as well as the period of delay, the author of the gloss believes the litigation should have been dismissed.

21 For example, it is worth paying attention to the judgment of the Supreme Court of 9 July 2008, V CSK 43/08, Legalis No. 340496.

22 Accurately about the possibilities and circumstances of the application of art. 5 of the Civil Code in relation to the alleged limitation of pleadings – a similar factual state – the Appeal Court in Katowice appealed – I Civil Department of 8 July 2016, I ACa 265/16, Legalis No. 1509011.

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A few Comments on the Rights of the Child as Depicted in the Book by Błażej Kmieciak "Prawa dziecka jako pacjenta" [Rights of Child as a Patient]

Wydawnictwo C.H. Beck, Warszawa, 2016, pp. 292

Reading Błażej Kmieciak's book, the reader asks the question why the child needs their rights. The answer to this question may be twofold. To protect the child who is as precious and exceptional as any human being or, additionally, to protect other values such as family or public interest. The author himself confirms the occurrence of certain discord between the values writing that children rights compete with family and State interests. This way we reach the core of the problem, namely the fact that the child is usually a member of a family based on the relation of subordination, where children are subordinated to their parents, as well as a part of the community – its future and next generation. Hence, this evokes a debate on the wording (tone) of the term of parental authority, doubts related to the introduction of changes in terminology resulting from the willingness to underline the importance of another element of the relation between the child and parents – instead of authority, care or responsibility[1]. Despite the tendencies observed by the author in the book that emphasize more partner-like family relations, he shares the opinion of J. Ignatowicz and M. Nazar[2] saying that "the term of authority strengthens respect for parents, which is of considerable importance when individuals with not fully developed

1 Compare the justification for amending the Family and Guardianship Code from 7 December 2007, print No. 629, p. 7 [uzasadnienie zmiany kodeksu rodzinnego i opiekuńczego z 7 grudnia 2007 r., druk nr 629, s. 7], http://ww2.senat.pl/k7/dok/sejm/022/629.pdf (accessed: 13 March 2017).

2 J. Ignatowicz, M. Nazar, Prawo rodzinne, Warszawa 2006, p. 284.

personality are subject to the duty of care. This entails a special obligation of parents to provide safety and security to children under their care" (p. 210-211). Apparently, such an attitude is not uncommon. The reasons to the amended Family and Guardianship Code of 2007 set forth that "Parents should have "executive" powers in relation to the child and his or her property who, due to their physical, psychological and intellectual condition and a lack of (or little) life experience is not able to make independent decisions in a manner assuring his or her wellbeing (interest). Parental authority does not exclude considering the child's opinion or co-deciding about the child's matters. Hence, it is doubtful whether replacing the term "authority" with "care" would have a significant "edifying" tone. We cannot disregard social and moral realities (the instable system of assessments and values, a decline and lack of moral authority (models) at the time of accelerated social and moral changes). [..] The terms "care" and "parental responsibility" excessively expose only some aspects of the complexity of the rights and duties embracing the legal situation of parents in the relation towards the child and third parties."

However, to support arguments for the change of terminology it can be said that in international instruments that originated at least during the last two decades of the 20th century, the notion of parental responsibly has been successfully applied[3]. It seems that this term illustrates parents' duties towards the child in the best way; it is indeed responsibility for children because parents are responsible for the child's actions. But above all, parents are responsible for development of a small and then young man so that he or she becomes a fully competent (that is not hurt, or emotionally and physically humiliated) adult. The term of authority (power) is associated with something achieved with the use of force, physicality, or violence while domestic violence is forbidden and parents are obliged to fulfil or help the child to fulfil his or her rights. It is not without reason that parents are called the children right's guardians, which is explicitly underlined by the author. On the other hand, due to the State interest, it is purposeful to quote the opinion held by L. Petrażycki, which was also used by the dissertation's author in a slightly different context. "Law is a psychological factor of social life and it acts psychologically. Its action involves, first of all, triggering and suppressing incentives to different actions and omissions thereof (motivational or impulsive operation of law). Secondly, it strengthens and develops some inclinations and features of a human character and weakens and eradicates

3 Compare Recommendation No. R (84) of 28 February 1984 on parental responsibility adopted by the Committee of Ministers of the Council of Europe; M. Safjan (ed.), Standardy prawne Rady Europy. Teksty i komentarze, t. I – Prawo Rodzinne, Instytut Wymiaru Sprawiedliwości, Warszawa 1994, p. 201 and following, Convention on jurisdiction, applicable law, recognition, enforcement and cooperation in respect of parental responsibility and measures for the protection of children, done at The Hague on 19 October 1996.

other"[4]. The issues depicted in B. Kmieciak's work refer to the sphere which is often the target of the State scheduled activity regarding limitation or increase of a birth rate, which entails penalization or legalization of abortion, restriction of legalization of surrogacy, etc. The author does not mention this. He has not included this problem in his work even though it is undeniably related to the subject matter of his paper.

Błażej Kmieciak asked himself more than one question and successfully found the answer thereto taking into account not only the perspective of law but also social sciences, in particular pedagogy, psychology and sociology. These questions are as follows: 1) What are the child's rights as a patient? 2) Can we discern a different scope of the rights the child is provided with pursuing the analysis of his or her development as a human being? 3) How are the child's rights protected during the provision of medical services? 4) What areas of the minors' rights are most often violated? 5) Can we perceive the emergence of "new children's rights" at the beginning of the 21 century? 6) How does the edifying and informative function of law affect development of the children's rights culture?

As a human being , the child is entitled to all rights that can be rationally distinguished from the entire catalogue of human rights as those inherent to an immature man. Generalizing and not pursuing an unnecessary analysis of these rights here, it can be said that children enjoy human rights and additionally those which are to protect their distinctness from adults and their exceptional sensitivity – so-called sector rights. Attempting to define human rights, the element of their universal necessity has evoked certain doubts[5]. However, in the context of multiculture, it meant that human dignity may be respected while man is entitled to specific rights even without the existence the catalogue of human rights, human rights as such and any rights called likewise. Despite this, both UN Covenants on Human Rights[6] and the European Convention on Human Rights and Fundamental Freedoms[7] are popular (common) and a number of countries signatories thereto is significant. In

4 L. Petrażycki, O ideale społecznym i odrodzeniu prawa naturalnego, (in:) O nauce, prawie i moralności. Pisma wybrane, Warszawa 1985, p. 157.

5 See the definition of human rights: a set of situationally stratified, natural human capacities, as to individual, but socially determined, equal, inalienable, temporarily permanent, subjectively universal, subjectively and territorially (and to some extent also culturally) necessary and always arising from the natural to every man of personal dignity. B. Gronowska, T. Jasudowicz, C. Mik, Prawa człowieka. Dokumenty międzynarodowe, Toruń 1996, p. 364.

6 International Covenant on Civil and Political Rights – 169 states-parties, https://treaties.un.org/Pages/ViewDetails. aspx?src=IND&mtdsg_no=IV-4&chapter=4&clang=_en (dostęp 13/03/2017), International Covenant on Economic, Social and Cultural Rights – 165 states-parties, https://treaties.un.org/Pages/ViewDetails. aspx?src=TREATY&mtdsg_no=IV-3&chapter=4&clang=_en (accessed: 13 March 2017).

7 45 ratifications within the Council of Europe, 2 signatures without the following ratification, http://www.coe.int/en/web/conventions/full-list/-/conventions/treaty/009/signatures?p_auth=f2GPfawW (accessed: 13 March 2017).

some countries, as in Great Britain, the legislation is evaluated with regard to the compliance with human rights derived from the European Convention on Human Rights and Fundamental Freedoms, which is one of the most important sources of law in the country whose system of law, paradoxically, is unwritten – the common law system[8]. Moreover, the Convention on the Rights of the Child is the most popular one among all international conventions worldwide[9].

According to P. Aries, the author of the book "*Centuries of Childhood*" (1962), the concept of childhood as a stage or circumstances distinct from adulthood appeared in the second half of the 17th century[10]. Perhaps it happened mainly due to the fact that John Locke[11], one of the pillars of the philosophical concept of human rights, became interested in childhood. On the other hand, the need to equip children with rights was first expressed not so long ago – as late as at the beginning of the 20th century – by Englantyne Jebb, a founder of the organization *Save the Children*[12]. Next declarations of children's rights of 1923[13] and 1959[14] as well as the Convention of the Rights of the Child of 1980 together with Protocols have designated quite permanently the range of protection. Despite being a little man, the child may also be a patient. Hence, if we accepted a wide range of the children rights' protection ensuing from the Convention, and such an intention may be derived from a very great interest of the countries therein and the highest number of its signatories as compared to any other international instrument worldwide, we should absolutely agree with the opinion expressed by Błażej Kmieciak in the book saying that "as a patient, the child, similar to an adult, enjoys the full right to respect for dignity, intimacy, access to health services adequate to the current state of medical knowledge, experience of death as inoffensively and painlessly and as possible, etc." (p. 282).

Although the author's considerations mainly refer to the Polish legal order, in some issues he reaches beyond this areas, for instance with regard to consent for the child's treatment, or foreign examples concerning new challenges. Within the context

8 Under Human Rights Act of 1988, which article 6 (1) provides that it is unlawful any action of a public authority contrary to the rights arising from the Convention. See: A. Gillespie, The English Legal System, Oxford 2009, p. 139-174, C. Elliott, F. Quinn, English Legal System, Harlow 2008, p. 253-275.

9 196 States Parties, outside the US, which have not yet ratified the Convention see: https://treaties.un.org/Pages/ViewDetails.aspx?src=TREATY&mtdsg_no=IV-11&chapter=4&clang=_en (accessed: 13 March 2017).

10 See: D. Archard, Children: Rights and Childhood, Nowy Jork 2015, p. 24.

11 *Ibidem*, p. 1-16

12 J. Starczewski, Z historii opieki nad dzieckiem. Karta praw dziecka, "Dom Dziecka" 1958, No. 4, p. 194, K. Bagan-Kurluta, Przysposobienie międzynarodowe dzieci, Temida2, Białystok 2009, p. 307.

13 J. Starczewski, *op. cit.*

14 Declaration of the Rights of the Child, G.A. res. 1386 (XIV), 14 U.N. GAOR Supp. (No. 16) at 19, U.N. Doc. A/4354 (1959).

of referring to foreign legal solutions, I wish he presented differences that could result from the mutual comparison of two concepts of the beginning of human life protection: the first one, supported by the author, which is based on the regulation ensuing from Art. 2 of the Act on the Ombudsman for Children (from conception to the age of majority)[15], and second one, based on the definition of a child under Art. 1 of the Convention on the Rights of the Child (a child means every human being below the age of eighteen years unless under the law applicable to the child, majority is attained earlier)[16]. Within this context, the author rightly repeats after M. Andrzejewski that a ban on abortion would be an essential foundation upon which the term "child" should be analyzed[17]. All the more, due to the lack of the legislator's consistency on the limit of the child's protection in criminal and civil law as well as the Act on Infertility Treatment (in the light of which embryos will live a separate life, abstracted both from the child and the woman, not mentioning the man)[18], and the use of terms "embryo", "foetus" or "conceptus" with regard to the prenatal period.

The work consists of six chapters. The first two are introductory – they refer to the child as a human being and beneficiary of human rights and patient's rights. The first chapter is devoted to the rights of the child as compared to human rights as well as the category of these rights and the child as an immature man. The next part of this chapter titled *Children's rights – selected aspects* (§ 4), appears to be mostly limited to the presentation of the rights from the theoretical perspective (in different contexts and aspects – the same terminology has been mistakenly used here in the title of the chapter and the title of the subchapter, which is not only a repetition (*Children's rights – selected aspects*) but, additionally, it does not provide the reader with any information – it does not present the background against which the author wants to analyze these rights). The second chapter titled *Children's rights and patient's rights* consists of two parts: the first one devoted to the patient's rights, and the second one – to the minor patient's rights, while the latter one refers to the sources of the rights' protection and selected institutional actions to defend them. The subchapter concerning the examples of activities discusses solely those undertaken by the Ombudsman for Children and Patient Ombudsman. It could have been shown in the title and, additionally, indicated whether other institutional activities simply do not exist, or those selected are for some reason the most essential. In this part the author refers to a very interesting issue, namely why patient's rights were regulated as late as

15 Act of 6 January 2000 on the Children's Ombudsman (Journal of Laws 2015, item 2086 as amended [Ustawa z 6 stycznia 2000 r. o Rzeczniku Praw Dziecka, Dz.U. z 2015 r., poz. 2086 ze zm.].

16 Convention on the Rights of the Child adopted by the General Assembly of the United Nations of 20 November 1989 (Journal of Laws 1991, No. 120 item 526, as amended) [Konwencja o Prawach Dziecka przyjęta przez Zgromadzenie Ogólne Narodów Zjednoczonych 20.11.1989 r. (Dz.U. z 1991 r., Nr 120, poz. 526 ze zm.)].

17 M. Andrzejewski, Prawna ochrona rodziny, Warszawa 1999, p. 172.

18 Ustawa z dnia 25 czerwca 2015 r. o leczeniu niepłodności, Dz.U. z 2015 r., poz. 1087.

at the end of the 20th century. He rightly sees the causes thereof by quoting A. Doroszewska "in wider transformations of social life related to the emergence of consumer movement and increased awareness of inherent consumer rights"[19]. It seems that similar to the reference to the increasing child's awareness discussed by the author in connection with new challenges for the minor patient's rights, it can be well stated that ICT revolution carried out by traditional media and the Internet brought about changes in the relation between a patient and doctor from the relation: an object of medical treatment – a decision-maker of supernatural or nearly divine power, into the relation: an informed demanding patient – a man without the attribute of divinity using therapeutic methods. Three further chapters are, in sequence, devoted to: the child's right to medical services, the minor patient's right to information, and the child's right to give consent for the provision of health services. I do not really know why chapter III titled *The child's right to health services* is followed by the introductory subchapter to be continued by another one titled *The child's right to health services – selected aspects*. What is more, chapters III and IV refer solely to the patient's right to health services in life threatening circumstances discussed in chapter II but not generally to the right to health services. It is a pity that subchapter III devoted to the challenges and dilemmas does not discuss the issue of girls' vasectomy (not only in connection with danger to the child's life). This extremely controversial topic was the subject of the doctrinal and jurisdictional debate in the common law countries – Great Britain, the USA and Canada[20]. Interestingly and importantly enough, in two landmark judgments on the vasectomy of girls at the beginning of puberty, the issue of the so called basic human right to reproduce have been presented differently. In the first judgment, Judge Heilbron ruled that vasectomy should be banned as it is contrary to the child's interest and irreversibly and non-therapeutically deprives the child of the right to reproduce[21]. On the other hand, in the second judgment, Lord Justice Hailsham decided that the basic human right to reproduce does not matter at all if a person lacks capacity to make an informed decision with regard to matters related to pregnancy and giving birth to a child[22]. The admissibility of depriving the child of a future possibility to reproduce remains

19 A. Doroszewska, Socjologiczne aspekty praw pacjenta – analiza wybranych problemów, (in:) T. Mróz (ed.), Uwarunkowania prawne, ekonomiczne i socjologiczne funkcjonowania wybranych systemów ochrony zdrowia, Białystok 2011, p. 122.

20 Re D (Sterilisation) [1976] Fam 185, Re B (A Minor) (Wardship: Sterilisation) [1988] AC 199, Re P (A Minor) (Wardship: Sterilisation) [1989] 1 FLR 182, T v T [1988] Fam 52 And many other later cases.

21 Re D (Sterilisation) [1976] Fam 185. The case concerned an 11-year-old girl suffering from Sotos syndrome. Compare: A. Bainham, S. Cretney, Children. The Modern Law, Bristol, 1993, p. 255-257.

22 Re B (A Minor) (Wardship: Sterilisation) [1988] AC 199, a case called Jeanette's case regarding a 17-year-old girl with a five-year-old mentality. See: A. Bainham, S. Cretney, *op. cit.*, p. 257-259.

controversial even if her mental conditions differ from the norm. Disregarding unfortunate historical associations evoked by vasectomy carried out on mentally ill people, the question arises here whose interest is protected through vasectomy, and whether it is actually the child's interest. What is more, I think that discussing legal aspects (are there any illegal ones the author does not depict?) of the protection of the child's rights in the prenatal stage (§ 4) and legal aspects of in vitro conception just in this chapter is not really reasonable. For instance, there are considerations therein on embryos as patients – this may evoke doubts as to their other rights (if they have any) apart from the right to medical services. Furthermore, the part devoted to the patient's right to information contains very interesting comments on intimacy and confidentiality and unaccompanied visits at the doctor's, in particular from the point of view of children during puberty on the threshold of adulthood. Failure to report this in medical records is particularly interesting and controversial. It implies concealed prescription of contraceptives, attestation of untruth and doctor's criminal liability for it. It would be reasonable here to refer to the British case law and analyze the judgment in the case of Gillick v. West Norfolk & Wisbech Area Health Authority[23] and its impact on further proceedings in similar cases. The author's critique of the model of cumulative consent adopted in Poland is worth considering. However, in the context of the child's increasing maturity developing with the lapse of time, it seems debatable to apply the formula used for a medical experiment (a written consent of the child's statutory representative and, if the child attained 16 years of age, or did not attain 16 years of age and is able to sufficiently understand the situation and express his or her opinion on the participation in the experiment – his or her written consent too) "as standard conduct with regard to any surgeries and other medical interventions the minor is subject to. Since the child is not fully mature, he or she is not able to (and it should be assumed they should not be able to) make decisions themselves" (p. 236-237). Chapter VI (*The child's rights in medicine, new questions – new challenges)* refers to three contemporary challenges identified by the author. They embrace: 1) sex-changing treatment for children (double mastectomy of a minor female patent) in Poland; 2) withholding any medical and nursing treatment of the disabled or terminally ill children; 3) surgical limitation of physical development of profoundly physically and intellectually disabled children – in both cases in relation to foreign cases (Ashley Treatment and the case of Nancy Fitzmaurice). It seems that a new challenge faced by the contemporary world is the application of in vitro conception procedures, anonymity of genetic material donors, or the use of medical procedures in surrogacy (surrogate motherhood). This thesis, perhaps too premature in Poland, or paradoxically to late (due to the implementation of the Act on Infertility

23 [1985] UKHL 7 (17 October 1985). Por. K. Bagan-Kurluta, U. Drozdowska, Significance of minors' capacity assessment in the Polish and English law, Progress in Health Sciences . Dec 2015, Vol. 5, Issue 2, p. 149-159.

Treatment), refers well to the situation in many countries – and the author does not limit his considerations in this part of the book to Poland. Presenting examples of new challenges, he refers to two foreign cases (with regard to three examples contained in the book). It is true that the author perceives and depicts in the conclusion the novelty of the situation resulting from the development of medical science. He writes that this entails "the necessity to ask new questions about the rights of the child as a patient also in a similar biotechnological situation which, as depicted, has apparent impact on the future of an already born child" (p. 285). Writing about the perspective of new rights of the child-patient, the author points out to a certain type of exceptionality of in vitro method "during which a child is not only "created" but also diagnosed. He or she is then an "element/part" of actions undertaken during this procedure".

The work is abundant with conclusions, which have been included not only in the final part. It is absolutely worth noticing those which concern the child deciding about himself or herself – the exclusion of parents from a decision-making process, leaving the child alone with a doctor without a natural "guarantor" obliged to fight for his or her rights", but also abortion, prenatal adoption, a different range of protection depending on the branch of law and child's development (prenatal and postnatal stage), a distinction between the child's lack of or limited capacity to legal action and a possibility of expressing efficient consent for treatment by him or her. Another debatable issue raised by the author is the question about the future legal situation of a child-patient at the moment of being born by the biologically alien woman within the aspect of a possible protection of the child's right to healthcare corresponding to the up-to-date state of medical knowledge as well as the right to identity, family life, etc.

Summing up, Błażej Kmieciak's book is a very interesting approach to the problem of the rights of the child as a patient. It is a part of incessant interest in the rights of the child as a discipline of science and legislative achievement in the form of the Convention as well as another voice in the discussion on how to counteract their violation. The rights of the child are considered from the perspective of their compatibility with the rights of parents and state interest. None of the legal acts adopted so far have implied the child's empowerment. The child remains an element of the family and an individual building the society's future. The legislator decides about the legal framework of the child's consent for treatment, which has been presented in the publication, as well as the minimum age of acquiring legal competence to marry, obtain a driving licence, have sexual intercourse not fearing litigation, drink alcohol, and vote[24]. Some decisions of the legislator may appear peculiarly hilarious, e.g. why it has been decided that an 18 years old American has the right to marry but may not (for another three years) drink alcohol. These detailed regulations at

24 D. Archard, *op. cit*., p. 23.

least partially remain outside the sphere of the conventionally established catalogue of rights whereas they certainly belong to the sphere of the State's legislative empire. The legislator essentially decides about the range of liberties enjoyed by the child within the limits of the Convention. Although it is difficult to talk about the child's empowerment, the rights of the child have been empowered from human rights in their conventional catalogue. Their empowerment means that the child is entitled to them regardless of his or her dependence on parents. The best proof thereof is the judgment of the European Court of Human Rights in the case of Mennesson and others v. France[25] and in the case of Labbassee v. France[26]. The Court ruled that in France a lack of possibility to register a child born in result of the surrogacy contract does not violate the right to family life of adults (sociological parents) while at the same time it violates such a right with regard to children. Applications submitted by the parents and children were interconnected for obvious reasons and they were examined together while the Court's judgment confirms separateness of the rights of the child and the rights of adults (in this case of the sociological parent) and their independence. The right of the child should empower the child's interest and wellbeing; their fulfilment should entail the fulfilment of child's welfare. Yet, it is not always like this, and not always protecting the child legally means acting in compliance with the child's interest. Błażej Kmieciak's book considers this problem to a large extent. It was written at the time of changing morality as well as unquestionable acceptance of the child's welfare as a prerequisite in the proceedings dealing with such matters. The subject may be presented in many contexts and the introduction of various distinct legal solutions may be advocated for. The author has successfully realized his own concept.

25 Mennesson v. France, Application No. 65192/11), the judgment of 26 June 2014, http://hudoc.echr.coe.int/eng#{"fulltext":["Mennesson"],"documentcollectionid2":["GRANDCHAMBER", "CHAMBER"],"itemid":["001-145389"]} (accessed: 6 April 2017).

26 Case of Labassee v. France, Application No. 65941/11) the judgment of 26 June 2014, http://hudoc.echr.coe.int/eng#{"itemid":["001-145180"]} (accessed: 6 April 2017).

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