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Statements for the event of incapacity to consent: current issues and postulates regarding future law

Abstract

The issue of providing statements in the event of incapacity to consent to medical treatment is extremely complex. The international legal community grapples with terminological confusion, with the terms "living wills", "*pro futuro* statements", "advance medical directives", and the classic "statements for the event of future incapacity to consent" being used to describe the concept in question. What exactly, however, does this concept involve?

The article points out the legal differences between the classic expression of consent or objection as precisely defined in the Polish Act on the Profession of Physician and Dentist, and the making of a statement in the event of future incapacity to consent. The issue of the form required for the delivery of such statements was considered. Relevant Polish legislation was analysed with the legal basis facilitating (or not) the making of such statements being indicated and possible risks for physicians providing medical services to individuals who had delivered such statements being presented. Also presented are the necessary changes to Polish legislation regarding the institution of living wills as well as postulates regarding future law.

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Keywords: living will, *pro futuro* statement, advance medical directives, medical law, palliative care, patient autonomy, patient rights

Introduction

The issues of patient's consent and objection to a medical procedure are comprehensively regulated in the Act on the Profession of Physician and Dentist (hereinafter: PPD) [1]. As a general rule, consent to a medical procedure is given by an adult, incapacitated patient [PPD article 32(1)]. If the patient is a minor or incapable of giving informed consent, the consent of the patient's legal representative (a.k.a. surrogate consent) is required whereas, if the patient has no legal representative or if communication with the patient is impossible, the permission of the guardianship court is required [PPD Article 32(2)]. The law provides for situations in which consent for a medical procedure is not required, with the physicians having the right

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to take necessary measures when a delay caused by the consent procedure would endanger the patient with the danger of loss of life, grievous bodily harm, or serious health disorder [PPD Article 34(7)].

The problem arises when the patient is unable to decide on their own due to a progressive disease, being unconscious or receiving medication, among other things. With a view to fully implementing the autonomy of will directive, the patients deliver statements in cases of losing the ability to decide for themselves. The statement can take the form of both consent and objection as well as of indication of preference to undertake or not undertake certain measures. An example can be provided by a statement of objection to blood transfusion should it be required as made by Jehovah's Witnesses, or the indication of a preference for specific treatment as made by patients losing their consciousness due to progressive Alzheimer's disease [3]. At the heart of the institution of *pro futuro* statements lies the desire to extend the individual's ability to decide on their own fate beyond the moment the individual loses their ability to consciously express their will [4].

Without a doubt, the issue of providing statements in the event of future incapacity to consent to medical treatment is extremely complex. The international legal community grapples with terminological confusion, with the terms "living wills", "*pro futuro* statements", "advance medical directives", and the classic "statements for the event of future incapacity to consent" being used to describe the concept in question. While it is not the objective of this article to suggest the superiority of any of these terms over the remaining ones, the term "*pro futuro* statements" is used herein for the sake of clarity and precision. The article outlines the history of *pro futuro* statements and points out the differences between these and the classic consent and objection statements. The legal basis facilitating (or not) the making of such statements is analysed, and the issues regarding their legal characteristics and form are discussed. Postulates for future law are also presented.

Historical background

The term "living will" became widespread after being first used in 1969 as the title of a document drawn up by an American lawyer, Luis Kutner, in which an adult and competent individual expressed their directives regarding medical treatment in the event of incapacity. In the early stages of shaping the legislation, the statements concerned the patients' preferred course of action to be taken by physicians in advanced disease states. California was the first US state to pass legislation regulating living wills (Natural Death Act) in 1976 [5]. By 1986, similar legislations were enacted in 41 states. In 1991, the United States passed the Patient Self-Determination Act [6]. Healthcare providers, including hospitals and nursing homes, were required to inform patients of their rights to provide advance statements of intent in accordance with state law.

Over time, the concept of *pro futuro* statements has evolved, resulting in an expansion of their scope to situations other than those related to discontinuation of medical life support [7]. In Europe, the issue of *pro futuro* statements was first addressed in the Convention on Human Rights and Biomedicine as concluded in Oviedo on April 4, 1997 (hereinafter: the Oviedo Convention) [8]. The document used very general terms to indicate that previously expressed will regarding medical interventions to be provided to the person concerned should be taken into account if they are unable to express their will at the time of such intervention. However, the provisions of the Oviedo Convention do not specify the form in which such a statement should be delivered, nor do they precisely delineate the scope of medical interventions to be undertaken. Despite the attempts at fitting the concept of *pro futuro* statements within the existing legal framework in Poland or at direct application of the provisions of the Oviedo Convention have failed to deliver satisfactory results, the Convention indisputably provides an important interpretative guideline for understanding the institution of *pro fut*uro statements in the Polish legal system [9].

Pro futuro statements *vs.* the classic concept of consent and objection

Although both types of declarations are made in relation to future events, the basic difference between classic consent or objection and the *sensu stricto pro futuro* statements relates to different situations in which the statements in question are made. Although the doctrine is divided on this point, the position of Bosek, who distinguishes between two basic types of situations, is legitimate [10]. The classic consent or objection is emphasized to belong to the group of statements that concern future treatments with uncertain outcomes while being delivered to the physician in specific treatment situations. Thus, they relate e.g. to cases of patients being informed of the possibility of postoperative complications, but nevertheless giving consent for the procedure to be carried out. In this case, there is no doubt regarding the applicability of the provisions of the PPD Act.

The *pro futuro* statements, on the other hand, include the statements of preferences regarding medical

management methods or entities to provide medical procedures being formulated before there are medical indications for the procedure. A good example can be provided by the statements made by Jehovah's Witnesses with regard to cases involving blood transfusion being needed. There may be some doubt as to whether an objection to undergo a blood transfusion procedure expressed in the form of a written statement by a victim of a traffic accident is a *pro futuro* statement or a classic objection according to PPD. In light of the above reasoning, if the statement (and therefore consent, objection, or other declaration) was made before the prerequisites for the procedure were met, it should be treated as a *pro futuro* statement.

It is suggested, however, that *pro futuro* statements are intended to indicate the preferred method of treatment only if the patient is unable to independently express their will. If the patient regains consciousness for at least a brief period allowing them to make an independent decision, the *pro futuro* statement becomes irrelevant, and the PPD provisions apply. It should be emphasized that statements expressed following a misdiagnosis of a disease are not to be considered *pro futuro* statements, although misdiagnosis can obviously result in liability (criminal, civil, disciplinary) and all the related consequences on the part of the physician.

The legal basis for *pro futuro* statements

Rather than being regulated directly, the *pro futuro* statements are addressed within the Polish legal system indirectly within the context of the physician's duties and the patient's rights. This warrants an overview of relevant regulations in other European countries.

Pro futuro statements under the European Bioethics Convention

As indicated above, pursuant to Article 9 of the Oviedo Convention, advance statements made by the patient with regard to their will about medical intervention should be taken into account if the patient is unable to express that will at the time of the intervention. However, the Oviedo Convention was signed by Poland in 1999, its ratification has never been completed, and thus the act has not been put into force as part of the Polish legal order. Nonetheless, the Convention provides important guidance with regard to the interpretation of *pro futuro* statements. The guiding principle of the Oviedo Convention is related to the autonomy of the patient's will. Although Article 9 is found in Chapter II of the Convention, entitled "Consent", there is no doubt that the term "previously expressed wishes by a patient" is not relevant to the classic concept of consent or objection. As can be seen from an analysis of Chapter II, the issue of patient consent is regulated by Article 5 whereas the surrogate consent is addressed in Articles 6 and 7 of the Convention. On the other hand, Article 8 of the Convention is the equivalent of Article 34(7) of the PPD and addresses the authorization of treatment without consent in an emergency situation in which a person is unable to provide consent to medical intervention.

The Oviedo Convention does not elaborate on the question of how to treat "previously expressed wishes" and how strongly binding character is attributed to the term "taking into account". According to the Polish language dictionary, the expression *brać pod uwagę* [take into account] is synonymous with *uwzględniać* [consider] [11]. Based on a literal interpretation, it seems that the phrasing "previously expressed wishes […] shall be taken into account" is not binding for the physician. This position is confirmed by paragraph 62 of the Report of the Committee of Ministers of the Council of Europe clarifying the intention of the parties to the Oviedo Convention, stating that "taking previously expressed wishes into account does not mean that they should necessarily be followed". This, however, does not change the fact that the patient's autonomy should be duly respected, and the doctor should present arguments for not respecting the patient's wishes. In justifying their decision, the physician should demonstrate that the patient's will was taken into account.

Resolution of the Parliamentary Assembly of the Council of Europe "Protecting human rights and dignity by taking into account previously expressed wishes of patients"

The Resolution of the Parliamentary Assembly of the Council of Europe "Protecting human rights and dignity by taking into account previously expressed wishes of patients" (hereinafter: the Resolution) recommends that national parliaments, when legislating in the field of the protection of the human rights and dignity of the terminally ill and dying, respect, among others, the following principles [12]:

— self-determination for capable adults in the event of their future incapacity, by means of advance directives, living wills and/or continuing powers of attorney, should be promoted and given priority over other measures of protection (Section 7.1);
— advance directives, living wills and/or continuing powers of attorney should, in principle, be made in writing and be fully taken into account when properly validated and registered (ideally in state registries) (Section 7.2);

— prior instructions contained in advance directives and/or living wills which are against the law, or good practice, or those which do not correspond to the actual situation that the interested party anticipated at the time of signing the document, should not be applied (Section 7.4);
— advance directives, living wills and/or continuing powers of attorney should be accessible to all; complicated forms or expensive formalities should thus be avoided (Section 7.5);
— a system of supervision to fight abuse should be established under which a competent authority is empowered to investigate, and, if necessary, intervene (Section 7.7).

Although the presented above is just a part of the guidance provided to Member States in the Resolution, a significant difference can be easily seen in the level of detail between the Resolution and the Oviedo Convention, the former providing clear indications on how to shape legal regulations regarding *pro futuro* statements.

Recommendation (2009)11 on principles of continuing powers of attorney and advance directives for incapacity

The principles presented in Recommendation (2009)11 on principles of continuing powers of attorney and advance directives for incapacity (hereinafter: the Recommendation) largely coincide with those introduced by the Resolution [13]. However, attention should be paid to the issue of the binding effect of *pro futuro* statements. Principle 15 of the Recommendation provides that it is up to the states to decide to what extent (if any) the advance directives (i.e. *pro futuro* statements) have a binding effect. Where advance directives have no binding effect, they must be treated as statements of wishes and be given due respect as such. In addition, states should regulate situations that arise in the event of a substantial change in circumstances following the issue of an advance directive. As clearly seen in the cited principle, the choice of a particular legislative path is ultimately left to the discretion of Member States. However, upon deciding to ascribe binding effect to advance directives, directives that have not been declared binding should also be respected by the legislator. The meaning of "substantial change in circumstances" has not been explained in the recommendation either. Solutions for the event of substantial change in circumstances in the period between the expression of the will and the delivery of treatment remain in the full regulatory capacity of the national legislator.

Supreme Court Order of 27.10.2005, ref. no. III CK 155/05

When discussing the understanding of *pro futuro* statements within the Polish legal order, due mention must be made to the relevant case law. The Supreme Court's order of October 27, 2005, ref. no. III CK 155/05, is an example of Polish legal practice aimed at resolving the questions of acceptability and legal meaning of *pro futuro* statements. The Supreme Court unequivocally asserted that a patient's *pro futuro* statement setting forth his or her will regarding medical treatment provided to him or her in situations that may arise is binding for the physician if made in clear and unambigous manner.

A woman had been involved in a traffic accident that left her unconscious, and the medical condition resulting from her injuries required a transfusion of blood and blood products. A written statement found with the woman, drawn up on January 6, 2004 and titled "A Statement to the Health Service — no blood" indicated that the subject did not agree to "any form of blood transfusion regardless of the circumstances", even if, in the physician's opinion, such a transfusion would be necessary to save her health and life. Simultaneously, the subject stated that she would accept non-blood-derived agents to increase the amount of plasma, medications to stop bleeding, and agents to stimulate the production of red blood cells and that she agreed to other alternative treatments not involving the administration of blood. The subject's husband had died in the accident. Using the information about the patient's health status as provided by the Independent Public Health Care Centre in Węgrów and acting *ex officio*, the District Court in Węgrów, in its decision dated August 19, 2004, authorized the delivery of medical procedures involving transfusion of blood and blood products to save the woman's life. The woman appealed the decision of the trial court. Having examined the appeal, the Regional Court in Siedlce, in its decision dated December 20, 2004, reversed the appealed ruling and discontinued the proceedings.

Last resort appeal was allowed, with the Supreme Court reversing the appealed decision and remanding the case to the Regional Court in Siedlce for reconsideration. To quote the main arguments presented in the rationale, the Supreme Court stressed that in a democratic state under the rule of law, freedom is specially protected, including the freedom of private life and the autonomy of choices made. One of the manifestations of an individual's autonomy and freedom of choice consists in the right to decide for oneself, including the choice of treatment methods.

The principle of respect for patient's autonomy dictates that the patient is respected regardless of motives (religious, ideological, health-related) — the patient's lack of consent to a certain procedure (type of treatment) is binding on the physician and removes any criminal or civil liability while delegalizing the procedure in the event it is carried out. In the elaboration on the initial statement, references were made by the Supreme Court not only to constitutional motives but also to the Oviedo Convention as discussed above.

Despite the lack of national legislation on *pro futuro* statements, it is pointed out that they are acceptable and binding on the physician once the conditions specified in the Supreme Court's decision are met. Some commentators, however, expressed their critical opinion on the order in question, stressing that the Court had not carried out a systemic analysis of *pro fut*uro statements or specifically addressed the relationship between the provisions of the PPD Act and those of the Civil Code. An argument has been raised that the Court did not reflect on the prerequisites for the effectiveness of such a statement which, contrary to the Court's intention, might result in problems with respecting the patient's will in practice [14].

Legal characteristics and form of *pro futuro* statements within the Polish legal order

Despite the aforementioned concerns, the view that *pro futuro statements* are declarations of intent as expressed by the Supreme Court has met an approving reception [15]. According to the part of the doctrine, *pro futuro* statements have the legal character of a declaration of will under Article 60 of the Civil Code [16–18]. It is pointed out that both the consent to treatment in case of incapacitation and the refusal of such consent can be included in this group [15]. Kulesza [19] agrees that a *pro futuro* statement constitutes consent but points out, contrary to the Supreme Court's reasoning, that it does not have the character of a classic declaration of will. The second view propounded by the Supreme Court is that consent is a statement of knowledge similar to a declaration of will so that the rules on declarations of will and legal actions shall apply accordingly [20]. Smyk [21] and Sośniak [22] qualify the consent as a legal action similar to a declaration of will, specifically approving the freedom to respect the requirements of civil law as provided by the present solution for the aforementioned legal constructs.

Regardless of the above, *pro futuro* statements are not acts of disposition of health and life. After all, the intended effect of such statements is to deprive another entity of the authority to decide for themselves on issues related to the patient's health and life. As is clear from the current legislation, the patient does not have to consent to life-saving therapy, therefore, if the consent is not given, the physician cannot carry out the planned procedure.

The effectiveness of the statements in the event of incapacity to consent cannot be undermined based on a failure to provide the submitter with medical information before making such a declaration. It should be emphasized that in addition to their right to information, the patient also has the right to demand that the doctor not inform him, said right arising from Article 9(4) of the Act on the Patient's Rights and the Patient's Rights Ombudsman [23]. Failure to provide the patient with information upon their request deprives the consent of legal effect unless the patient waives their right to obtain information.

Despite the need for the autonomy of the will directive to be applied to the fullest possible extent, it is pointed out that the will of the patient is not a sufficient premise for the legality of any medical procedure. The *pro futuro* statement can be binding only with regard to procedures that are permitted by Polish law. If a certain medical procedure is prohibited, the patient's willingness to undergo such a procedure does not deprive its performance of the feature of illegality [10]. Given the above, there is no doubt that by no way euthanasia procedures shall be legalized by *pro futuro* statements.

Today, a *pro futuro* statement can be delivered in any form, provided that it is made in a clear, unambiguous and unmistakable manner, as is clear from the Supreme Court's decision discussed above. The statement can take the form of either a formal document or a casual note, albeit the handwriting stating the writer's will must be easily legible. There are no requirements as to the verbal *vs.* written mode. Janiszewska's [3] position that the written form has an awareness-raising function, as it allows the patient to understand the finality of their decision, is justified. A written statement makes it easier for the physician to become free of liability in the event of possible claims made by the patient's family, and therefore it is arguably the safest option, for both the physician and the patient.

MP's project to regulate previously expressed wishes in the form of a living will

During the sessions of the Sixth Parliament, a bill was filed to regulate the issues of *pro futuro* statements in the context of living wills [24]. The issues

were to be included in the Act on the Patient's Rights and the Patient's Rights Ombudsman. The draft proposed that a voluntary and informed written objection to the provision of life-sustaining health care as provided by an adult patient was to be binding on the physician in the event of incapacity to consent. The condition for the validity of the objection would consist of its being registered within the Central Biomedical Registry and recorded in the patient's medical records. The person closest to the patient would be entitled to apply to the court to have the objection declared invalid if the omission of treatment would harm the patient's interest. However, the draft stressed that only an objection expressed in connection with a terminal illness from which the patient was suffering at the time of stating their objection would be legally binding. Revocation of this objection would be possible at any time and in any form, thus making the proposed provisions somewhat similar to those regarding classic objection under the PPD Act.

Ultimately, the bill has not been passed. Some of the solutions were evaluated positively — the idea of introducing a Central Biomedical Registry as a method of providing the physician with the possibility of obtaining confirmed information on whether a given patient had made a *pro futuro* statement was received with the greatest approval in the literature [25]. Controversies arose over the limited range of situations for which such a statement could be made — the implementation of the aforementioned statements was to result in the discontinuation of treatment and the death of the patient [26]. Statements such as those regarding the preferred methods of treatment or Jehovah's Witnesses' objection to the use of blood products were left outside the scope of the regulation. Concerns were also raised with regard to granting the court the ability to review the validity of a patient's statement based on a broad criterion of the patient's interest. No indication regarding the possible interpretation of this concept by the court was provided in the proposed bill.

Postulates regarding future law

While being far from perfect, the provisions proposed in the parliamentary bill to regulate previously expressed wishes in the form of a living will introduced a precise legal framework. The initiative to establish a Central Biomedical Registry seems to be the best way to provide physicians with the ability to obtain verified information on whether a particular patient had expressed his or her will regarding treatment methods in the event of incapacity to consent. The draft indicated that the platform would be publicly accessible for physicians while containing only information on the patient's objection rather than on the suggested methods of treatment. The actual rules of operation for the Central Biomedical Registry should be clarified in terms of the broader requests expressed by patients with regard to their future treatment [27]. With that in mind, the medical rationale for the patient's making demands regarding their treatment should be clearly and explicitly defined. Only in legitimate medical circumstances and based on the existing legal grounds, could a patient, on the basis of the comprehensive information they had received from their physician, make a *pro futuro* statement regarding participation in the choice of proposed therapies [28].

With regard to the mode of delivery, the written option as proposed in the draft bill is best for the physician and the patient. The effects of *pro futuro* statements are often irreversible and thus of significant importance to patients. The patient may therefore expect that their statement will be binding on the physician. The physician, on the other hand, should be able to practice his profession without fear that due to informational chaos, their decisions might subject them to civil, disciplinary, or criminal liability.

An argument against the introduction of this regulation consists of the narrow catalogue of entities capable of making such declarations of will. As mentioned above, *pro futuro* statements are not only objections to medical services that sustain vital functions in the event of incapacity to consent. Narrowing the catalogue to a single situation may be perceived as unjustified and consequently deepen the legal and terminological chaos in the field of *pro futuro* statements. Without a doubt, the possibility of judicial review of *pro futuro* statements in the event of significant changes in circumstances, for example, a patient's change of religion if the statement was dictated by religious reasons and the patient did not have time to change the statement in the register, should be provided for in the regulations.

Summary

The issue of broadly understood *pro futuro* statements is extremely important yet complex. Addressing all legal aspects of statements in the event of incapacity to consent is a significant challenge. Without a doubt, the Polish legislators should reattempt regulating the issue of *pro futuro* statements, with future ratification of the Oviedo Convention being a potential measure to accelerate this process. Examples of countries having introduced legal regulations on *pro futuro* statements may provide ground for in-depth

reflection. Comprehensive regulation of the issue in question may contribute to reducing medical paternalism and expanding the patients' awareness of their rights [29, 30]. In the longer run, it may also contribute to the elimination of legal chaos and a greater sense of security for physicians.

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