

LEGAL ASPECTS OF PERFORMING AESTHETIC MEDICINE PROCEDURES – A CASE STUDY

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Abstract. This paper deals with the issue of regulation of aesthetic medicine at the level of the Polish legal system. The starting point is the analysis of the institution of the patient's consent to a non-therapeutic intervention the primary aim of which is improving appearance. The article pays particular attention to the conditions of the legality of the patient's consent, taking into account the views of the doctrine of medical law and current case law of the Supreme Court of Poland. Theoretical considerations were based on a case study related to health complications in patients who underwent breast augmentation procedures with a preparation containing polyacrylamide. Drafts of future legislative changes regarding patient consent for aesthetic medicine procedures are proposed.

Keywords: aesthetic medicine; polyacrylamide; patient consent; physician liability; dangerous product.

INTRODUCTION

The authors were prompted to analyze the issue of the legal aspects of performing procedures in the field of aesthetic medicine by media reports about health complications in patients who underwent breast augmentation procedures with the use of a preparation containing polyacrylamide (PAAG). The discussion took place not only in the medical community,¹

¹ See Treatment of complications after breast augmentation with Aquafilling gel: <https://www.cmkp.edu.pl/ksztalcenie/szkola-nauk-medycznych/klinika-chirurgii-plastycznej> [accessed: 13.10.2024].

the Ombudsman for Patients' Rights also spoke on the subject,² and the authorities authorized to prosecute crimes conducted preparatory proceedings concerning the market introduction of the preparation called Aquafilling Bodyline.³ It is worth mentioning that as of November 2019 the Ombudsman for Patients' Rights has initiated 11 investigations in connection with breast augmentation/modeling procedures using Aquafilling Bodyline.⁴

The subject of this article will be the limits of a doctor's legal liability related to the performance of non-therapeutic interventions that are primarily aimed at improving appearance. The primary purpose of the paper will be to try to answer the question: whether a medical error could have been committed during aesthetic procedures performed with the Aquafilling Bodyline substance.

Analysis of this question requires addressing several issues. These are: 1) the patient's legally compliant consent to the procedure, 2) performance of the procedure by a person with the appropriate qualifications, 3) the conduct of the procedure in accordance with the principles of medicine, including, among other things, conducting tests before and after the procedure, as recommended by the manufacturer of the medical device, 4) the use of an appropriate substance and possible liability introducing a dangerous product to the market.

The article will also address the doctor's liability related to with the failure to achieve the desired effect or the planned end result, and the possibility of complications after the procedure. Given the broad scope of the subject matter in question, this paper will primarily discuss the issue of the patient's consent to a non-therapeutic procedure. Other issues will be covered only in brief. In addition, proposals for *de lege ferenda* changes regarding the patient's consent to an aesthetic medicine procedure will be formulated.

1. PATIENT CONSENT FOR A MEDICAL PROCEDURE

At the outset of the discussion, it is indispensable to clarify the meaning of the concept of patient consent to a medical procedure. In the literature, patient consent is defined as: "freely taken and expressed according to the rules of meaning available to other participants in the medical

² See The Ombudsman for Patients' Rights supports patients injured as a result of Aquafilling gel treatments: <https://www.gov.pl/web/rpp/rzecznik-praw-pacjenta-wspiera-pacjentki-poszkodowane-w-wyniku-zabiegow-zelem-aquafilling> [accessed 13.10.2024].

³ See Regional Prosecutor's Office in Warsaw, Notification on the suspension of the investigation with the reference no. PO I Ds 38.2020, <https://www.gov.pl/web/po-warszawa/zwiadomienie-o-zawieszeniu-sledztwa-o-sygnaturze-po-i-ds-382020> [accessed: 13.10.2024].

⁴ See The Ombudsman for Patients' Right sums up the activities related to breast augmentation procedures with Aquafilling Bodyline gel: <https://www.gov.pl/web/rpp/rzecznik-praw-pacjenta-podsumowuje-dzialania-zwiazane-z-zabiegami-powiekszenia-piersi-zelem-aquafilling-bodyline> [accessed: 02.11.2024].

process, an act of the patient's or his legal representative's will, taken on the basis of accessible, reliable information as to all stages of the medical procedure" [Świdarska 2007, 19]. For a patient's consent to a medical intervention to be legally effective, several prerequisites must be met. First, the person who gives consent must be an authorized person, and the decision regarding medical interference should be free and informed. The consent should be in the form provided by the provisions of the applicable law, and finally, the statement of intent must be given before the undertaking of the intervention, it cannot be a retroactive consent.⁵ Informed consent means that the person giving consent has the information necessary to give it, i.e. they are aware of the possible consequences, defined as awareness of danger [Michałowska 2014, 68]. Failure to meet this condition makes the patient's consent unlawful [ibid.]. The doctrine also stresses that consent to a medical procedure must be specific and concrete, not merely general and abstract [Świdarska 2007, 20]. In addition, it can cover only such a subject matter that is at the disposition of the consenting person otherwise it is an illegal consent [ibid., 21]. It is worth noting at this point that there is no established position defining the scope of personal rights in relation to which their disposer may express the will to violate them or expose them to harm [Kubiak 2019, 787]. Therefore, it is not possible to determine unequivocally how far the patient's consent legalizes the doctor's actions [ibid.].

De lege lata, a patient's consent to a medical procedure is regulated by two legal acts: the Act of December 5, 1996 on the professions of physician and dentist⁶ and the Act of November 6, 2008 on patient's rights and the Ombudsman for Patients' Rights.⁷ According to Article 32(1) of the Act on the professions of physician and dentist, a physician may conduct an examination or provide other health service, subject to the exceptions provided for in the Act, after the patient has expressed consent. Moreover, according to Article 32(7) of the Act on the professions of physician and dentist, unless the Act provides otherwise, consent may be expressed orally or even through such conduct that clearly indicates the will to submit to the medical procedures proposed by physician. According to Article 34(1) of the Act on the professions of physician and dentist, a physician may perform a surgical procedure or apply a method of treatment or diagnosis that poses an increased risk to the patient, after obtaining the patient's written consent. Article 34(2) of the Act on the profession of physician and dentist requires

⁵ See Giving informed consent, Supreme Medical Chamber: <https://nil.org.pl/dla-lekarzy/prawo/dokumentacja-medyczna/4262-udzielenie-swiadomej-zgody#:~:text=Brak%20odebrania%20%20swiadomej%20zgody%20pacjenta%20skutkuje%20odpowiedzialno%C5%9Cci%C4%85%20cywiln%C4%85,w%C3%B3wczas%20%20gd%C5%9C%20wykonany%20jest%20zgodnie%20z%20zasadami%20wiedzy> [accessed: 20.10.2024].

⁶ Journal of Laws of 2024, item 1287.

⁷ Journal of Laws of 2022, item 1876 as amended.

the physician to provide information to the patient before the patient gives consent. It should be noted that in Article 34(1) of the Act on the profession of physician and dentist, the legislator uses the phrase: “in the case of a surgical procedure or the use of a method of treatment or diagnosis that poses an increased risk to the patient”. A linguistic interpretation of the cited provision indicates that the regulation applies only to a therapeutic or diagnostic procedure or surgery. It is worth emphasizing here, referring to the subject of this article, that an aesthetic procedure involving the administration of an injection of a preparation, although it is an invasive procedure, since it involves the interruption of tissue continuity, is certainly not a surgical procedure, nor does it constitute a therapeutic or diagnostic method. This also applies to the method used for breast correction with Aquafilling Bodyline. This leads to the conclusion that in the current legal system the aesthetic medicine procedures require only oral consent. However, it should be noted that poses an increased risk to the patient.

Based solely on a linguistic interpretation of the provisions on the form of consent, i.e., the aforementioned Article 34(1) of the Act on the profession of physician and dentist and Article 18(1) of the Act on patients’ rights and the Ombudsman for Patients’ Rights, it can be seen that aesthetic medicine interventions involving only the injection of a preparation would not require written consent. Nevertheless, in this case, in addition to linguistic rules, systemic-axiological reasoning should be used. According to this interpretation, in validation determinations, establishing the sources of the normative basis of the decision, in the absence of a basis in the legislation, an adequate basis should be created in the so-called system of preferences in the basic legislation, assuming axiological consistency of the legislator. In such a situation, it should be assumed that the legislator would have regulated the given state of affairs similarly if he had foreseen it [Leszczyński 2004, 129]. In the doctrine we notice a loophole in the laws regarding the regulation of aesthetic treatments and it indicates that the provisions should be applied accordingly by inference *per analogiam legis* [Gądzik 2022, 181]. The notion that in the case of an invasive aesthetic medicine procedure, which is not a surgical procedure, the regulations on consent to surgery, i.e. Article 34 of the Act on the profession of physician and dentist, should be applied accordingly seems correct. Thus, the patient’s consent to such an intervention should be in writing.

At this point, it is worth noting that the written form of the patient’s consent is quite simple to demonstrate during the collection of evidence. In the situation of a possible lawsuit, it increases the legal security of the doctor. The Supreme Court, in its judgment of December 17, 2004,⁸ held that it is the doctor who bears the burden of proof of fulfilling the obligation to provide

⁸ Judgement of the Supreme Court of 17 December 2004, ref. no. II CK 303/04, Legalis no. 66293.

the patient or the patient's statutory representative with the information that, according to the will of the legislator, should precede obtaining the consent. In the rationale of the above judgment, the Supreme Court further emphasized that only consent that is "explained" or "informed" causes the patient to assume the risk of the procedure. If the doctor does not provide the patient with accessible information, he acts under conditions of illegality.⁹ If the consent is, "unexplained", then the doctor acts without consent, which may give rise to civil liability for the damage caused, as pointed out by the District Court in Sieradz – I Civil Division in its judgment of November 25, 2021.¹⁰

The case law further indicates that the information provided by the doctor should be comprehensive and understandable, while the degree of detail must be high. The patient should be informed of the possibility of typical complications, all of which should be included in the written consent to the procedure.¹¹

Turning to the question of the scope of consent, it is necessary to note the view presented both in the judicature and in the doctrine, according to which the scope of the duty to inform depends on the type and nature of the medical intervention.¹² The Supreme Court, in its judgment of August 28, 1973,¹³ stressed that, "at the same time, the doctor cannot be required to warn the patient about all possible complications, especially those that occur extremely rarely.

Such forewarning could lead to unnecessary worsening of the patient's well-being and to an unfounded refusal to consent to the procedure.¹⁴ However, this view appears to apply to procedures that are curative in nature.

According to the normative view of guilt in civil law, three conditions must be met for verdict of liability: 1) unlawfulness of the behavior, 2) intentionality or unintentionality (negligence), 3) the culpability of the perpetrator [Lewaszkiewicz-Petrykowska 1999, 122].

Relating this to the responsibility of the doctor for the actions taken, in order to charge, the court must attribute fault to the doctor [ibid.]. In view of the above, it is possible to defend the view that the mere occurrence of negative health effects after the performance of the procedure does not determine the fault of the doctor.

Transferring the above considerations to the issue of the administration of Aquafilling Bodyline, it should be considered that if the doctor used

⁹ Ibid.

¹⁰ Judgement of the District Court in Sieradz of 25 November 2021, ref. no. I C 351/19, Legalis no. 2650907.

¹¹ Ibid.

¹² Judgement of the Supreme Court of 28 August 1973, ref. no. ICR 441/73, Legalis no. 17300.

¹³ Ibid.

¹⁴ Ibid.

a medical device that was legally marketed and during this procedure there was no medical malpractice, and the patient's consent to the procedure was legally effective, it is difficult to attribute an element of guilt to the doctor, and therefore it is impossible to conclude that the doctor's action was unlawful.

2. LEGAL REGULATION OF AESTHETIC MEDICINE

Even at the beginning of the 20th century aesthetic medicine procedures, not being of a curative nature, were forbidden, but as their positive effects on improving mental health were noted, they became part of aesthetic medicine and plastic surgery [Michałowska 2014, 182-83]. In recent years, medicine aimed at improving appearance has been growing rapidly.

According to survey data from the International Society for Plastic and Aesthetic Surgery, more than 17,295,000 aesthetic procedures (surgical and non-surgical) were already performed by 2009 [Kubiak 2019, 780]. However, with the growing scale of aesthetic medicine procedures, there are insufficient regulations in the Polish legal order. Despite the fact that the Supreme Medical Council issues recommendations aimed at clearing up questionable issues, such as by publishing Position No. 1/21/VIII of January 29, 2021 on the adoption of a definition of aesthetic medicine,¹⁵ it must be emphasized that this is an act of internal regulations and not a source of universally binding law.

In view of this state of affairs, it should be considered necessary to adjust the legal regulation of patient consent for aesthetic medicine procedures. Legally effective patient consent is an essential element of a doctor's legal compliance. It is impossible not to agree with the view that such procedures may pose risks to the health of the person undergoing the procedure. Determining the long-term consequences of such procedures is sometimes difficult. It would be worthwhile *de lege ferenda* to introduce a qualified form of written consent. It could include a requirement to specify specific, foreseeable post-complications at a given time. In addition, it would be worth including a clause informing the patient that at the time of giving consent it is not possible to foresee all possible adverse consequences that may occur in the future. The proposed modification would make it possible to more effectively guarantee the realization of the patient's right to information, and would also increase the legal security of doctors performing aesthetic procedures. In legal proceedings, the doctor would be able to demonstrate that the consent was duly explained and that the patient knowingly accepted the risks of the procedure.

¹⁵ Position No. 1/21/VIII of the Supreme Medical Council of 29 January 2021 on the adoption of the definition of aesthetic medicine, https://nil.org.pl/uploaded_files/documents/doc_1612526221_rs001-21-viii.pdf [accessed: 15.10.2024].

3. POSSESSION OF APPROPRIATE QUALIFICATIONS – THE POSITION OF DOCTRINE AND THE LINE OF JURISPRUDENCE

The lack of unambiguous regulations in the area of performing interventions referred to as non-therapeutic aesthetic medicine procedures was pointed out by the Supreme Court in the Order of May 26, 2021.¹⁶ The case in question concerned the filing of a cassation appeal against a ruling of the Supreme Medical Court concerning a dentist accused of a professional tort, namely, performing a breast augmentation procedure with Aquafilling without the required qualifications. The Supreme Court, referring to the charges raised in the cassation filed by the dentist's defense counsel, expressed the view that the Aquafilling breast augmentation procedure is a medical action, which, due to its invasive nature and the conditions for its performance, falls within the legal definition of "health care service". The Supreme Court held that given the place of injection of the preparation (the patient's breast area), it cannot be performed by a dentist.

In the justification of the judgment, the Supreme Court shared the view of the Supreme Medical Court, according to which the, "liquid prosthesis" of the breast using Aquafilling should be applied only by doctors. It further stated, relying on the instructions for using Aquafilling, that it should be administered, only by specialists who are certified and properly qualified in accordance with local regulations. The Supreme Court stressed that according to the Aquafilling manufacturer's guidelines, the doctor performing the procedure when qualifying the patient must rule out contraindications to the procedure and carry out the recommended appropriate medical procedures, both before and after the procedure. It follows that in the case at hand, the performance of a breast augmentation procedure using Aquafilling was not considered unacceptable. The Supreme Court said that, having fulfilled certain conditions, it could only be performed by doctors who are qualified in accordance with local regulations. After the ruling in question, the Supreme Court did not question the possibility of using the preparation while it was authorized as a medical device.

It should be mentioned that according to the position of the Director of the Department of Supervision and Clinical Trials of Medical Devices of the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products, in response to the letter of the President of the Polish Society of Plastic, Reconstructive and Aesthetic Surgery, Aquafilling Bodyline was a preparation that was qualified for Class III medical devices, had CE certificate No. 41015/101/1/2012/CE issued on March 22, 2012 valid until

¹⁶ Order of the Supreme Court of 26 May 2021, ref. no. I KK 23/21, *Legalis* no. 2612411.

March 21, 2017.¹⁷ In the letter, the President of the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products said that as of December 2016, it had not received any reports of medical incidents involving the preparations Aquafilling Bodyline and Aquafilling faceline. The first report of a complication in a patient was received in December 2016. Aquafilling Bodyline was not withdrawn from the market until January 27, 2020, by decision of the President of the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products.¹⁸

In order to proceed to the determination of who was authorized to perform the procedure discussed in the article, it is first necessary to make a determination of what category of procedures the Aquafilling gel breast correction should be included in. Does it fall into the category of aesthetic medicine procedures, or is it rather a plastic surgery procedure. In considering procedures aimed at a cosmetic, beautifying effect, it is impossible not to refer to the meaning of the term aesthetic medicine itself. The legislator has not formulated a legal definition of this concept, in the literature of medical law it is assumed that procedures in the field of aesthetic medicine are, unlike plastic surgery procedures, less invasive, and do not involve the violation of the continuity of tissues with a scalpel [Budyn-Kulik 2018, 279].

The Supreme Medical Council has noted the need to regulate the matter of performing aesthetic medicine procedures, related to the encroachment of the continuity of the body.¹⁹ In the absence of a statutory definition and to meet the need to clarify the meaning of the concept of aesthetic medicine, the Supreme Medical Council adopted its own definition of the concept. According to the Position of the Supreme Medical Council No. 1/21/VIII of January 29, 2021: “aesthetic medicine consists of health services, involving interference with human tissues, provided by physicians and dentists for the purpose of restoring or improving the physical and mental self-perception and social functioning of the patient, by changing his or her appearance.”²⁰

In an attempt to find the “relevant regulations” regarding the appropriate qualifications of persons authorized to perform the injection of a medical device for aesthetic purposes in the current legal system, one cannot find a provision that directly regulates the issue in question. The lack of relevant legal regulations was probably the reason for the issuance of another position

¹⁷ See Letter of the Director of the Department of Supervision and Clinical Trials of Medical Devices of the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products of 29.10.2018, https://www.ptchprie.pl/img/custom/pdf/20181029_pismo_URPL.pdf [accessed: 3.11.2024].

¹⁸ See The Ombudsman for Patients' Rights sums up the activities related to breast augmentation procedures with Aquafilling Bodyline gel.

¹⁹ See Position No. 1/21/VIII of the Supreme Medical Council of 29 January 2021.

²⁰ Ibid.

by the Supreme Medical Council on the eligibility to perform procedures included in scope of aesthetic medicine.²¹ It is worth noting that the Supreme Medical Council has firmly stated that when injecting a specific substance or mixtures of products, the risk of side effects should be taken into account in each case, albeit with varying probability. Referring to the injection of the most commonly used preparation, which is hyaluronic acid, the Supreme Medical Council found that it cannot be administered by non-doctors.²² However, this document is not a source of universally applicable law.

In the cosmetic surgery procedures listed in the Plastic Surgery Specialty Program of November 13, 2018, there is a point on surgical procedures for breast augmentation (point 8, 3, a), but there is no procedure for non-surgical administration of breast fillers listed there explicitly. It should be noted that non-surgical procedures for facial rejuvenation, such as chemical peeling, fillers, botulinum toxin are listed explicitly in the document.²³

In conclusion, it can be considered that in the current legal system there are no clearly defined regulations that clearly regulate the competence of physicians who can apply treatments related to the administration of injectables within the framework of so-called aesthetic medicine.

4. TIMING OF DISCLOSURE OF THE EFFECTS OF A MEDICAL PROCEDURE AND THE CONDITIONS FOR ITS LEGALITY

In the doctrine of medical law, it is argued that the risk of a given medical action or method used should be evaluated *ex ante*, i.e. from the point of view of the moment when the action was performed, and not *ex post*, i.e. from the moment when its effects were revealed [Michałowska 2014, 71]. Therefore, the legal qualification of medical actions in the context of consent to a medical procedure should be made in relation to the performance of the action, not its result [ibid.]. To address the correctness of a medical procedure, what is relevant is the state of medical knowledge that existed when the action

²¹ See Authorization to perform procedures included in aesthetic medicine treatments, Position No. 48/21/P-VIII of the Presidium of the Supreme Medical Council of 15 April 2021 on authorization to perform procedures included in aesthetic medicine treatment, <http://nil.org.pl/dla-lekarzy/prawo/medycyna-estetyczna/5418-uprawnienia-do-procedur-wchodzacych-w-sklad-zabiegow-medycyny-estetycznej> [accessed: 03.11.2024].

²² Ibid.

²³ See Specialization program in the field of plastic surgery of 13 November 2018 for physicians with a first-degree specialization in the field of pediatric surgery or general surgery, Warsaw 2014, updated on 13.11.2018, <http://www.cmkp.edu.pl/wp-content/uploads/akredytacja2018/0738-program-2.pdf#:~:text=Celem%20szkolenia%20specjalizacyjnego%20w%20dziedzinie%20chirurgii%20plastycznej%20jest,choroby%20przewlekłej%2C%20procesów%20degeneracyjnych%20i%20starzenia%20się%20pacjentów> [accessed: 30.11.2024].

was taken, not from the time of adjudication [Boratyńska and Konieczniak 2019, 277]. As stated in the literature, it is necessary to reckon with “temporal changes” in medicine, since many of its fields can be included in the so-called “hot science” category, where transformations occur very quickly [ibid.]. Summarizing the considerations made above, it can be concluded that the use itself of the medical device Aquafilling Bodyline itself, prior to the withdrawal of the preparation from the market, was not an unlawful act.

Turning to a discussion of the conditions for the legality of a medical procedure, it should be noted that consent is only one element of a doctor’s lawful action. This is because there may be situations with properly given consent, the procedure was performed contrary to the art of medicine or was performed by a person without formal qualifications [Michałowska 2014, 72].

It is worthwhile at this point to present a rather radical view that can be encountered in doctrine and jurisprudence. Some authors believe that a doctor performing aesthetic procedures devoid of a therapeutic purpose may perform them only in cases where they involve only a small risk of negative consequences [Kubiak 2019, 786]. According to this position, the doctor can be attributed fault, and therefore can be held liable in a situation where the risks of the procedure significantly outweigh the expected aesthetic results. In such cases, he should refuse to perform the intervention [ibid., 786-87]. Similar positions are presented in the judicature. The Supreme Court, in its judgment of September 5, 1980,²⁴ held that an operation aimed solely at an aesthetic purpose is permissible only in those cases where it does not create a risk, “higher than average”, while exceeding this limit may be considered a medical error.

CONCLUSION

To sum up, a doctor is always obliged to obtain the patient’s consent to the interventions undertaken against him. Only in some cases e.g. surgical procedures is written consent expressly required. The scope of this requirement should be widened on aesthetic medicine procedures, because they pose an increased risk to the patient. In the Polish legal system the aesthetic medicine procedures require only oral consent. Therefore it seems advisable to amend Article 34(1) of the Act on the professions of physician and dentist and Article 18(1) of the Act on patients’ rights and the Ombudsman for Patients’ Rights, by including high-risk aesthetic medicine procedures in these provisions. Since these procedures are performed at the patient’s request, and are intended for cosmetic rather than therapeutic effect, it would

²⁴ Judgement of the Supreme Court of 5 September 1980, ref. no. II CR 280/80, *Legalis* no. 22216.

be worthwhile *de lege ferenda* to introduce a qualified form of written consent. Consent for a procedure could include a requirement to detail specific, foreseeable complications at the time. In addition, it would be worthwhile to include a clause informing the patient that, at the time of giving consent, it is impossible to foresee all possible adverse consequences that may occur in the future. In the event of potential lawsuits, this would be important evidence that the patient was informed of the risks correctly and that he or she knowingly accepted those risks.

A definite pronouncement as to the possibility of medical error on the part of the doctor performing Aquafilling breast augmentation procedures remains solely within the jurisdiction of the court. After gathering all the evidence, the court should evaluate it in accordance with the principles of knowledge, logic and life experience, and on its basis make accurate factual findings. In a particular case, the parties, witnesses and plastic surgery experts should be interviewed, and medical records should be analyzed.

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