LEGAL POSSIBILITIES OF USING AI IN MEDICINE, WITH PARTICULAR EMPHASIS ON IMAGING DIAGNOSTICS AND RESPONSIBILITY OF MEDICAL ENTITIES – POLISH PERSPECTIVE

Dr. habil. Justyna Król–Całkowska, University Professor

Department of International and European Law, Lazarski University in Warsaw, Poland
e-mail: kancelaria.prawomed@gmail.com; https://orcid.org/0000-0002-8370-0154

Daniel Walczak, M.A.

Postgraduate Education Center, Medical University of Warsaw, Poland
e-mail: daniwalczak@gmail.com; https://orcid.org/0000-0001-8981-506X

Abstract. The method/practise of providing healthcare services has been significantly modified due to the development of the pandemic. In everyday medical practice, the use of telecommunication media has begun to be widely used, which enable the provision of healthcare services at a distance. The next step is the use of artificial intelligence during the planning, implementation and control of medical activities, which will support and even replace humans at various stages of medical activities. The article discusses issues related to the use of artificial intelligence in the process of medical activities, referring the above to the perspective of current legal regulations. Considering the nature of civilization diseases, the paper refers to the use of AI on the basis of imaging diagnostics constituting the basis for cancer diagnosis and therapy. The choice of this broad topic was motivated by the indications of the latest literature, which emphasize that malignant tumor is the most common cause of death in developed countries and it is estimated that the number of cases will continue to increase in aging populations. The article is one of the first attempts to analyze the principles of using AI in medicine and the principles of its liability for potential damage. The authors used the method of analyzing the applicable regulations, including regulations under European law, and also made a synthetic analysis of the position of the judicature and doctrine. The article indicates that the liability for damage caused by AI should be identified with liability for a dangerous product. At the same time, the civil liability of the medical entity for damages resulting from the use of AI in the diagnostic imaging process will be subject to the general regime of tort liability.

Keywords: artificial intelligence, deep learning, machine learning; medical imaging, diagnostic imaging

INTRODUCTION

Considering the nature of civilization diseases, the paper refers to the use of AI on the basis of imaging diagnostics constituting the basis for cancer diagnosis and therapy. The choice of this broad topic was motivated by the indications of the latest literature, which emphasize that malignant tumor is the most common cause of death in developed countries and it is estimated that the number of cases will continue to increase in aging populations [Siegel, Miller, and Jemal 2019, 7–34; DeSantis, Miller, and Dale 2019, 452–67].

The study uses the method of analyzing the applicable regulations, as well as the literature relating to the subject matter. Particular attention was paid to cataloging AI as a medical device, as well as to the issues of qualifying legal liability for damages caused by AI during health services, which should be understood as actions aimed at preserving, saving, restoring or improving health, are health services (Article 2(1)(10) of the Act of 15 April 2011 on Medical Activity).[1]

The creator of the term "artificial intelligence" is John McCarthy, who formulated this concept during the conference in Dartmouth in 1956 [Górski 2019]. Although there are many definitions of artificial intelligence at present, the definition presented by A. Kaplan and M. Haenlein deserves particular attention, according to which artificial intelligence is "the ability of a system to correctly interpret data from outside, learn from it and use this knowledge to perform defined tasks and achieve goals through flexible adaptation" [Kaplan and Haenlin 2019].

In the Communication from the European Commission of 25 April 2018 to the European Parliament, the European Council, the European Economic and Social Committee and the Committee of the Regions, "Artificial Intelligence for Europe" defined artificial intelligence as systems that demonstrate intelligent behavior by analyzing the environment and taking action, to a certain extent autonomously in order to achieve specific goals.

In the context of the use of AI in medicine, the White Paper published on 19 February 2020 by the European Commission deserves attention. This document describes a new European approach to the evolution of artificial intelligence based on the criteria of excellence and trust. Despite the fact that the White Paper is not a legal act, but a collection of concepts and ideas, they may set the direction of future legislative changes in the field of artificial intelligence in the European Union. According to the Commission, the establishment of a legal framework that will ensure the ethical development of artificial intelligence and guarantee the supreme role of humans is necessary to maintain the security of this technology. The adoption of the excellence criterion is to lead to the creation of a single legal framework for Artificial Intelligence at the EU and national level. Developing the second criterion is to increase public confidence in Artificial Intelligence.

The creators of the Policy for the Development of Artificial Intelligence in Poland for 2019–2027 prepared by the Ministry of Digital Affairs clearly emphasize the importance of the concept of artificial intelligence focused on humans and their environment (HumanCentricApproach), the aim of which is to make human values key to the way in which systems artificial intelligence are developed, implemented, used and monitored.

The Resolution of the European Parliament of 16 February 2017 put forward the concept of "giving robots a special legal status in the long term," and "granting the status of electronic persons responsible for repairing any damage that could be caused, and possibly the use of electronic personality in the event that ro-

---

[1] Journal of Laws of 2021, item 711 [hereinafter: UDL].

bots undertake autonomous decisions or their independent interaction with third parties." The above aims to create a new legal category, different from natural persons or legal persons – "electronic persons." At present, liability for damages caused by the broadly understood activities of artificial intelligence can be considered at the level of liability for the functioning of a dangerous product. If a medical entity uses AI equipment which, by its action, will directly or indirectly cause damage, that medical entity will be liable for damages, but it will be able to file a recourse claim to the entity that produced or placed the product on the market.

Although in this work the authors do not refer to the rules of criminal liability, it should be that this issue occurs naturally in connection with activities in the area of healthcare. Pursuant to the provisions of the Polish Criminal Code, only the person who commits an act prohibited under penalty by the law in force at the time of its commission is subject to criminal liability. The perpetrator of the prohibited act does not commit a crime if he cannot be guilty at the time of the act. There is no doubt that in the current legal state, criminal liability can only be assigned to a person and, in certain cases, to collective entities, on the basis of separate provisions. However, if you imagine the criminal liability of the robots, there would be problems with blaming them. In addition, it is necessary to answer the question whether, for the purposes of criminal law for AI, including robots, the negative prerequisites for attribution of blame. In the last context, one should refer to the possibility of assigning AI to insanity (e.g. in relation to a cyber attack) or recognizing that AI's action was of a higher necessity (e.g. in the event that AI decides to perform the procedure in a wider scope than previously planned in order to protect patient's health).

1. THE USE OF ARTIFICIAL INTELLIGENCE IN IMAGING DIAGNOSTICS

The literature emphasizes the legitimacy of using this AI in the area of healthcare, including the protection of public healthcare [Benke and Benke 2018; Niel and Bastard 2019; Hessler and Baringhaus 2019]. The use of AI is also possible on the level of fighting the pandemic – e.g. by performing initial, screening macro-scale health assessment, selecting diagnostics as well as monitoring the health of infected people who are quarantined and isolated [Mei and Lee 2020].

As indicated by the latest research [Mayo and Leung 2018], AI can provide significant support, among others, in imaging diagnostics by quickly identifying negative results of tests performed with the use of computed tomography and magnetic resonance imaging.

According to some authors, "it is evident that not many foresee the imminent replacement of radiologists by AI. The common thought is that radiologists will remain a central and crucial cog in the diagnostic process of image-based medicine, with AI acting as a «cognitive companion». It will likely improve patient outcomes and save money in the process" [Anderson, Torreggiani, and Munk, et al. 2020].

Some international studies show positive reactions to the willingness to integrate selected medical personnel with the use of artificial intelligence as a diagnostic support tool [Sarwar, Dent, and Faust, et al. 2019]. On the other hand, the media coverage of medical AI concerns mainly social progress and economic development, whereas the spheres of ethics, law and social trust are ignored in general [Frost and Carter 2019].

Below, reference is made to the use of AI in the process of providing health services financed from public funds. The conditions for using health services by a patient, including diagnostics, are set out in the Act of 27 August 2004 on healthcare services financed from public funds.[2] Bearing in mind the characteristics of civilization diseases, which include cancers, it is necessary to pay attention to the use of artificial intelligence in cancer diagnostics, taking into account the standard diagnostic procedure and the so-called "fast diagnostic path," that is the Charter of Diagnostics and Treatment of Oncology.[3]

The Oncological Diagnostics and Treatment Card is a solution introduced from 1 January 2015, pursuant to an amendment to the Public Healthcare Act, for patients in whom a primary care physician or a doctor providing outpatient specialist services has made an initial diagnosis of a malignant tumour. The indicated patients are entitled to oncological diagnostics without a referral, based on the DiLO card issued (Article 32a USOZ). When a malignant tumour is diagnosed as a result of oncological diagnostics, hospital treatment or procedures performed as part of healthcare programs, DiLO is the basis for initiating oncological treatment without referral. The set of rules for the fast track diagnosis is known as "the set of oncological services" and is not subject to limits on the financing of healthcare services.

In 2019, the number of radiologists in Poland amounted to 3.7 thousand (in the field of radiology and imaging diagnostics and oncological radiology). Data on the number of employed medical personnel are presented in the publicly available Internet application of the Ministry of Health, "Maps of health needs. Effective Operation Through Mapping." According to the information from 28 January 2021 obtained from the Ministry of Health, gained through the access to public information, the number of patients who were issued a DiLO card in individual years was: in 2015: 226.5 thousand; in 2016: 187.3 thousand; in 2017: 204.2 thousand, in 2018: 224.1 thousand, in 2019: 245.7 thousand.

The data presented above show that in 2015–2019, one radiologist provided medical care to approximately 58 patients. Although the indicated number of patients is not large, it should be emphasised that this estimate applies only to patients qualified for "the set of oncological services" with suspected malignant tumour. In the event that the patient's health condition is not properly assessed, the person who has started the carcinogenic process cannot be qualified for the above-mentioned set of oncological services. According to the data collected and

---

[2] Journal of Laws of 2021, item 1285 [hereinafter: USOZ].
[3] Hereinafter: DiLO.

processed by the WHC Foundation, the waiting time for an appointment with an oncologist for patients without a DiLO card (BkDiLO) and with a DiLO card (ZkDiLO) was, respectively: in September 2016 – 5.1 weeks (BkDiLO), 1 week (ZkDiLO); in January 2017 – 4.8 weeks (BkDiLO), 1.7 week (ZkDiLO); in May 2017 – 5.7 weeks (BkDiLO), 1.4 week (ZkDiLO); in September 2017 – 4.9 weeks (BkDiLO) 2 weeks (ZkDiLO).

Since the introduction of the DiLO card regulations, the waiting time for diagnostics by patients without the set of oncological services has been gradually increasing. In September 2015, the waiting time was 4.4 weeks, in January 2016 – 5 weeks, in May 2016 – 5.3 weeks, in September 2016 – 5.4 weeks, in January 2017 – 5.8 weeks, and in May 2017 – 6.5 weeks. The system of artificial intelligence is based on the concept of a machine that can affect the environment by making recommendations, predictions or decisions about a given set of goals. It operates by using input, whether acquired through machine learning or provided by human data: a. perceive real or virtual environments; b. summarizing such perceptions into models manually or automatically; and c. using model interpretation to formulate output options. As part of artificial intelligence, four basic technologies that can be used in the area of healthcare should be distinguished, including the following technology: algorithmic, where the programmer reads the expert's knowledge and codes it as programs; convolutional neural network – in this technology, knowledge is presented to the computer as a database in which the computer (machine) searches for dependencies between the data; generative adversarial network, which is able to generate new concept, ideas, images. Creative generative adversarial network can be used, *inter alia*, to create images of non-existent people or creative bone planning, e.g. in the craniofacial area; pure artificial intelligence, that is a program that independently searches for information and is able to use it creatively.

In Poland, the use of artificial intelligence in the area of healthcare focuses primarily on the use of convolutional neural network[4] technology – e.g. for remote assessment of cardiac arrhythmias. CNN technology can also be used in the process of assessing radiological tests. The current legal conditions in Poland make it possible to describe a radiological examination only by a physician with the appropriate specialization. Performing the description of the study by artificial intelligence could accelerate the obtaining of the test result, as well as affect its accuracy and relevance, which results from the specificity of learning from convolutional neural network (machine learning). This is because CNN can read thousands of test results in a short time, which is the basis for acquiring the experience necessary to make an accurate diagnosis. In the case of humans, the cognitive process is significantly extended to the extent indicated. The use of artificial intelligence in imaging diagnostics may affect not only the accuracy of the description but also the time of its execution.

---

[4] Hereinafter: CNN.

Recent studies have shown that AI is able to describe skin lesions (including melanoma) as accurately as experts in dermatologists [Shimizu and Nakayama 2020]. AI has also achieved a level of accuracy similar to that provided by medical professionals in interpreting breast cancer screening tests [Rodrigez–Ruiz and Lang 2019]. In addition, deep CNN was able to detect enlarged lymph nodes or colon polyps on computed tomography images [Roth, Lu, and Liu 2016]. The above is directly related to the minimization of healthcare costs and the elimination of costs related to the treatment of complications and adverse events resulting from not starting treatment at the optimal time for the patient.

2. THE CONCEPT OF ARTIFICIAL INTELLIGENCE IN LEGAL TERMS

Although the phenomenon of AI is widely discussed within the Polish political strategy of digitization, no uniformly binding definition of this concept has been established in law. The above gives rise to doubts in the context of legal classification. Thus, the question arises whether AI used in medicine, including medical diagnostics, should be classified as a medical device or a different type of product. In order for a computer program with artificial intelligence ("diagnostic tool") to be considered a medical device, it must meet the requirements set out in the Act of 20 May 2010 on Medical Devices.[5] Pursuant to Article 2(1)(38) UWM, it must be intended by the manufacturer for the use in humans for the purposes of a) diagnosing, preventing, monitoring, treating or alleviating the course of a disease, b) diagnosing, monitoring, treating, alleviating or compensating for the effects of an injury or impairment, c) testing, substitution or modification an anatomical structure or a physiological process, d) regulation of conception – which does not achieve the essential intended effect in or on the human body by pharmacological, immunological or metabolic agents, but whose action can be aided by such agents. The wording of this provision is a direct implementation of European legislation, in particular Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices (EU Regulation 2017/745).

The consequence of recognizing a computer program as a medical device is also reflected in the judgments of the Court of Justice of the European Union (CJEU). The CJEU ruled on 22 November 2012 (Case C 219/11) that software treated on its own is a medical device if it is specifically intended by the manufacturer to be used for at least one medical purpose specified in the definition of a medical device. However, the use of software by a healthcare entity for general purposes (other than strictly medical) will cause it to be considered a non-medical device. In another judgment of 7 December 2017 (Case C–329/16), the CJEU expressed the thesis that the software, of which one of the functionalities allows the use of patient data, in particular to detect contraindications, interaction with other drugs or the excess dosage, constitutes a medical device within the meaning of

---

[5] Journal of Laws of 2020, item 186 as amended [hereinafter: UWM].

these provisions, even if such software does not have a direct impact on the human body. However, a software which sole purpose is to archive, collect and transmit data, will not be a medical device, such as software for storing medical data of a patient.

3. ARTIFICIAL INTELLIGENCE – A DANGEROUS PRODUCT

The regulation providing for strict liability for a dangerous product was introduced to the Civil Code of Poland[6] by the Act of 2 March 2000 on the protection of certain consumer rights and liability for damage caused by a dangerous product, as a consequence of its implementation into the Polish legal order Council Directive 85/374/EEC of 25 July 1985 on the approximation of the laws, regulations and administrative provisions of the Member States concerning liability for defective products (hereinafter: Directive 85/374/EEC). Considerations on whether the phenomenon of AI may be a dangerous product should be preceded by the meaning of the term "movable thing" as a single designate, or this phrase should be considered as separate designations: "thing" and "movable." The first case is justified by a specific reading of the provisions contained in Article $449^1(2)$ CC. According to some researchers [Bosek 2019], the argument for including computer programs under the term "movable thing" is the fact that certain categories of intellectual goods (e.g. computer programs) are in the public market and it is difficult to deny them the quality of goods. There are purposeful reasons for this, as these goods can be a source of serious damage.[7] In functional terms, however, there are claims that the legislator has envisaged a broad formula that allows to consider intellectual goods as a "product" e.g. computer programs, but also cases of such goods that due to the commercial way of functioning in trade or due to the danger they can cause to the environment, are similar in nature to typical goods that are dealt with by the regime of liability for a dangerous product.

A computer program is a work, an intangible manifestation of human creativity. It is indisputable that AI can be part of a computer program, and the latter can be an element or component of a product-thing (e.g. a car, computer or robot). When considering the issue of a "dangerous product," understood as a material object into which a computer program is loaded, it will be assessed as a whole whether it exhibits any features of danger.

Neither Directive 85/374/EEC nor the Civil Code contain a catalog of dangerous products. As a rule, a product is dangerous, which, due to its features and certain properties, is already dangerous.

Whether a product is safe is decided by the circumstances at the time of placing it on the market, in accordance with Article $449^1(3)$ CC. Generally non-hazardous products are assessed according to the principle of normal and expected use of the product. By meeting these determinants, a product that is used in a comple-

---

[6] Journal of Laws of 2020, item 1740 as amended [hereinafter: CC].
[7] See commentary to Article 449^1, thesis no. 26 [Banaszczyk 2020].

tely normal, foreseen manner on a daily basis will not be considered dangerous, if it does not reveal dangerous features (due to its construction or the wrong quality components used in it). The legal regulation of "normal product use" is, however, one-sided. The thesis is valid that the Polish legislator too freely considered the implementation of the regulation contained in Article 6(1) of Directive 85/374/EEC that relates to the way in which the product can be used normally. In the doctrine [Kuźnicka–Sulikowska 2013, 260] there are also opinions that the preamble to Directive 85/374/EEC refers to the assessment of product defect made not in terms of its suitability for use, but the lack of safety when society has the right to expect security. Such a purposeful formulation of the directive should be helpful in this regard. Even more so as the CJEU in its judgments (e.g. of 21 June 2017 Case C–621/15, and of 20 November 2014, Case C–310/13), clearly indicates that the system of liability for a dangerous product must be complete and effective, which consequently requires not only appropriate regulation, but also the application of principles, the application of which should implement the purpose of the directive, and that the application of national provisions must not compromise the effectiveness of Community law.

4. DAMAGE CAUSED BY AI

AI algorithms undoubtedly support medical activities, including the assessment of diagnostic imaging tests. When analyzing the use of AI in the process of healthcare services, it is necessary to answer the question: what is the responsibility for the incorrect functioning of the algorithm or the lack of security measures that will most likely eliminate the occurrence of damage? It should be taken for granted that a patient referred for a diagnostic examination expects that the medical equipment is trustworthy and works efficiently. The standard (according to the intended use, instructions and manufacturer's recommendations) use of computer hardware with defective software is burdened with the producer's responsibility, which results from the fact that the function limitations or algorithm error should be known to the producer from the beginning. It should also be concluded that a medical device containing a computer program may be assigned the features of a dangerous product, and responsibility may be assigned to the entity that produced the product or placed it on the market.

However, this regulation will not apply to a *per se* computer program that is used separately but in conjunction with medical equipment. An example of such a state of affairs would be a program installed on a computer (not supplied by the manufacturer of medical equipment) connected to the medical equipment in order to transmit, receive and read the data necessary to perform diagnostics. In such a situation, the liability of the entity granting the license to use the computer program will be a contractual liability towards the medical entity. The damage caused to a patient as a result of the use of such a computer program by a medical entity will be charged to that medical entity as the user of that computer program.

On the other hand, the healthcare entity will be able to file a recourse claim to the software provider, on the basis of Article 441 CC. It should be noted that the responsibility for a dangerous product does not exclude the liability of other people, based on other regulations (Article 449[10] CC). At the same time, in order to avoid interpretation and exponential problems, computer programs or even some of their components, such as AI, should be legally objectified.

5. TORT LIABILITY OF MEDICAL ENTITIES

One should agree with the researchers [Bosek 2020; Wałachowska 2020], who argue that the current regulations are sufficient to assign responsibility to specific entities for damage caused by intelligent medical robots (also recognized as devices, equipment or apparatus with artificial intelligence, capable of performing diagnostics).

Both the provisions on tort and contractual liability will apply to the provision of healthcare services due to the legal relationship between the patient and the entity performing medical activities, as a consequence of the treatment contract. The law allows for the convergence of such a basis of responsibility, as a consequence of Article 443 CC, the more so as the parties to this legal relationship do not shape it arbitrarily, do not exclude the application of certain provisions shaping the rights and obligations, and even less do not affect the withdrawal from due diligence.

Entities performing medical activities are responsible for the use of medical equipment. If it is malfunctioning, these entities, in the event of being liable for the damage caused, may file a recourse claim against the entity that produced or placed the product on the market.

Entities performing medical activities are liable pursuant to Article 415, 416, 429 and 430 CC, depending on the actual state of affairs. For the medical staff, the healthcare entity (e.g. hospital) is responsible for the guilt in choosing based on Article 429 CC or liability for damage caused by a subordinate on the terms set out in Article 430 CC. These provisions will remain in line with Article 415 or 416 CC depending on whether it is possible to establish the individual guilt of the perpetrator or the guilt of an organ of a legal person.

However, the relation of Article 415 and Article 416 CC, due to the fact that both provisions impose an obligation to compensate for damage caused by human fault. Article 415 CC relates directly to the actions of the perpetrator of an act that can be attributed to his own guilt. In turn, Article 416 CC determines the operation of the authority, and in connection with Article 38 CC it should be referred to that action is taken on behalf of a legal person in the manner provided for in the law and in the statute based on it. Thus, the behavior of the perpetrator under Article 415 CC is the behaviour on its own account, and the behavior specified in Article 416 CC, is an action taken for the benefit of a legal person, within the framework of its authorization. It should be noted that legal persons are, for exa-

mple, independent public health care institutions in accordance with Article 50a(2) UDL.

In the case of legal persons and their collective bodies, it may be problematic to determine the guilt of individual members of this body for specific behavior. Judicature, such as the judgment of the Supreme Court of 11 May 2005 (Case III CK 652/04), in such situations has developed the concept of so-called "nameless guilt" or "anonymous guilt," according to which the liability of medical entities can be linked to the detriment.

This applies to situations in which it is necessary to break the personal relationship between the activity or omission leading to the damage and the allegation of improper behavior, stopping at establishing that the competent authority or employee of the legal person has undoubtedly been at fault. Thus, the fault is related to the perceived defects in the operation of a team of people or the functioning of a specific organizational structure, assessed with the measure of diligence that should be required pursuant to Article 355 CC and comparing with this standard of actions that actually took place – for example, the judgment of the Supreme Court of 11 May 2005 (Case III CK 652/04).

Anonymous guilt may be related to the concept of "organizational guilt" manifested in neglect in terms of organization, safety, hygiene and patient care. It is irrelevant which of the hospital employees was negligent. If the personal guilt of the medical staff is not established, the principle of anonymous guilt is adopted, referring to, for example, failure to ensure the patient's safety of stay, failure to provide appropriate treatment conditions, appropriate equipment, appropriate and qualified personnel (Judgment of the Court of Appeal in Szczecin of September 24, 2018, I ACa 222/18). With such an understanding of liability, it is sufficient to prove, at least on the basis of a factual presumption, that there has been a culpable breach of the principles and standards of dealing with the patient when providing health services, in order to recognize that the medical entity is liable for the damage sustained by the patient. Responsibility for anonymous or organizational guilt should be regarded as the responsibility for someone else's guilt, regulated in the provisions of Article 429 and 430 CC.

Guilt in the choosing as defined in Article 429 CC assigns responsibility for the behavior of the perpetrator of the damage, who was entrusted with the performance of the activities. This entrustment does not have to result from a contract[8] named or unnamed (rather from a civil-legal relationship than from an employment contract, e.g. a contract of mandate, provision of a service, treatment contract, etc.), and may also result from the actual situation. Assigning liability to the entrusting entity will become possible when the damage is the result of an unlawful act of the perpetrator entrusted with the performance of the activity, and there is a normal causal link between his action and the damage, which is functionally related to the entrusted activity. This means that for the obligation of compensa-

---

[8] See commentary to Article 429, thesis No. 1–2 [Długoszewska–Kruk 2019].

tion to arise, the preparator must act in such a way that is characterized by behavior within the limits of the authorization (otherwise the contractor's personal liability will result from Article 415 or 416 CC), and the damage is the result of entrusting the activities, and not on the occasion of its performance.

As an example of the emergence of a compensation obligation resulting from the guilt in the choosing, it would be entrusting a doctor with a given specialization to perform activities in the field of another specialization, where the entrusting entity is aware of this, and what was the cause of the damage. When selecting a contractor, the entrusting entity should exercise due diligence.

The exculpatory premises[9] include the lack of guilt in the choosing, entrusting the performance of the activity to a specialist, and the existence of a subordination relationship between the contractor and the entrusting entity. Proving these facts in order to free oneself from liability under Article 429 CC, rests with the entrusting entity, but it is enough to prove one of these three cases mentioned above. No guilt in the choosing is to exercise due diligence when entrusting activities to perform by a specific person – checking their predispositions, qualifications, knowledge and skills, including, for example, the right to practice a profession or having the right to perform certain activities. Releasing oneself from liability is also possible by showing that the activities have been entrusted to a specialist (a person, enterprise or establishment which, in the scope of their professional activity, performs such activities).

The exculpatory premises specified in Article 429 CC will apply when the aggrieved party demonstrates two facts: entrusting the activities and unlawful conduct of the contractor, which is causally related to the damage. On the other hand, the existence of guilt in the choosing is a presumption (rebuttable on the part of the entrusting entity), which the aggrieved party does not have to prove [Safjan 2020]. It should be noted, however, that in the event of direct and willful fault of the contractor, it may constitute a premise for joint and several liability of the contractor and the entrusting entity, pursuant to the wording of Article 441 CC. Exculpation of the entrusting entity, consisting in no guilt in the choosing, is not possible in the case of the anonymity of the contractor, unless the entrusting entity proves that they are is not guilty in the choosing with regards all persons entrusted with the performance of the activities.[10]

Pursuant to Article 430 CC the contractor who was entrusted with the activity, and who is the perpetrator of the damage, must be subject to the management and follow the instructions of the entrusting entity (the premise of supremacy). Entrusting the performance of activities must take place on the entrusting party's own account. This type of tort refers to the person performing the entrusted activity, who will cause damage with their unlawful behavior. The premise of supremacy will usually apply here to employment contracts concluded between the entrusting party and the contractor, but it will mainly apply to the actual state of the

---

[9] See commentary to Article 429, theses No. 6–9 [Safjan 2020].
[10] See commentary to Article 429, theses No. 49 [Borysiak 2020].

supremacy exercised. At this point it should be noted that the contracting autho-
rity (e.g. medical entity) will be responsible for the contractor (e.g. medical perso-
nnel). The condition is exercising supervision, which is defined not as interferen-
ce with the physician's autonomy in providing medical services, but rather based
on the organisational relationship of subordination, the more so as this relation-
ship does not oppose the physician's independence in carrying out the process of
treatment, diagnosis and therapy – such as in the judgment of the Supreme Court
of 26 January 2011 (Case IV CSK 308/10). The above reflexions regarding the
guilt also apply to this provision.

In the cases specified in Article 429 and 430 CC additional provisions on the
liability of an *ex contractu* may also apply, which results from Article 443 CC.
Such a coincidence of application of the provisions applies, as indicated in the li-
terature on the subject [Safjan 2020], to a situation when, for example, the pa-
tient's body is damaged in connection with a faulty medical treatment by a doctor
with whom the entity performing medical activities concluded a medical service
contract. Due diligence will be assessed taking into account of the professional
character of that activity and specific tortious behavior, on the basis of an abstract
state/stage and concrete comparison – whether the applicable procedures were
complied with, whether the principle of the art of the profession was followed.
The obligation of such an assessment results from the directive outlined in the
provisions of Article 472 in connection with Article 471 CC and with regard to
due diligence, outlined in relation to professionals (Article 355(2) CC). When
assigning responsibility for someone else's guilt, one must also take into account
the legal relationship between the medical entity and people who are medical per-
sonnel. Pursuant to Article 33 UDL in the case of medical activities performed
by a physician as part of an individual medical practice only in a medical institu-
tion on the basis of an agreement with the medical entity running this institution
or on the basis of an individual specialist medical practice only in a medical insti-
tution on the basis of an agreement with the medical entity running this institu-
tion, the physician and the medical entity shall bear joint and several liability for
damages resulting from the provision of healthcare services or unlawful omission
to provide healthcare services.

It should be noted, however, that liability for damages does not always have
to be complete. It depends both on the ordinary effects of the action or omission
of the person liable for compensation (Article 361(1) CC) and on the injured par-
ty's possible contribution to the increase or occurrence of the damage (Article
362 CC). It's worth noting that the injured party's contribution is his action and
omission. The ordinary effects from which the damage resulted are assessed[11] on
the basis of experience, knowledge and logical reasoning by the court, and con-
sists, in a way, of recreating the past, based on the collected evidence of the course
of events. In the case of damages caused by the fault of entities performing me-

---

[11] See commentary to Article 361, theses No. 5–7 [Banaszczyk 2020].

dical activities, the difficulty in determining the causal relationship is mainly due to the assessment of the omission. In the doctrine[12] and jurisprudence, it is assumed that in order to establish such a fact it is sufficient to settle for findings that if it had not been for the omission, the damage would not have occurred.

Bearing in mind the above analysis, it should be emphasized once again that responsibility for the use of a medical device, such as a computer program with AI, or a device with artificial intelligence, will be borne by the entity performing the medical activity, which will have the right to make a recourse claim against the manufacturer of this device in case it malfunctions.

CONCLUSIONS

Bearing in mind the considerations presented above, it should be emphasized that while the provision of healthcare services with the use of teleinformatic means has been directly provided for by the law (Article 3(1) UDL), the use of AI for the implementation of medical activities has not been regulated directly. Thus, it is necessary to create legal regulations that will organize the rules of using AI in medicine, and at the same time define the rules of liability for damages resulting from its functioning. Currently, Polish law does not even define a legal definition of a concept of artificial intelligence. Under Polish law, the term AI appears only in the Act of 17 January 2019 on the Future Industry Platform Foundation, as well as in the Regulation of the Council of Ministers of 7 June 2017 on granting the Scientific and Academic Computer Network the status of a state research institute. At the moment, the rules of civil liability for damages caused as a result of AI's actions should be considered from the perspective of the analogy legis. As indicated in the content of this paper, liability for damage caused by AI should be identified with liability for a dangerous product. At the same time, the civil liability of the medical entity for damages resulting from the use of AI in the diagnostic imaging process will be subject to the general regime of tort liability. Regardless of the need to regulate the legal aspects of the functioning of artificial intelligence and the rules of liability for damage caused by it, it is necessary to consider the ethical aspects of its use, especially on the grounds related to the protection of human life and health.

REFERENCES

Anderson, Toni, William C. Torreggiani, Peter L. Munk, et al. 2020. "The impact of the introduction of artificial intelligence in radiology and its potential legal implications in the UK and Ireland." *BJR Open* 2 (1):20200030. https://doi.org/10.1259/bjro.20200030

Banaszczyk, Zbigniew. 2020. *Kodeks cywilny. Komentarz.* Vol. 1: *Art. 1–449^{10}.* 10th edition. Edited by Krzysztof Pietrzykowski. Warsaw: C.H. Beck.

---

[12] See commentary to Article 361, thesis No. 21 [Banaszczyk 2020].

Benke, Kurt, and Geza Benke. 2018. "Artificial Intelligence and Big Data in Public Health." *Int. J Environ. Res Public Health* 15 (12):2796. https://doi.org/10.3390/ijerph15122796

Borysiak, Witold. 2020. *Komentarz. Kodeks cywilny.* 27th edition. Edited by Konrad Osajda. Warsaw: C.H. Beck.

Bosek, Leszek. 2019. "Perspektywy rozwoju odpowiedzialności cywilnej – zagadnienia wybrane odpowiedzialności za inteligentne roboty." *Forum Prawnicze* 2 (52). https://doi.org/10.32082/fp.v2i52.200

DeSanti, Carol, Kimberly Miller, William Dale, et al. 2019. "Cancer statistics for adults aged 85 years and older, 2019." *CA Cancer J Clin* 69:452–67.

Długoszewska–Kruk, Iwona. 2019. *Kodeks cywilny. Komentarz*. 2nd edition. Edited by Mariusz Załucki. Warsaw: C.H. Beck.

Frost Emma K., and Stacy M. Carter. 2020. "Reporting of screening and diagnostic AI rarely acknowledges ethical, legal, and social implications: a mass media frame analysis." *BMC Medical Informatics and Decision Making* 20 (1):325. https://doi.org/10.1186/s12911-020-01353-1

Górski, Sebastain. 2019. "Najważniejsze momenty w historii rozwoju SI #1. Od Turinga do pierwszej zimy." https://www.sztucznainteligencja.org.pl/najwazniejsze-momenty-w-historii-rozwoju-si-1-od-turinga-do-pierwszej-zimy/ [accessed: 03.03.2021].

Hessler, Gerhard, and Karl–Heinz Baringhaus. 2019. "Artificial Intelligence in Drug Design Molecules." *Molecules* 23 (10), 2520. https://doi.org/10.3390/molecules23102520

Kaplan, Andreas, and Michael Haenlein. 2019. "Siri, Siri in my Hand, who's the Fairest in the Land? On the Interpretations, Illustrations and Implications of Artificial Intelligence." *Business Horizons* 62 (1):15–25.

Kuźmicka–Sulikowska, Joanna. 2013. "Pojęcie produktu niebezpiecznego na gruncie przepisów kodeksu cywilnego dotyczących odpowiedzialności za szkodę wyrządzoną przez ten product." https://www.bibliotekacyfrowa.pl/dlibra/show-content/publication/edition/42758?id=42758 [accessed: 11.01.2021].

Mayo, Roy Cody, and Jessica Leung. 2018. "Artificial intelligence and deep learning-Radology's next frontier?" *Clin Imaging* 49:87–88.

Mei, Xueyan, Hao–Chih Lee, et al. 2020. "Artificial intelligence–enabled rapid diagnosis of patients with COVID-19." *Nature Medicine* 26:1224–228. https://doi.org/10.1038/s41591-020-0931-3

Niel, Olivier, and Paul Bastard. 2019. "Artificial Intelligence in Nephrology: Core Concepts, Clinical Applications, and Perspectives." *Am J Kideny Dis*. 74 (6):803–10. https://doi.org/10.1053/j.ajkd.2019.05.020

Rodriguez–Ruiz, Alejandro, Kristina Lång, et al. 2019. "Stand-alone artificial intelligence for breast cancer detection in mammography: comparison with 101 radiologists." *J Natl Cancer Inst* 111:916–22.

Roth, Holger, Le Lu, Jiamin Liu, et al. 2016. "Improving computer-aided detection using convolutional neural networks and random view aggregation." *IEEE Trans Med Imaging* 35:1170–181.

Safjan, Marek. 2020. *Kodeks cywilny*. Vol. 1. *Komentarz do art. 1–449^{10}*. 10th edition. Edited by Krzysztof Pietrzykowski. Warsaw: C.H. Beck.

Sarwar, Shihab, Anglin Dent, Kevin Faust, et al. 2019. "Physician perspectives on integration of artificial intelligence into diagnostic pathology." *NPJ Digit Med.* 2:28. https://doi.org/10.1038/s41746-019-0106-0

Shimizu, Hideyuki, and Keiichi I. Nakayama. 2020. "Artificial intelligence in oncology." *Cancer sience* 111 (5):1452–460. https://doi.org/10.1111/cas.14377

Siegel, Rebeca, Kimberly Miller, and Ahmedin Jemal. 2019. "Cancer statistics, 2019." *CA Cancer J Clin* 69:7–34.

Wałachowska, Monika. 2020. "Sztuczna inteligencja a zasady odpowiedzialności cywilnej." In *Prawo sztucznej inteligencji*, edited by Luigi Lai, and Marek Świerczyński, 57–68. Warsaw: C.H. Beck.

.