

Artificial Intelligence and Medical Devices: Do We Need New Regulation?*

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Abstract

The article deals with the legal aspects of the use of artificial intelligence in health care, with a focus on clinical decision support systems and surgical robots. Emphasis is placed on the regulation of medical devices and product liability. The author analyses how the current European legislation affects the use of the above technologies in health care and examines its shortcomings. She then uses these findings to evaluate whether new comprehensive legislation is needed or whether it would be sufficient to adjust the current legislation to the specific features of artificial intelligence.

Keywords

Artificial Intelligence; Robot; Health Care; Medical Devices; Civil Liability; Product Liability; European Law.

Introduction

Artificial intelligence (hereinafter “AI”) can be viewed as a field of study¹ or as a specific emerging technology.² This article will be based on the latter view.

There are a number of doctrinal definitions of AI, but most of them are so general that they cannot be used for the purposes of legal regulation. For example, Russel and Norwig’s overview of AI definitions³ indicates that AI is a system that thinks or acts rationally, like a human. More specifically, Bellman considers AI to be a system performing “*activities that we associate with human thinking, activities such as decision-making, problem solving, learning, creating,*

* This article was created within the project “Grantová schémata na UK” (reg. no. CZ.02.2.69/0.0/0.0/19_073/0016935) no. START/SOC/017 titled Law and Artificial Intelligence – Challenges and Opportunities, solved at the Faculty of Law, Charles University.

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1 KURZWEIL, R. What Is Artificial Intelligence Anyway? As the techniques of computing grow more sophisticated, machines are beginning to appear intelligent – but can they actually think? *American Scientist*. 1985, Vol. 73, no. 3, pp. 258–264. ISSN 0003-0996.

2 Explanatory memorandum to the proposal for a regulation of the European Parliament and of the council laying down harmonised rules on artificial intelligence (Artificial Intelligence Act) and amending certain union legislative acts (COM/2021/206), Art. 1.1.

3 RUSSEL, S., NORWIG, P. *Artificial Intelligence: A Modern Approach*. 3. ed. New Jersey: Prentice Hall, 2009, p. 2. ISBN 978-0136042594.

game playing, and so on".⁴ Similarly, O'Neill defines AI as a "computer system that can do tasks that humans need intelligence to do".⁵

Would it be effective to use such definitions in terms of imposing legal obligations on legal persons? In particular, would it be effective to require anyone developing systems corresponding to such a definition to be insured? I argue that this kind of regulation would bring no benefit, as no one would know for certain whether they fall within the scope of AI or not. This uncertainty would discourage companies from developing AI technologies.

However, a more precise definition of AI can be found in a proposal laying down harmonised rules on artificial intelligence (Artificial Intelligence Act), which was introduced by the European Commission (hereinafter the "AI Act").⁶ Article 3(1) of the AI Act states:

*"'artificial intelligence system' (AI system) means a system that is designed to operate with elements of autonomy and that, based on machine and/or human-provided data and inputs, infers how to achieve a given set of objectives using machine learning and/or logic- and knowledge based approaches, and produces system-generated outputs such as content (generative AI systems), predictions, recommendations or decisions, influencing the environments with which the AI system interacts."*⁷

This article will follow the definition of AI introduced in the AI Act.

To make this article specific, I will focus on two particular applications of AI in health care: clinical decision support systems (hereinafter "CDSS") and surgical robots.

By examining these particular applications, I will seek to answer my research question: Do we need new regulation of the use of AI-powered medical devices? There is no doubt that regulation of AI-powered medical devices is essential. For instance, if we should fail to regulate AI-powered medical devices sufficiently, unreliable technologies lacking interpretability and transparency might find use in this sector. This could result in failures that would, in turn, cause AI to be rejected by both regulators and users. Quinn argues:

*"The partial or complete rejection of potentially beneficial AI medicine by regulators and users should cause concern, since it prevents healthcare from achieving its basic moral and social goals of continually improving the health of individuals and populations while avoiding unnecessary harm. At the limit, a serious erosion of public trust in medical AI as it begins to take hold could even damage trust in healthcare systems themselves."*⁸

⁴ BELLMAN, R. *An introduction to artificial intelligence: can computers think?* San Francisco: Boyd and Fraser Publishing Company, 1978, p. 3. ISBN 978-0878350667.

⁵ O'NEILL, M. Explainer: what is artificial intelligence? *ABC News* [online]. 2017 [cit. 16. 1. 2022]. Available at: <http://www.abc.net.au/news/2017-08-07/explainer-what-is-artificial-intelligence/8771632>

⁶ Proposal for a Regulation of the European Parliament and of the Council laying down harmonised rules on artificial intelligence (Artificial Intelligence Act) and amending certain Union legislative acts, version as of 25 November 2022.

⁷ Artificial Intelligence Act, op. cit., Art. 3(1).

⁸ QUINN, T., JACOBS, S., SENADEERA, M., LE, V., COGHLAN, S. The three ghosts of medical AI: Can the black-box present deliver? *Artificial Intelligence in Medicine* [online]. 2022, Vol. 124. DOI: <http://doi.org/10.1016/j.artmed.2021.102158>

So the question is not whether we need regulation of AI-powered medical devices, but rather whether we need comprehensive new regulation or whether the current regulation of medical devices and product liability can suffice, with some modifications.

I will follow the methodological approaches described by Petit,⁹ i.e. black letter law approach and emergent approach. Under the black letter law approach, I will analyse how current law applies / is applicable analogously to the AI applications under scrutiny. Within the emergent approach, I will determine whether the specific use of AI requires new comprehensive statutory law.¹⁰

In other words, I will assess whether current law is sufficient to address the major issues related to the specific application of AI in health care or whether new, comprehensive legal regulation is inevitable. The basic idea formulated by Petit is that the emergent approach might lead to the creation of redundant law – meaning the existence of a large number of laws that are not actually needed in practice. On the other hand, analogous application of existing law to this new technology might be fragmented and based on an imperfect understanding of the specific use of AI.¹¹ Hence, an in-depth analysis is necessary.

In this article, I will focus mostly on European law, and to a lesser extent, on German and Czech laws. I have chosen to focus primarily on European law, with a secondary emphasis on German and Czech laws, for several reasons.

Firstly, European law provides a comprehensive framework for regulating medical devices across multiple member states. It encompasses directives and regulations that harmonize the legal requirements and ensure consistent standards within the European Union.

Secondly, Germany and the Czech Republic are chosen as specific examples due to the similarity of their legal systems, particularly concerning civil liability issues, as well as the common practices observed within the respective jurisdictions.

1 Background

In this chapter, I will present the aforementioned means of AI's application in health care.

1.1 Clinical decision support systems

Generally, CDSS is software designed to support clinicians when making decisions about diagnosis, treatment, medicament dosage, etc. This software is first trained using a vast number of data (data base); then, with regard to a specific patient, it generates relevant medical knowledge useful for the clinician.¹²

⁹ Nicolas Petit, professor at the European University Institute, specialising i.a. in law and technology.

¹⁰ PETIT, N., COOMAN, J. de. Models of Law and Regulation for AI. *Working paper EUI* [online]. RSCAS 2020/63 [cit. 12. 3. 2022]. Available at: <https://cadmus.eui.eu/handle/1814/68536>

¹¹ Ibid.

¹² European Commission, Guideline Implementation with Decision Support systems.

There are a variety of CDSSs. The simplest ones are not even deemed to be AI-powered. Such simple CDSS feature no human-like activity, such as perceiving, natural language processing or learning. They only trigger alerts and send notifications.

By contrast, the oldest AI-powered CDSSs use inferential reasoning or predict the likelihood of a particular diagnosis. For instance, in the 1970s Stanford University developed a CDSS called MYCIN, which was able to recognise bacterial infection and suggest treatment.¹³

However, such knowledge-based systems, which generate recommendations through a series of encoded conditional instructions, were insufficient to solve more complex problems. Almost 20 years later, machine learning systems were developed. These systems “*seek to relate variables to outcomes through complex non-linear functions learned directly from the data (without necessarily having prior domain knowledge)*”.¹⁴

Even more sophisticated CDSSs, based on neural networks, were developed at the turn of the millennium.¹⁵ They are able to solve difficult problems, such as natural language processing or recognising patterns in complex data sets.¹⁶ One of the most famous CDSSs is IBM’s Watson for Oncology.¹⁷

IBM intended to create an AI-powered tool that would facilitate the clinicians’ work by generating a list of treatment options. The principal idea was that there is an overwhelming amount of medical expert knowledge and new publications come out daily. It is therefore extremely difficult for a clinician to keep track of all this information.

Watson for Oncology was designed to use natural language processing to draw from over 300 medical journals and over 200 textbooks, and extract patient’s clinical data from medical records to generate a prioritised list of treatment options. Watson should also display relevant published evidence and literature so that they are at hand for the clinician.¹⁸

Unfortunately, although IBM had invested huge amounts in the development of this technology, Watson for Oncology ultimately failed. The recommendations it made were unsafe and incorrect.¹⁹

More promising results can be expected from CDSSs focusing on diagnostics. For example, AI can be used to detect skin cancer. It can be trained to recognise various types of skin lesions by recording numerous input images, i.e. training data. Subsequently, the system

¹³ BENNET, C., DOUB, T. Expert Systems in Mental Healthcare: AI Applications in Decision Making and Consultation. In: LUXTON, D. (ed.). *Artificial Intelligence in Behavioral and Mental Health Care*. Elsevier, 2016, pp. 27–47. ISBN 978-0124202481. DOI: <https://doi.org/10.1016/B978-0-12-420248-1.00002-7>

¹⁴ QUINN, JACOBS, SENADEERA, LE, COGHLAN, op. cit.

¹⁵ Ibid.

¹⁶ BENNET, DOUB, op. cit.

¹⁷ FROOMKIN, M., KERR, I., PINEAU, J. When AIs Outperform Doctors: Confronting the Challenges of a Tort-Induced Over-Reliance on Machine Learning. *Arizona Law Review*. 2019, Vol. 61, no. 33, pp. 32–99. ISSN 0004–153X.

¹⁸ MCDUGALL, R. Computer knows best? The need for value-flexibility in medical AI. *Medical Ethics* [online]. 2019, Vol. 45, no. 3, pp. 156–160. DOI: <http://doi.org/10.1136/medethics-2018-105118>

¹⁹ Artificial Intelligence Failure at IBM ‘Watson for Oncology’. *ICMR* [online]. 2022 [cit. 28. 7. 2022]. Available at: <https://icmrindia.org/casestudies/catalogue/IT%20and%20Systems/ITSY126.htm>

is able to classify patient's skin lesions.²⁰ In 2017 research showed that AI had the capacity to classify skin lesions with the same degree of success as experienced dermatologists.²¹ CDSSs are intended to support clinicians in their decision-making; they are not meant to replace clinicians and treat patients autonomously. That being said, the US Food and Drug Administration²² approved an AI-powered software to detect diabetic retinopathy in 2018.²³ This software is able to determine autonomously whether a patient should be referred to a clinician or rescreened in 12 months.²⁴

1.2 Surgical robots

The term “robot” has its origins in the world of science-fiction. It was first used by Karel Čapek²⁵ in his play R.U.R of 1920, where Čapek described the destruction of humanity as a consequence of overly advanced technology that got out of control.²⁶ The topic of robots became quite common in science-fiction, and in 1942, Asimov²⁷ formulated his famous Three Laws of Robotics (in a story named Runaround).²⁸ The popularity of robots grew even farther when R2-D2 and C-3PO first appeared in George Lucas's Star Wars film in 1977.²⁹

Nevertheless, robots are no longer science-fiction. They are widely used both in industry (e.g. Selective Compliance Assembly Robot Arm, SCARA)³⁰ and in households (e.g. vacuum

²⁰ FILIPPO, R., HILLIGOSS, H., KRISHNAMURTHY, V., BAVITZ, C., KIM, L. Artificial Intelligence & Human Rights: Opportunities & Risks. *Berkman Klein Center for Internet & Society Scholarly Articles* [online]. 2018 [cit. 8. 8. 2022]. Available at: <https://dash.harvard.edu/handle/1/38021439>

²¹ ESTEVA, A., KUPREL, B., NOVOA R. et al. Dermatologist level classification of skin cancer with deep neural networks. *Nature* [online]. 2017, Vol. 7639, no. 542, pp. 115–118. DOI: <http://doi.org/10.1038/nature21056>

²² US federal agency of the Department of Health and Human Services supervising i.a. medical devices.

²³ Eye disease affecting patients with diabetes.

²⁴ FDA permits marketing of artificial intelligence-based device to detect certain diabetes-related eye problems. *US Food and Drug Administration* [online]. 2018 [cit. 27. 2. 2022]. Available at: <https://www.fda.gov/news-events/press-announcements/fda-permits-marketing-artificial-intelligence-based-device-det-ect-certain-diabetes-related-eye>

²⁵ Karel, Čapek, Czech writer, playwright and critic.

²⁶ ČAPEK, K. *Dramata: Loupežník: R.U.R.: Věc Makropulos: Bílá nemoc: Matka*. Prague: Československý spisovatel, 1992, p. 102. ISBN 802020363X.

²⁷ Isaac Asimov, American science fiction author.

²⁸ ASIMOV, I. *I, Robot*. New York: Spectra, 1991, p. 30. ISBN 978-0553294385.

The Three Laws of Robotics:

1) A robot may not injure a human being or, through inaction, allow a human being to come to harm.

2) A robot must obey orders given to it by human beings except where such orders would conflict with the First Law.

3) A robot must protect its own existence as long as such protection does not conflict with the First or Second Law.

²⁹ 25 Great Moments In Robotics History. *Forbes* [online]. 2006 [cit. 20. 3. 2022]. Available at: https://www.forbes.com/2006/08/17/cx_de_0817robottime.html?sh=7c9652f73dae

³⁰ Scara. *The Robot Hall of Fame* [online]. 2006 [cit. 4. 4. 2022]. Available at: <http://www.robothalloffame.org/inductees/06inductees/scara.html>

cleaners).³¹ Robots also serve in health care – Danbury Hospital, US, used one named HelpMate as early as 1987. HelpMate is a transport service robot able to navigate the hospital environment and carry various medical materials.³²

Regarding surgical robots, they are used to conduct robot-assisted surgeries. For instance, a robot named Da Vinci has been approved in the US to this end.³³ During an operation, the surgeon sits in a console and uses a vision system that zooms in on the surgical area and handles tiny instruments. These instruments are more precise than human hands and can access hard-to-reach organs and body parts.³⁴ Today's surgical robots are used and controlled by humans and are therefore not considered autonomous AI.³⁵

However, autonomous surgical robots are already being developed (e.g. the Smart Tissue Autonomous Robot). These robots must have the ability of human-like perception, i.e. they must see the environment, and the ability to think and act, to successfully perform the surgery. Despite the complexity of autonomous surgical robots, Panesar argues that we can expect to see them being deployed by the end of the 21st century.³⁶

Surgical robots can perform surgeries and related tasks more accurately and quickly than a human surgeon, and through a single incision.³⁷ Thus, surgical robots will serve to satisfy the patient's right to the highest attainable standard of health.³⁸

The benefits of surgical robots, such as the accuracy of intervention and the potential to reduce health care costs, was acknowledged by the European Parliament in its recommendation on Civil Law Rules on Robotics.³⁹ On the other hand, the patient might suffer serious harm in case of an error. Such robots must therefore undergo rigorous certification. The challenges associated with surgical robots were highlighted in the aforementioned recommendation as the European Parliament:

“[u]nderlines the need to define the minimum professional requirements that a surgeon must meet in order to operate and be allowed to use surgical robots; considers it vital to respect the principle of the

³¹ Home is Where the Robot is: Vacuum Cleaners, Security Guards, and Old-Age Companions. *The New Atlantis* [online]. 2003, no. 1, pp. 136–138. Available at: <https://www.jstor.org/stable/43152865>

³² ENGELBERGER, G. HelpMate, a service robot with experience. *Industrial Robot* [online]. 1998, Vol. 25, no. 2, pp. 101–104. DOI: <http://doi.org/10.1108/01439919810204667>

³³ PANESAR, S., CAGLE, Y., CHANDER, D., MOREY, J., FERNANDEZ-MIRANDA, J., KLIOT, M. Artificial Intelligence and the Future of Surgical Robotics. *Annals of Surgery* [online]. 2019, Vol. 270, no. 2, pp. 223–226. DOI: <http://doi.org/10.1097/SLA.0000000000003262>

³⁴ COMPTON, K. Da Vinci Surgical System. *Drugwatch* [online]. 2021 [cit. 5. 2. 2022]. Available at: <https://www.drugwatch.com/davinci-surgery/>

³⁵ PANESAR, CAGLE, CHANDER, MOREY, FERNANDEZ-MIRANDA, KLIOT, op. cit.

³⁶ Ibid.

³⁷ DEVLIN, H. The Robots Helping NHS Surgeons Perform Better, Faster and For Longer. *The Guardian* [online]. 2018 [cit. 17. 4. 2022]. Available at: <http://www.theguardian.com/society/2018/jul/04/robots-nhs-surgeons-keyhole-surgery-versus>

³⁸ CESCR General Comment No. 14: The Right to the Highest Attainable Standard of Health (Art. 12), no. E/C.12/2000/4.

³⁹ European Parliament resolution of 16 February 2017 with recommendations to the Commission on Civil Law Rules on Robotics (2015/2103(INL), Art. 34.

*supervised autonomy of robots, whereby the initial planning of treatment and the final decision regarding its execution will always remain with a human surgeon; emphasises the special importance of training for users to allow them to familiarise themselves with the technological requirements in this field...*⁴⁰

2 Certification of medical devices

The use of AI-powered tools might significantly improve the quality and accessibility of health care. The importance of AI in health care was also recognised by the European Parliament in its recommendation on Civil Law Rules on Robotics. The European Parliament emphasised “*the growing trend towards self-diagnosis using a mobile robot and [...] the need for doctors to be trained in dealing with self-diagnosed cases*”, and acknowledged that diagnostic technology might reduce the risk of human error and increase the quality of life and life expectancy.⁴¹ Although the recommendation deals expressly with robots, the statement regarding self-diagnosis and reducing human error is more relevant to CDSS.

Nevertheless, the use of AI in health care raises a number of questions. The most obvious one is: Who has to compensate the patient for any harm caused by AI? Other, no less important, issues relate to ensuring the security of technology, avoiding bias, respecting privacy and protecting personal data.

In addition, there are a number of ethical issues associated with the use of this technology (e.g. prioritising generally accepted values over patient-specific values, resulting in disrespect to patient’s autonomy),⁴² but these are beyond the scope of this article.

In European civil codes, civil liability is usually based on fault, while strict liability tends to be an exception, relevant for entities carrying out an abnormally dangerous activity and some other cases set out by national law.⁴³

When it comes to health care, clinicians must adhere to a certain standard of care, both in Germany and in the Czech Republic. If they do so, they cannot be found culpable of any harm (no subjective fault) and will thus not be held liable in the event of an injury.^{44,45} This, however, does not rule out that their health care facility might be required to compensate the patient for damage on the basis of strict liability imposed on the facility by national law.

It is crucial for the assessment of a clinician’s fault-based liability whether the AI-powered tool he/she has used was properly certified and employed in accordance with the manufacturer’s instructions, as the use of non-certified tool as well as any failure to adhere to such instructions would be considered a violation of standard of care.

⁴⁰ European Parliament resolution of 16 February 2017 with recommendations to the Commission on Civil Law Rules on Robotics (2015/2103(INL)), Art. 33.

⁴¹ Ibid., Art. 33.

⁴² MCDUGALL, op. cit.

⁴³ Principles of European Tort Law (PETL), Chapters 4 and 5.

⁴⁴ DETTLING, H. Künstliche Intelligenz und digitale Unterstützung ärztlicher Entscheidungen in Diagnostik und Therapie. *Pharma Recht*. 2019, Vol. 41, no. 12, pp. 633–642. ISSN 0172-6617.

⁴⁵ HOLČAPEK, T. Občanskoprávní odpovědnost v medicíně a její uplatňování u českých soudů. *Právní rozhledy*. 2016, Vol. 24, no. 9, pp. 305–311. ISSN 1210-6410.

Both CDSSs and surgical robots are considered a medical device pursuant to Article 2(1) of Regulation (EU) 2017/745 on medical devices⁴⁶ (hereinafter the “MD Regulation”). Each medical device must meet the safety requirements set out in the MD Regulation before it is placed on the market.⁴⁷ The MD Regulation divides medical devices into classes I, IIa, IIb and III, according to the associated risk.⁴⁸

I agree with Dettling that, in view of their function, CDSSs fall at least in category IIa. The same applies to surgical robots according to Article 5.2 of Annex VIII to the MD Regulation. Consequently, before such tool is placed on the market, it has to undergo a certification process, which always requires, as a minimum, that a Member State’s conformity assessment body is involved in the process (the ‘notified body’).⁴⁹ Clinical investigations including scientific and ethical reviews performed by an ethics committee are necessary in the case of class III medical devices.⁵⁰

To receive a certification, the tool must meet the requirements laid down by the MD Regulation, in particular:

“Devices that incorporate electronic programmable systems, including software, or software that are devices in themselves, shall be designed to ensure repeatability, reliability and performance in line with their intended use. In the event of a single fault condition, appropriate means shall be adopted to eliminate or reduce as far as possible consequent risks or impairment of performance.

For devices that incorporate software or for software that are devices in themselves, the software shall be developed and manufactured in accordance with the state of the art taking into account the principles of development life cycle, risk management, including information security, verification and validation.”⁵¹

Dettling notes critically that repeatability and reliability cannot be guaranteed for AI-powered tools based on machine learning, and governmental authorities might therefore be hesitant to certify such products.⁵² The problem is that machine learning allows the system to continue to evolve after it is deployed in practice.

I believe that the process of certification is very important and the benefits of this process fully outweigh the necessary administrative burden. In health care, it is not desirable for a medical device to evolve on the basis of machine learning after its deployment.

Nevertheless, the benefits of machine learning might still be exploited. I suggest that a medical device could be designed on the basis of machine learning principles, but the developments in the device’s procedures should always be put in place only after an update has been approved by human experts. That means that the tool would remain static until

⁴⁶ Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017, on medical devices, as amended.

⁴⁷ Ibid., Art. 5(1).

⁴⁸ Ibid., Art. 51(1).

⁴⁹ DETTLING, op. cit.

⁵⁰ Regulation (EU) 2017/745, op. cit., Art. 61 and 62.

⁵¹ Regulation (EU) 2017/745, op. cit., Annex I, Art. 17. 1. and 17. 2.

⁵² DETTLING, op. cit.

it is updated. *De lege ferenda*, a simpler and faster certification process should be available for an updated version of a medical device.

Although medical devices are primarily governed by the MD Regulation, the AI Act might apply to medical devices in relation to training data. MD Regulation focuses on technical standards for risk assessment in order to guarantee safety, but it does not prevent potential harm arising from using inappropriate data sets.⁵³ This issue could be addressed by the AI Act as the proposal contains data sets regulation.

The AI Act also sets out that the providers of high-risk AI systems are required to establish a risk management system,⁵⁴ design the system to enable human oversight,⁵⁵ and ensure safety during the whole lifecycle of the AI system.⁵⁶

The requirement of enabling human oversight is often criticised, as the interpretability and transparency of neural network systems might be impossible to ensure in view of their complexity.⁵⁷ Nonetheless, Quinn states:

*“In more complex models that use more complex reasoning, the direct interpretation process becomes complicated and quickly expands beyond simple logical comprehensibility (as is the case for many deep neural networks, in which the opacity arises from the multiple layers of non-linearity). However, there are ongoing efforts to make deep models more interpretable, including the thinning of neural connections and the imposing of semantic monotonicity constraints.”*⁵⁸

Human oversight and transparency are very important to enable a dialogue between clinicians and patients, and I therefore consider it essential to insist on the transparency requirement.

To conclude: in terms of civil liability, if clinicians use an AI-powered tool and their patient suffers harm, the clinicians will not be required to pay damages provided that they met the mandatory standard of care. This standard of care has been met if the tool was certified, properly installed, maintained, and used in accordance with its intended purpose.⁵⁹

As mentioned above, the use of AI-powered tools might significantly improve the quality and accessibility of health care. Therefore, the certification process laid down by the MD Regulation could be simplified at least for updated versions of previously certified medical devices. In addition, the introduction of a requirement for certification should be considered for data products supplied by data suppliers, as the training data accessible

⁵³ OIRSCHOT, J., KOLFSCHOOTEN, H. The EU Medical Devices Regulation and the EU AI Act: A short comparison. *Health Action International* [online]. 2023 [cit. 4. 6. 2023]. Available at: https://haiweb.org/wp-content/uploads/2023/03/MDR-AIAct_OnePager_FINAL.pdf

⁵⁴ Artificial Intelligence Act, op. cit., Art. 9.

⁵⁵ *Ibid.*, Art. 14.

⁵⁶ Explanatory memorandum, op. cit.

⁵⁷ WACHTER, S., MITTELSTADT M., RUSSELL, C. Counterfactual Explanations without Opening the Black Box: Automated Decisions and the GDPR. *Harvard Journal of Law & Technology* [online]. 2018, Vol. 31, no. 2, pp. 841–887. DOI: <http://doi.org/10.48550/arXiv.1711.00399>

⁵⁸ QUINN, JACOBS, SENADEERA, LE, COGHLAN, op. cit.

⁵⁹ DETTLING, op. cit.

to the system has a major impact on the software's proper functioning. As mentioned above, this could be achieved by the AI Act.

On the other hand, a new branch of law governing specifically certification of AI-powered medical devices would be redundant as it is already covered by the MD Regulation, and AI-powered medical devices do not differ substantially from any other medical software.

3 Product liability

Primarily, safety rules need to be established to avoid accidents. This has been achieved through the MD Regulation, which lays down conformity assessment rules. That being said, accidents cannot be completely eliminated in the world of emerging technologies. Civil liability thus needs to be set up appropriately so that an injured patient receives fair compensation for damage and so that manufacturers, programmers, AI trainers and users are incentivised to design, train and use AI responsibly. On the other hand, the rules should not be so strict as to discourage manufacturers from developing AI systems which benefit humanity.⁶⁰

3.1 Applicable law

Product liability is harmonised in the EU by the Product Liability Directive,⁶¹ which lays down the manufacturer's strict liability for defective products. The injured party must prove the existence of damage, the defect in the product, and a causal link between the damage and defect.⁶²

However, in view of the complexity of AI and the opacity of the algorithms used, I find it very difficult for the injured patient to prove that damage he/she has suffered was indeed caused by a defect in the product (e.g. the surgical robot). An injury itself does not imply that the surgical robot is defective. There are numerous interrelated processes in the human body, and it is not objectively possible to analyse and evaluate all these processes in detail. Hence, it might be very difficult to prove the existence of defect. Because of the need to prove the existence of defect, Zech even perceives product liability as *de facto* liability for negligence.⁶³

Another issue lies in the unclear definition of a product. According to the Product Liability Directive, product is understood as any movable object. Nevertheless, there are various types of software (e.g. stand-alone software, embodied software) and multiple opinions

⁶⁰ European Commission, Report on the safety and liability implications of Artificial Intelligence, the Internet of Things and robotics, p. 13.

⁶¹ Council Directive of 25 July 1985 on the approximation of the laws, regulations and administrative provisions of the Member States concerning liability for defective products (85/374/EEC) (Product Liability Directive), as amended.

⁶² *Ibid.*, Art. 4.

⁶³ ZECH, H. Liability for AI: Public policy considerations. *ERA Forum* [online]. 2021, Vol. 22, no. 1, pp. 147–158. DOI: <http://doi.org/10.1007/s12027-020-00648-0>

on whether software is indeed a product.⁶⁴ In the case of surgical robots, software might be considered a component of a robot, i.e. product. With CDSS as stand-alone software, the answer is unclear.

The European Commission pointed out:

“Although the Product Liability Directive’s definition of product is broad, its scope could be further clarified to better reflect the complexity of emerging technologies and ensure that compensation is always available for damage caused by products that are defective because of software or other digital features. This would better enable economic actors, such as software developers, to assess whether they could be considered producers according to the Product Liability Directive.”⁶⁵

In addition, it is unclear whether damage caused by a cybersecurity breach falls within the scope of the Product Liability Directive.⁶⁶

Further, the manufacturer may be exempted from liability if it proves *“that the state of scientific and technical knowledge at the time when he put the product into circulation was not such as to enable the existence of the defect to be discovered”*.⁶⁷ However, this provision may not be applicable in all Member States as individual Member States may opt for a derogation.

3.2 Considerations de lege ferenda

The Product Liability Directive was transposed to German law by the Product Liability Act (Produkthaftungsgesetz)⁶⁸ and to Czech law by the Civil Code (občanský zákoník).⁶⁹ Along with liability for defective products, both German and Czech laws contain a number of other types of liability that an injured party can invoke. However, many of them are based on fault (culpability), and the patient therefore needs to prove the existence damage, the existence of fault (culpability) and the causal link between the two.⁷⁰ This might be very difficult in the case of an injury sustained during a robotic surgery. On top of that, the patient may even suffer harm in cases where no subjective fault (culpability) is involved.

I consider it important to recognise fault-based liability of a clinician for harm caused by an insufficient level of care. However, complementary strict liability is necessary in the case of AI-powered medical devices.

Zech analysed the risks associated with the use of AI and the impact of liability rules on risk mitigation, and stated:

“In the case of development risks which are yet unknowable based on the state of scientific and technical knowledge, fault-based liability fails. There is no duty to avoid the unknowable. However, it would be sensible to hold those liable who are closest to the development and who are best able to foresee the

⁶⁴ European Commission, Report, op. cit., p. 14.

⁶⁵ Ibid.

⁶⁶ Ibid.

⁶⁷ Product Liability Directive, op. cit., Art. 7.

⁶⁸ German Product Liability Act, as amended (Gesetz über die Haftung für fehlerhafte Produkte).

⁶⁹ Czech Civil Code, as amended.

⁷⁰ European Commission, Report, op. cit., p. 13.

emerging risks, so that an incentive is created to acquire the necessary risk knowledge. This idea is, among others, the basis of strict liability. [...] Strict liability not only influences the level of care but also the activity level by fully internalising economic risks of AI, thereby activating private risk knowledge. It also incentivises the further development of existing technologies and, arguably, helps public acceptance.”⁷¹

Although various concepts of strict liability exist in both Germany and the Czech Republic, they do not regulate specifically liability related to AI. Yet, AI differs significantly from other products and activities. In the case of machine learning, for instance, data suppliers and machine trainers play an important role in the process, and the programmer is unable to fully control the system during its whole lifecycle.⁷²

Hence, I consider it necessary to adopt completely new legal regulation of product liability in relation to AI. The European Parliament is probably of the same opinion, as it adopted a legislative resolution on civil liability for the operation of AI systems in October 2020 and requested the European Commission to propose new law.^{73,74} The European Commission subsequently published proposals for an Artificial Intelligence Liability Directive (hereinafter “AILD”) and a Directive on Liability for Defective Product (hereinafter “DLDP”) on 28 September 2022.⁷⁵

The AILD specifically covers non-contractual civil law claims for damages caused by an AI system. It applies to situations where these claims are brought under fault-based liability regimes, which include statutory provisions that hold individuals responsible for compensating damage caused intentionally or due to negligence.⁷⁶

The DLDP should replace the currently effective Product Liability Directive and explicitly ensure that individuals who have been harmed have the right to seek compensation in cases where software or AI systems have caused damage.⁷⁷

The DLDP expands the definition of product to encompass not only physical items but also movables integrated into other movables or immovables, electricity, digital manufacturing files, and software. The scope of potentially liable parties has been expanded compared to the current Product Liability Directive. In addition to the manufacturer and quasi-manufacturer, the new directive includes the importer of the defective product, the authorized representative of the manufacturer, and fulfillment service providers as parties who can be held liable for product defects in the same manner as a manufacturer. Further,

⁷¹ ZECH, op. cit.

⁷² Ibid.

⁷³ European Parliament resolution, op. cit.

⁷⁴ Liability Rules for Artificial Intelligence. *European Commission* [online]. 28. 9. 2022 [cit. 26. 10. 2022]. Available at: https://commission.europa.eu/business-economy-euro/doing-business-eu/contract-rules/digital-contracts/liability-rules-artificial-intelligence_en

⁷⁵ Ibid.

⁷⁶ Executive summary of the impact assessment report. Proposal for a Directive of the European Parliament and of the Council on adapting non-contractual civil liability rules to artificial intelligence (AI Liability Directive).

⁷⁷ Proposal for a Directive of the European Parliament and of the Council on liability for defective products (COM/2022/495 final).

the proposed DLDP introduces a shift in the burden of proof concerning the defectiveness of the product, favoring the claimant.⁷⁸

In my opinion, the proposed directive is heading in the right direction. The inclusion of movables integrated into other movables or immovables, electricity, digital manufacturing files, and software within the definition of a product demonstrates an understanding of the evolving technological landscape. Additionally, the reversal of the burden of proof in favor of the claimant provides a fairer and more accessible avenue for seeking compensation in cases of product defectiveness of medical devices.

Conclusion

The use of AI-powered medical devices can increase the quality and accessibility of health care while reducing costs in the long-term. In other words, the use of medical AI appears to be essential to ensure everyone's enjoyment of the highest attainable standard of physical and mental health.

On the other hand, medical AI poses a number of challenges. An AI-powered medical device might fail, e.g. give a wrong recommendation. Such situations could be prevented by appropriate certification requirements. Nevertheless, the certification process must be clear and reasonable, so as not to discourage the stakeholders. If AI-powered medical device still fails in a particular case, fair compensation must be available to the patient. Therefore, we need a consistent regulation taking into account the specific nature of AI.

Medical devices are currently regulated both by European law and by national laws of the individual Member States. However, the problem is that current legislation, e.g. the MD Regulation, was not designed to regulate the use of such technologies and, hence, does not adequately anticipate the specifics of their functioning and risks.

For instance, certification rules for AI-powered medical devices should take into consideration the technical issues of transparency and explainability of AI. The regulation of medical devices should also clearly address the unpredictability of open AI and lay down rules for data products supplied by data suppliers.

Although medical devices are primarily governed by the MD Regulation, some of the issues above could be addressed by the proposed AI Act, e.g. data governance.

As far as product liability is concerned, an injured patient should not be required to bear the burden of proving the existence of a defect in the medical device, as this is a complicated task in view of AI's nature. Further, the regulation of product liability should foresee that the manufacturer of an open AI using machine learning cannot fully influence the quality of the data to which the AI-powered medical device is exposed. This is because this emerging technology partly shifts the risk control from the manufacturer to other actors, such as data suppliers, machine trainers and users (e.g. clinicians).

⁷⁸ Statement Bundesrat: Product Liability Directive Proposal. Indications of the national legislator regarding the implementation. *Deloitte* [online]. 2022 [cit. 15. 5. 2023]. Available at: <https://www2.deloitte.com/dl/en/pages/legal/articles/produktthaftung-produzentenhaftung.html>

In view of all these reasons, the current MD Regulation should be partially adjusted with respect to the specific nature of AI, e.g. simplified certification process for updated AI-powered medical devices could be introduced.

AI product liability then calls for the enactment of comprehensive legal regulation, which has already been proposed by the European Commission.