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AI in Neurosurgery: Liability Implications in the light of the EU Product Liability Directive Proposal

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I. Introduction

In the present day, AI systems have reached a remarkable capability to handle tasks that were once the exclusive domain of human expertise. These tasks span essential responsibilities of physicians, including the intricate processes of diagnosis, treatment planning, and comprehensive patient care.¹ In the realm of neurosurgery, artificial intelligence (AI) is becoming a tool that enhances both precision and efficiency especially considering that approximately one-quarter of errors in neurosurgery can be attributed solely to technical issues (related to the execution of the surgery itself).² AI can be used in interventional and noninterventional parts of neurosurgery during pre-, intra-, and postoperative care, such as diagnosis, clinical decision making, surgical operation, prognosis, data acquisition, and research.³ Furthermore, when integrated with surgical robotics and other advanced surgical tools like image guidance, AI could seamlessly integrate itself into the operating room. This integration could pave the way for surgeries of greater precision, marked by fewer errors and more accurate interventions.⁴ The synergy between AI and neurosurgery can forge a new relationship between neurosurgeons and AI, propelling the boundaries of the field to new horizons. AI's capabilities serve as a driving force, enabling neurosurgery to reach uncharted territories of precision and innovation.⁵

Concurrently, the integration of AI into medicine can present a variety of challenges. These challenges can manifest in both direct and indirect manners.⁶ On one hand, faulty, insufficiently trained, or poorly comprehended algorithms can yield inaccurate outcomes. On the other hand, the growing integration of automation might inadvertently contribute to the erosion of human physicians' skills, driven by excessive dependence, inadequate grasp of the technology, undue self-assurance, and a potential decline in the vigilant oversight essential for an automated clinical workflow.⁷ Additionally, certain distorters are challenging as there exists a scarcity of conclusive evidence and established guidelines for optimal treatments in certain disorders. This is compounded by a significant diversity in the approaches to surgical interventions for these conditions.⁸

As a result, the integration of AI into the fields of neurology and neurosurgery holds the promise of enhancing healthcare quality while simultaneously giving rise to a host of novel questions including legal ones. As regards the legal questions, which is the focus of this paper, it encompasses considerations such as the establishment of

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* Lawyer at the European Commission (Directorate-General for Health and Food Safety). I am grateful to Mark Geistfeld for the invaluable and insightful discussions we engaged in concerning liability. Additionally, I would like to express my appreciation to Mark Beamish for his thoughtful comments on the proposed Product Liability Directive. The views expressed are personal, do not necessarily represent the official position of the European Commission. ChatGPT was used to enhance the grammatical structure of the text.

1 - Such as the first AI-based medical device approved by the U.S. Food and Drug Administration (FDA) to detect the eye disease diabetic retinopathy; see FDA press release - FDA permits marketing of artificial intelligence-based device to detect certain diabetes-related eye problems (April 11, 2018).

2 - John D Rolston, et al., *Medical errors in neurosurgery*, 5 *Surgical Neurology International* (2014); Javed Iqbal, et al., *The future of artificial intelligence in neurosurgery: a narrative review*, 13 *Surgical Neurology International* (2022) and Mohammad Mofatteh, *Neurosurgery and artificial intelligence*, 8 *AIMS neuroscience* (2021).

3 - Mofatteh, *AIMS neuroscience*, (2021).

4 - Sandip S Panesar, et al., *Promises and perils of artificial intelligence in neurosurgery*, 87 *Neurosurgery* (2020).

5 - See Mofatteh, *AIMS neuroscience*, (2021). Joeky T Senders, et al., *Natural and artificial intelligence in neurosurgery: a systematic review*, 83 *Neurosurgery* (2018).

6 - Panesar, et al., *Neurosurgery*, (2020).

7 - Id.

8 - See for lumbar spine disease Matthew D Alvin, et al., *Spine surgeon treatment variability: the impact on costs*, 8 *Global spine journal* (2018).

potentially new healthcare standards, assessing whether the performance of the AI system, which contributed to adverse effects, was defective and whether the defect in the AI system was the proximate cause of the adverse effects. This paper delves into the European Commission's proposal concerning liability, specifically the proposed Product Liability Directive (proposed PLD or PLD 2022)⁹ and highlights the connections between the PLD 2022 and the Regulation laying down harmonized rules on artificial intelligence (Artificial Intelligence Act or AIA or AI Act)¹⁰ that provide answers to some of the above questions.

II. The Application of the proposed PLD to AI medical purpose systems

As introduced above, AI is gaining a great momentum in medicine including neurology and neurosurgery. At this stage of AI evolution, AI systems provide valuable information to physicians rather than acting autonomously to perform, for example, a neurosurgical operation. AI-based medical purpose software is becoming more and more important in healthcare, and it essentially consists of:¹¹

(1) software in a medical device (also referred to as “embedded” or “part of”) or serving the functionality of the product without being integrated therein (non-embedded)¹² and

(2) software as medical device (SaMD)¹³ (i.e. software that can perform its medical functions without hardware)¹⁴

The proposed PLD incorporates “software” within the definition of products.¹⁵ The proposed PLD recitals clarify that software can be marketed as a standalone product (e.g., AI systems that provide medical information to a physician) and should be categorized as a product regardless of its supply or usage method.¹⁶

The subsequent step involves evaluating whether this AI-based software has resulted in any of the compensable damages specified in the proposed PLD.¹⁷ For instance, if there are claims that the standalone software has caused death or personal injury including medically recognized psychological harm, it would be subject to assessment under the proposed PLD.¹⁸ However, if the allegations pertain to the software contributing for example to discriminatory practices, it would fall outside the proposed PLD's scope.¹⁹

If the damage aligns with one of the compensable categories outlined in the proposed PLD, the next consideration revolves around establishing whether the performance of the AI system, which contributed to adverse effects, was defective and whether these defects were the proximate causes of the resulting harm. Defining what qualifies as a defect in an AI system has proven to be one of the most daunting challenges. The proposed PLD that amends the current PLD (1985)²⁰, as elucidated below, offers additional clarification on when a product, such as an AI system providing medical information to a physician, should be classified as defective. Specifically, when dealing with AI systems that offer information, as opposed to systems that autonomously drive or conduct surgeries, the primary challenge lies in determining causation. Essentially, the central question is whether the performance of the AI system in generating medical information, including treatment recommendations, which contributed to adverse

9 - https://single-market-economy.ec.europa.eu/document/3193da9a-cecb-44ad-9a9c-7b6b23220bcd_en.

10 - <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A52021PC0206>.

11 - International Medical Devices Regulators Forum, IMDRF/SaMD WG/N10FINAL:2013 at: <http://www.imdrf.org/docs/imdrf/final/technical/imdrf-tech-131209-samd-key-definitions-140901.pdf>.

12 - Rec. 6 AIA that refers to AI systems designed to be used as a “component of a product” irrespective of whether the system is physically integrated into the product (“embedded”) or serve the functionality of the product without being integrated therein (“non-embedded”).

13 - SaMD is referred to in EU Regulation 2017/745 on medical devices as “software in its own right” (Rec. 19). The AIA describes this type of medical device in recital 6 as AI systems that are designed to be used on a “stand-alone basis.”

14 - See Boris Babic, et al., *When Machine Learning Goes Off the Rails*, Harvard Business Review 2021.

15 - Articles 2(1) and 4(1) PLD.

16 - Recital 12.

17 - See definition of damage in Article 4(6) PLD.

18 - Medically recognized harm to psychological health is one of damages listed in the PLD (Article 4(6)(a) PLD).

19 - See the definition of damage in Article 4(6) PLD. See also Explanatory Memorandum to the PLD, references to recruitment software under Option 1c, p. 9 (https://single-market-economy.ec.europa.eu/system/files/2022-09/COM_2022_495_1_EN_ACT_part1_v6.pdf).

20 - <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A31985L0374>.

effects, can be identified as the proximate cause of any ensuing harm.²¹ The challenges related to causation as well as the potential establishment of a new standard of care following AI integration in clinical practice become more complex in medical fields such as neurology and neurosurgery, where a variety of opinions and approaches may coexist. Additionally, a perplexing question concerning the ‘erroneous’ information produced by AI revolves around whether it stems from the inherent characteristics of AI, malfunctions, or other types of defects as the liability implications would be different.

The PLD 2022 utilizes a “safety expectation test”²² to ascertain whether a product is defective.²³ Under this test, a product is deemed defective if it falls short of delivering the level of “safety which the public at large is entitled to expect.”²⁴ In assessing the public at large expectation, the assessment should involve an “objective analysis” and not refer to the safety that any person is entitled to expect.²⁵ The proposed PLD delineates various factors to be considered when determining defectiveness, including the product’s presentation, which encompasses instructions for installation, use, and maintenance.²⁶ Specifically, Article 9(2)(c) of the PLD 2022 introduces a presumption of defectiveness when the claimant can establish an “obvious malfunction” of the product during its regular use or under normal circumstances. As a consequence, a crucial point for investigation is whether the AI system’s performance, which played a role in adverse effects, can be linked to a malfunction. As noted above, a “safety expectation test” is employed within the framework of the PLD 2022 to assess defectiveness that includes malfunctions.²⁷

Therefore, the question is whether AI system’s performance, which played a role in adverse effects, falls short of delivering the level of safety that the public at large is entitled to expect. The “safety expectation test” approach operates under the assumption that both physicians and patients hold reasonable expectations regarding the safe performance of AI systems.²⁸ Within this context, they maintain at least a baseline expectation that the system should not experience malfunctions arising from factors like programming errors or bugs.²⁹ As a result, in cases where a claim seeks compensation for damages stemming from a defective product, it becomes imperative for the injured party to secure relevant evidence, often within the defendant’s control, to ascertain whether the product fell short of meeting these expectations.

The proposed PLD, imposes an obligation on Member States to ensure that national courts are empowered, upon a request by the plaintiff (“the claimant”)³⁰ who has presented facts and evidence to support the plausibility of the claim for compensation, to order the defendant to disclose relevant evidence.³¹ In instances where the defendant fails to fulfill their obligation to disclose relevant evidence, the PLD 2022 presumes product defectiveness.³²

However, within the healthcare domain, where the distinction between acceptable and unacceptable outcomes can sometimes be unclear, there may be expectations for a baseline of safe performance that extend beyond mere programming errors or bugs. This can potentially lead to allegations of AI system malfunction. Geistfeld argues, in

21 - It was argued that most standalone software will rarely cause physical injury as pointed out, inter alia, by Siemens in their position paper in response to the public consultation, Civil liability – adapting liability rules to the digital age and artificial intelligence (https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12979-Civil-liability-adapting-liability-rules-to-the-digital-age-and-artificial-intelligence/public-consultation_en) as noted in the Commission Staff Working Document, Impact Assessment Report, SWD(2022) 316 final, Brussels, 28.9.2022 p. 41 (https://single-market-economy.ec.europa.eu/system/files/2022-09/SWD_2022_316_1_EN_impact_assessment_part1_v2.pdf). At the same time, it was pointed out that defective medical devices software could cause physical injuries (as noted in the Commission Staff Working Document, Impact Assessment Report, SWD(2022) 316 final, Brussels, 28.9.2022 at 41 (https://single-market-economy.ec.europa.eu/system/files/2022-09/SWD_2022_316_1_EN_impact_assessment_part1_v2.pdf). See also study supporting the impact assessment (<https://op.europa.eu/en/publication-detail/-/publication/ba5708d0-3ed7-11ed-92ed-01aa75ed71a1/language-en/format-PDF/source-268778161>).

22 - Some U.S. states employ a test known as the “consumer expectation test.”

23 - See Article 6 PLD and recital 22 PLD.

24 - Article 6 PLD. The same test has been also applied by the 1985 PLD (see sixth recital of PLD (1985)). For further explanations refer to, Judgment of 5 March 2015, Boston Scientific Medizintechnik, C-503/13 and C-504/13, EU:C:2015:148, paragraph 37.

25 - Recital 22 PLD.

26 - Article 6(1)(a)-(h) PLD.

27 - The “consumer expectation test” is used by most states in the US to evaluate malfunction.

28 - Point raised by Geistfeld in the US context in relation to the consumers’ expectations concerning autonomous vehicle (Mark A Geistfeld, *A Roadmap for Autonomous Vehicles: State Tort Liability, Automobile Insurance, and Federal Safety Regulation*, 105 Calif. L. Rev. (2017). 1638).

29 - Point raised by Geistfeld in the US context in relation to the consumers’ expectations concerning autonomous vehicle (id. at 1638).

30 - Term is used in the PLD 2022.

31 - Articles 8 PLD and see Article 3 AILD.

32 - Article 9(2)(a) PLD.

the context of autonomous vehicles in the United States,³³ that manufacturers can absolve themselves of liability for accidents under the malfunction doctrine by providing adequate warnings about foreseeable risks that are inherent in a safely designed vehicle or unavoidable.³⁴ This raises the crucial question of what specific information and level of detail is necessary in these warnings to ensure that healthcare professionals and patients possess a clear understanding of the risks associated with AI-based medical systems.³⁵ Article 13 of the AI Act outlines the requisite information that manufacturers of high-risk AI systems must furnish to users. While providing this information does not exempt a product from liability claims, it does establish a framework for the type of information that should be provided, although the interpretation and transformation into standards of these high-level provisions (essential requirements) in the AIA would still be necessary. Generally, once the essential requirements are set out in EU law, like the AIA, they are followed by the development of standards which provide technical solutions to providers in ensuring compliance with the AIA.³⁶ Additionally, the AIA provides that the Commission could adopt common technical specifications in areas where no harmonization standards exists or where they are insufficient.³⁷

Even when comprehensive warnings and information regarding associated risks have been provided, the plaintiff may still argue that the AI system should have been designed differently to prevent these adverse effects from occurring.³⁸ Once again, the determination of whether the AI system should have been designed differently would be assessed under the “safety expectation test.” As noted above, recital 22 of the PLD 2022 underscores the importance of an “objective analysis” in determining the consumer expectation. This clarification in Recital 22 reflects the decision of the Court of Justice of the EU (CJEU), referencing the safety which a person is entitled to expect under the PLD (1985), held that the assessment must be conducted with regard to the “reasonable” expectations of the public at large.³⁹ Essentially, consumer expectations should align with what is considered “reasonable,” and an “objective” analysis is carried out to determine this. Especially in cases involving complex products like AI systems and domains like the medical one, where the average consumer may lack specific design expectations, an objective test incorporating various balancing factors would be applied.

Hence, the pivotal question, pertains to the elements that should be considered and the appropriate balances that need to be established. The AIA plays a substantial role in addressing these concerns by imposing obligations on the design and development of AI systems. It encompasses requirements related to human oversight,⁴⁰ accuracy, robustness, cybersecurity,⁴¹ and the quality of data used for training, testing, and evaluating algorithms.⁴²

In instances where claimants assert that the AI system’s error resulted from defects within the AI system, and the developer of the AI system failed to fulfill obligations stipulated in the AIA, several rebuttable presumptions come into play. Under the proposed PLD, it is presumed that the AI system is defective if the developer did not comply with safety requirements. Some of these requirements, which may align with those specified in the AIA, are designed to mitigate the risk of the damage that has occurred.⁴³

Moreover, the proposed PLD introduces supplementary presumptions to bolster claimants’ positions in product liability cases that encompass “technical or scientific complexity” when establishing the product’s defectiveness or the causal connection between the defect and the resulting damage.⁴⁴ Within these presumptions, according to the proposed PLD, the presence of defectiveness or a causal link exists when the claimant can successfully demonstrate two crucial elements: firstly, that the product contributed to the damage, and secondly, that it is likely that the

33 - The proposed PLD does not differentiate, like in the US, between these three types of defects. Instead, it employs a safety expectation test to determine if a product is defective.

34 - Satisfying the duty to warn does not necessarily satisfy the duty for a non-defective design (see Geistfeld, Calif. L. Rev., 1639 (2017)).

35 - See further Yiannos Toliás, *Explainable AI in Medicine, Confidence Intervals and Warnings*, Jean Monnet Working Paper 4/19 (2019).

36 - Compliance with harmonized standards as defined in Regulation (EU) 1025/2012 is a means for providers to demonstrate conformity with EU regulatory frameworks.

37 - See Arts. 40 and 41.

38 - Geistfeld, Calif. L. Rev., at 1641 (2017).

39 - Judgment of 5 March 2015, Boston Scientific Medizintechnik, C-503/13 and C-504/13, EU:C:2015:148 at paragraph 37.

40 - Article 14 AIA.

41 - Article 15 AIA.

42 - Article 10 AIA.

43 - Article 9(2)(b) PLD.

44 - Article 9(4) PLD.

product was defective or that its defectiveness is a likely cause of the damage, or both. In other words, national courts should presume the defectiveness of the product or the causal link between the defectiveness and the damage, or both where notwithstanding the defendant's disclosure of information, it is still excessively difficult for the claimant considering the technical or scientific complexities to prove the defectiveness and/or the causal link.⁴⁵ These presumptions could be particularly useful in the pharmaceutical domain and appear to draw inspiration from the ruling of the CJEU in the *Sanofi Pasteur et al* case.⁴⁶ Regarding their application to AI-based products, recital 34 of the PLD 2022 states that the "technical and scientific" complexity of the product would be determined by the courts on a case-by-case basis, considering several factors, including the complex nature of the technology, such as machine learning.

III. Conclusion

Research has shown that collaborative clinical decision-making involving AI could enhance accuracy, when compared to AI or physicians working in isolation.⁴⁷ This improvement is most notable among less experienced clinicians who benefit the most from AI support.⁴⁸ Furthermore, in fields such as neurology and neurosurgery, where conclusive evidence and well-established treatment guidance for certain disorders are often lacking,⁴⁹ and considering that one-quarter of errors in neurosurgery can be solely attributed to technical issues during surgery execution,⁵⁰ the introduction of a collaboration between neurologists, neurosurgeons, and AI holds the potential to enhance the delivery of healthcare.

However, the physician-AI collaboration could also complicate the determination of standard care practices. As medical practices evolve, the integration of AI may reach a point where it becomes part of the standard of care,⁵¹ a trend not unfamiliar in the history of healthcare technologies. Technologies like X-rays, for instance, once advanced to the status of standard care.⁵² In the case of X-rays, a form of "collaboration" emerged between humans and X-ray machines, enhancing the quality of healthcare. Tasks were allocated based on the strengths of humans and machines thereby optimizing patient care. A comparable approach to the incorporation of X-rays in clinical practice, one that focused on what machines and humans could do best, although more intricate, can be applied to the utilization of AI in healthcare. This evolution may lead to the establishment of new standards of care, accompanied by revised clinical workflows and guidelines. Implementing these changes can be challenging, especially considering the diversity of opinions when addressing specific disorders.

The European Commission proposals such as the European Health Data Space Regulation (EHDS),⁵³ AIA and proposed PLD play pivotal roles in this complex landscape. The EHDS provides the necessary health data to develop AI capable of performing effectively in diverse geographical, behavioral, or functional settings.⁵⁴ The AIA aids in ensuring the trustworthiness of AI, thereby instilling trust and acceptability in relying on AI predictions. The proposed PLD delineates manufacturers' liability, thus aiding in ensuring that AI systems lawfully marketed are free from defects.

45 - See Article 9 PLD and recital 34 PLD.

46 - Judgment of the Court of 21 June 2017, *N. W and Others v Sanofi Pasteur MSD SNC and Others*, C-621/15, EU:C:2017:484.

47 - See for example, in the case of skin cancer diagnosis, Philipp Tschandl, et al., *Human-computer collaboration for skin cancer recognition*, 26 *Nature Medicine* (2020).

48 - *Id.*

49 - See for lumbar spine disease Alvin, et al., *Global spine journal*, (2018).

50 - Rolston, et al., *Surgical Neurology International*, (2014).

51 - In this context see also the analysis by Froomkin et al., *When AIS Outperform Doctors: Confronting the Challenges of a Tort - Induced Over-Reliance on Machine Learning*, 61 *Ariz. L. Rev.* 33.

52 - See cases on how x-rays became the standard of care: *Lippold v Kidd*, 269 P. 210, 213 (or. 1928); *Wells v Ferry-Baker Lumber Co.* 107 P. 869, 870 (Wash. 1910) and *Gonzales v Peterson*, 359 P. 2d 307, 310 (Wash. 1961). Regarding automated external defibrillators that became the standard of care see Richard O. Cummins, *From Concept to Standard of-Care? Review of the Clinical Experience with Automated External Defibrillators*, 18 *Annals Emergency Med.* 1269, 1270 (1989); see further on these, Froomkin et al., *When AIS Outperform Doctors: Confronting the Challenges of a Tort - Induced Over-Reliance on Machine Learning*, 61 *Ariz. L. Rev.* 33 at 55-58.

53 - <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52022PC0197>.

54 - See in this regard the obligation in Article 10(4) AIA.

While considerable efforts and initiatives have been dedicated to fostering trustworthiness in AI development, we are now entering a phase of AI evolution, which demands a more concerted focus on addressing the challenges associated with AI deployment in clinical practice. This approach has the potential to expedite the safe and effective integration of AI in healthcare, ultimately enabling individuals, including patients, to reap the benefits of AI advancement in the healthcare sector.”

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