LIABILITY FOR AI SYSTEMS IN HEALTHCARE

PROF. DR. SUSANA NAVAS NAVARRO

EJTN CIVIL JUSTICE SEMINAR
CIVIL LIABILITY DUE TO ARTIFICIAL INTELLIGENCE
LIABILITY FOR AI SYSTEMS IN HEALTHCARE

I. Preliminary remarks

II. Liability in the application of AI systems in healthcare

1. Medical/hospital liability as operator liability
2. Medical malpractice
3. The liability of the producer. Some issues

III. The proof of the liability elements. Access to data
Study on eHealth, Interoperability of Health Data and AI for Health and Care in the EU (PwC, 2021)

- Disease diagnosis – 42%
- Patient monitoring – 39%
- Robotic medicine – 28%
- Others – 17%
- Analysis of genome – 14%
1. MEDICAL/HOSPITAL LIABILITY AS OPERATOR LIABILITY

a) *stand-alone* AI system: e. g. diagnosis

b) *embedded* AI system: e. g. robotic surgery
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- **front-end operator:** “any natural or legal person who exercises a degree of control over a risk connected with the operation and functioning of the AI system and benefits from its operation” (Art. 3 e)

- **back-end operator:** “any natural or legal person who, on a continuous basis, defines the features of the technology and provides data and an essential backend support service and therefore also exercises a degree of control over the risk connected with the operation and functioning of the AI system” (Art. 3 f)
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Proposal for the regulation on a civil liability in AI (20. October 2020)

Definition of “high-risk AI system” - strict liability

“‘high risk’ means a significant potential in an autonomously operating AI-system to cause harm or damage to one or more persons in a manner that is random and goes beyond what can reasonably be expected; the significance of the potential depends on the interplay between the severity of possible harm or damage, the degree of autonomy of decision-making, the likelihood that the risk materializes and the manner and the context in which the AI-system is being used (Art. 3 lit. c).
Proposal for the regulation on a civil liability in AI (20. October 2020)

Art. 11

- If there is only one operator, who is also the producer of the AI system, the Proposal shall prevail over the PLD.

- If the front-end operator is also the producer, the Proposal shall prevail over the PLD.

- If the back-end operator also qualifies as a producer, the PLD should apply to him or her.
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Proposal for the regulation on a civil liability in AI (20. October 2020)

Low-risk systems – Fault-based liability (Art. 8)

(a) the AI-system was activated without his or her knowledge while all reasonable and necessary measures to avoid such activation outside of the operator’s control were taken, or

(b) due diligence was observed by performing all the following actions: selecting a suitable AI-system for the right task and skills, putting the AI-system duly into operation, monitoring the activities and maintaining the operational reliability by regularly installing all available updates.
Proposal for the regulation on a civil liability in AI (20. October 2020)

Art. 2 para. 3

“This Regulation is without prejudice to any additional liability claims resulting from contractual relationships, as well as from regulations on product liability, consumer protection, anti-discrimination, labour and environmental protection between the operator and the natural or legal person who suffered harm or damage because of the AI-system and that may be brought against the operator under Union or national law”.
LIABILITY FOR AI SYSTEMS IN HEALTHCARE

2. MEDICAL MALPRACTICE

3. LIABILITY OF THE PRODUCER. CURRENT LAW AND UPCOMING AMENDMENTS

a) Can an AI system be a “product”?

b) Concept of “defect” – consumers expectation test

c) Notion of producer – PLD and MDR
a) Can an AI system be a “product”?

Art. 2 PLD: tangible versus intangible goods
b) Concept of defect – consumer expectations test

Art. 6 PLD: A product is defective when it does not provide the safety which a person is entitled to expect, taking all circumstances into account, including: (a) the presentation of the product; (b) the use to which it could reasonably be expected that the product would be put; (c) the time when the product was put into circulation.
c) Notion of producer – PLD and MDR

**Art. 3 PLD:** 'Producer' means the manufacturer of a finished product, the producer of any raw material or the manufacturer of a component part and any person who, by putting his name, trademark or other distinguishing feature on the product presents himself as its producer.
c) Notion of producer – PLD and MDR

Art. 2 nr. 30 MDR: 'Producer' means a natural or legal person who manufactures, or fully refurbished, and markets that device or has a device designed, manufactured or fully refurbished, and markets that device under its name or trademark.
A “commercial and technological unit” means:

• (a) any joint or coordinated marketing of the different elements

• (b) the degree of their technical interdependence and interoperation; and the degree of specificity or exclusivity of their combination”.
III. THE PROOF OF THE LIABILITY ELEMENTS. ACCESS TO DATA

Expert Group on Liability and New Technologies (NTF)

- Recommendation nr. 26: reversal of the burden of proof of the causal link
- Recommendation nr. 24: presumption of the causal link, fault and existence of the defect
- Logging by design
Recommendation nr. 26: reversal of the burden of proof of the causal link

- the probability that the technology contributed to the harm
- the probability that the damage would have been caused either by the intervention of technology or by another cause, that is within the same sphere of control
- the risk of a known flaw in the technology, even though its impact on the causal link is not obvious
- the degree of ex post traceability and intelligibility of the AI-governed processes that may have contributed to causing the damage (informational asymmetry)
- the degree of subsequent access and understanding of the data collected and generated by the technology and
- the type and level of potential and actual damage caused.
"An operator held liable may use the data generated by the AI-system to prove contributory negligence on the part of the affected person, in accordance with Regulation (EU) 2016/679 and other relevant data protection laws. The affected person may also use such data as a means of proof or clarification in the liability claim".
Absence of informed consent

a) if the patient had not undergone the medical treatment if he had known all the details, the causal link is established between the lack of information and the damage.

b) if the patient had also undergone the medical treatment, there will be no liability and

c) if there is causal uncertainty since it cannot be known, ex post, whether or not he would have undergone the medical treatment if he had got all the information required.
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BURDEN OF PROOF

Absence of informed consent

• Daño desproporcionado (Spain)
• Res ipsa Loquitur (UK)
• Anscheinsbeweis (Germany)
• Faute virtuelle (France)
MANY THANKS

Susana.Navas@uab.cat