SUBSTANTIAL MODIFICATION OF MEDICAL AI AND PRODUCT LIABILITY

professor Marija Ampovska
Faculty of Law, Goce Delcev University Stip, North Macedonia

21st Joint Seminar of EALE and The Geneva Association
LEGAL AND ECONOMIC ISSUES IN (EMERGING) LIABILITY RISKS, JESUS COLLEGE CAMBRIDGE UNIVERSITY UK

The central question

Traditional view: Healthcare professionals and hospitals are users of medical devices. Liability is fault-based (malpractice) or strict liability based on the risk created (for the hospital).

The shift under rPLD:

- A professional or institution *who/which substantially modifies* an AI-enabled medical device becomes a **manufacturer**.
- This triggers **strict liability** under rPLD Article 8.

The underexplored question:

- When does interaction cross the threshold of "substantial modification"?

The Thesis Statement

Main thesis:

- The rPLD creates a **distinct, strict liability pathway** that reallocates risk to the party with the highest degree of control over the AI system's final safety configuration.

The threshold:

- Substantial modification (rPLD Art. 8 + Recital 39) is the legal mechanism that triggers this reallocation.

RESEARCH STRUCTURE & METHODOLOGY

Research Structure (Three Stages)

1. **Establish the regulatory baseline** – What is an AI-enabled medical device under EU law? (MDR, AI Act)
2. **Analyze "substantial modification"** across four instruments (MDR, GPSR, rPLD, AI Act)
3. **Apply Article 8 rPLD to the healthcare context** – Distinguish professionals vs. institutions, objective vs. subjective elements, and the boundary between modification and off-label use.

Methodology – Doctrinal Analysis

Research question (single, underexplored):

Under what circumstances does a healthcare professional's interaction with an AI-enabled medical device constitute "substantial modification" under the rPLD?

Method: Doctrinal analysis of EU primary law (regulations, directives).

Exclusions: National implementation materials used only as illustrations (e.g., German Draft on the German Product Liability Act).

DEFINITIONAL FRAMEWORK

Defining the medical AI device – MDR + AI Act

MDR Article 2(1): Medical device defined by *intended medical purpose*, not technology.

Software is explicitly included – AI software falls squarely within scope.

MDR categories relevant to AI:

Software as an active device (Art. 2(4))	System (Art. 2(11))	Accessory (Art. 2(2))

AI Act: Most AI-powered medical devices (Classes IIa, IIb, III) are automatically classified as "high-risk AI systems" under Article 6(1) AI Act. Under Article 6(1) and Annex I of the AI Act, high-risk AI systems include AI systems that are intended to be used as a safety component of a product, or that are in itself a product, subject to the EU Medical Device Regulation (2017/745) or the EU In Vitro Diagnostic (IVD) Medical Device Regulation (2017/746).