The Digitalization and Integration of Health Products – Liability and Technology

Ina Brock, Partner
Matthias Schweiger, Senior Associate

11th Annual Liability Regimes Conference

Keeping the Floodgates Shut? Mastering Accumulation and Bodily Injury Exposures in a Rapidly Changing Environment

4–5 November 2015, Rüschlikon
Digitalization and Integration of Health Products – Liability and Technology

Annual Liability Regimes Conference, Rüschlikon

Ina Brock, Partner
Matthias Schweiger, Senior Associate

5 November 2015
Product Liability / Munich
Agenda

- Opportunities and liability risks in digitalization and integration of health products
- Legal issues beyond technology
  - Product compliance
  - Product stewardship
  - Perception by patients and professionals
  - Data governance
Overview

1. Liability for Products and More

2. The Data Issues
Product Liability – or not?

• Manifold technologies and possibilities
  e.g.
  – Integrated data collection for clinical studies or for determining therapy
  – Health Apps
  – Smart drugs and devices

• Classification
  e.g.
  – Lifestyle product v. medical device
  – Software v. medical device
  – Companion diagnostics

Service or product?
Liability Issues

- Tort
- Professional liability
- Contractual
- Responsibility under criminal law
Negligence regarding Medical Condition?

Example

- Data re medical condition available to manufacturer, maybe even looked at by a medical professional as part of a study
- Data reveals life threatening condition

Failure to render assistance?

Negligence?
Smart Pills and Devices deciding autonomously?

**Example 1**
- Device assessing patient data and recommending drug intake or therapy

  - Malfunctioning of the device?
  - Wrongful inclusion / exclusion of therapy?
  - Unauthorized practice of medicine / nursing?
  - Unauthorized practice of pharmacy?
  - Violation of professional licensure statute?

**Example 2**
- Device assessing patient data and providing tailored delivery of active ingredients to patient
Ways for Mitigating the Liability Risks

- Robust warnings
- Disclaimers
  - Contracts
  - Product literature
  - Websites
- Description of platform / services
- Clear protocols and standards for notifying users of updates and issues
- Quality audits
Collecting and Using Data - The Issues

Data breach

Non-compliant data governance

Losing data

Regulatory requirements for telecommunication and privacy
Data Issues can have grave Consequences

- Lack of functionality of product
- Breach of personal freedom
- Economic damages

Product stewardship = data stewardship?
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