

The Digitalization and Integration of Health Products – Liability and Technology

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11th Annual Liability Regimes Conference

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

4–5 November 2015, Rüslikon

Digitalization and Integration of Health Products – Liability and Technology

Annual Liability Regimes Conference, Rüschtikon

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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

Contractual

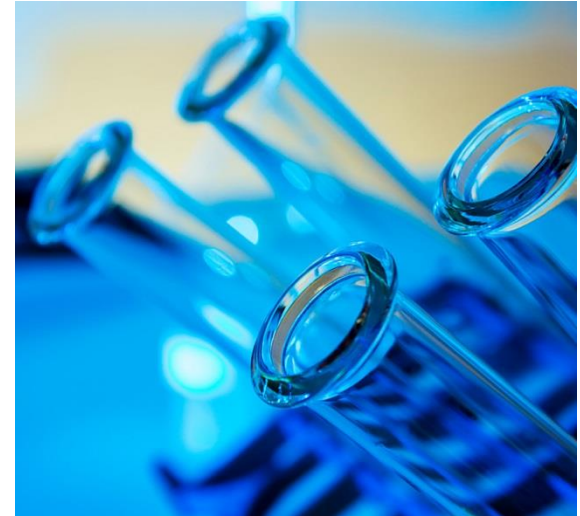
**Professional
liability**

**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

Example 2

- Device assessing patient data and providing tailored delivery of active ingredients to patient

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

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

Overview

1 Liability for Products and More

2 The Data Issues

Collecting and Using Data - The Issues

Data breach

Losing data

**Non-compliant data
governance**

**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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