

***Robotic Surgery:***  
**Regulatory Issues in**  
**Comparative Perspective**

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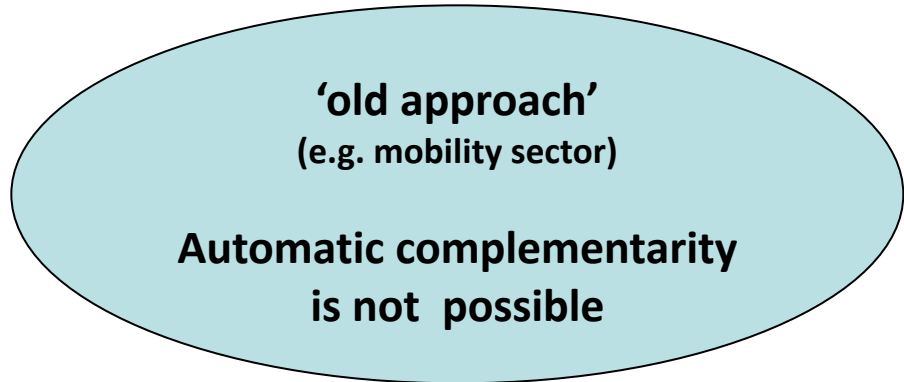
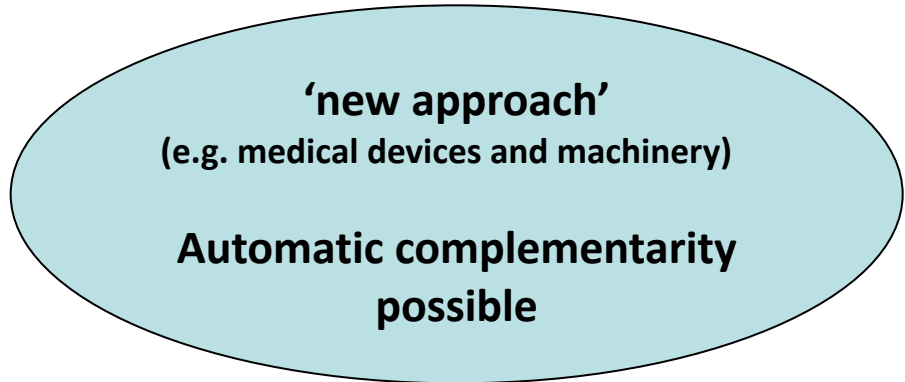
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# General and Specific remarks on EU law about AI applications





\* **Variety of applications: advanced laparoscopic; assisted and teleoperating arms; robot assistant (robot-surgeon)**

*All healthcare robots will go through **Conformité Européene (CE) Mark certification under the European Medical Devices Directive.***

*The class each robot is categorised under depends on its invasiveness in regard to its role within a healthcare environment. For example, the newest da Vinci X system from Intuitive Surgical recently acquired the CE Mark approval as a Class IIb CE 0543 device.*

*Each robotic surgical system and healthcare robot must go through CE Mark certification in order to be utilised in a healthcare institution within Europe.*

*AI Act --- European Medical Device Regulation 2017/745 (EU MDR)*





## Database MAUDE - Manufacturer and User Facility Device Experience of the Food and Drug Administration Agency

<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/search.cfm>

**Between 2000 and 2013:** 10,624 reports, of which 8,061 malfunctions; 1,391 physical injuries (Bowel and bladder injuries; perforated or cut ureters; organ perforations; organ burns), and 144 deaths.

**2013:** procedure of FDA surveillance

Out-of-court settlements (U.S. Securities and Exchange Commission, 2018)

*Multi-District Litigation (MDL)*

Producer → Surgeon - Da Vinci Robot → Patient

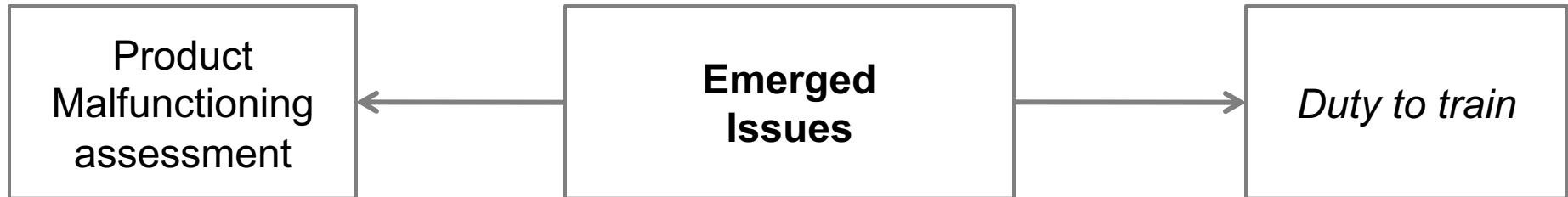


Risk:

the potential tendency to turn actions against the surgeon into actions against the manufacturers



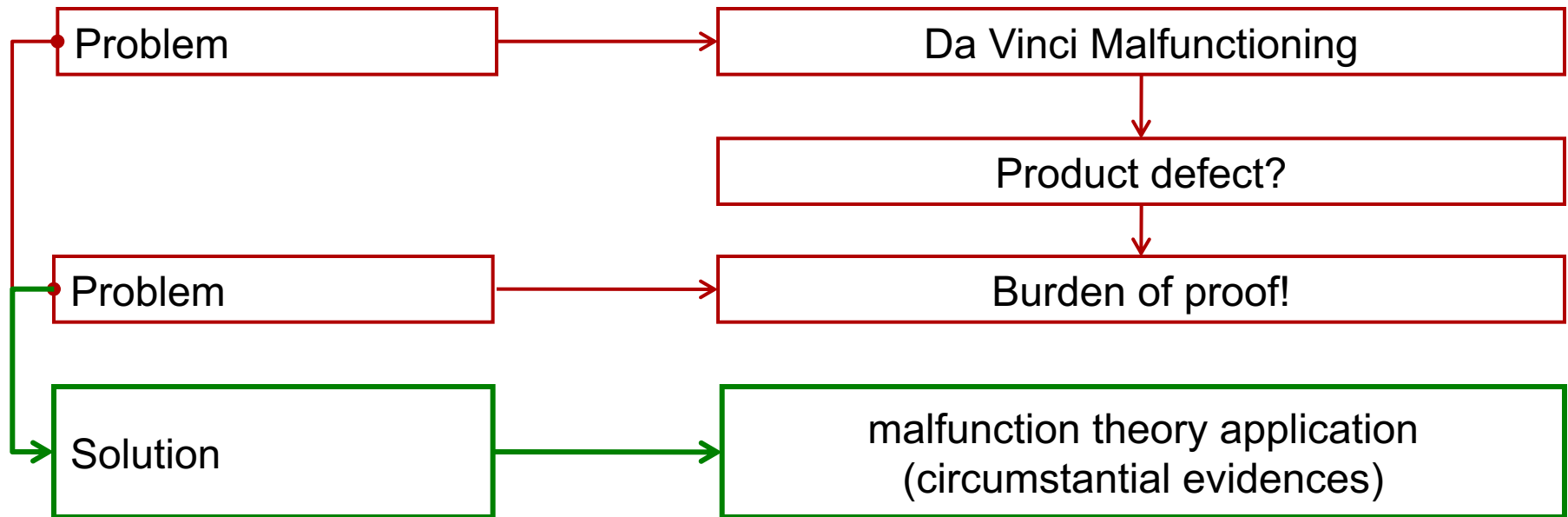
## US CASE LAW (*Da Vinci product liability*)



(Main cases: *Mracek v. Bryn Mawr Hosp. and Intuitive Surgical Inc* (2005); *Daniel J. O'Brien vs. Intuitive Surgical Inc* (2010); *Silvestrini v. University Healthcare System, L.C., d/b/a Tulane University Hospital and Clinic ("TUHC") e Intuitive Surgical, Inc.* (2012); *Taylor v. Intuitive Surgical Inc* (2013; appello 2015; e Supreme Court 2017); *Zarick v. Intuitive Surgical Inc* (2016); *Mendoza v. Intuitive Surgical, Inc.* 2020 U.S. Dist. Court for the Northern District of California)



## Product liability without proof of defect: the *malfunction theory*



The "malfunction doctrine" derives from the traditional rule *res ipsa loquitur*, and it is contemplated by § 3 of the Third Restatement of Torts "Circumstantial evidence supporting inference of product defect". Under this provision, the plaintiff gets around the difficulty of proving the defect when the circumstances indicate that its malfunction most likely: i) stems from a manufacturing defect; ii) there are no other secondary causes; iii) there has been no abnormal use of the product.

**Critics!**



## Duty to train



### **case *Taylor v. Intuitive Surgical Inc***

(188 Wn. App. 776, 355 P.3d 309 (2015))



the plaintiff sets up the manufacturer's liability for breaching of duty to warn and train medical personnel (marketing duties).

In 2017, the Washington Superior Court ruled that this manufacturer's duty also existed with respect to the hospital facility purchasing the robot (No. 92210-1, Wash. Feb. 9, 2017)

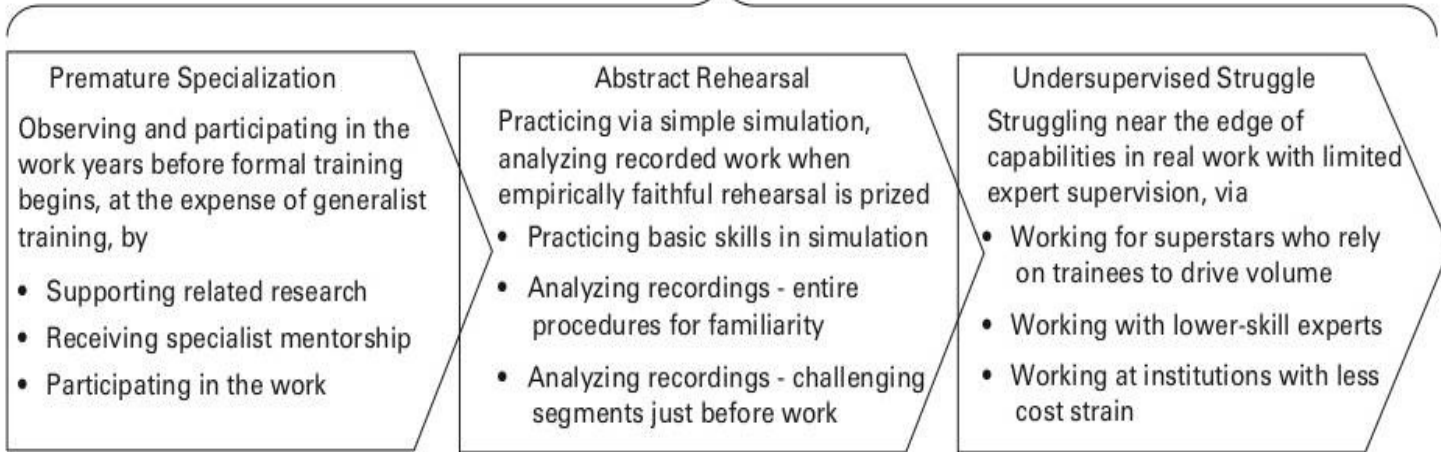




# The «shadow learning»: an empirical study

## Robotics and devices that harness the power of AI require a different kind of training and practice than traditional ones?

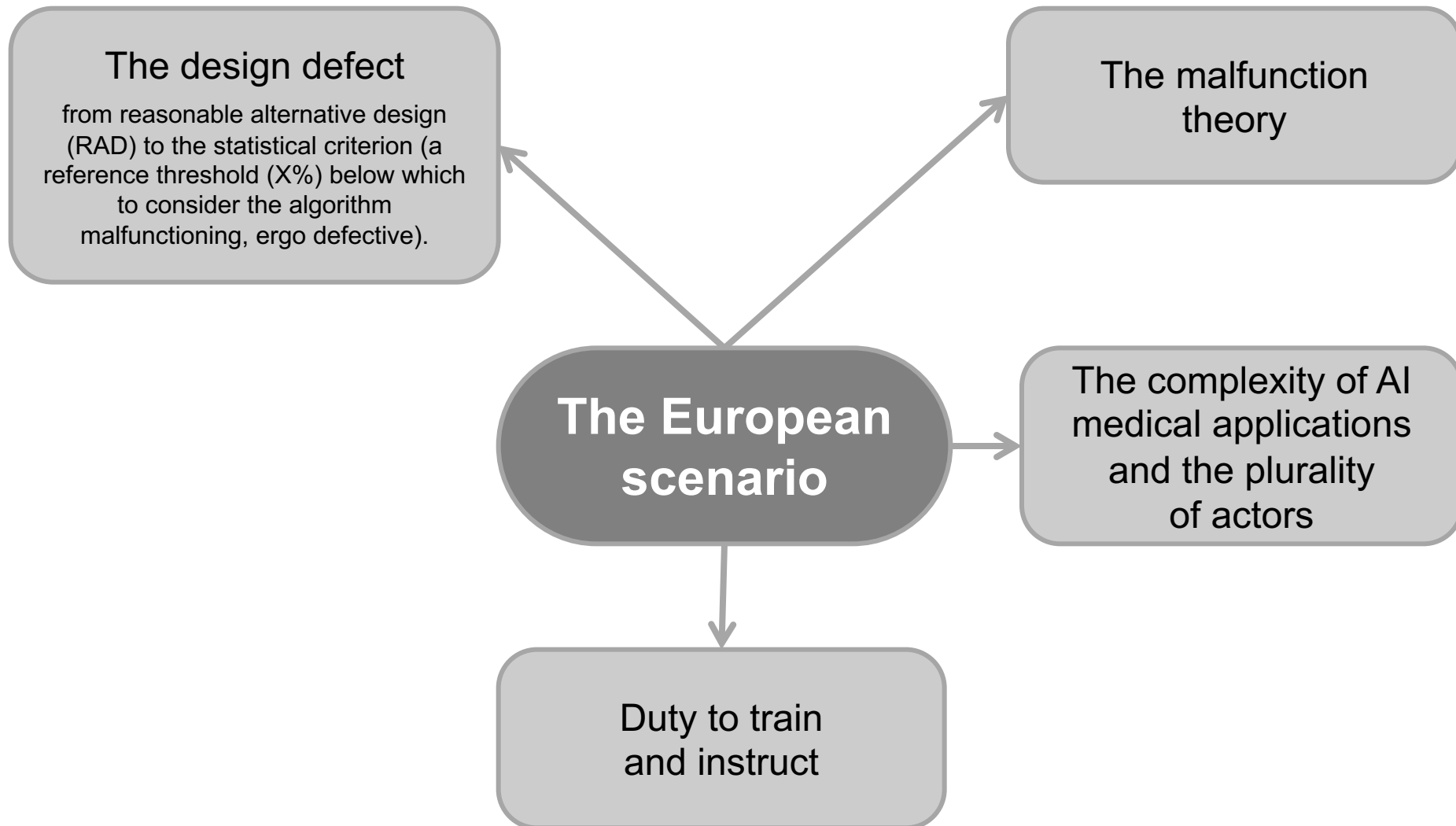
### Shadow Learning over Time



- First-order Consequences Learning**
  - Those who engage in shadow learning build significant skill
- Second-order Consequences Individual: Hyperspecialization**
  - Preparing for specialized work yet taking generalist positions
  - Delaying entry into workforce
  - Privileging “underproven” technique
- Cohort: Matthew Effect for Skill**
  - Getting rapid, unequal, and exclusive access to the work
  - Limiting the supply of experts
- Community: Limited Learning**
  - Slowing adaptation to tolerated, undiscussed practices



# Back to the European scenario





## Robotic surgery deeply impacts on the Product Liability regime



- Interdisciplinary research
- The '*action of things*' and the new parameters of product liability
- The evolution of the concept of safety (information as an integral part)
- Damage caused by a product which complies with safety requirement



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