



Pregnancy and Lactation Labeling: A Law and Ethics Perspective

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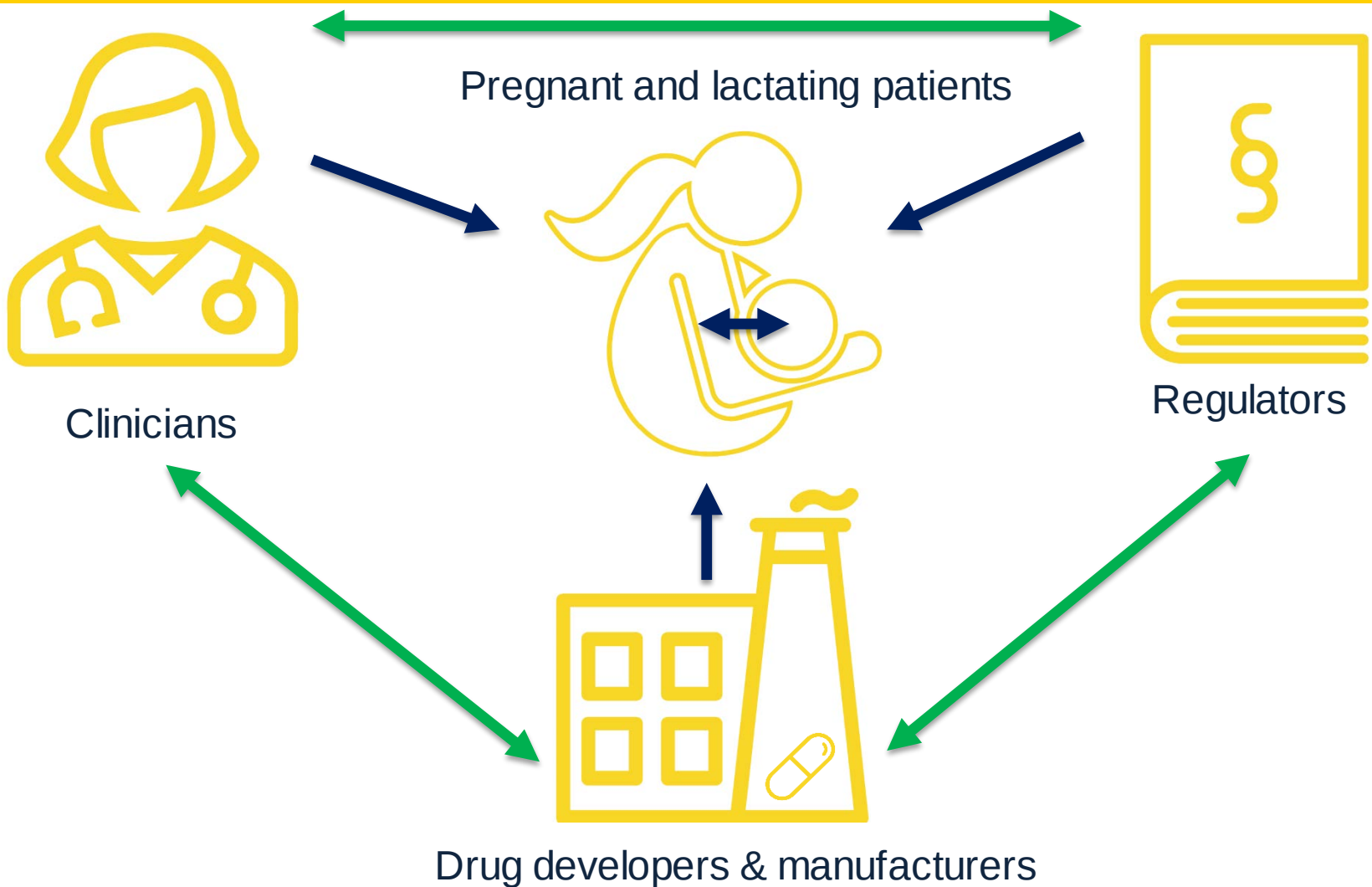


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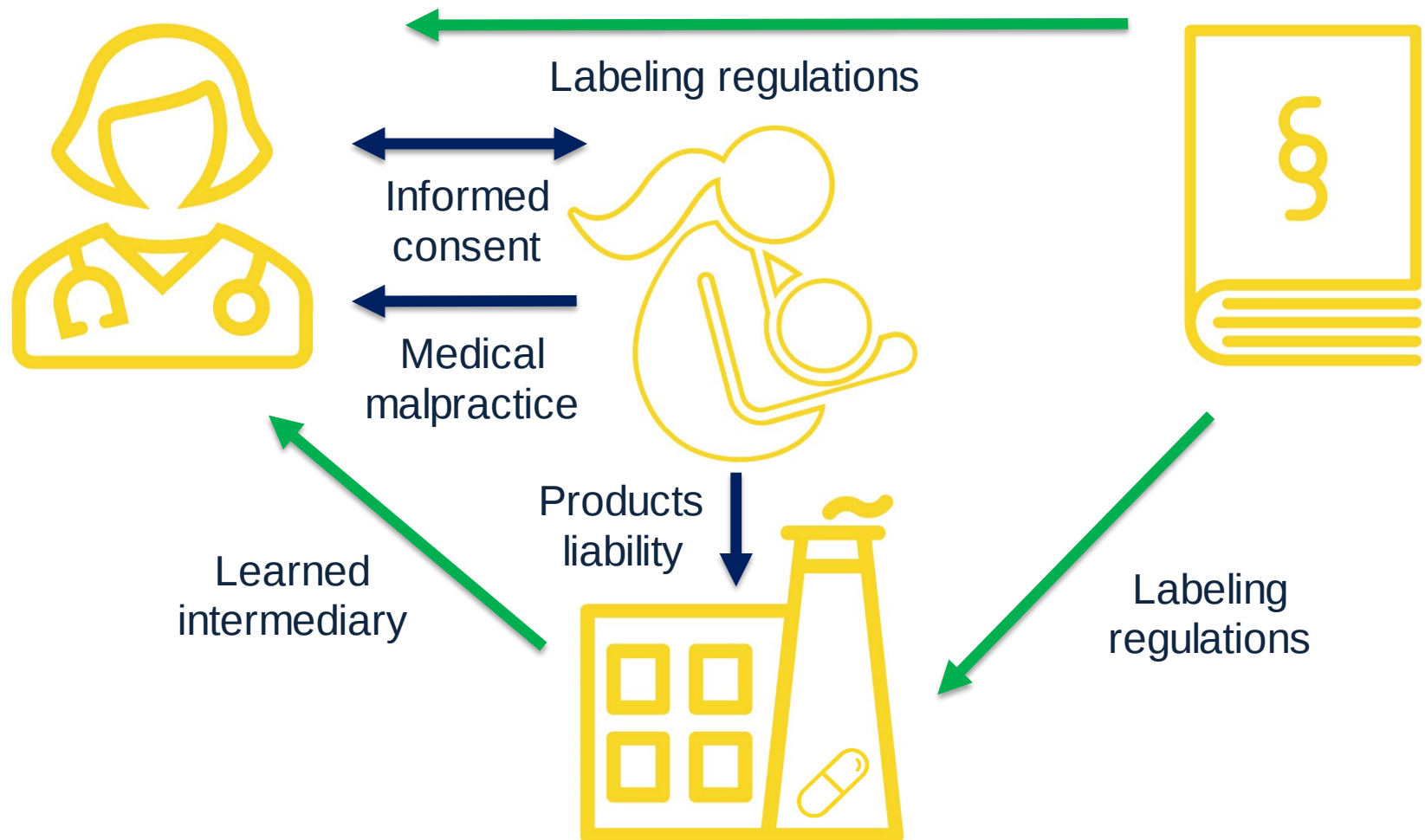
Overview

- Stakeholder interests
- Legal constructs
- Why it's even more complicated than that...

Stakeholder interests in drug labeling for pregnant and lactating patients



Legal constructs in drug labeling for pregnant and lactating patients



Products liability

- Drug and device cases almost 45% of federal caseload
- Baseline rate of pregnancies affected by miscarriage and birth defects
- Case study: Bendectin



Medical malpractice

- 74% of OBGYNs have professional liability claim filed during career
- Standard of care



Informed consent

- Capacity, information, freedom from coercion
 - **Autonomy**: Has to cover facts “necessary to form the basis of an intelligent consent...to the proposed treatment”
 - **Beneficence**: “the patient’s mental and emotional condition is important and in certain cases may be crucial...in discussing the element of risk a certain amount of discretion must be employed...”

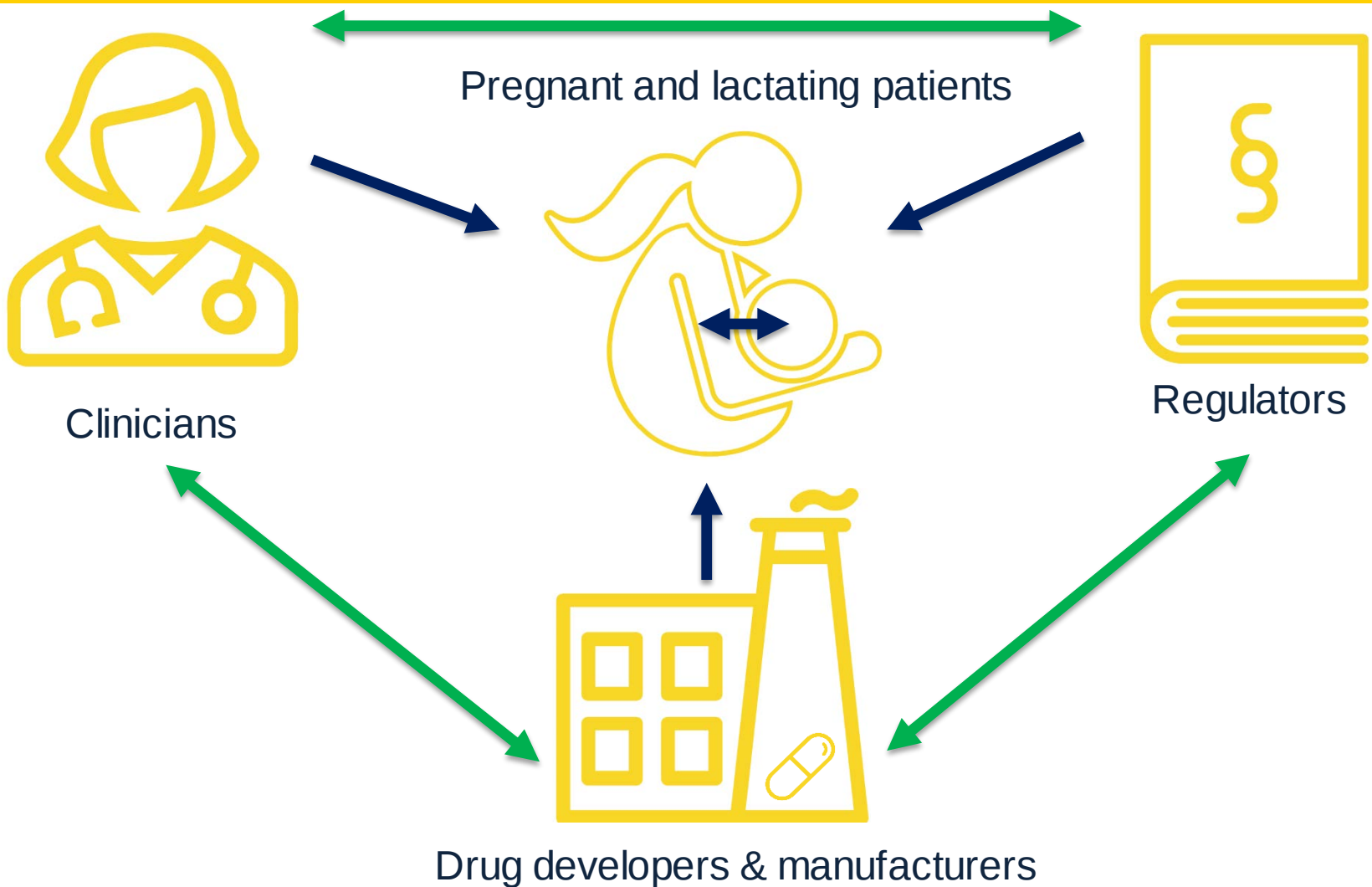


Labeling regulations

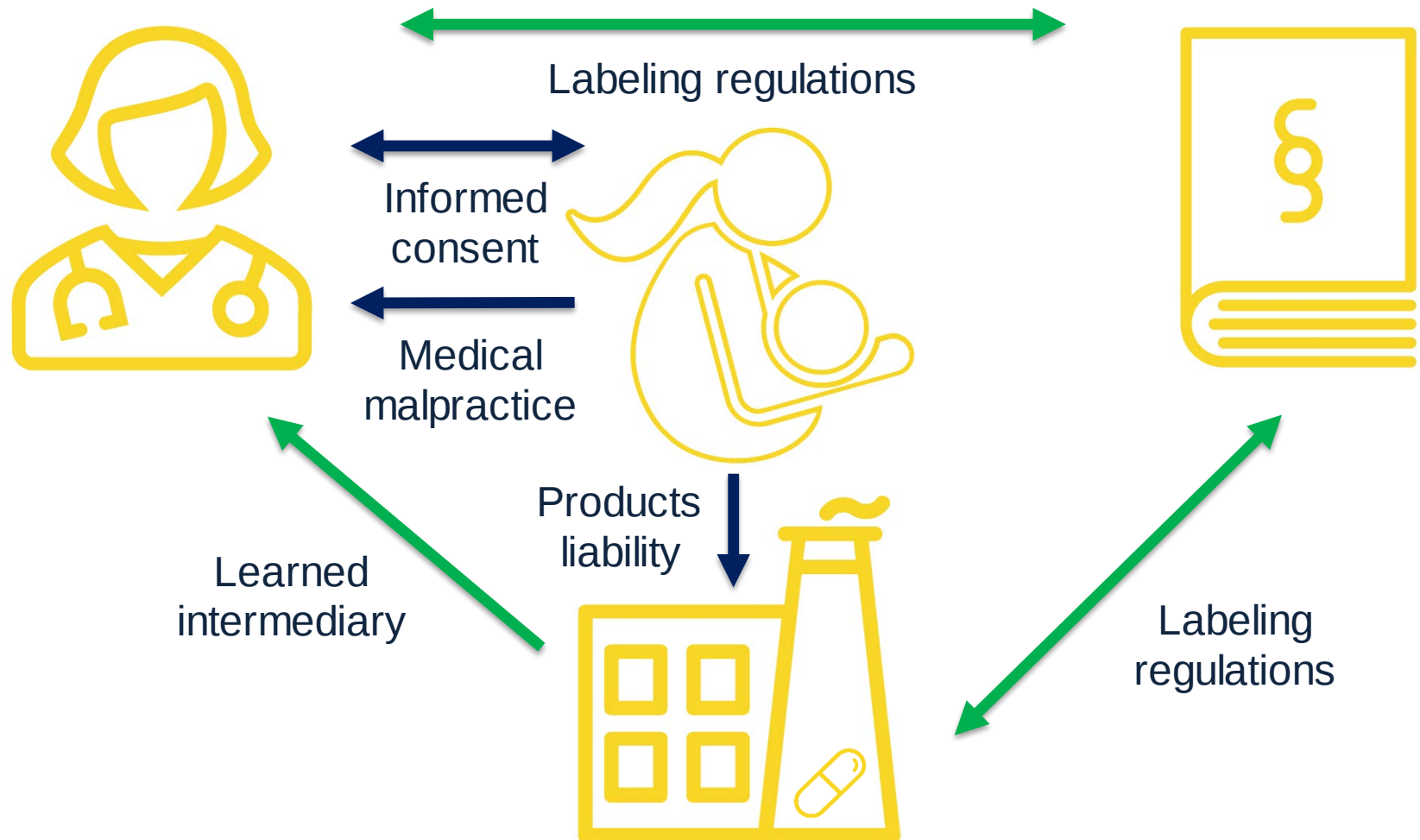
- Intersection with standard of care
- Floor to ceiling?
- *Wyeth v Levine* (2009)



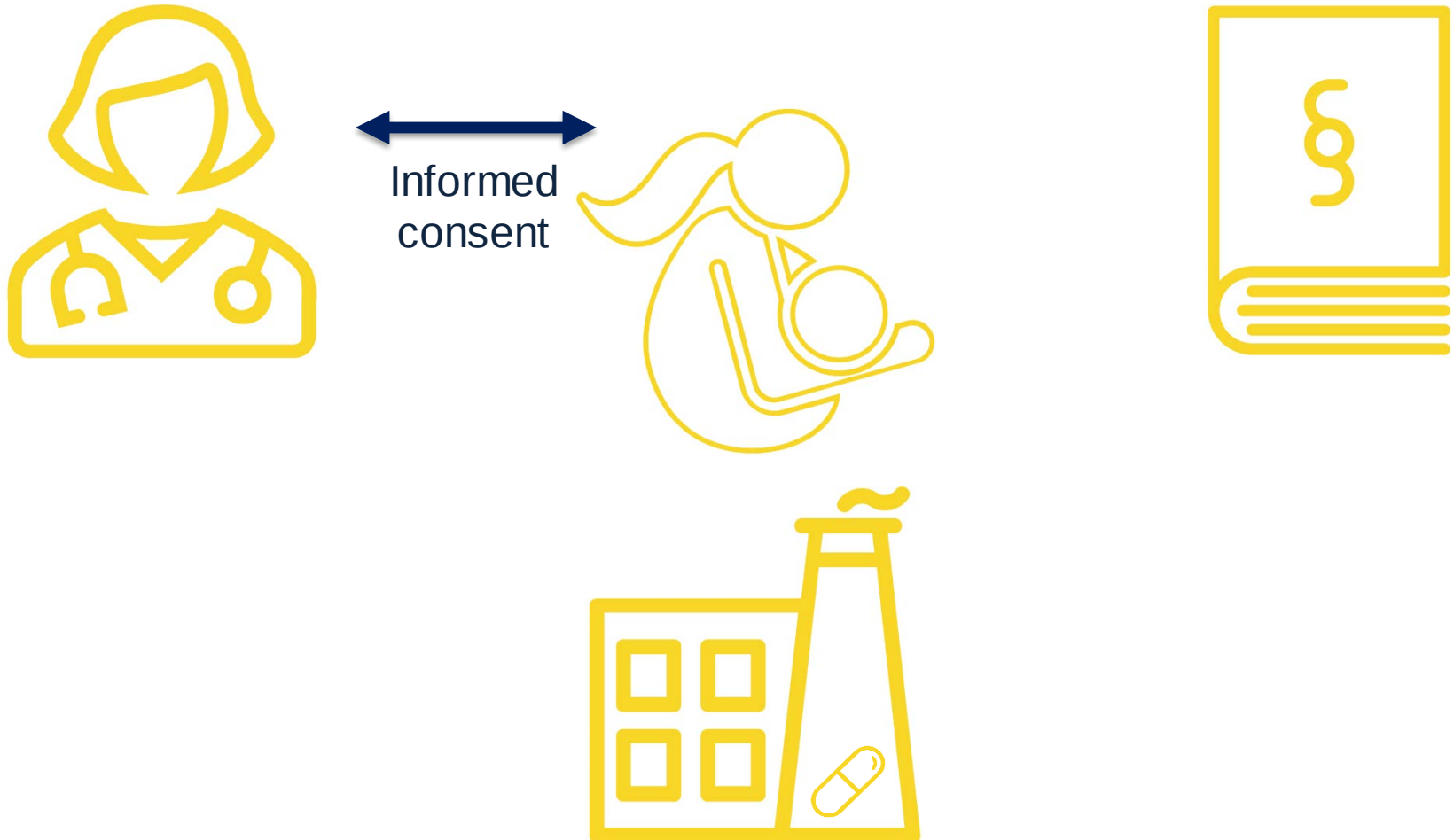
Stakeholder interests in drug labeling for pregnant and lactating patients



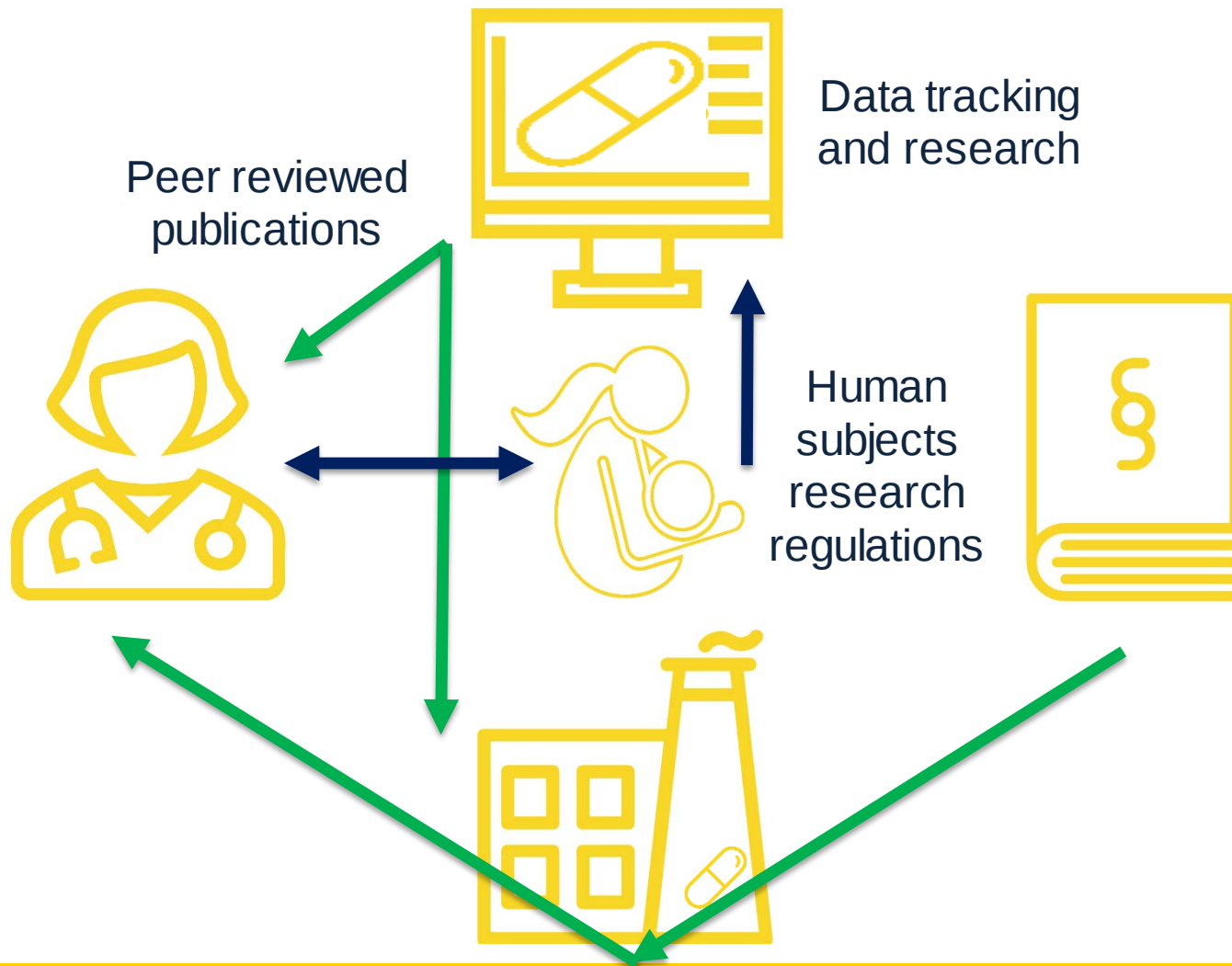
Legal constructs in drug labeling for pregnant and lactating patients



Legal constructs in drug labeling for pregnant and lactating patients



Data generation versus disclosure

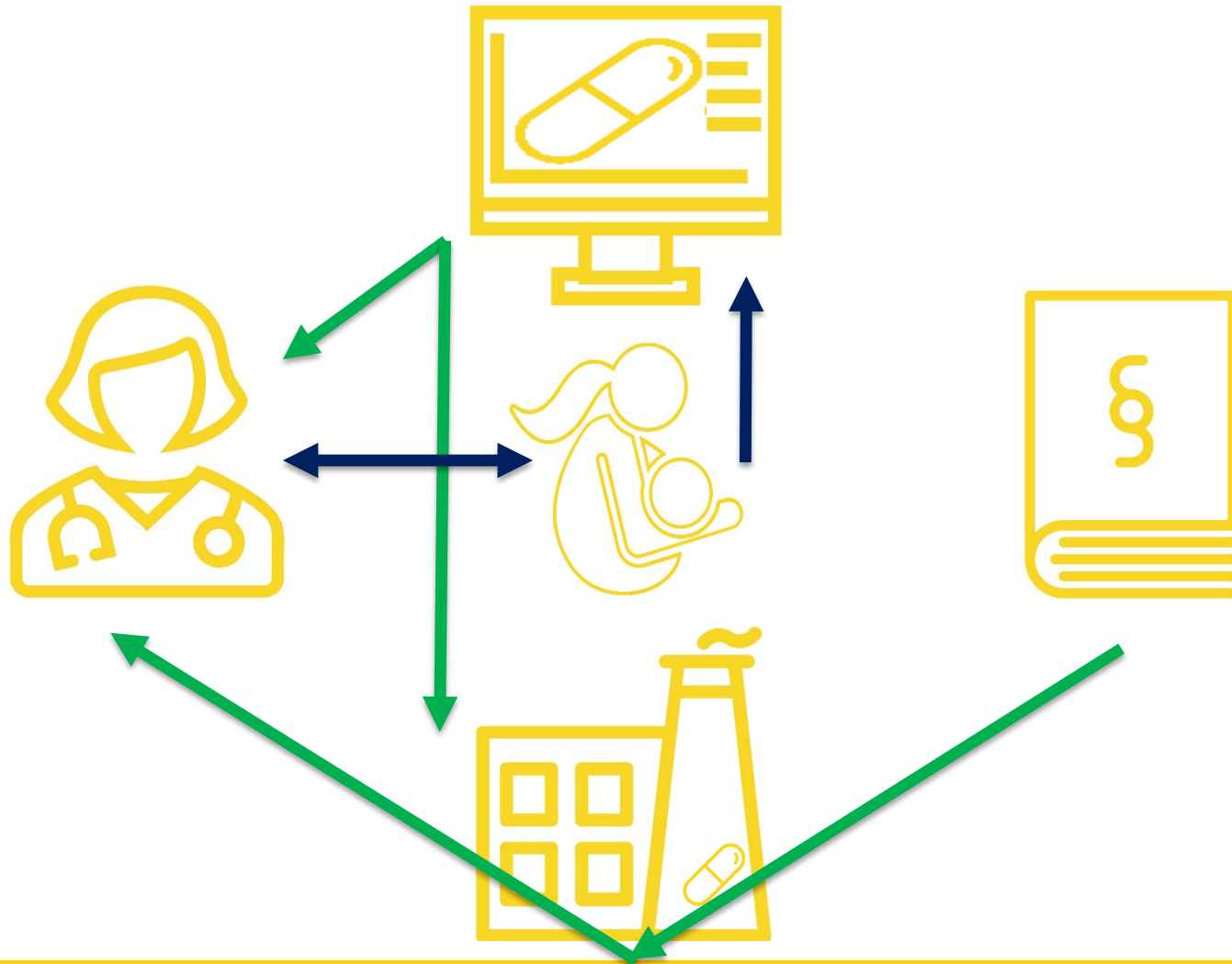


Protection versus access

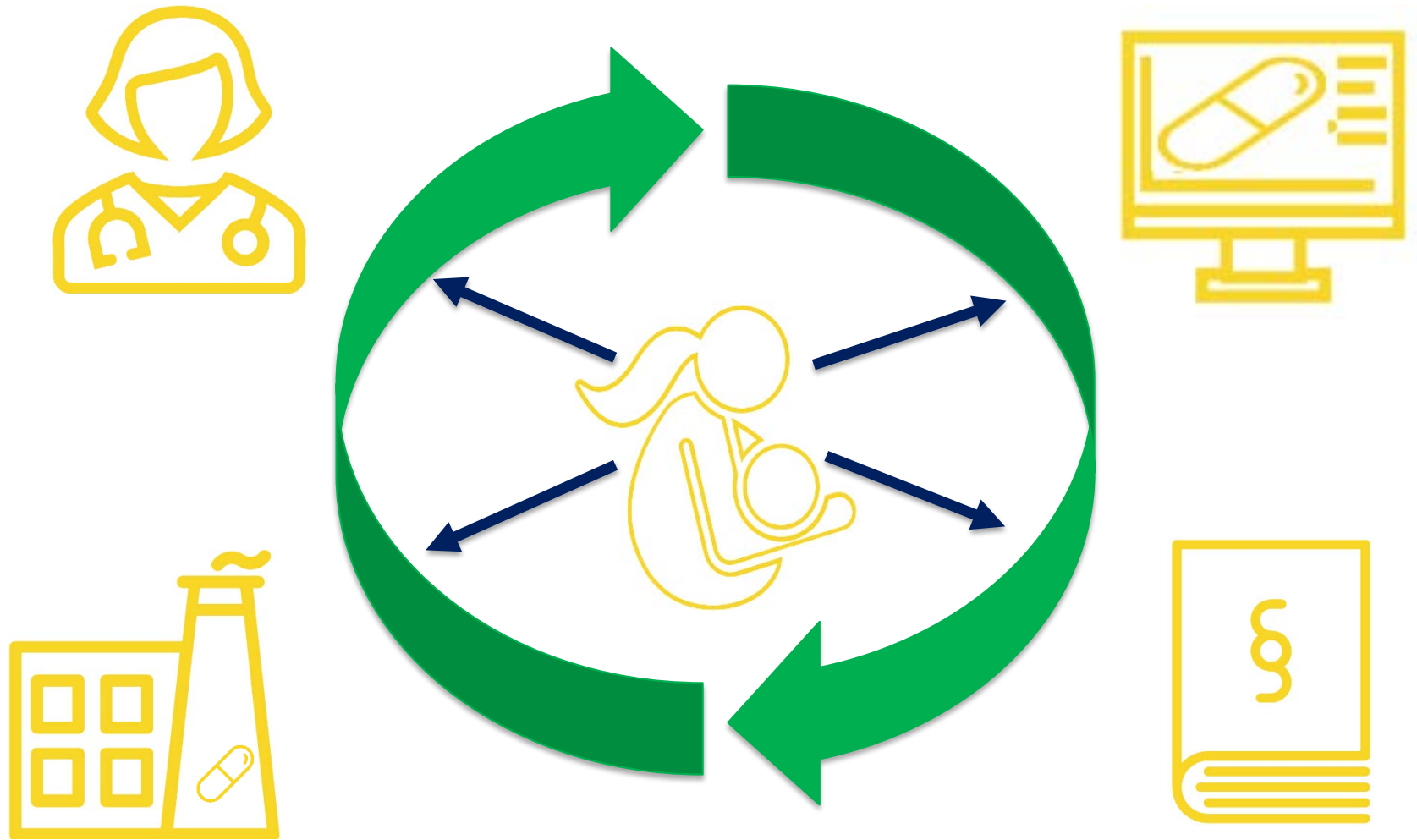
- Exclusion of pregnant women from research
 - Risk to fetus solely for prospect of direct benefit for the woman or the fetus OR
 - Risk to fetus not greater than minimal and purpose important knowledge which cannot otherwise be obtained
 - Any risk is the least possible
- Example: ACE inhibitors



Data generation versus disclosure



Learning health systems





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