



Pregnancy and Lactation Labeling: A Law and Ethics Perspective

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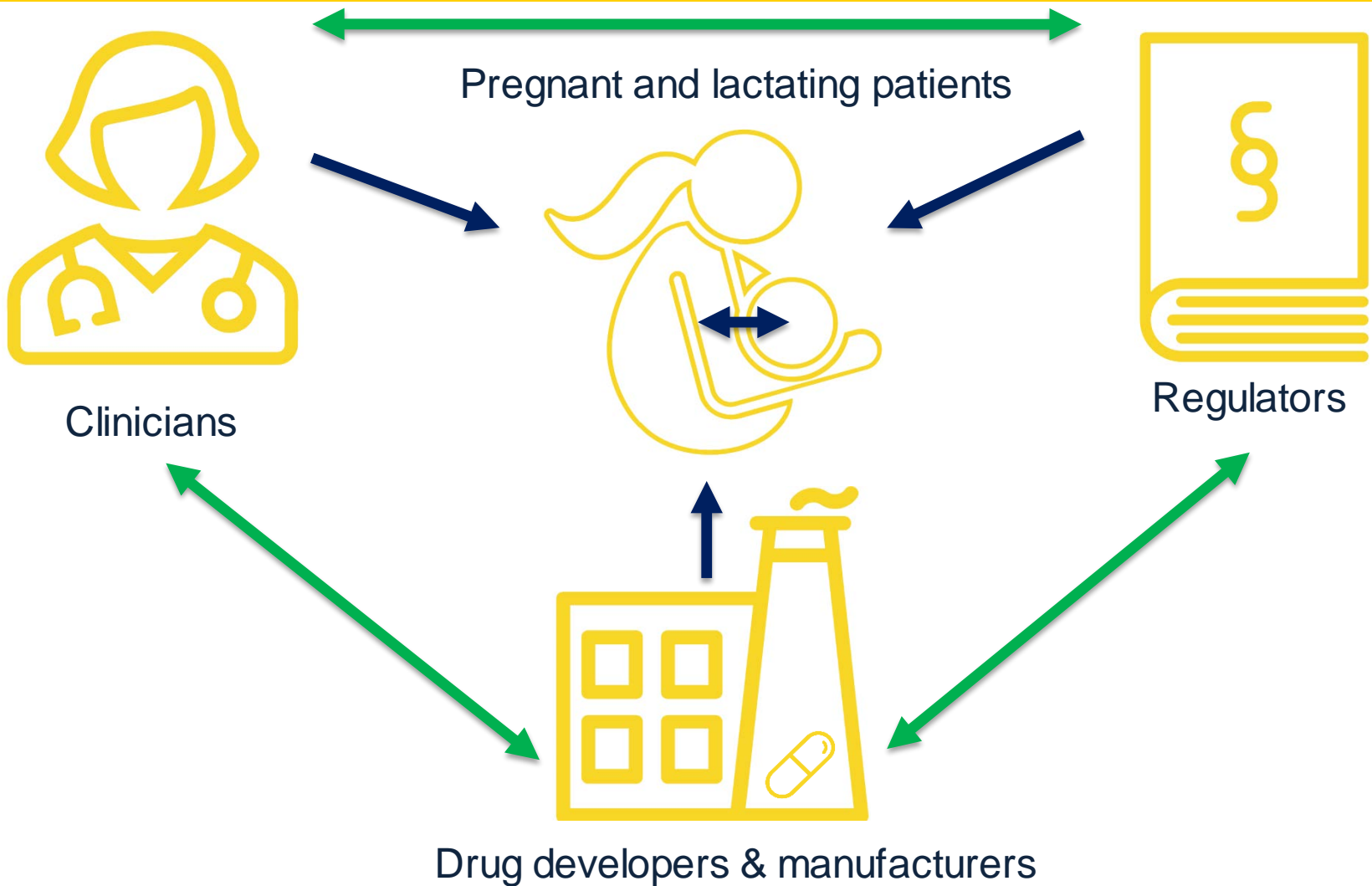


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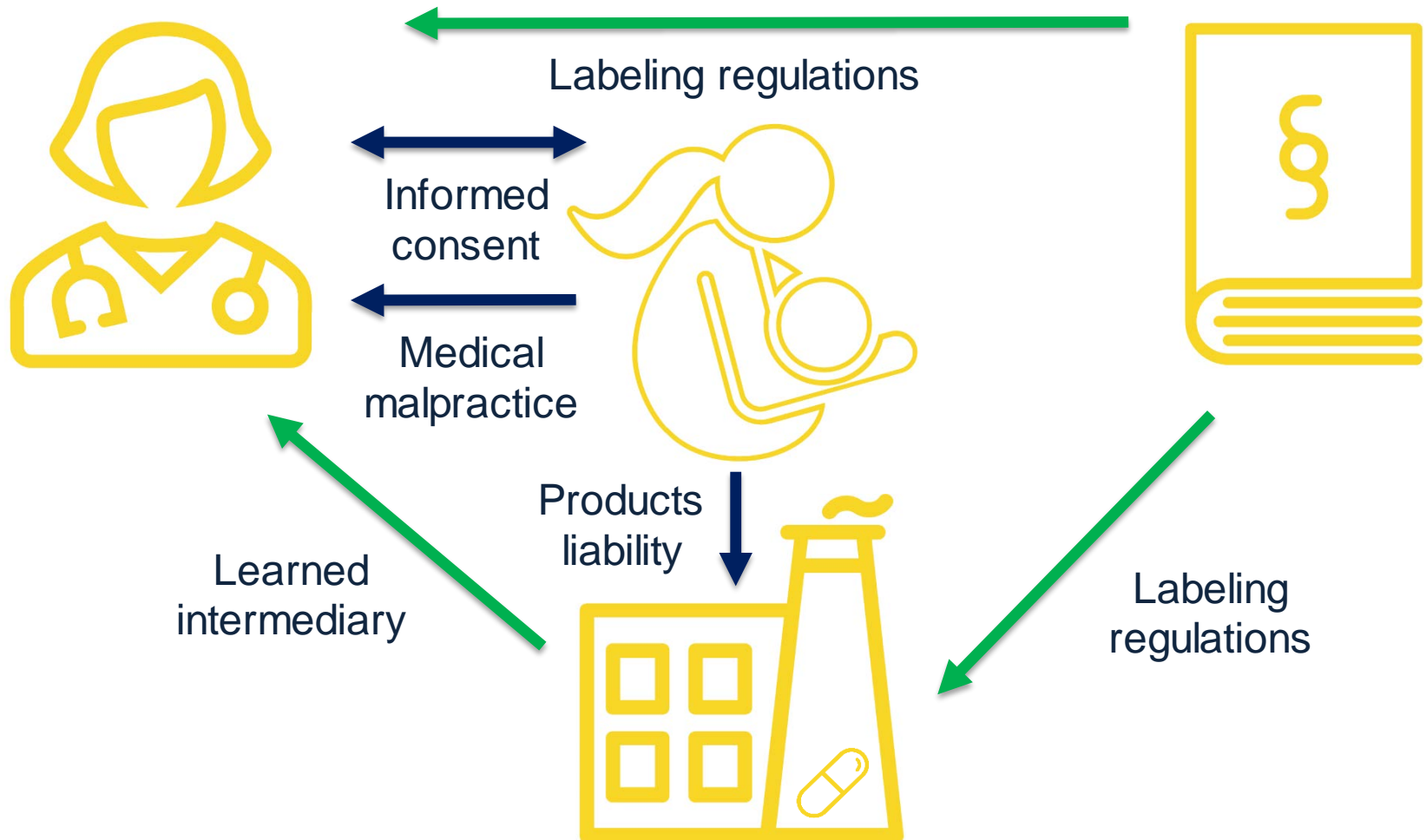
Overview

- 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...”

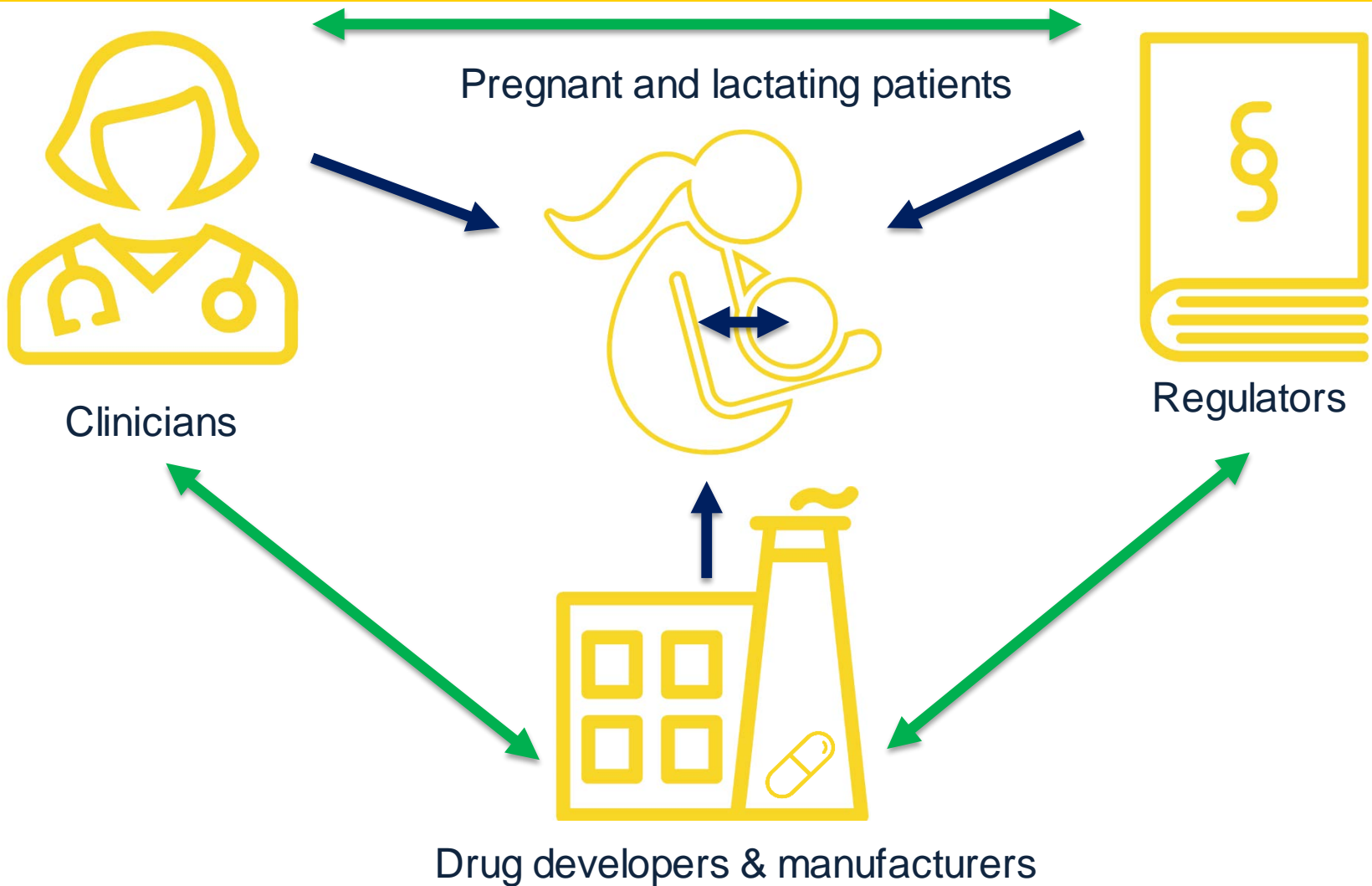


Labeling regulations

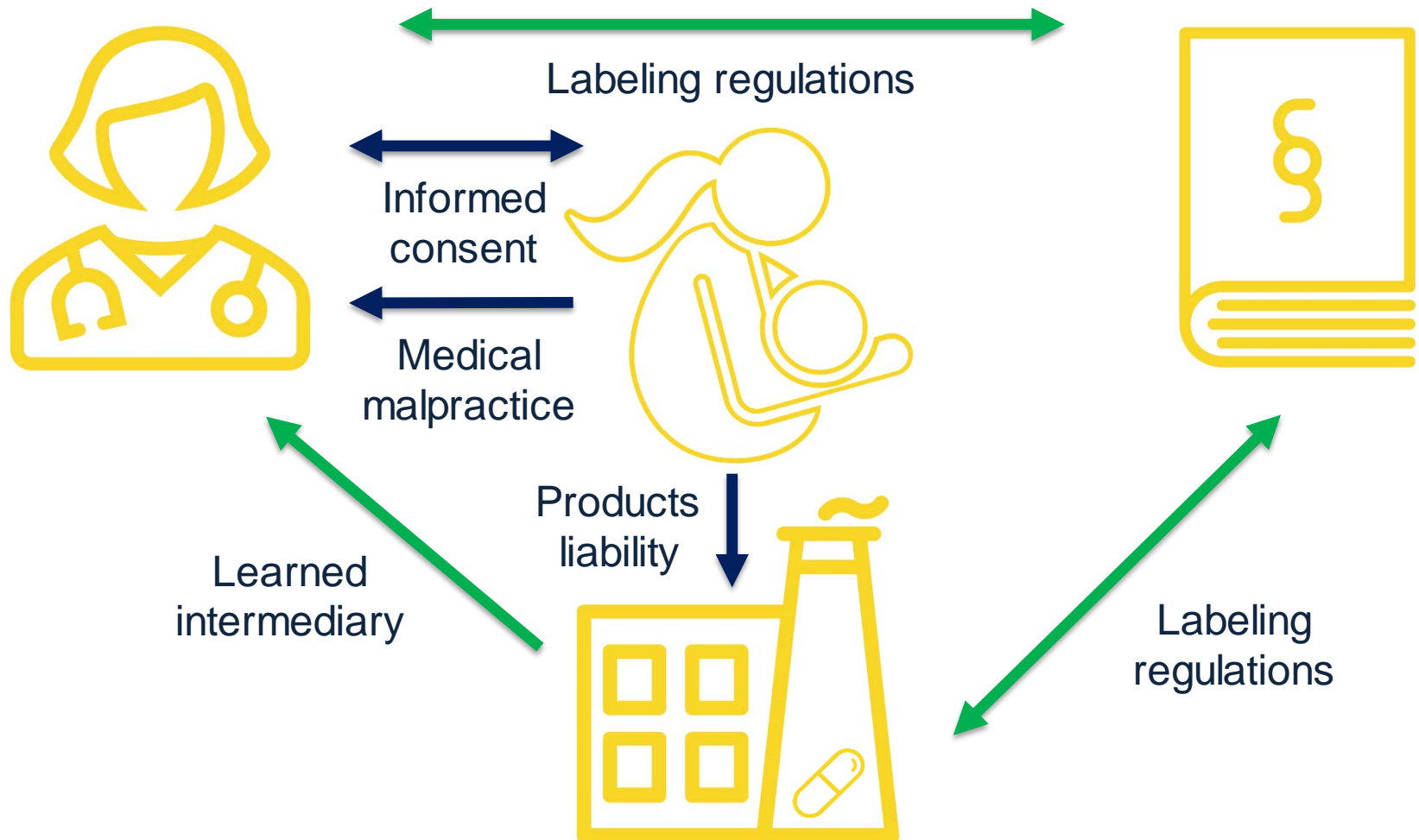
- Intersection with standard of care
- Floor to ceiling?
- *Wyeth v Levine* (2009)



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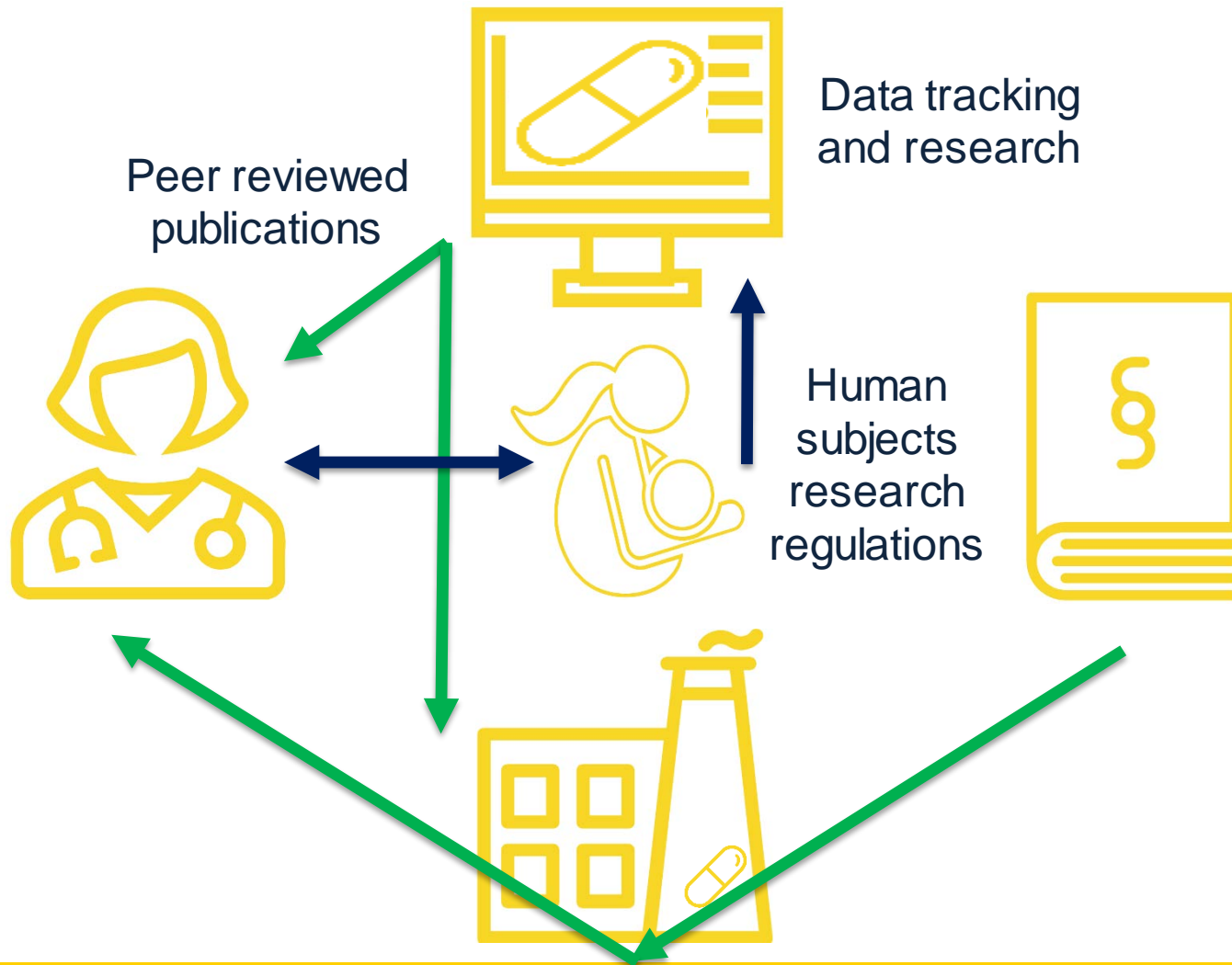
Legal constructs in drug labeling for pregnant and lactating patients



Informed consent



Data generation versus disclosure

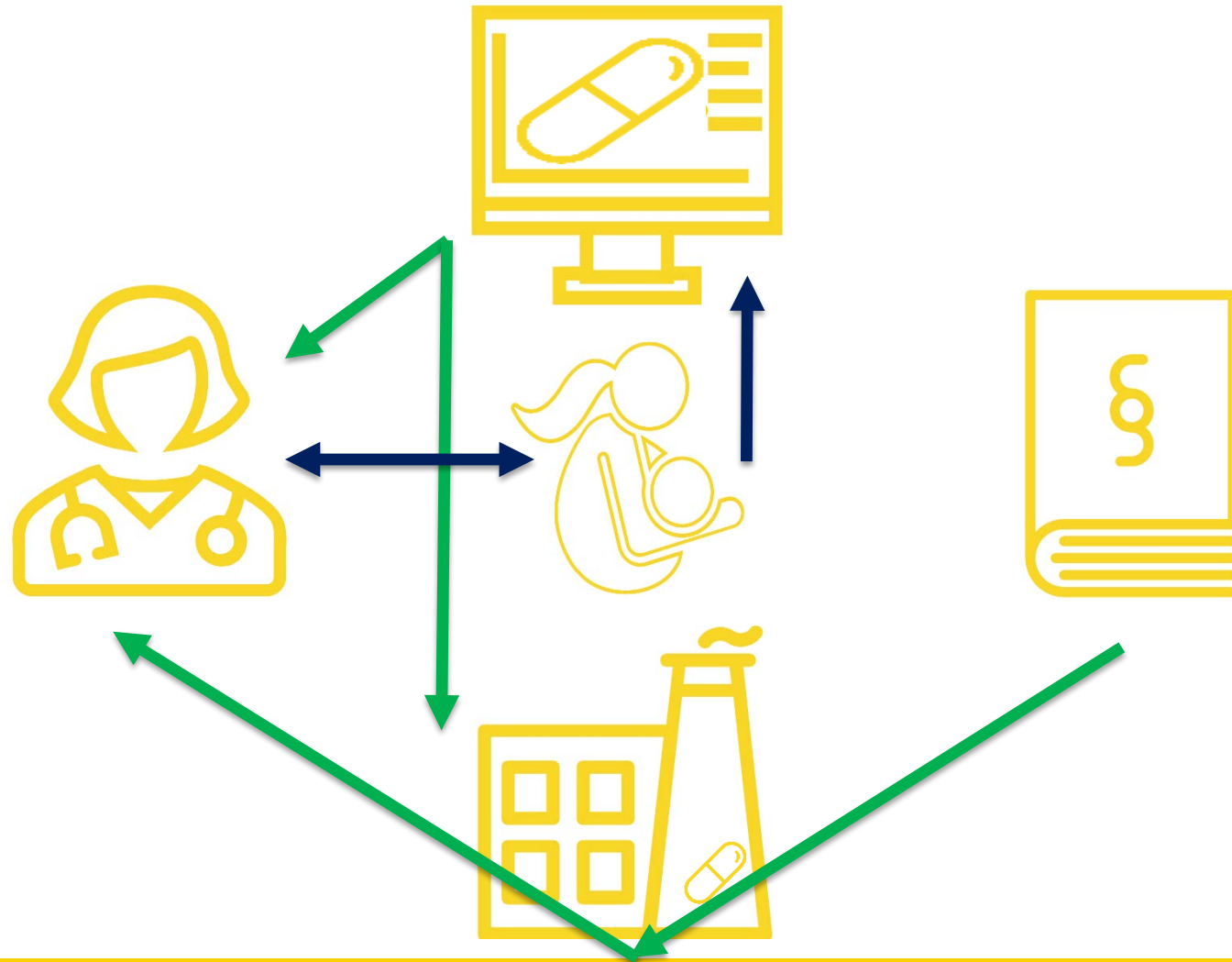


Protection versus access

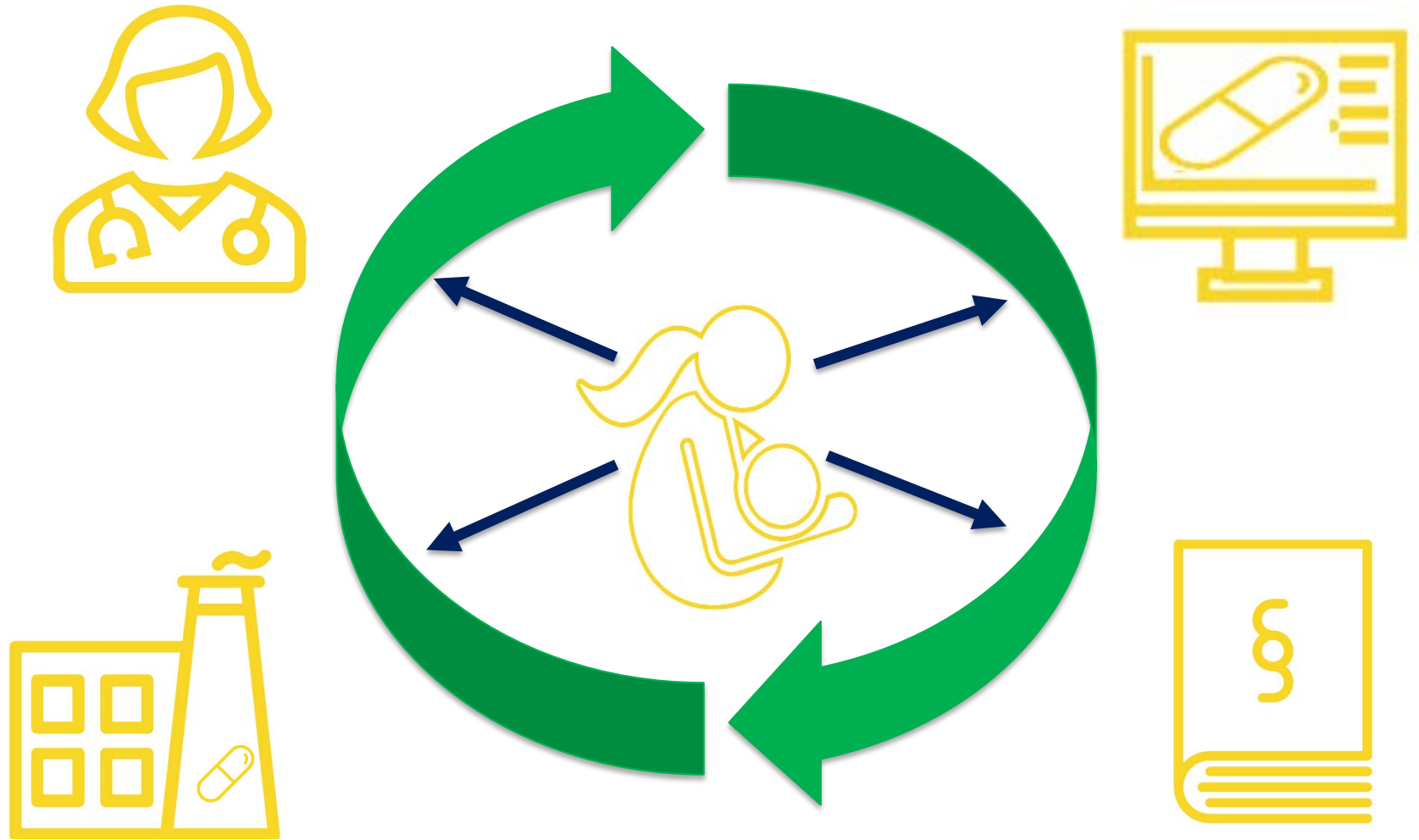
- Exclusion of pregnant women from research
 - Risk to fetus solely for prospect of direct benefit for the woman or the fetus OR
 - Risk to fetus not greater than minimal and purpose important knowledge which cannot otherwise be obtained
 - Any risk is the least possible
- Example: ACE inhibitors



Data generation versus disclosure



Learning health systems





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