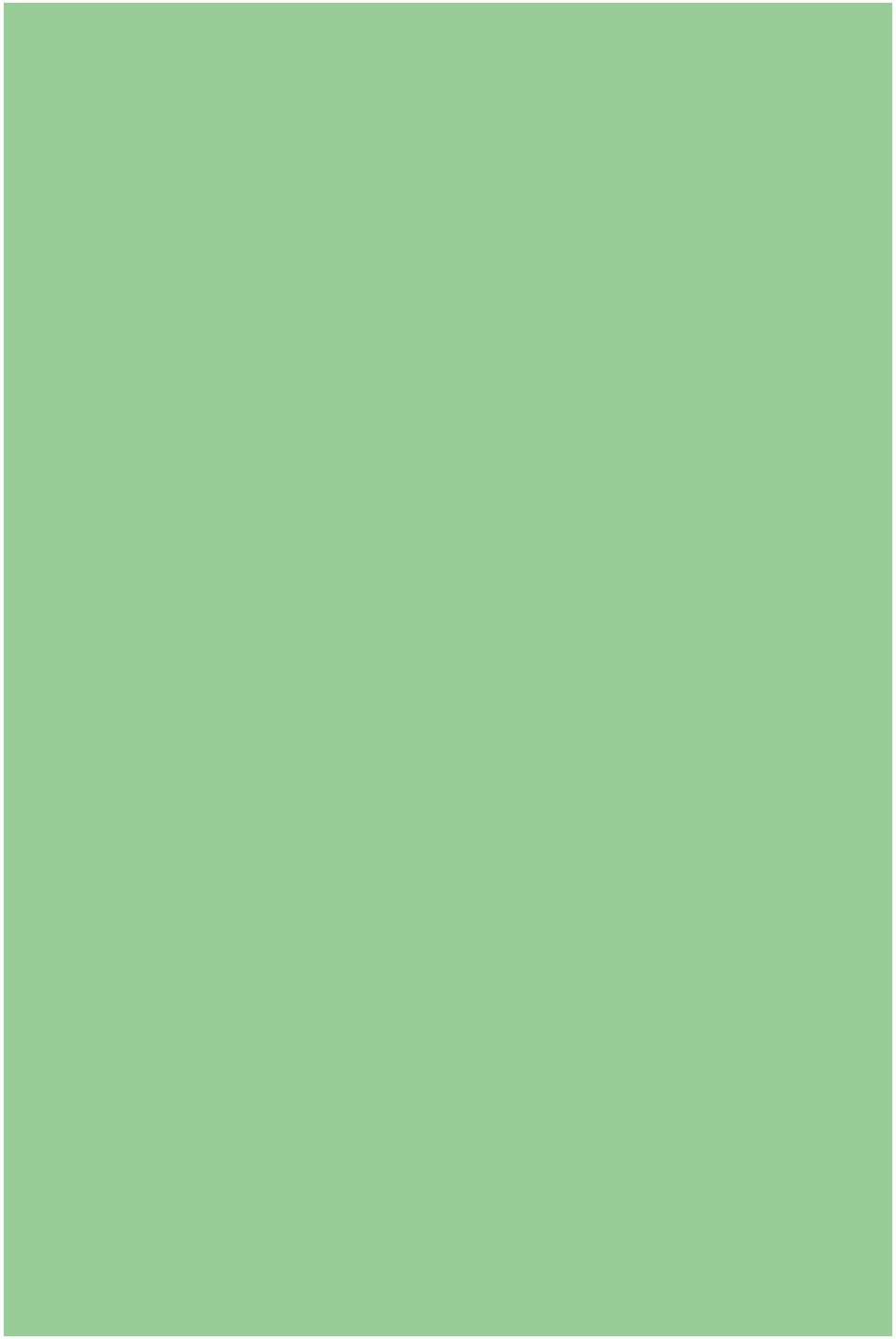

What is personalized medicine?

- Broad and narrow definitions
- Broad: use of pharmacogenomics information
  - Screening for adverse events
  - Selecting dosing
  - Predictive biomarkers
- Narrow: identifying responders and non-responders
  - Predictive biomarkers for patient screening

Current state of play

- Pharmacogenomics information
  - Currently 111 examples on Rx drug labels
  - Mostly related to adverse events and dosing
- Patient screening information
  - Currently 18 examples, with 16 of 18 approved in past decade
  - 17 of 18 were for cancer treatments
  - In 2001, 2 new cancer drugs approved with companion diagnostic tests

Thoughts on the future

- Obvious next step is use of predictive biomarkers for non-cancer treatments
  - Only current non-cancer predictive biomarker is for a hematology drug
- More companion approvals (drug plus diagnostic) approvals
- Incentives and policy
  - Under current conditions, do incentives on balance work in favor or against investment in predictive biomarkers and companion tests?
  - Will policies and regulations need to change?