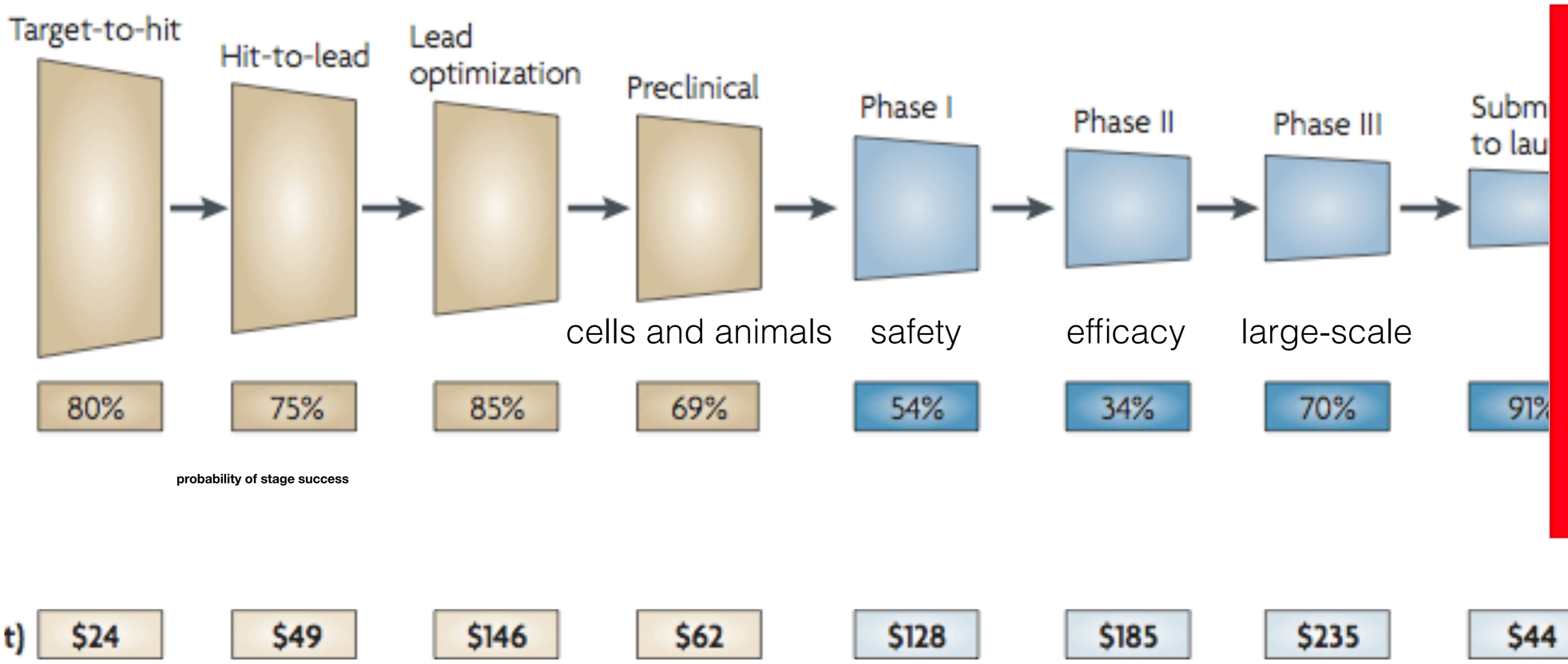
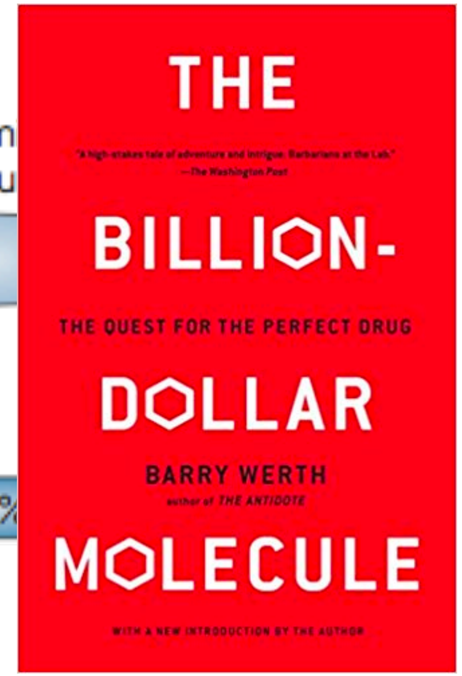
3/31/2020 Week 11 Module 1
Access to Medicines

- In this module, we will discuss
  - the pharmaceutical industry business model
    - how are drugs discovered?
    - how does it make money?
  - impact of the model on
    - research priorities
    - access to medicines
- We will focus on Xtandi (enzalutamide) as a case study

Drug discovery is expensive and often fails





Paul et al. Nat. Rev. Drug Disc. 9:203, 2010.
Chodera et al. Curr. Opin. Struct. Biol., 21:150, 2011.

Intellectual property

- Research and development much more expensive than manufacturing
- Income from drug sales
- How do we incentivize R&D (opposed to making old drugs)?
- Patents
  - must be novel, non-obvious, and useful. usually true for drugs.
  - provide monopoly on legal sales for a temporary period (in the U.S., 20 years from earliest filing)
  - need to be filed in country-by-country

Market failures

- The current business model has paved the way for many medical advances
- However, there are major problems with
  - costs
    - for new drugs can be exorbitant, as drug makers can charge whatever they want
    - the model does not maximize access to medicines, particularly for developing countries and for poor- or middle-class people in rich countries
  - research directions
    - on profitable (erectile dysfunction and hair growth) opposed to essential medicines
    - little research in
      - rare diseases
      - diseases that primarily affect the developing world, e.g. malaria, tuberculosis, Chagas disease, river blindness, cholera (2% of R&D on diseases that affect 1/6 of the world's population)

Addressing market failures?

- A global R&D agreement
  - Funding commitment to invest in R&D based on public health needs not profit
  - Financing research without relying on patents and high prices
  - Sharing knowledge between researchers
- Discuss: How else could market failures be addressed?

- https://vimeo.com/144622081

Xtandi (enzalutamide), a case study

- Xtandi (enzalutamide) is a prostate cancer drug
- Costs $30K in Canada and $130K in the U.S.
- History
  - Developed at UCLA
  - 2005 - Licensed to Medivation
  - 2012 - Approved by FDA
  - 2016 - Rights purchased by Pfizer for $14 billion
  - 2016 - Patent rejected by Indian patent office, paving way for generic manufacture
  - 2017 - Over activist opposition, UCLA files appeal of patent rejection
  - 2019 - UCLA wins appeal

- https://www.lamag.com/citythinkblog/ucla-xtandi-india/?fbclid=IwAR0u_3PhbddYniDynlwH-kZFkjn5QY6FbUBZtaRN_zE0kCkLW6ipRuC5hhc