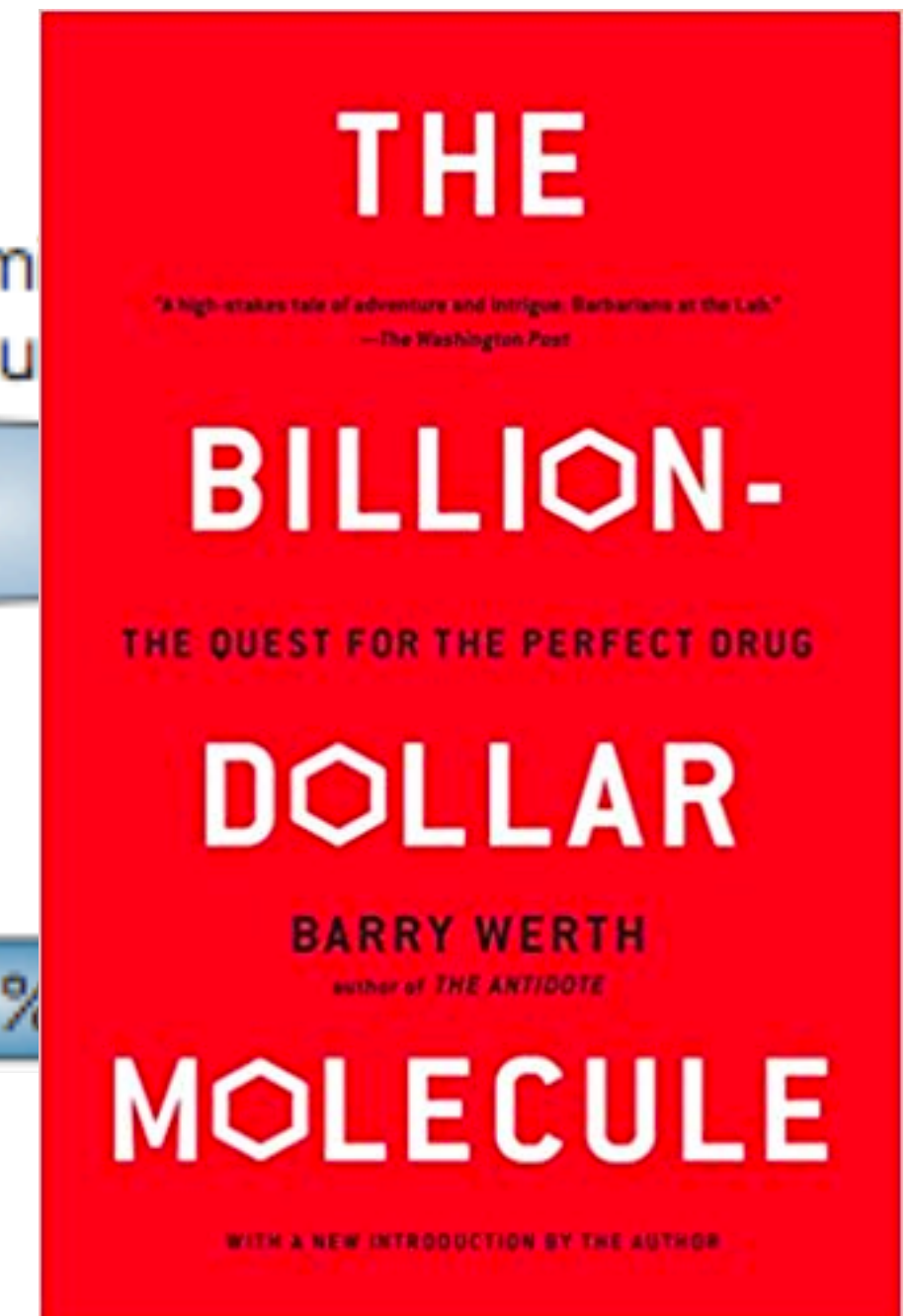
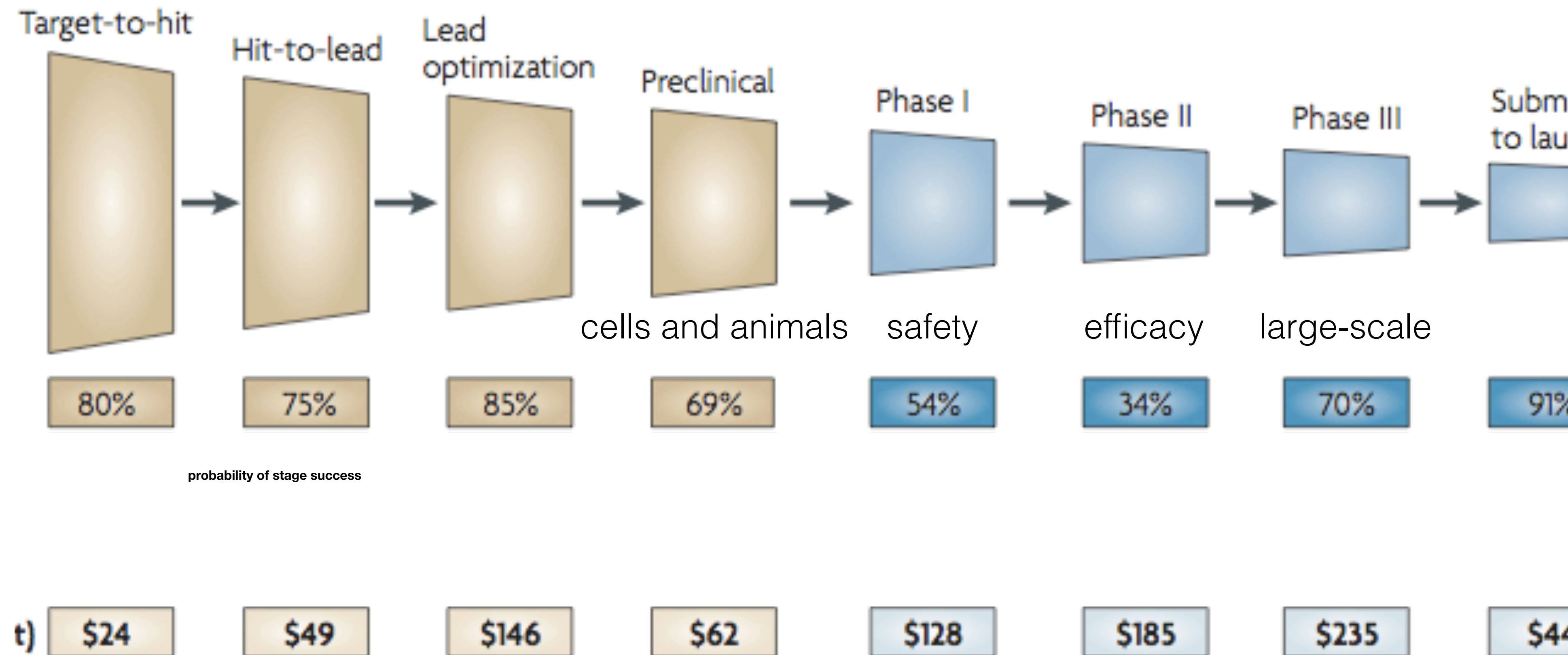


9/14/2022 Access to Medicines

- 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
- Then we will talk about access to COVID-19 vaccines and the TRIPS waiver

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>

Access to COVID-19 vaccines

- COVID-19 vaccines are effective, and the mRNA vaccines are the most effective vaccines known
- Why haven't more people been vaccinated?
 - Production limits
 - supplies
 - producers
 - IP protections - addressed by TRIPS waiver
 - Practical knowledge
 - Distribution
 - purchased by governments
 - U.S. has several times more doses than population, but other countries don't have enough
 - Hesitancy/refusal

Trade-Related Aspects of Intellectual Property Rights (TRIPS)

- International legal agreement between all WTO members (most of the world) in effect since 1995
- Minimum standards of IP protection, including
 - Patents must be granted for "inventions" in all "fields of technology" provided they meet all other patentability requirements (although exceptions for certain public interests are allowed (Art. 27.2 and 27.3)[9] and must be enforceable for at least 20 years (Art 33).
 - Copyright must be granted automatically, and not based upon any "formality", such as registrations, as specified in the Berne Convention. (Art. 9)

<https://en.wikipedia.org/wiki/>

[TRIPS_Agreement#:~:text=The%20Agreement%20on%20Trade%2DRelated,World%20Trade%20Organization%20\(WTO\)](#)

https://www.wto.org/english/tratop_e/trips_e/intel2_e.htm

TRIPS Waiver Process

- 10/2020 - India & South Africa sought waiver for patents, trade secrets, copyrights, and industrial designs related to COVID-19 vaccines, diagnostics, and therapeutics [1]
- 12/2021 - Quadrilateral discussions with US & EU [2]
- 3/2022 - Draft waiver [2]
- 6/2022 - Agreement [3] for Low- and middle-income countries to
 - Temporarily (5 years) waive protections on COVID-19 vaccine patents
 - No waiver for trade secrets, copyrights, and industrial designs
 - Push back a decision on treatments and tests by six months

TRIPS Waiver Response

- “It is hard to imagine anything with fewer benefits than this, as a response to a massive global health emergency.” - James Love, the director of Knowledge Ecology International [3]
- “A slap in the face for Pharmaceutical manufacturing firms [in Least Developed Countries]” because WTO “refused to grant an unconditional waiver beyond the next five years” [4]
- PhRMA statement on the TRIPS Waiver Agreement [5]
 - “Vaccine manufacturers have produced more than 13 billion COVID-19 vaccine doses and built capacity to vaccinate everyone in the world... last-mile distribution challenges are causing countries around the world to destroy unused vaccines and turn away donations.”
 - “gave away valuable American technologies to foreign competitors, undermining the millions of American jobs supported by our industry.”

References

- [1] <https://www.monitor.co.ug/uganda/business/prosper/trips-agreement-a-slap-in-the-face-for-pharmaceutical-manufacturing-firms-3923634>
- [2] <https://www.fasken.com/en/knowledge/2022/06/breaking-news-from-the-wto-limited-trips-waiver-for-covid-19-vaccines>
- [3] <https://www.devex.com/news/wto-finally-agrees-on-a-trips-deal-but-not-everyone-is-happy-103476>
- [4] <https://www.monitor.co.ug/uganda/business/prosper/trips-agreement-a-slap-in-the-face-for-pharmaceutical-manufacturing-firms-3923634>
- [5] <https://phrma.org/resource-center/Topics/Trade/PhRMA-Statement-on-the-TRIPS-Waiver-Agreement>