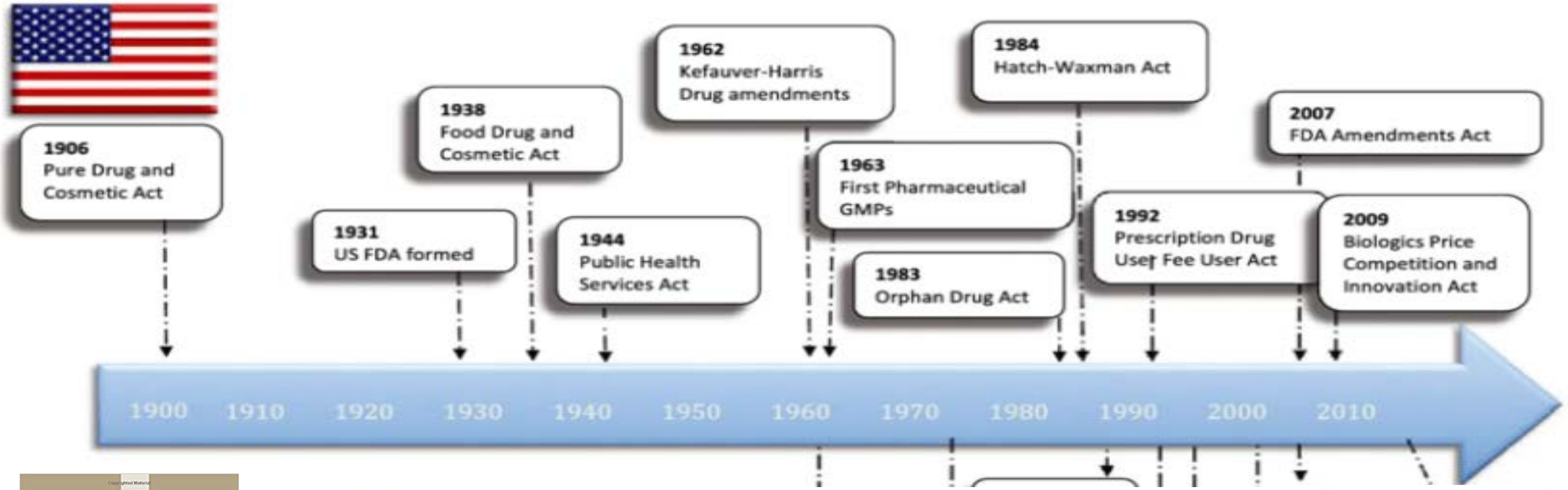
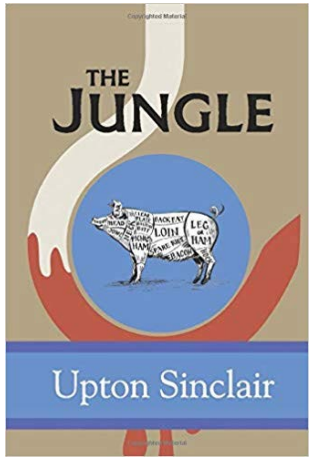
Does the FDA Need a Reboot?

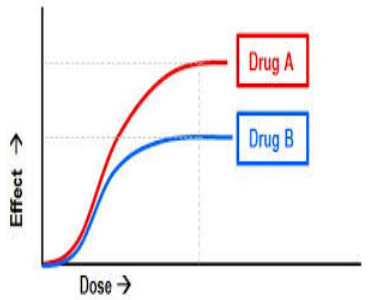
PhUSE Single Day Event: Durham, NC 2019
Chris Decker, d-wise

The Regulatory Review Process has become a Roadblock to Innovation

How did we get here…history lesson







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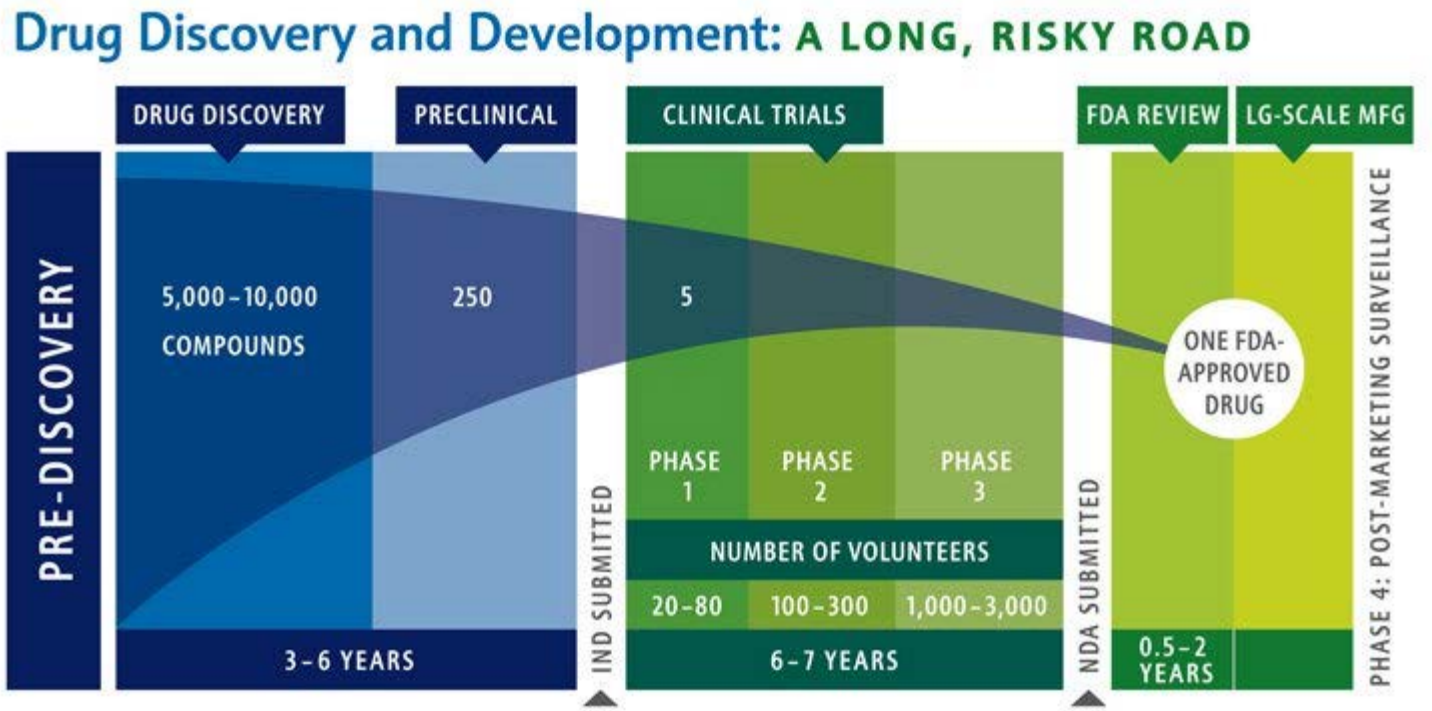
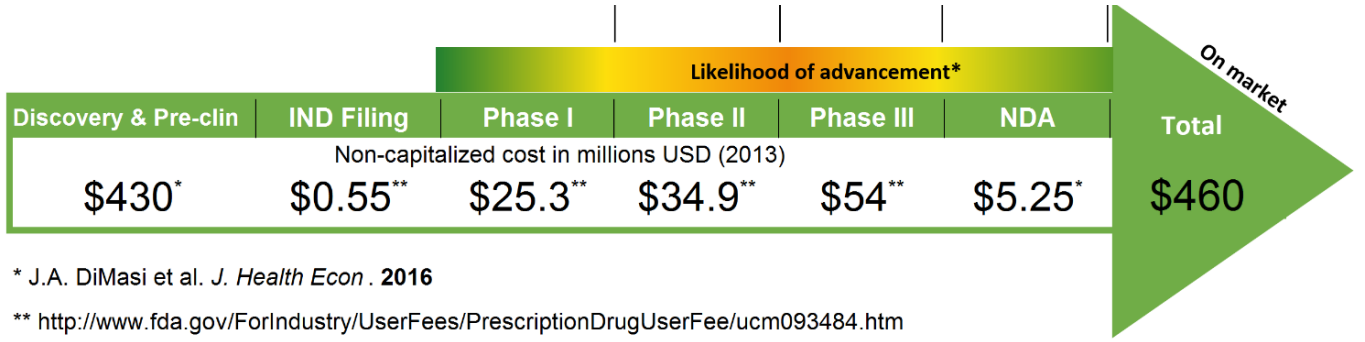
Time & Cost to bring a drug to market



Source: Pharmaceutical Research and Manufacturers of America



* J.A. DiMasi et al. *J. Health Econ* . **2016**

** http://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee/ucm093484.htm

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Department of Defense (DOD)

- 2017: Department of Defense proposed bill to give the DOD power to approve drugs

"emergency uses for medical products to reduce deaths and severity of injuries caused by agents of war."

Example:

- Freeze-dried plasma for troops in the field
- 10 years waiting for this

Critics – Review process is…

- Too expensive
- Too slow
- Not achieving the overall goal

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What if...
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What if....we skip the FDA

Proposal

- Right to Try Movement: FDA get out of the way and let patients decide how much risk they want to take on unproven drugs

Advocates

- FDA substituting its judgement for the patient's judgement

Critics

- Without proper safety review, patients aren't equipped to assess risk

What if….we let the market decide

Proposal

- Limited approval quickly with early data and revise decisions later; expanded approvals as more robust data and proof are collected

Advocates

- Drugs in patient's hands more quickly saves lives; health insurers and doctors decide what to cover or prescribe

Critics

- 90% of drugs are already making it to market; physicians could also have incomplete information

What if….empower other agencies

Proposal

- Example: DOD has a better sense about what military personnel need as they face a very different set of health risks

Advocates

- Other agencies have proven they can bring new 'technologies' to market much quicker than the existing process so why not drugs for certain needs

Critics

- Different paths and rules for approval would lead to inconsistency and the agencies are not equipped to scale to ensure rigorous processes

What if….we fix the FDA

Proposal

- Continue to force transformation within the FDA and loosen its regulations on clinical trials as FDA has become too risk-averse

Advocates

- FDA's recent new tools and pathways are transformative, like accelerated approvals and breakthrough therapy designations market; Starting something new or handing off powers to other isn't practical

Critics

- Impossible to transform an organization and mindset of this size; Going to rapidly could put patient's safety at risk

What if….got back to basics

Proposal

- Actually tighten its processes and DON'T look to speed up the process

Advocates

- 90% approval rate is a sign that the agency has already bent to far to pressure; 1 in 3 drugs approved between 01-10 had a major safety action; Approving faster then any other agency in the world

Critics

- Drugs are not getting approved fast enough and bureaucratic processes are not focused on the true safety and efficacy of drugs

So where do we go?

- Are any of these off the wall approaches viable?
- FDA should continue to focus on
  - Ensuring the safety and efficacy of drugs
  - More resources focused on reviewing outcomes and real-world data
  - Better understand dramatic new therapies (e.g. stem cell and personal digital devices)
- Yale researcher Joseph Ross quote:

"The entire world relies on FDA. No regulator reviews the evidence as closely as FDA does. But the FDA is in the worst position of every agency because no one is ever happy with what they're doing."

Questions

https://www.politico.com/agenda/story/2017/12/13/fda-approval-alternatives-000593

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