



**Innovation and Public Investment in Prescription Drug Development**  
**Stan Dorn, Families USA Senior Fellow**  
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**Public Citizen Conference: “Affordable Medicines Now”**

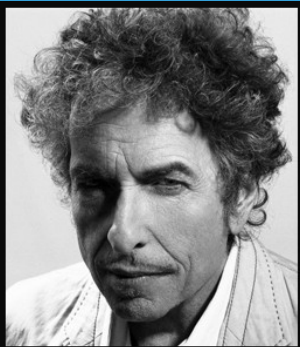


# Presentation overview

**Why do these issues matter?**

Policy options for progress

# Symptoms of major policy disorder



And something is happening here, but you  
don't know what it is, do you Mr. Jones?

(Bob Dylan)

Extortionate prices charged to desperate patients

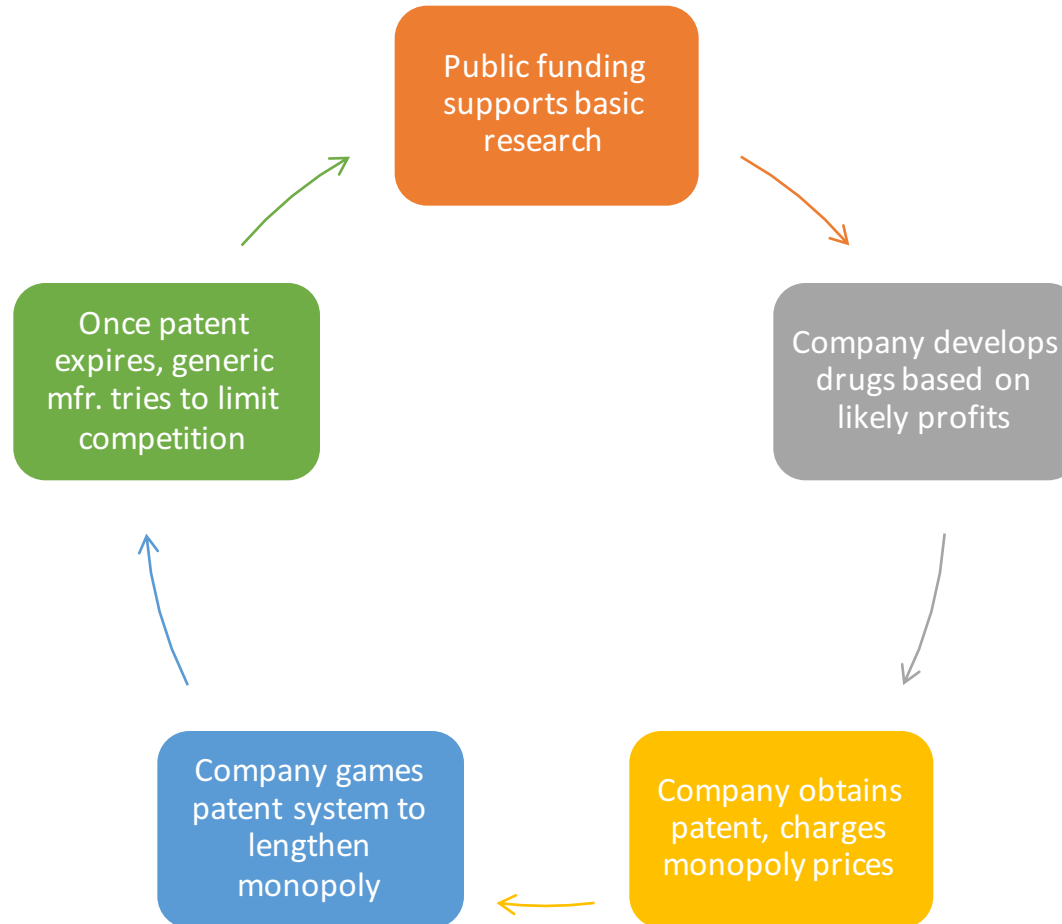
Innovation gone awry

- 78% of patents from 2005 through 2015 involved changes to existing drugs, not new drugs (Feldman 2017)
- Only 9% of new drugs between 2000-2013 offered clinical benefit over existing treatment (La Revue Prescrire 2016)
- Key public health needs going unmet. Examples:
  - ❖ Where's the significantly more effective flu vaccine?
  - ❖ Where's the treatment for sickle-cell anemia?
  - ❖ Why no treatment for “super-bugs” that are projected to kill 10 million world-wide?
  - ❖ Why no treatment for “tropical diseases,” which affect people in U.S. and elsewhere?
  - ❖ Why no major new class of antibiotics since the 1980s?

Enormous profits

- Both generic and name-brand manufacturers among the most profitable industrial sectors
- Stock market growth for large drug companies significantly faster than the S&P 500

# Root cause: funding drug development through government-protected monopoly profits and public “seed money” for research



# The role of NIH funding in drug development: 2010-2016

Drug category	% of drugs in category benefiting from NIH-funded research	Funding years of NIH project support	Amount of NIH funding	% of NIH funding involving basic research
All 210 new molecular entities approved by FDA	100%	221,891	\$115.3 billion	89%
All 84 first-in-class products approved by FDA	100%	196,970	\$64.6 billion	89%

Source: Cleary, et al. 2018.



# Implications

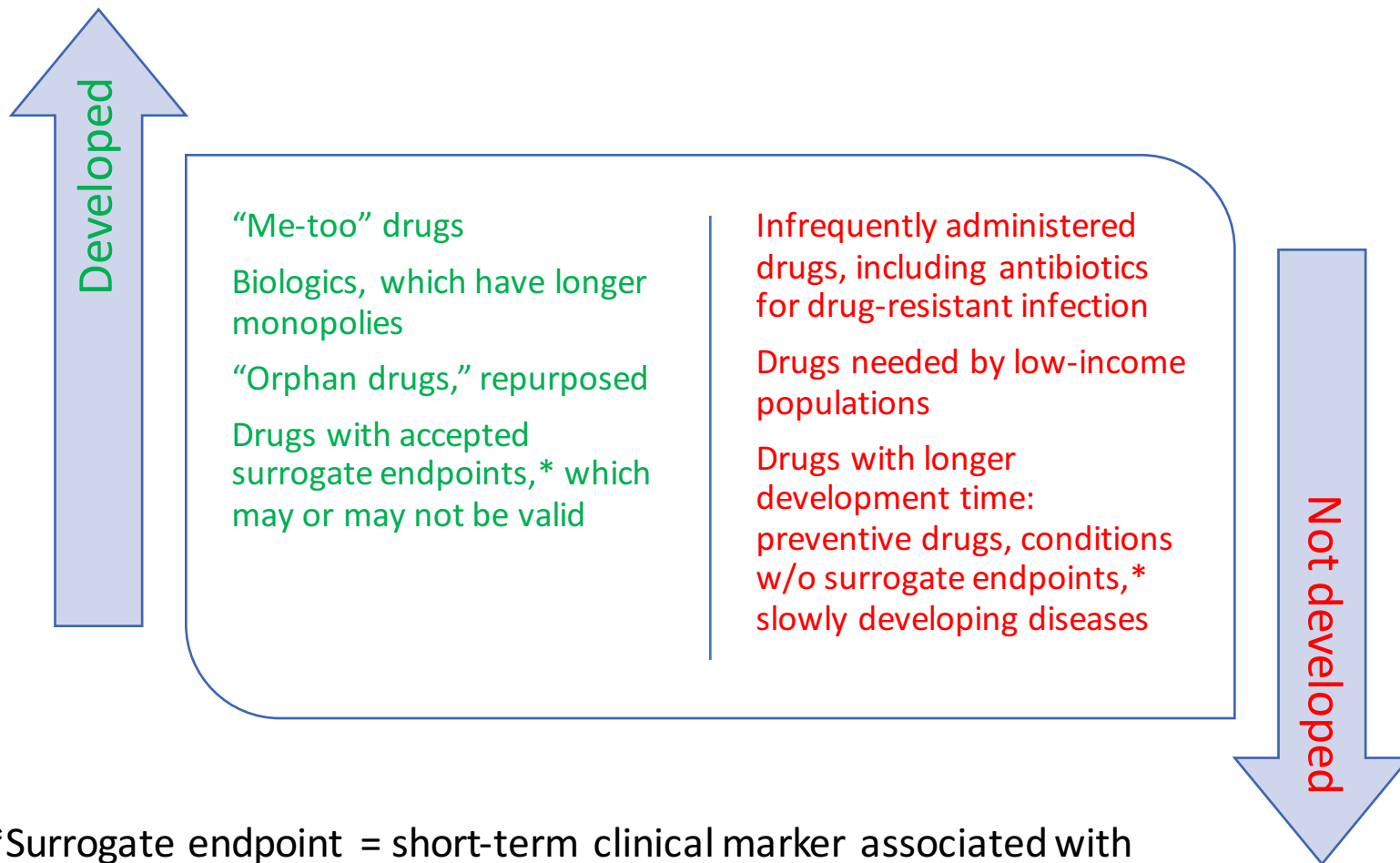
Public pays twice for the same drugs

- Public funding for basic research
- Exorbitant prices for resulting drugs

Private corporations leverage public research dollars to maximize private profits, rather than gains to public health



# Which drugs get developed? Which don't?



\*Surrogate endpoint = short-term clinical marker associated with ultimate positive health outcomes. For example, shrunken tumors can be a surrogate endpoint for longer survival.

# Why these issues matter

They directly affect people

They affect messaging





# Presentation overview

Why do these issues matter?

**Policy options for progress**

# Public duties for beneficiaries of public funding



When drug development benefits from public research funding, ensure prices that are affordable to the public

- Attach conditions to funding requiring affordable access to resulting products
- Require manufacturers to enter into pricing or licensing agreements with HHS, potentially capping prices at those charged in other wealthy countries
- Drugs developed with significant taxpayer support could be ineligible for patent protection and be sold as generics
- Publicly-licensed production for essential drugs developed with significant public help

Mandate disclosure of all data developed with public research funding

- De-identified to protect privacy
- Prevent cherry-picked, selective publication of favorable data

# Fund innovation with methods other than monopoly pricing

Public funding of research and development, potentially at a much higher level than today

- Research grants
- Publicly supported clinical trials
- Publicly-funded prizes for high-impact R&D
- “Space program for drug research”

“Open source” R&D

- Publicly-identified target conditions
- Partnerships between government, industry, academia, non-profits
- All results publicly available
- Ensure public accountability through
  - ❖ Publicly available governing and financing documents
  - ❖ Balanced stakeholder representation on governing boards

Assured markets

- Guaranteed purchase

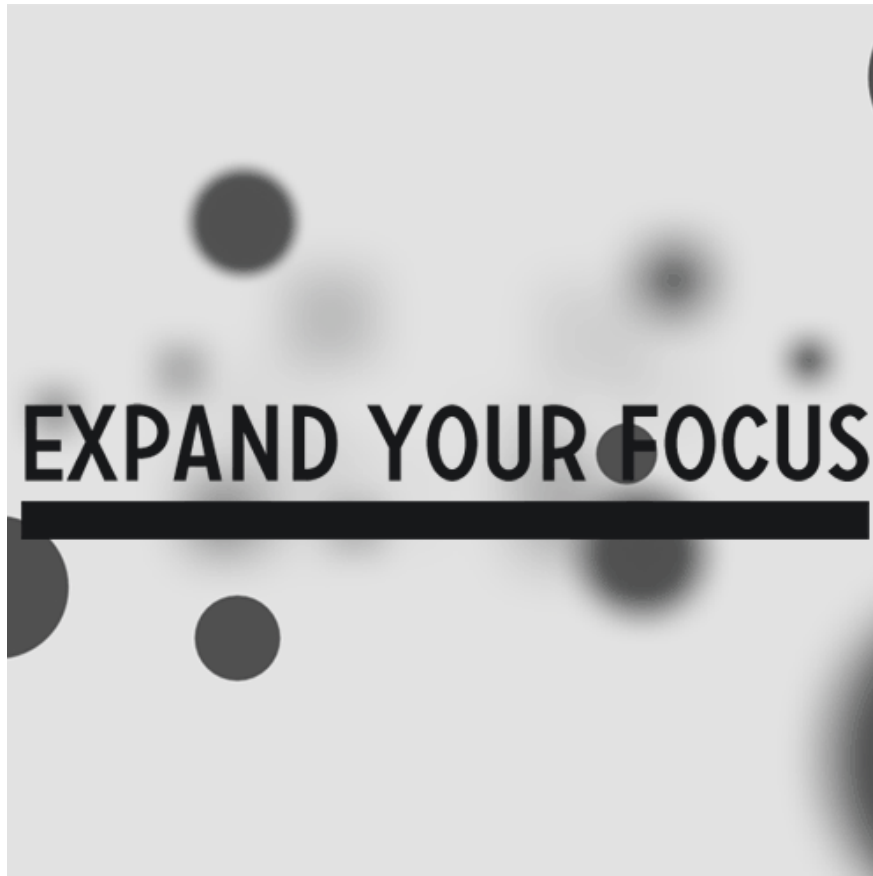
Scope

- Address market failures: key health needs going unmet by profit-driven system
- Larger-scale replacement of patent system

# Conclusion

Drug prices have rightly generated public outrage

Innovation and public return on public investment are also worth considering for inclusion in a broader campaign directed at drug industry abuses





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