Policy & Drug Development

David Ridley, Duke University

- Neglected diseases & bioterrorism
  - "Developing Drugs for Developing Countries" (with Grabowski & Moe) *Health Affairs*, 2006
  - Supported by grants from Glaxo Foundation & Center for Advancement of Social Entrepreneurship
- Generic biologics
  - "Entry & Competition in Generic Biologicals" (with Grabowski & Schulman) *Managerial & Decision Economics*, 2007
  - Supported by grant from Genentech

Problem: Little private financial incentive to develop treatments for

Orphan diseases	Neglected diseases	Bioterrorist attacks
Have $, but few	Many, but poor	Unlikely to need and if need then give away

Incentives for R&D

funds inputs (R&D)	$ for R&D
	Tax credits for R&D
funds outputs (drugs, vax)	Advance markets: Prize=price subsidy
	Patent extension voucher: Prize=longer patent for *different* drug/vax
	Priority review voucher: Prize=priority review for *different* drug/vax

Some push mechanisms are in place and advance market is very close. Other mechanisms could complement.

Priority Review Voucher Creates Win-Win

- Benefits people suffering from neglected diseases
- Benefits patients in the U.S. who receive earlier access to the priority drug
- U.S. patients also get earlier access to the generic because drugs with faster FDA review typically have earlier patent expirations
- Concept could also be applied to treatments for bioterrorism

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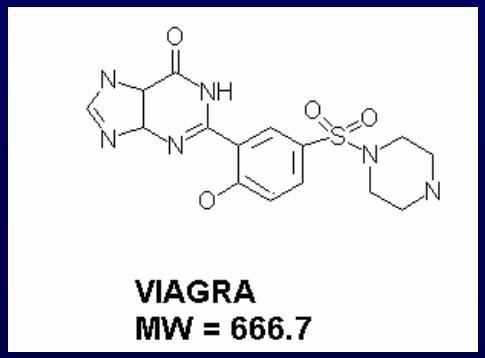
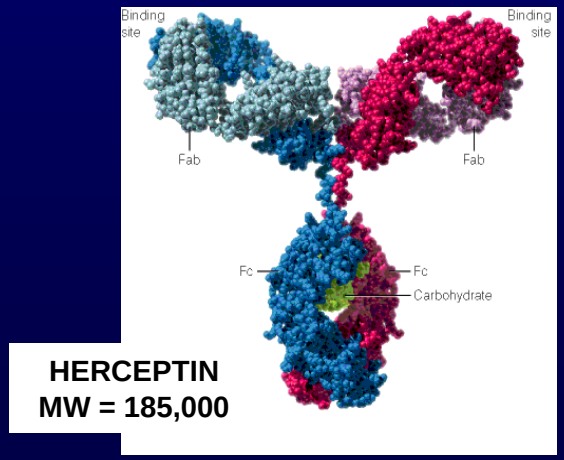
Pharmaceuticals vs. Biologics

	Pharmaceuticals	Biologics
Size (MW)	Small (<1000)	Large (>10,000)
Source	Chemical synthesis	Cultures of living cells
Form	Generally oral solids	Often injected or infused
Reimbursement	Pharmacy benefit	Often medical benefit
Generic Law	1984 Hatch-Waxman	No expedited provision for substances approved as biologics under Pub Health Services Act
Example	Viagra (erectile dysfunction) 	Herceptin (breast cancer) 

No Generic Biologics Yet Because…

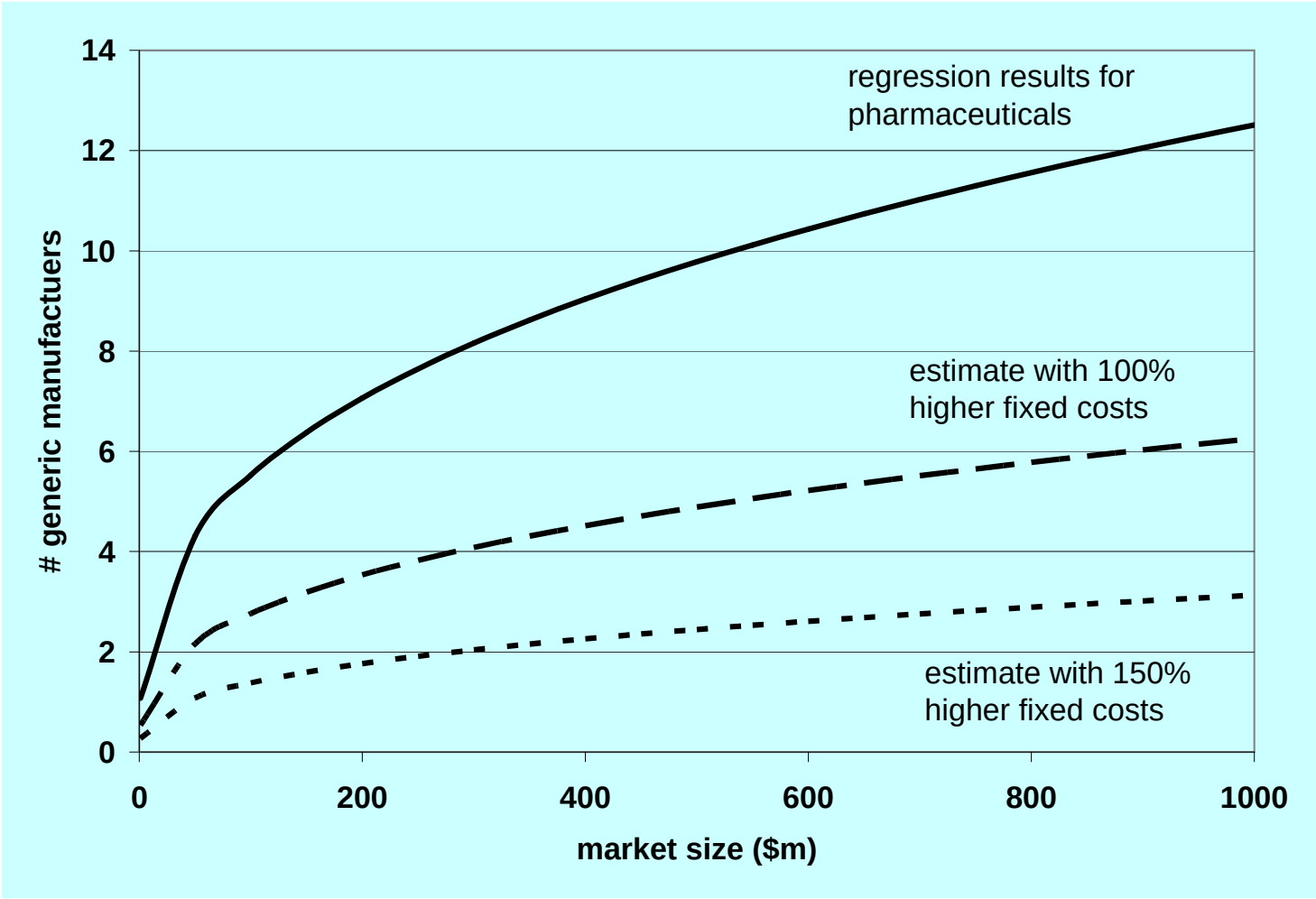
1. Biotech is young. Few patents expired
2. Need new law
3. Biotech manufacturing is costly & complex

- 1, 2, & perhaps 3 change soon
  - In September, Waxman, Schumer, & Clinton introduced "Access to Life-Saving Medicine Act" which would create abbreviated path for generic biologics and would "have a dramatic impact in stemming the rising costs of prescription drugs"

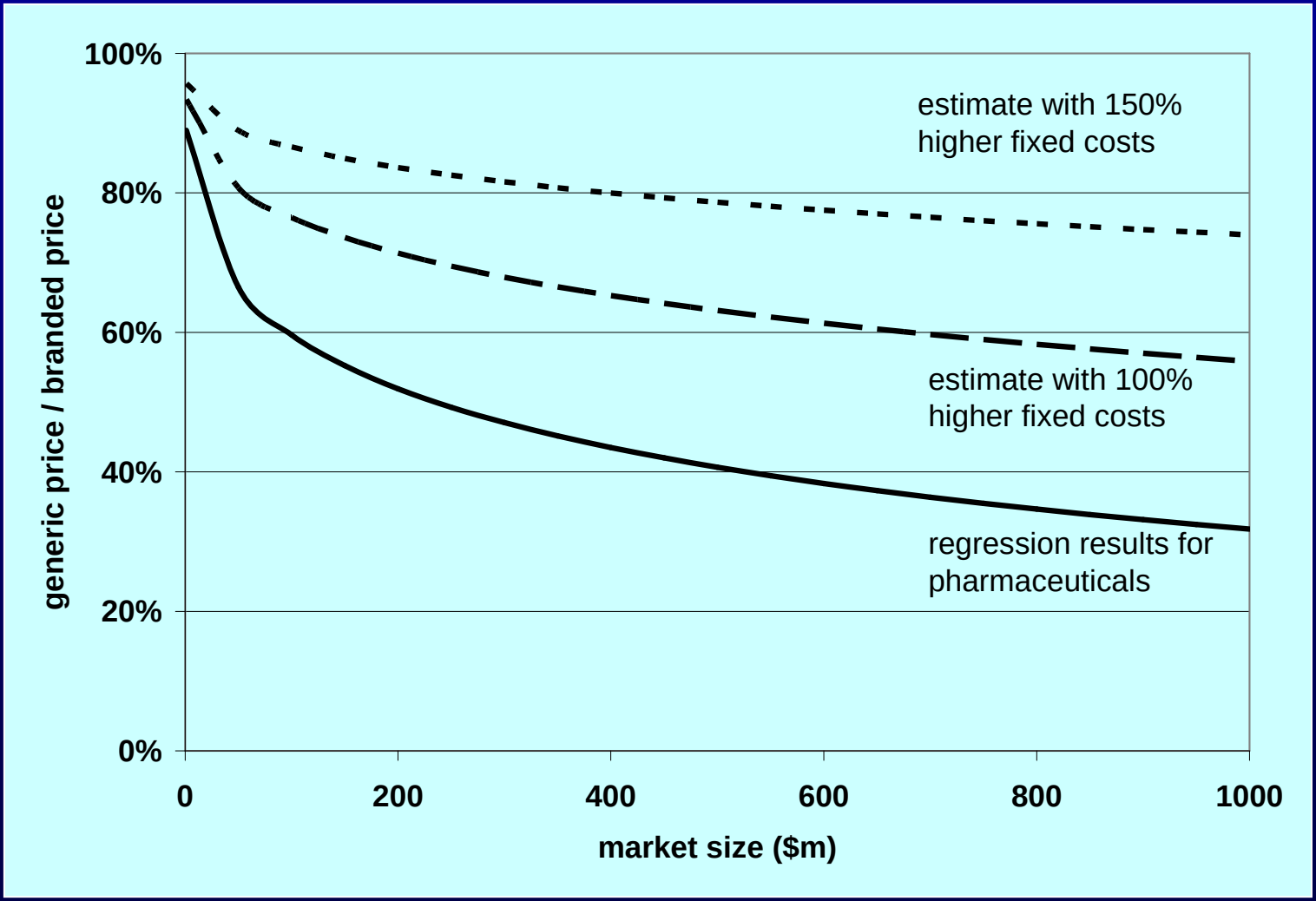
Generic Biologics Raise Several Questions

- Legal question:
  - What new laws are needed?
- Health question:
  - Is it safe to approve generic biologics without significant clinical testing?
- ✓ Economic question:
  - "Generic" implies low price, but only if sufficient entry to create competition.
  - We combine theoretical model of generic biologics with empirical data on generic pharmaceuticals to estimate entry and prices for generic biologics

If branded market $500m, 10 generic pharma might enter, but only 3 generic biologics



If branded market $500m, generic pharma price 40% of branded, but generic bio price 80% of branded



Conclusions

1. Neglected diseases & bioterrorism
   - Push (R&D funding) and pull (prizes) mechanisms could help motivate firms to develop treatments
   - We propose a priority review voucher prize to complement other mechanisms
2. Generic biologics
   - “Generic” not synonymous with “cheap”
   - Generic prices depend on # firms which depend on expected revenue & on regulatory & manufacturing costs
   - Be cautious about assuming big price discounts from generic biologics