

# The Economics of Follow-On Biologics

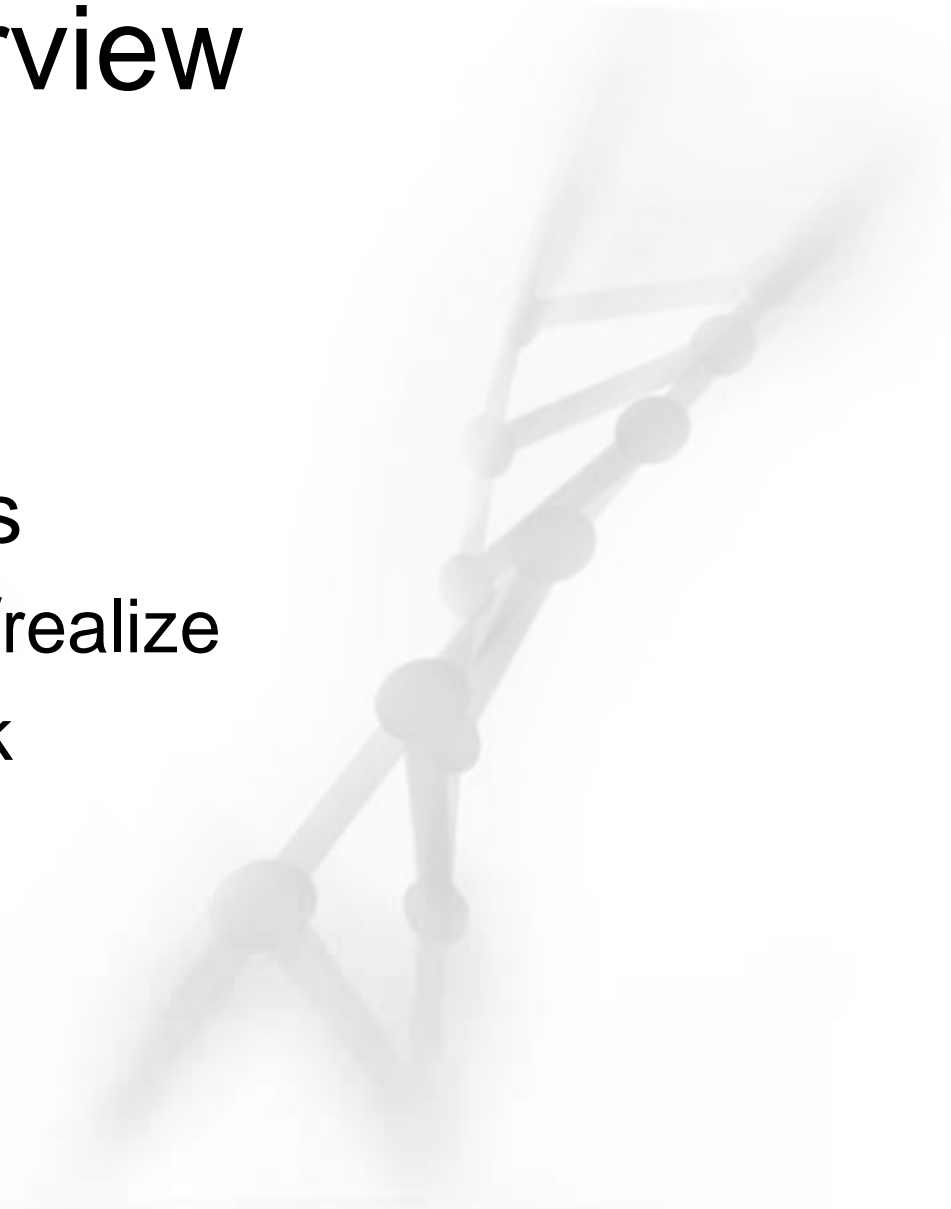
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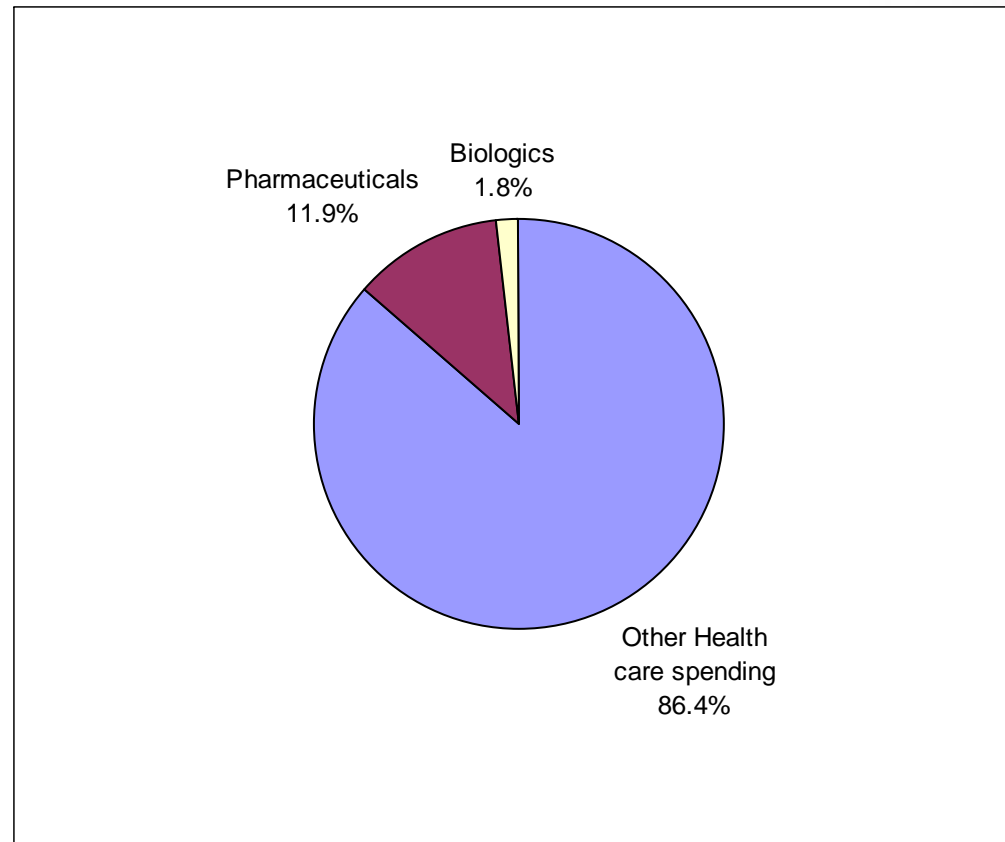
September 25, 2007

# Overview

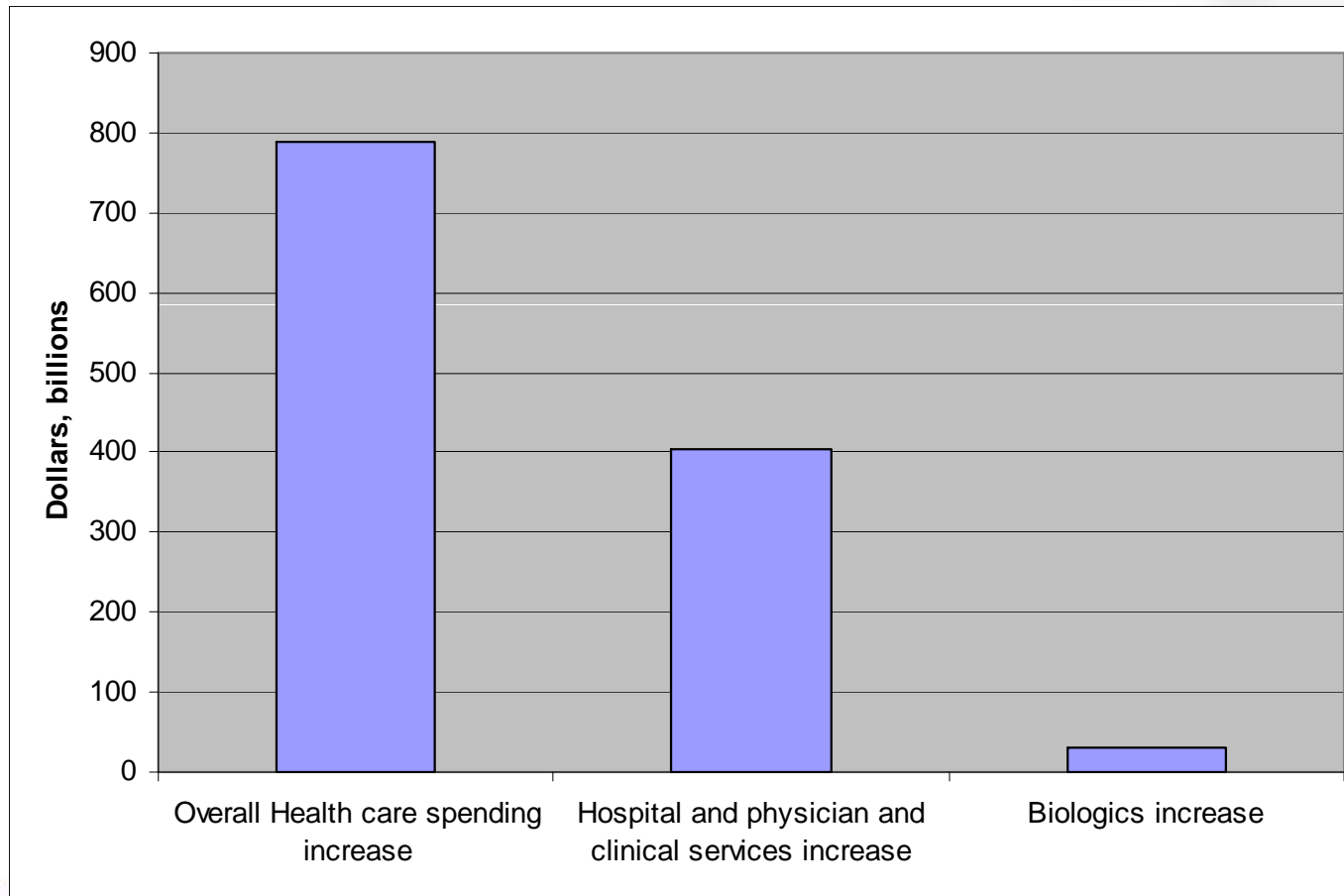
- Contextualization
- The Market for FOBs
  - Things to remember/realize
  - Empirical Framework



# Biologics Percentage of Overall Health Care Spending



# Changes in Spending from 2005 - 2010



Source: <http://www.cms.hhs.gov/NationalHealthExpendData/downloads/proj2006.pdf>;

Pharmaceutical Business Review Online. "Biologics Driving Growth to 2010" June 22, 2006.

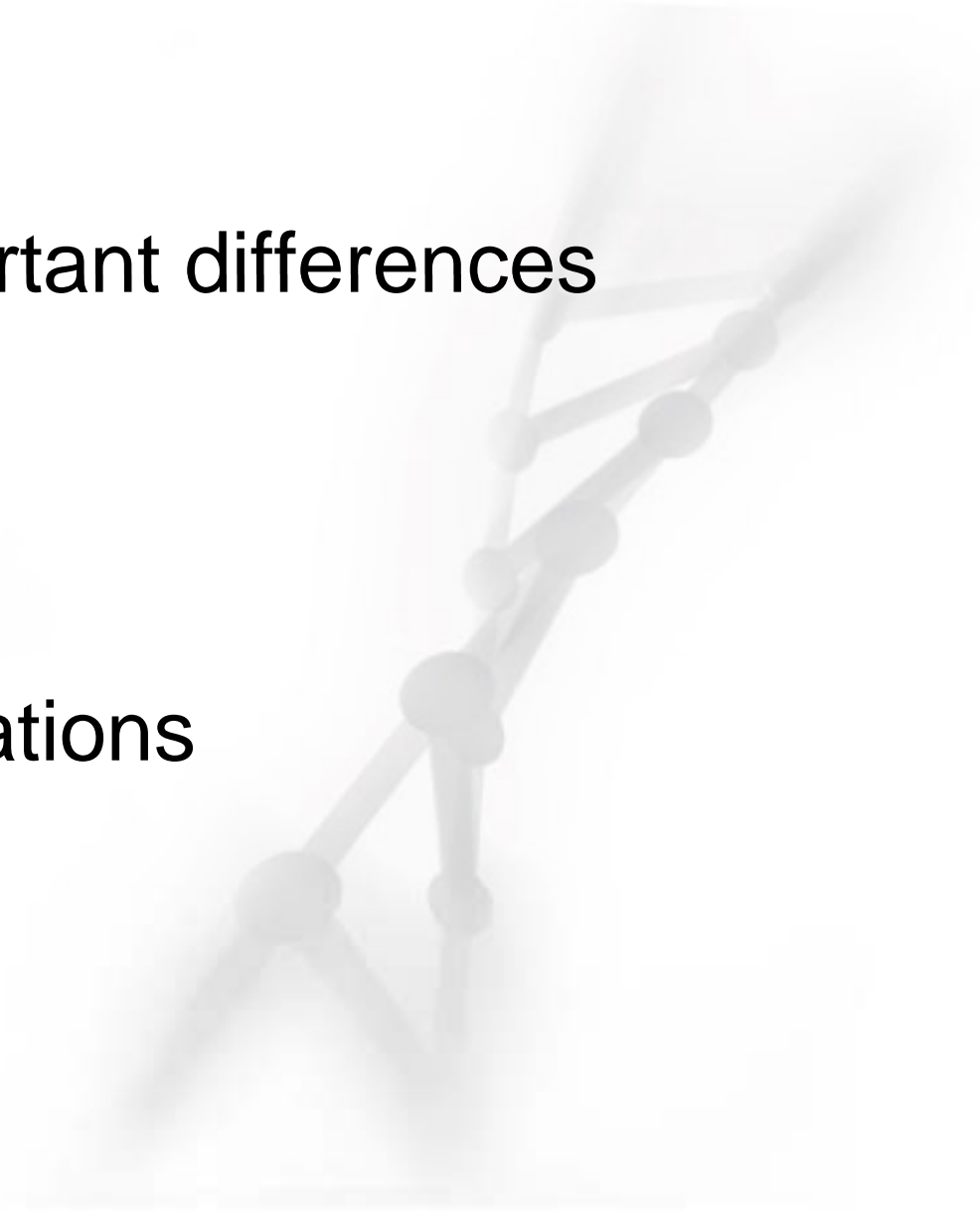
# Some Argue...

- Many new entrants
- Prices will drop rapidly
- Rapid penetration
- All biologics will have a follow-on products
- Large cost-savings will occur

# However...

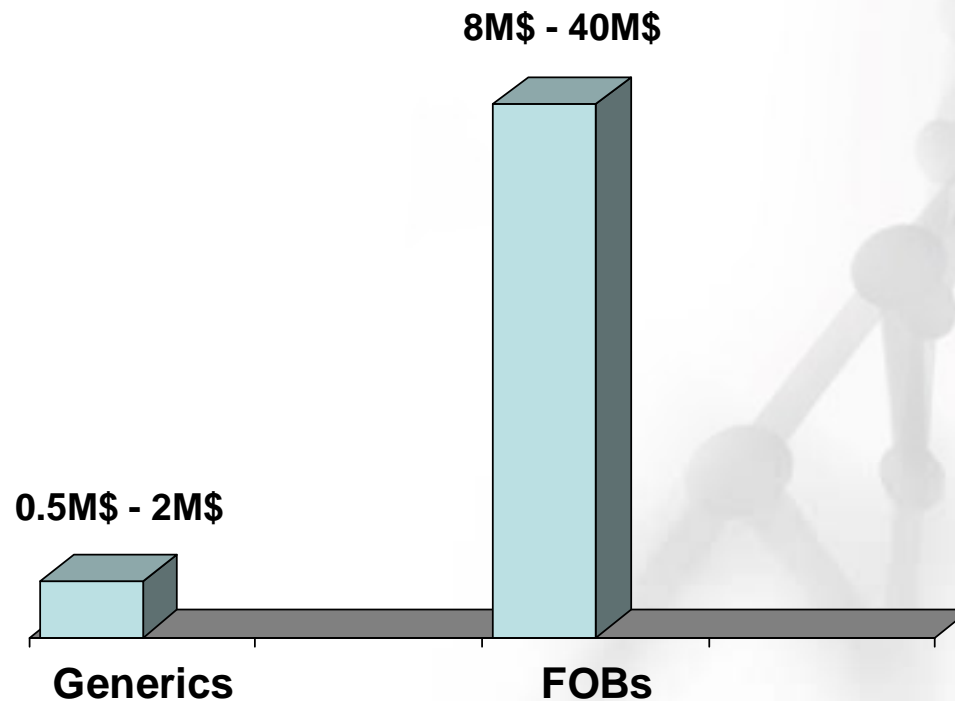
There are some important differences including:

- Development costs
- Regulatory considerations



# Development Costs

Development costs for FOBs may be more than an order of magnitude higher than for generics



# Regulatory Considerations

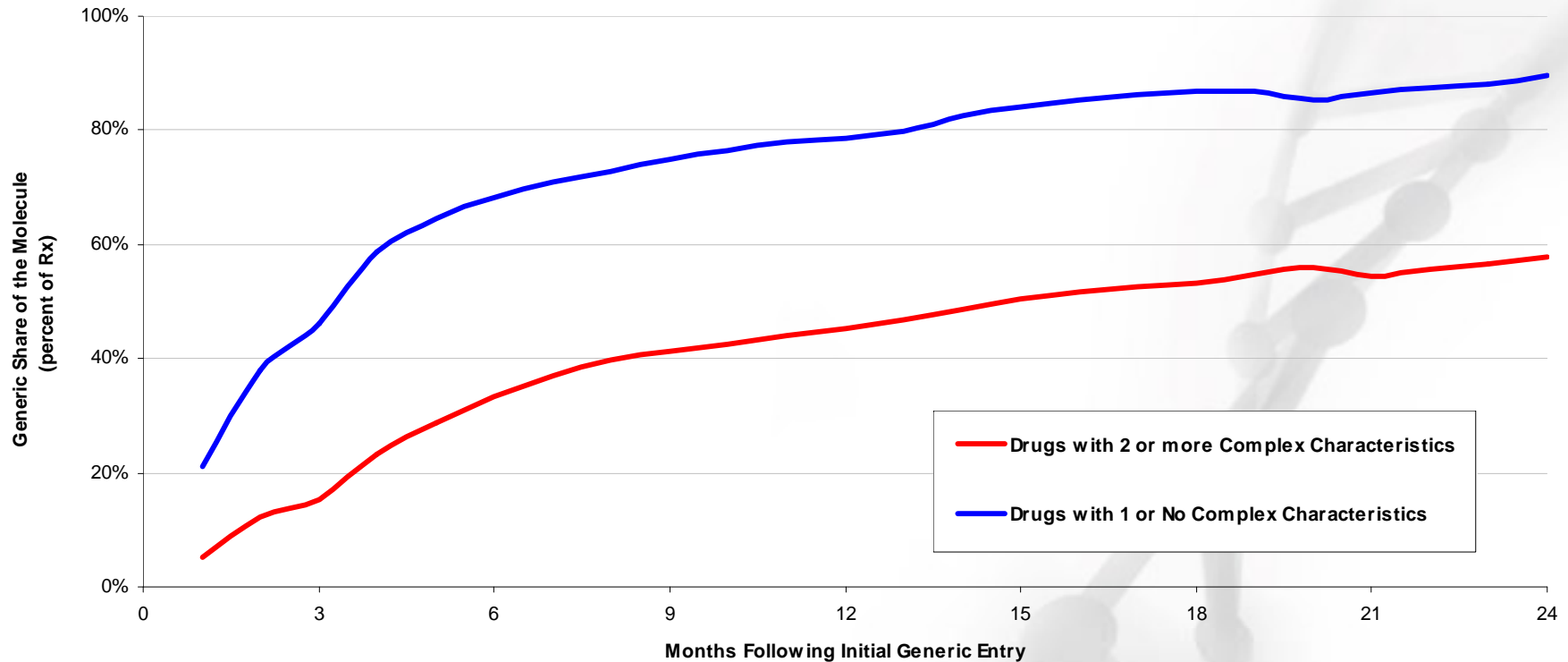
- IF FOBs are not rated as interchangeable by FDA, they will compete as therapeutic alternatives
- Non-interchangeable rating will require FOB companies to invest more to achieve market penetration and will result in slower market penetration

# Predicted Market Shares for FOB Entry

10-45% of the Total Units Dispensed

- Based on empirical analysis of:
  - Generic drugs with complex characteristics
  - Medicaid reimbursement for hGH biologicals

# Average Generic Share of Molecule by Complex Drug Characteristic

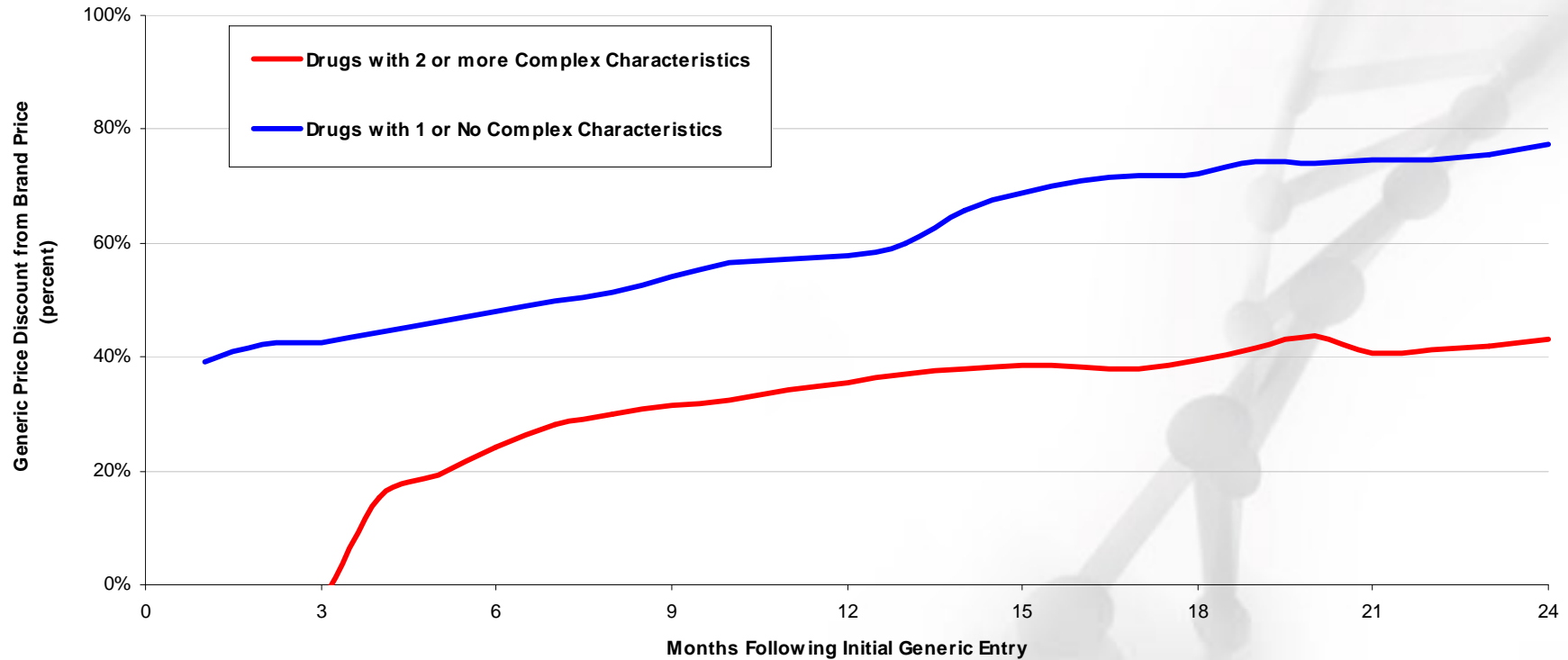


# Predicted Price Discounts from FOB Entry

10-30% off Pre-entry Brand Price

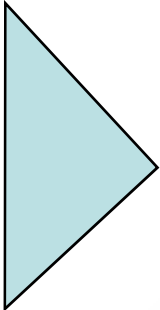
- Based on empirical analysis of:
  - Generic drugs with complex characteristics
  - Medicaid reimbursement for hGH biologicals
  - Omnitrope pricing in Europe

# Average Generic Price Discount from Brand Price for the Molecule By Complex Drug Characteristics



Source: Duke University/Analysis Group September 2007 Working Paper  
[http://www.econ.duke.edu/Papers/PDF/The Effect on Federal Spending of Legislation  
Creating a Regulatory Framework for Follow-on Biologics: Key Issues and Assumptions.pdf](http://www.econ.duke.edu/Papers/PDF/The_Effect_on_Federal_Spending_of_Legislation_Creating_a_Regulatory_Framework_for_Follow-on_Biologics:_Key_Issues_and_Assumptions.pdf)

# Savings Will Be Modest

- Fewer entrants due to technological complexity and development costs
  - Lack of interchangeability
  - Not all products will have follow-on products
- 
- Savings will be likely be at the low end of the estimates (e.g. Avalere Health or less)

# Final Thoughts

- Projected total national healthcare expenditure from 2008 – 2017
- Savings from an FOB pathway from 2008 – 2017 will be likely be at the low end of the estimates
- \$33,385 billion (i.e., approximately \$33.4 trillion.)\*
- Much less than \$14 billion

- A well functioning pathway for Follow-On Biologics must ensure patient safety and preserve incentives for innovation
- Follow-On Biologics will not accrue huge savings nor “save the US healthcare system”