

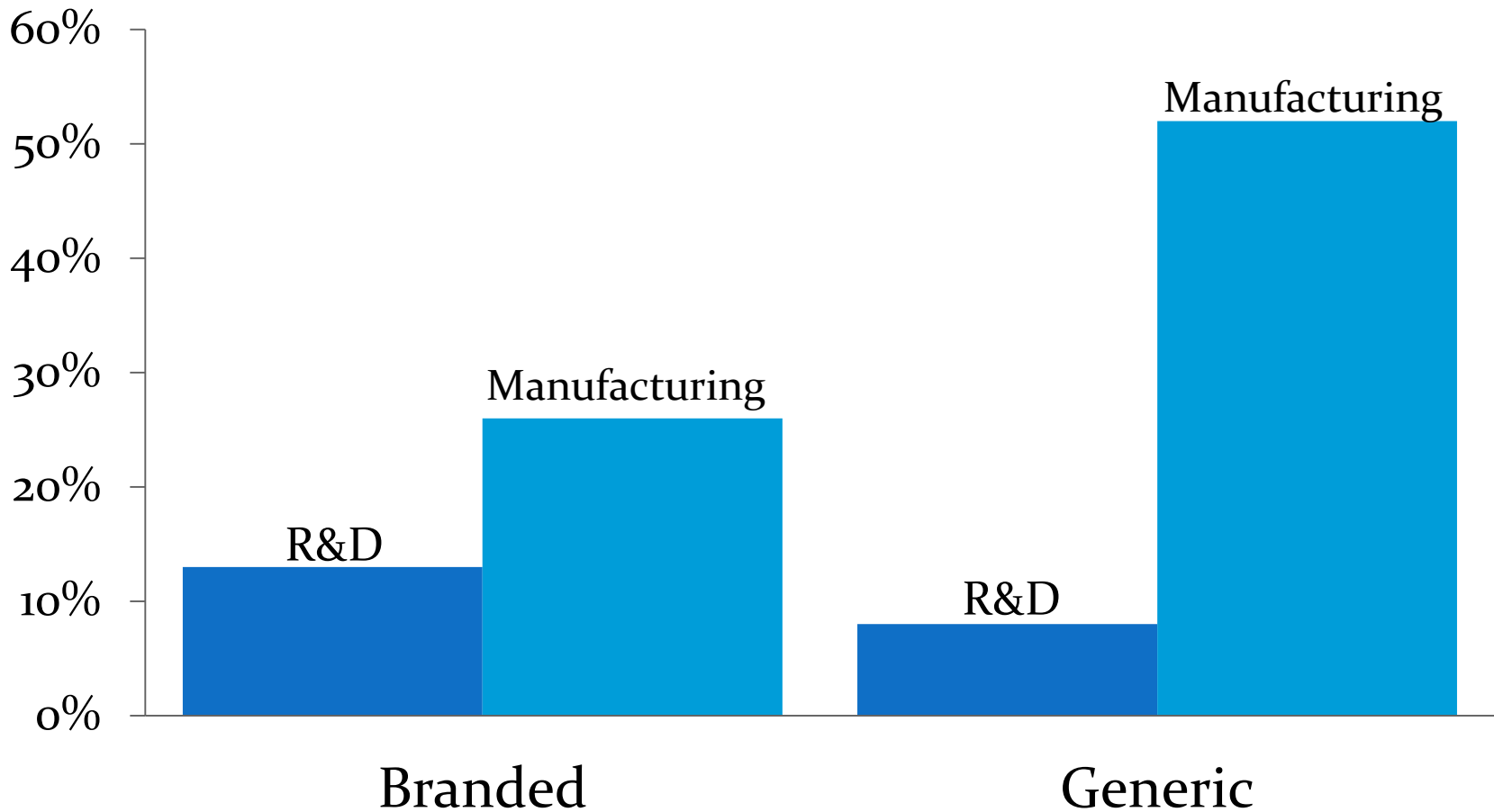


Innovation in Pharmaceutical Manufacturing

W. Nicholson Price II
Petrie-Flom Center
Harvard Law School
wprice@law.harvard.edu

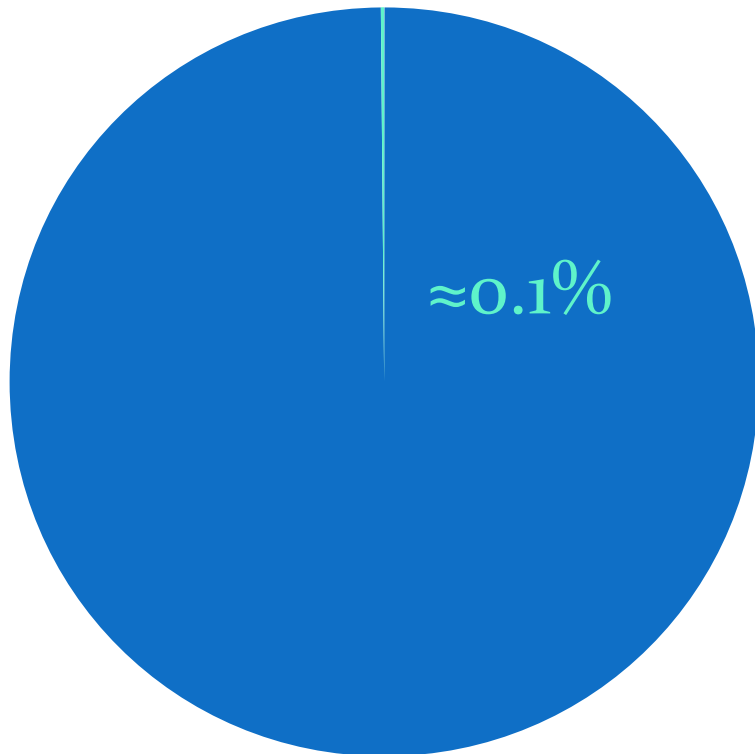


Company Costs: small molecules

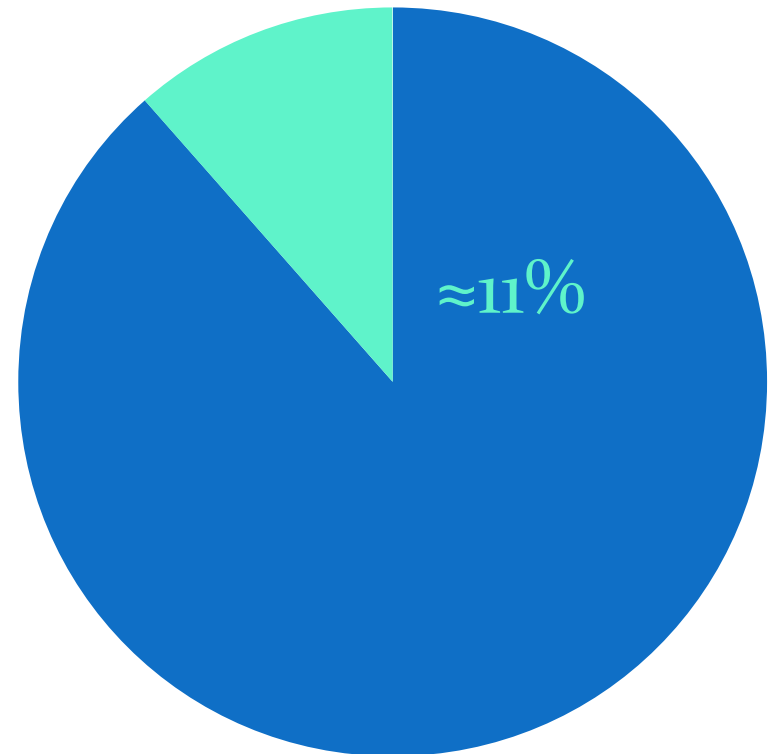


Manufacturing discard rate

Most industries



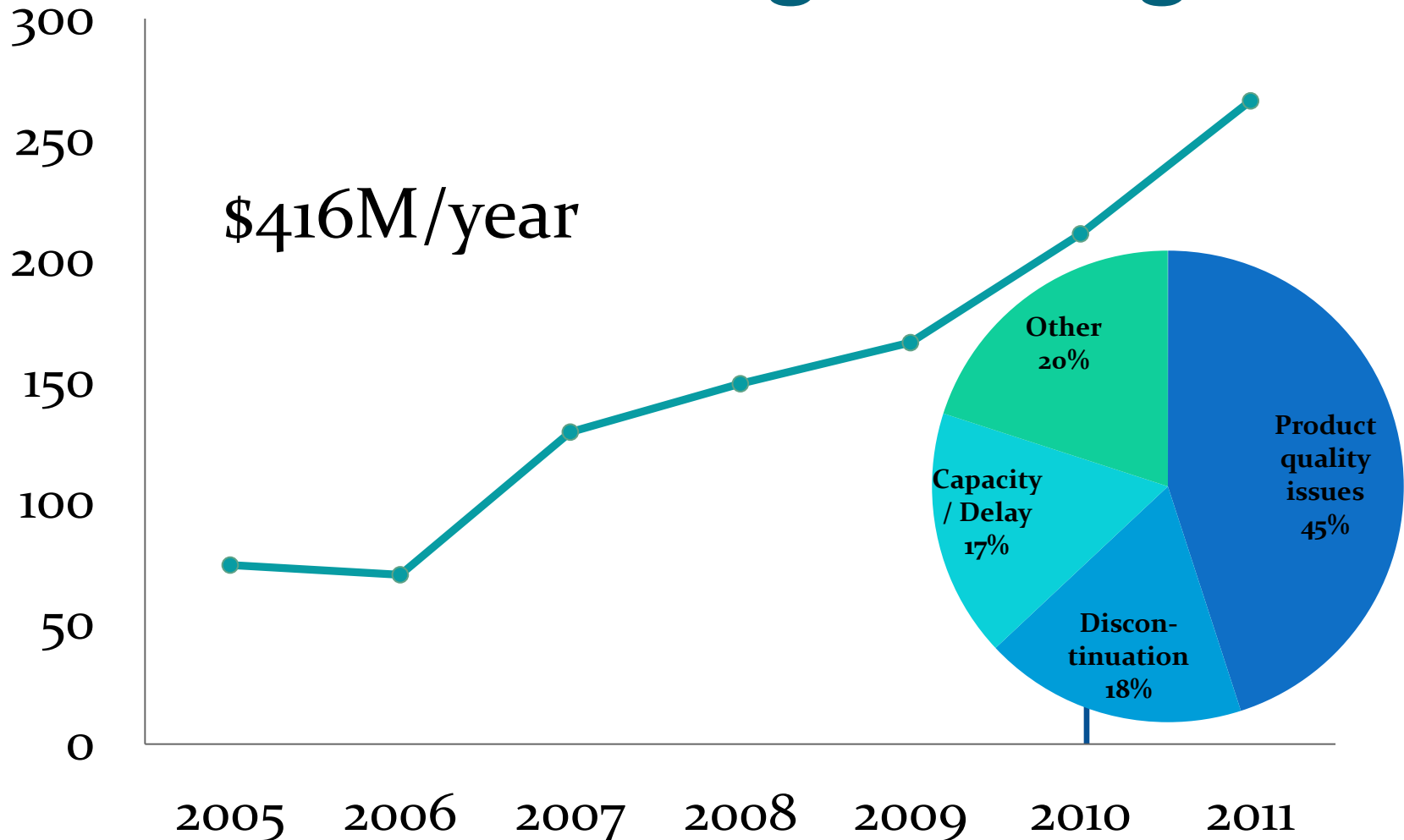
Pharma



Human costs: drug recalls

- Over 2,000 in 2011
- 2009: contaminated propofol
- 2012: Excedrin with opiates

Human costs: drug shortages



Economic costs/opportunities

20% cost decrease

lower prices

higher R&D

\$50B surplus/yr.

\$574B health gains/yr.

Why?

	Patents/IP	Regulation
Discovery	+	+

Why?

	Patents/IP	Regulation
Discovery	+	+
Manufacturing	<ul style="list-style-type: none">• Enforcement• Trade Secrets	-

Why?

	Patents/IP	Regulation
Discovery	+	+
Manufacturing	-	<ul style="list-style-type: none">•Pre-approval•Post-approval

Solutions

	Patents/IP	Regulation
Discovery	+	+
Manufacturing	-	-

The table illustrates the relationship between Patents/IP and Regulation across two stages: Discovery and Manufacturing. In the Discovery stage, both Patents/IP and Regulation have a positive impact (+), and they are interconnected by a double-headed arrow. In the Manufacturing stage, the impact of Patents/IP is crossed out with a red 'X', and the impact of Regulation is negative (-). A green dashed circle with an arrow points from the Regulation cell in the Manufacturing row back to the Patents/IP cell in the same row, indicating a feedback loop.

Regulation: innovation by fiat

Firms

Empiricism  Understanding

End testing  Control throughout



Rigid oversight  Flexibility

Quality signals

SANITARY INSPECTION GRADE



Card Number: _____
Establishment Name: _____
Date Issued: _____
NYC
Health
For additional information
or a copy of an inspection
report, call 311 or visit
nyc.gov/health

SANITARY INSPECTION GRADE

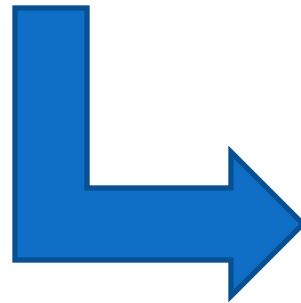


Card Number: _____
Establishment Name: _____
Date Issued: _____
NYC
Health
For additional information
or a copy of an inspection
report, call 311 or visit
nyc.gov/health

SANITARY INSPECTION GRADE

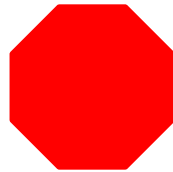
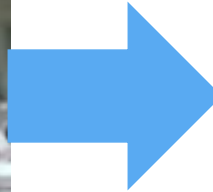
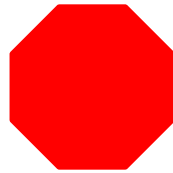


Card Number: _____
Establishment Name: _____
Date Issued: _____
NYC
Health
For additional information
or a copy of an inspection
report, call 311 or visit
nyc.gov/health

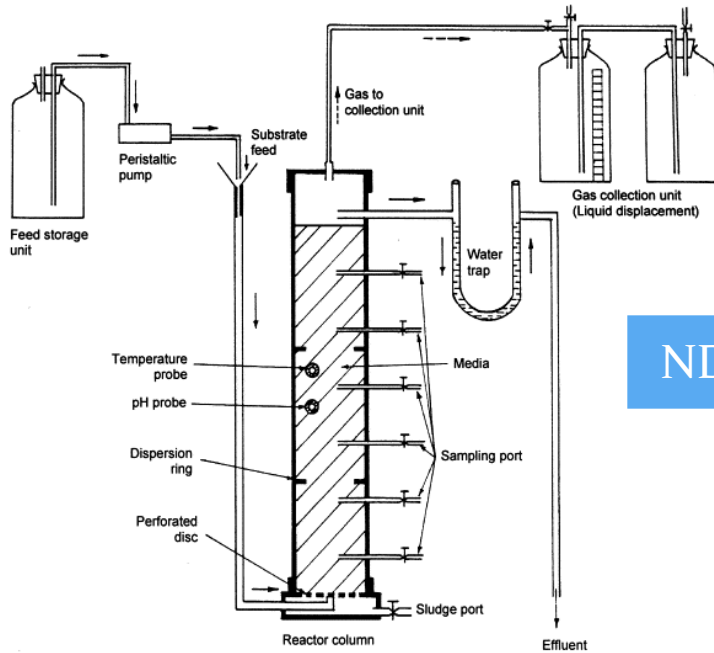


NDA

Regulation → IP: parallel

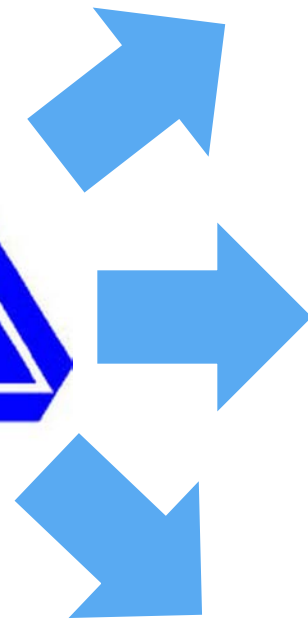


Regulation → IP: altering



NDA

FDA



Other possibilities

- Method validation
- Prizes
- Grants



Questions/Reactions?