MANUFACTURING IN THE PHARMACEUTICAL VALUE CHAIN

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Drug Development Lectures
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THE STATE OF THE PHARMACEUTICAL INDUSTRY

Where is it going in 2014?

- **Sales** ~$1 trillion and growing at <4%
- **R & D** ~ 15% of sales - an increasingly virtual infrastructure
- **Marketing** - pricing/advertising/e-commerce
- **Development** - increasing expectations, complexity in clinical trials, low productivity
- **Structure** - consolidation, partnerships and outsourcing

CHARACTERISTICS OF PHARMACEUTICAL MARKETS

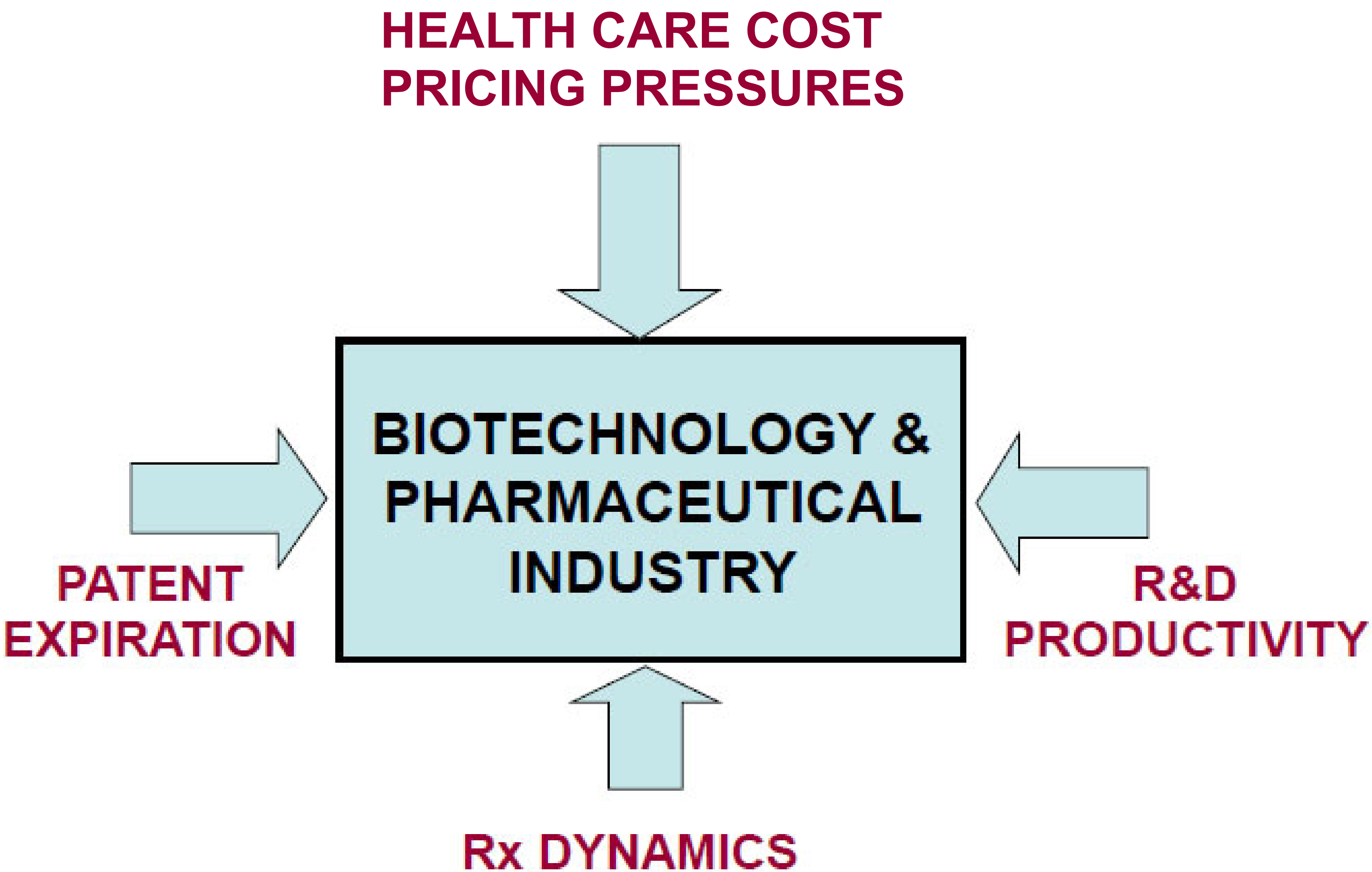
- **Concentrated** ~ 85% of market in 15 countries
- **Focused** - 4 therapeutic areas dominate market
  CV, GI, CNS, anti-infectives
- **Fragmented** -
  - Largest product (Lipitor) is ~ 5 % of market
  - Largest company (Pfizer) is ~$50 billion
  - Top 10 companies have one third of market
- **Technically diverse** - research strategy and production methods

There is a high cost of complexity

Global Sales

- ~$900 billion and growing at <5%
  - US growth at 1-2% to ~$300 billion
  - Top 5 EU (France, Germany, Spain, Italy, UK) 3-4% to ~$200 billion
  - Japan 3-4% to ~$85 billion
  - *Pharmamerging* at 14-15% to >$100 billion

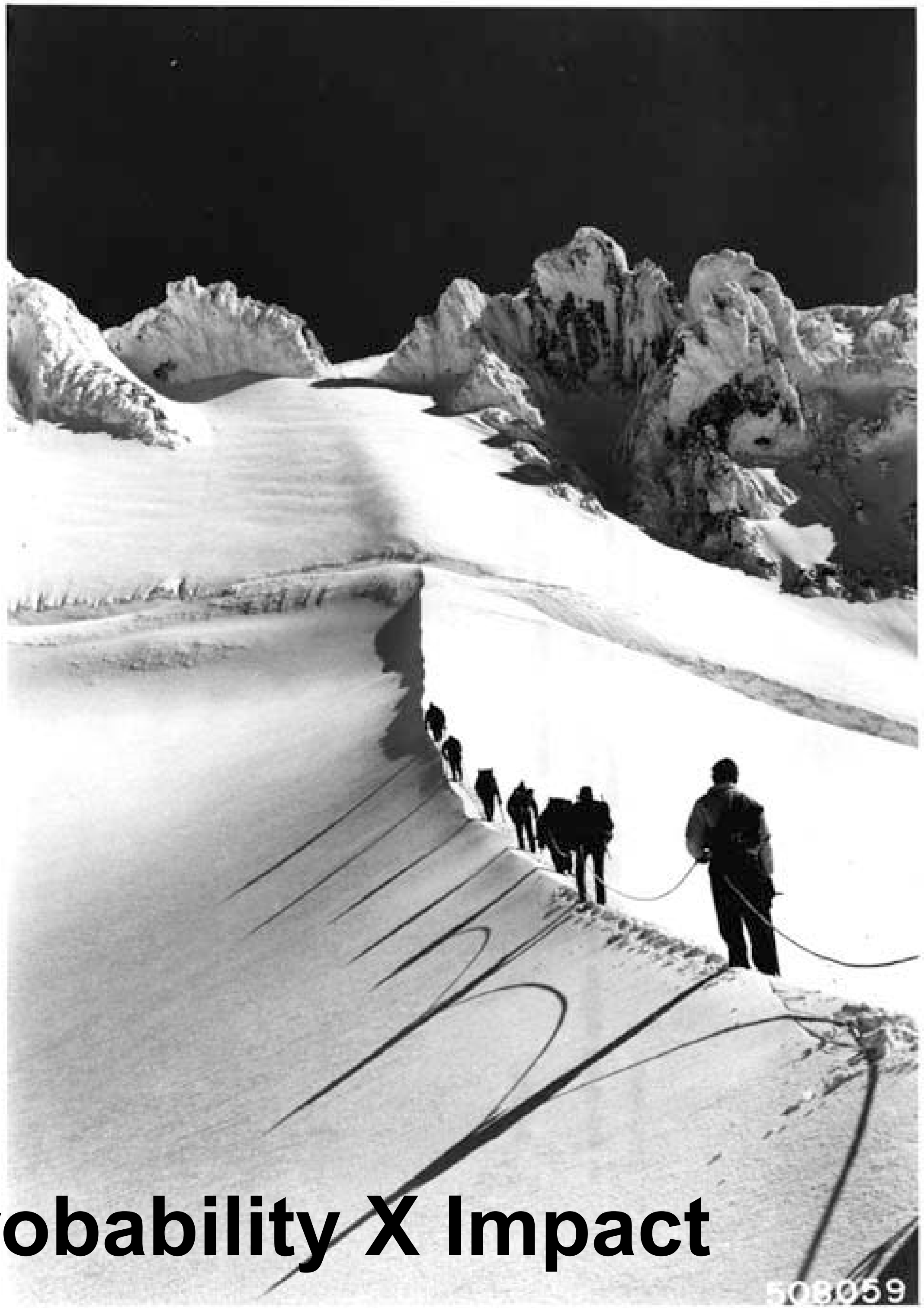
TODAY


HEALTH CARE COST
PRICING PRESSURES
BIOTECHNOLOGY &
PHARMACEUTICAL
INDUSTRY
PATENT
EXPIRATION
R&D
PRODUCTIVITY
Rx DYNAMICS

We Have a Problem

- Pressure on Pricing
  - Increased use of generics
  - Introduction of biosimilars
  - Therapeutic substitution
  - Demand for global access
  - Political and social activism
- Increased cost
  - Increased regulation
  - Smaller markets
  - Market and supply chain complexity
  - Security and integrity of supply chain

Risk = Probability X Impact



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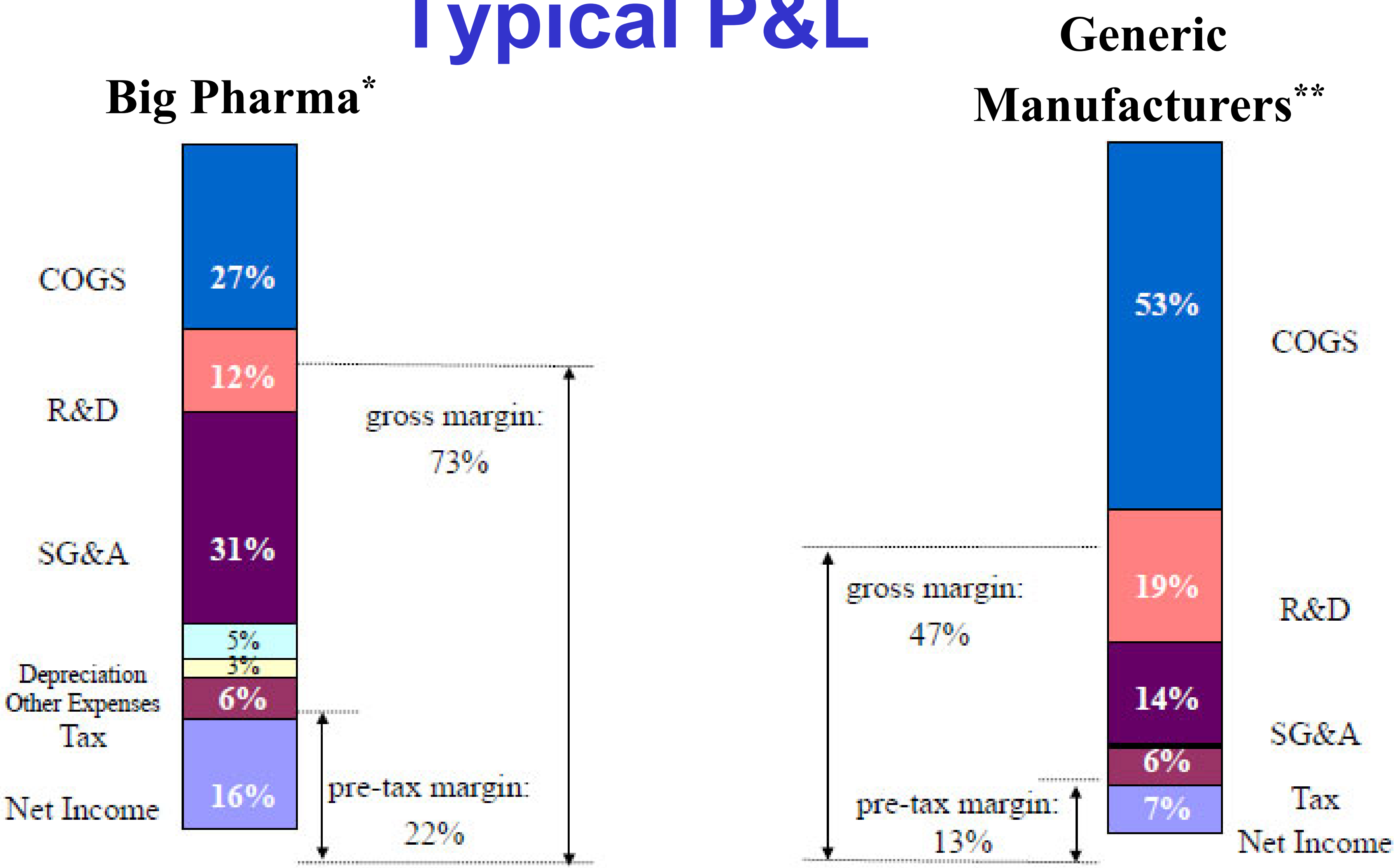
Typical P&L

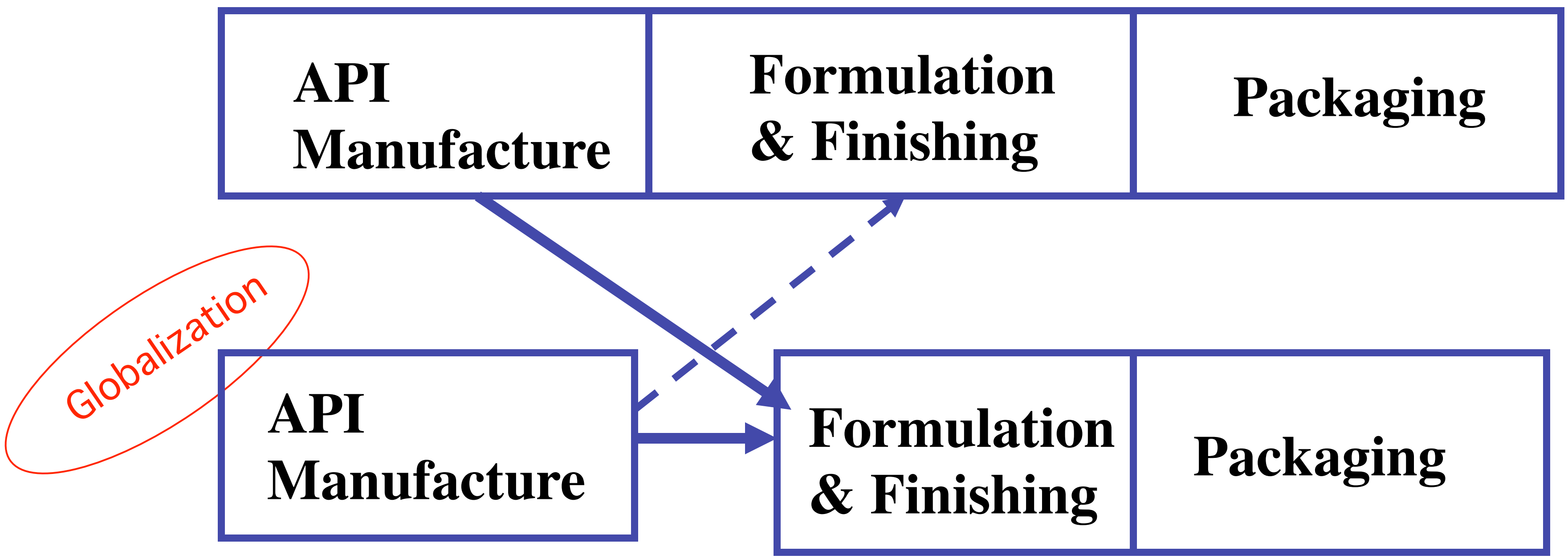


- COGS are a very significant portion of Generic's P&L
- COGS for Big Pharma are significant in absolute dollar terms

PHARMACEUTICAL INDUSTRY STRUCTURE

Value Chain Organization

Fully Integrated Producer of Drug Product



Generic Producer of API

Generic Producer of Drug Product

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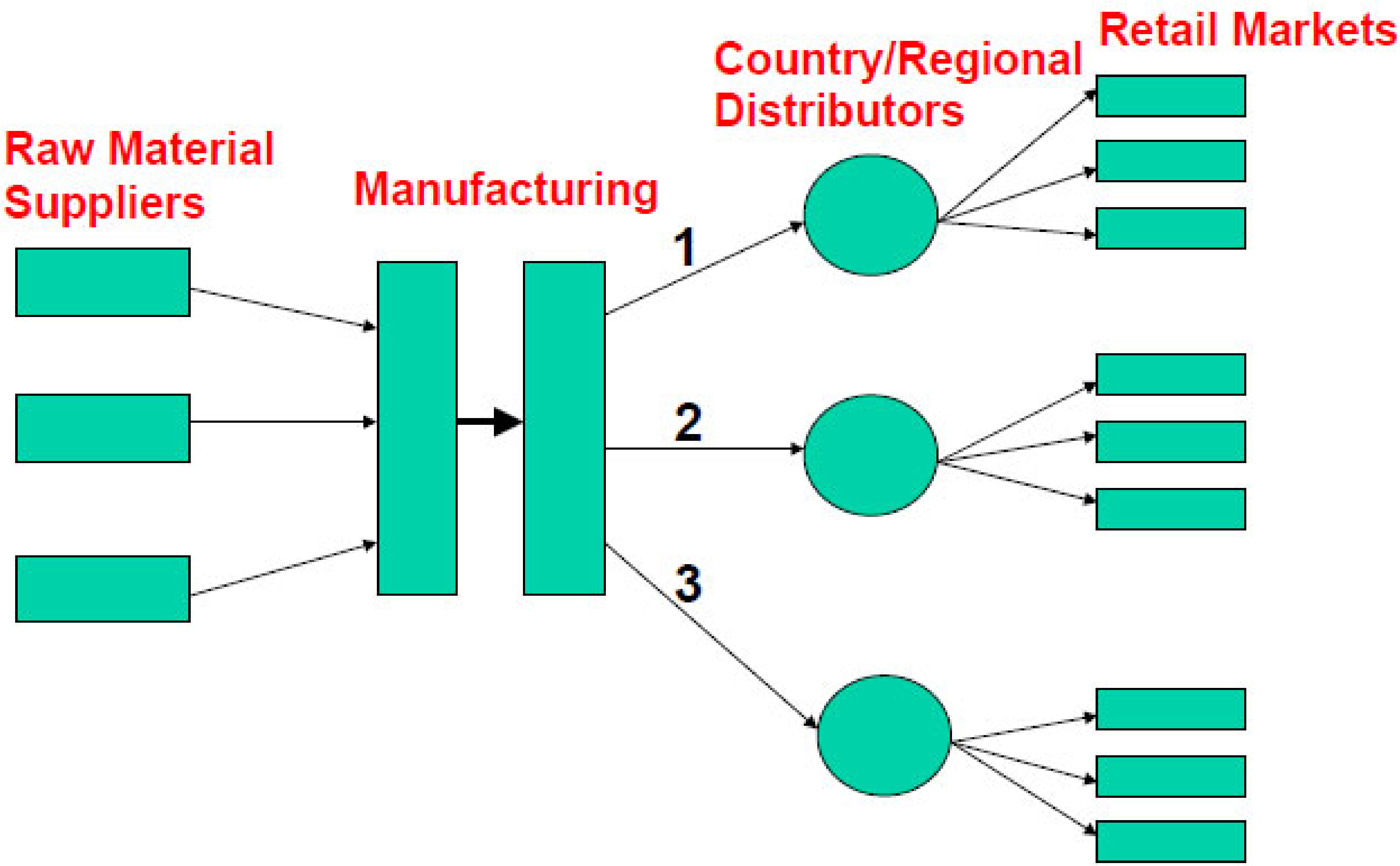
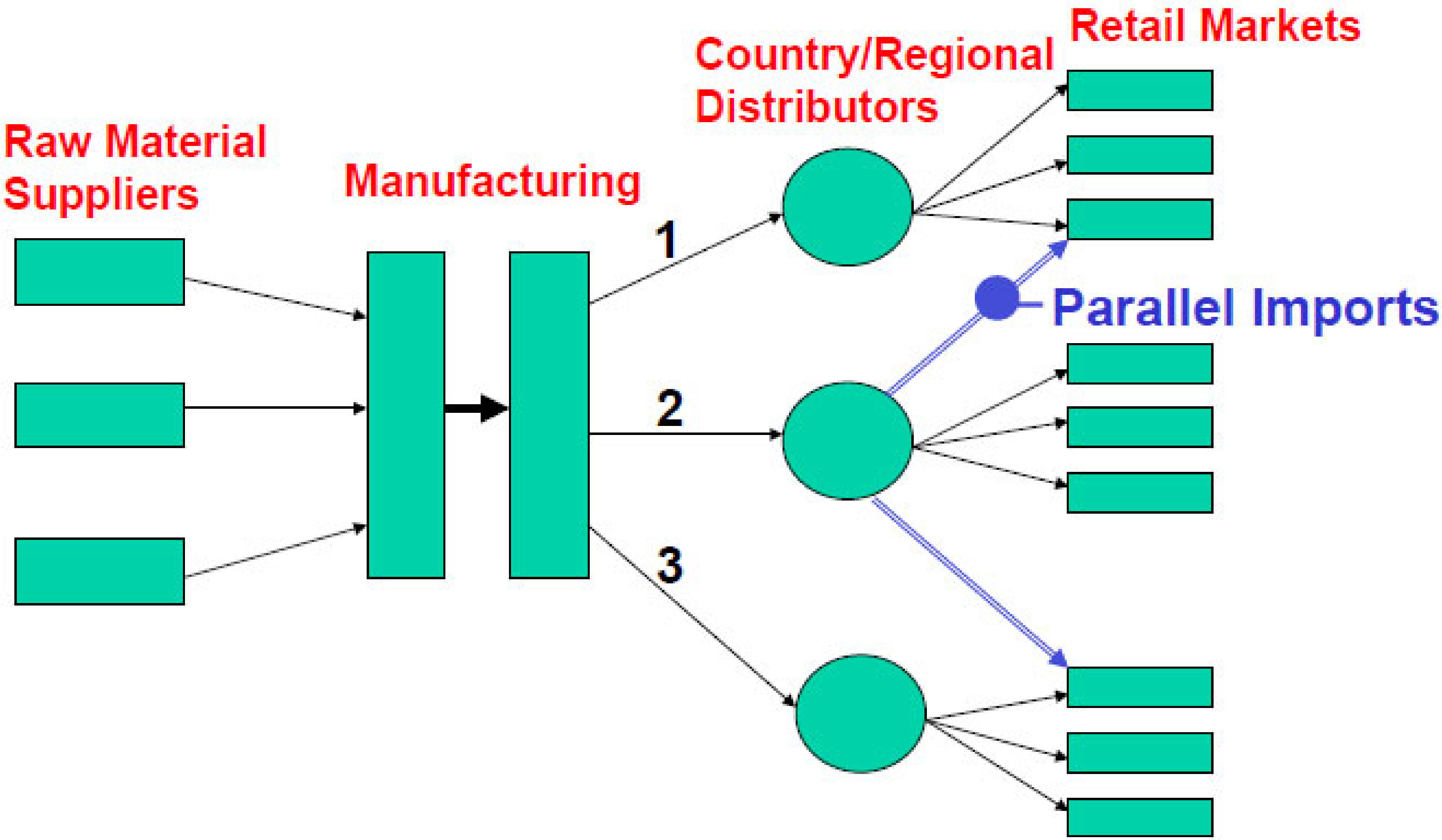
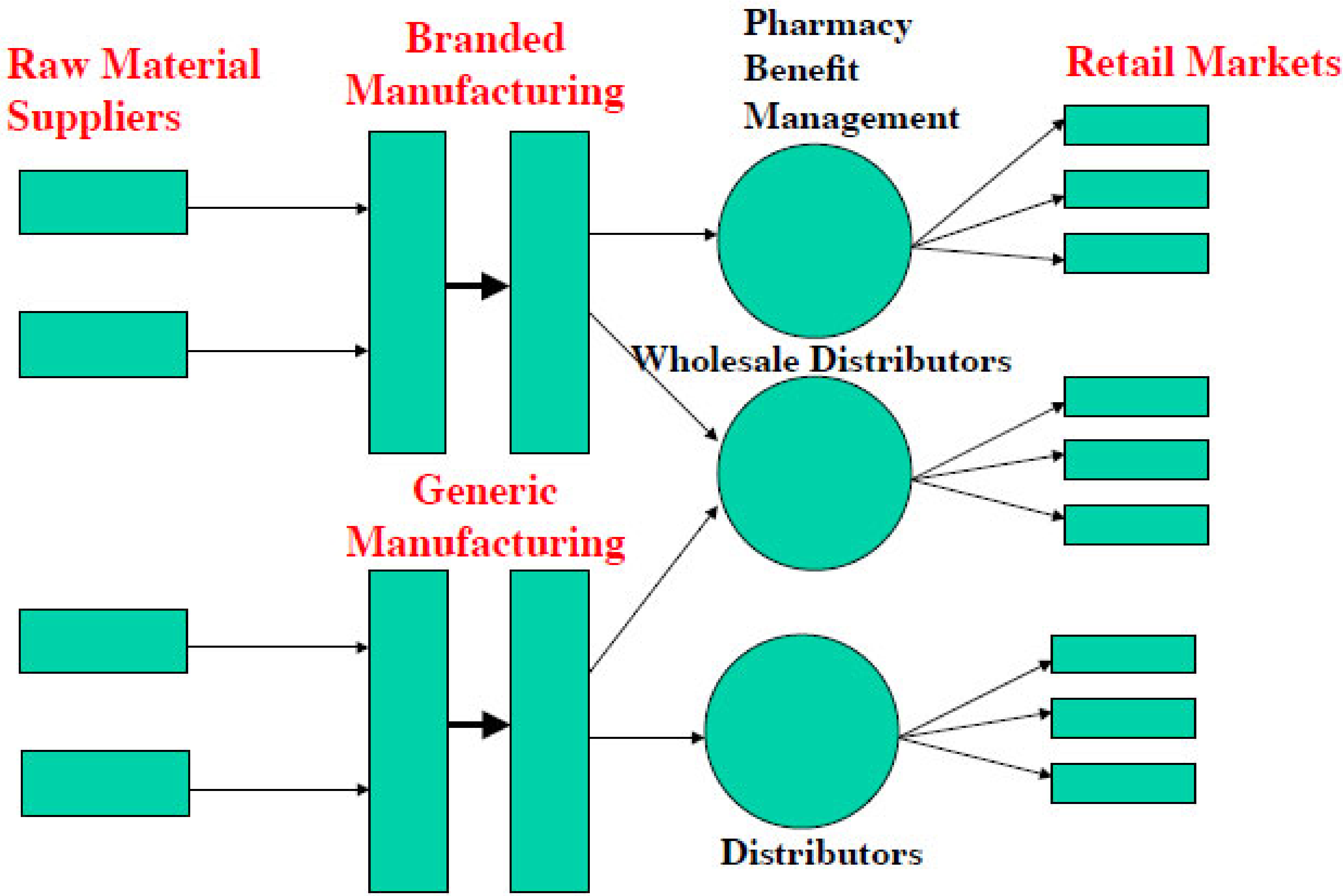
SUPPLY CHAIN IN PHARMACEUTICAL MANUFACTURING



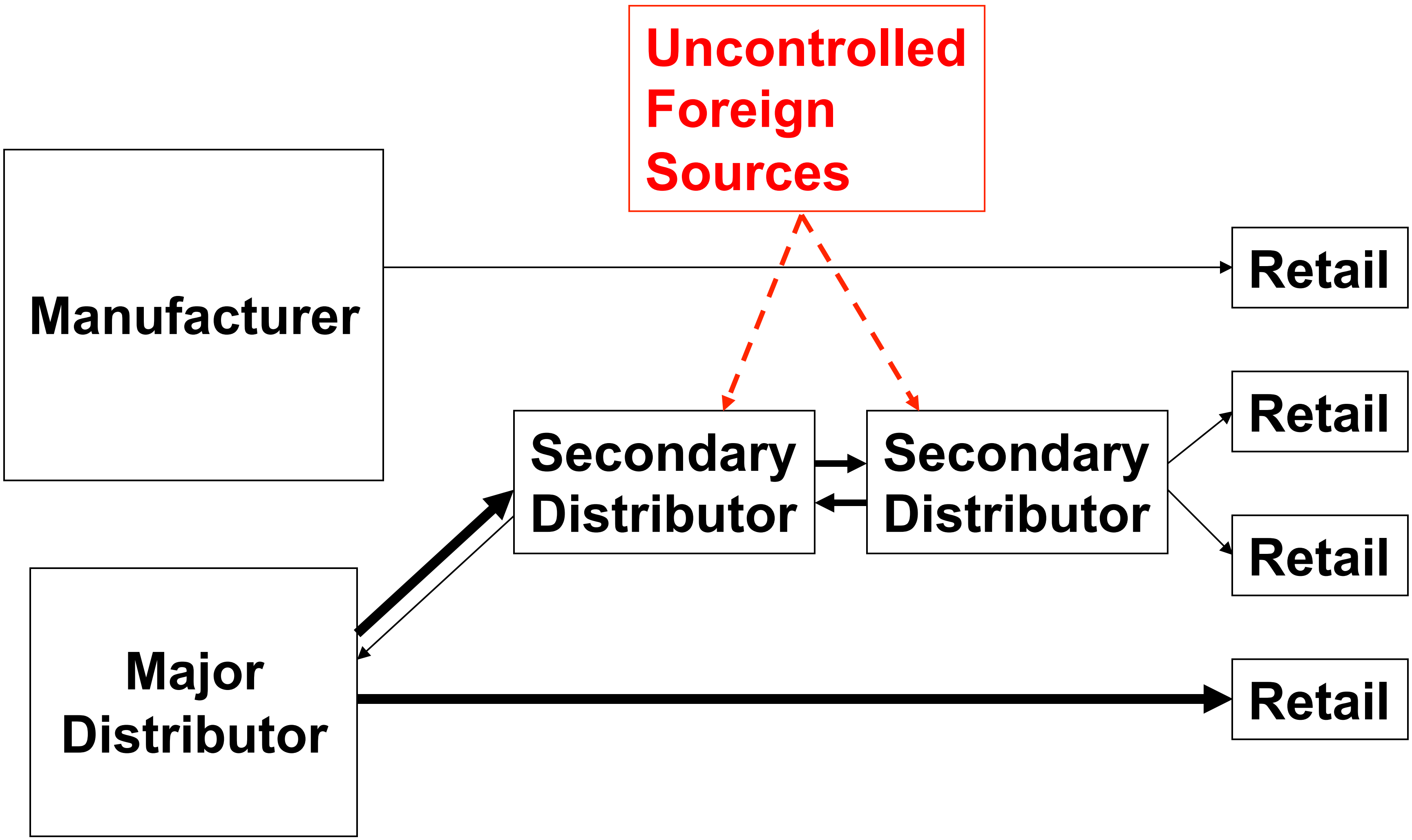
SUPPLY CHAIN IN PHARMACEUTICAL MANUFACTURING



SUPPLY CHAIN DYNAMICS



Secondary Drug Distribution



In practice, we must embrace & manage risk