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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• 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

API Manufacture

Formulation & Finishing

Packaging

Globalization
SUPPLY CHAIN IN PHARMACEUTICAL MANUFACTURING
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SUPPLY CHAIN DYNAMICS
In practice, we must embrace & manage risk

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