Pharmaceutical Paradigm Shift

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World Population

- 7 Billion with Growth rate of 1.1%
World GDP

- 70 Trillion Dollars with Growth rate of 5.2%
World Pharma Market

- 950 Billion Dollars with Growth rate of 6%
Today's Pharmaceutical Industry Challenges

Research & Development

Standards & Regulations

Sales

Information Technology
Today's Challenges – R&D

- Demands to improve clinical trial productivity and reduce time from “First in Man” studies to final approval
- Use of multidisciplinary teams that need:
  - Information from many sources that is readily available
  - Information that has been organized and appropriately contextualized
  - Information that has been personalized to each researcher’s needs
- Growing trend of outsourcing parts of the “clinical trial value chain” to CROs:
  - Data from many sources that needs to be standardized for cross-study analysis
  - Examination of alternative models for data management from multiple CROs – e.g., use of “super CROs” to coordinate data management from other CROs
  - Increasing emphasis on earlier availability of data for decision-making
- Growing need to share data, insights and conclusions with researchers and study coordinators who are likely to be geographically dispersed
- Need to share clinical trial data with multiple geographically dispersed investigators, monitors and
Declining R&D productivity increases the urge to transformation and establishing new innovative business models

- Pharmaceutical pipelines are drying out
- In-house developments are increasingly expensive and slow
- Increased need for a **paradigm shift** to innovatively aligned R&D models and creative organizations with entrepreneurial team management
- Enabling technologies, new targets and data evolve exponentially
- Biotech's creative and dynamic approaches deliver more products cheaper and faster, but not with a higher success guarantee

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The innovation cascade

- **Academic**
  - Biology
  - Biomarkers
  - Clinical
  - Technology

- **Biotech**
  - Translational
  - POC

- **Pharma**
  - Development
  - Regulatory
  - Payors
  - Global

Value To Patients

Government funded  VC funded  Capital Markets
Regulatory Challenges /

- ICH
- PAT
Today's Challenges – Standards & Regulations

- Need to accelerate the process of moving from drug discovery through clinical trials and then through approval by FDA and other (trans)national agencies
- Inconsistent organizational responses to Part 11 – some slow to start serious assessment and remediation while others are “setting the pace”
- Increased pressure by FDA on non-compliant organizations
- Multiple sources of regulatory references
- Multiple sources (or non-explicated sources) regarding advice process “shortcuts” and lessons learned
- Replicable approaches for opportunity teams for preparing data and cases to national advisory boards
## Very different success factors and characteristics

<table>
<thead>
<tr>
<th>Innovator model</th>
<th>Generics model</th>
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<tbody>
<tr>
<td>New chemical entities</td>
<td>Line extensions, fixed combinations</td>
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<tr>
<td>Long innovation cycle</td>
<td>Rapid innovation cycle</td>
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<tr>
<td>Patent strength</td>
<td>Speed to market</td>
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<tr>
<td>Patents</td>
<td>Brands</td>
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<td>US/EU focused registration</td>
<td>Local registration</td>
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<td>Manufacturing scale</td>
<td>Local manufacturing</td>
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<tr>
<td>Imports from high cost countries</td>
<td>Low cost sourcing &amp; manufacturing</td>
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<tr>
<td>One–to–one marketing</td>
<td>Stakeholder management</td>
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<tr>
<td>Global blockbuster model</td>
<td>Multiple smaller products often differentiated at local level</td>
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</table>
Trends driving the evolution of the global healthcare environment

- Blockbuster patent expirations
- R&D productivity crisis
- Pressure to control health care spending
- Rise of emerging markets
Personal Therapeutic

- Drugs and medicine designed for individuals
"New drugs to treat and cure sick patients are coming into the market in the United States at the slowest rate in a decade, despite billions invested by pharmaceutical companies on research and a costly expansion by the federal agency that reviews new medicines."

"The decline in the number of new drugs is most pronounced in the category considered by the Food and Drug Administration to have the greatest promise for patients -- those listed as breakthrough "priority" drugs and "new molecular entities" that are different from any others on the market."

Source: Washington Post, 11/18/02
Intellectual Property Rights

- Intellectual Property is globally understood as a proprietary interest, is an idea or a creation granted to the formulatory of the idea or the creator of the creation.
- Intellectual Property shares many of the same characteristics associated with real and personal property.
- For example, it is an asset and as such can be bought, sold, licensed, exchanged and given away like any other form of property.
Globalization

- Many worlds have become one world.
  - Integrated and interdependent.
  - More cross border trade and investment
  - A free market orientation adopted.
  - Geography and time zones matter less.
  - Different business systems.
  - Vastly different national cultures.
Most Favored Nation
Pakistan and India

- New Molecule Dilemma
- API’s dependence
Mergers & Acquisitions – 1

- Merck
- Crop Protection
- Novartis
  - 1996 CIBA Geigy
  - 1996 CIBA Specialties
  - 1996 Hoechst
  - 1996 Clariant
- Syngenta
- 2000 Syngenta
  - 1999 Astra AB
  - 1999 AstraZeneca
- 1993 ICI
- 1999 Zeneca
- 1993 ICI
Mergers & Acquisitions – 2

- **Rohm & Haas Ag**
- **Union Carbide**
  - **Bayer**
    - **Aventis CropScience**
      - **Aventis**
  - **2002**
  - **Dow**
    - **Collaborative BioAlliance**
      - **Celanese**
        - **Rhodia**
          - **Rhône-Poulenc**
            - **1997**
    - **1995**
    - **Marion Merrell**
    - **Hoechst**
      - **1999**
  - **1994**
    - **Roussel Uclaf**
      - **1999**
  - **1997**
    - **Mycogen**
    - **Elanco**
      - **1997**
    - **Lilly**
    - **Sandoz**
      - **1996**
    - **Clariant**
      - **1995**
    - **Rorer**
      - **1990**
      - **Fisons**
        - **1995**

**For the health of humanity**
Planning in the Supply Chain

- Connection of business partners in ways that allow for a new degree of communication and collaboration as part of a worldwide enterprise.
- The ability to tightly schedule operations with little or no need for inventory.
- Final product development can be delayed until the last minute to respond to changes in customer orders.
- Web-based exchanges to link customers with suppliers for individual transactions.
# A PEST Analysis of Environmental Influences

1. What environmental factors are affecting the organization?
2. Which of these are the most important at the present time? In the next few years?

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<th>Political / Legal</th>
<th>Economic factors</th>
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<td>Business cycles</td>
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<td>Environmental protection laws</td>
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<td>Government stability</td>
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<td>Disposable income</td>
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<td>Energy availability and cost</td>
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<th>Sociocultural factors</th>
<th>Technological</th>
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<td>Population demographics</td>
<td>Government spending on research</td>
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<tr>
<td>Income distribution</td>
<td>Government and industry focus on</td>
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<tr>
<td>Social mobility</td>
<td>technological effort</td>
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<tr>
<td>Lifestyle changes</td>
<td>New discoveries / development</td>
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<td>Attitudes to work and leisure</td>
<td>Speed of technology transfer</td>
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<td>Consumerism</td>
<td>Rates of obsolescence</td>
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<tr>
<td>Levels of education</td>
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</table>
Decision Making in Pharmaceutical Marketing

- Market and Marketing opportunity
- Legal Business and their Economic Objectives
- Cultural and physiographic Barriers
- Political Stability
- Economic Development and Performance
Pharmaceutical Marketing
The Environment of Pharmaceutical Marketing

- External Environment
  - Economic Factors
  - Social and Cultural Factors
  - Political Factors
  - Technologic Changes
  - Governmental and Legal Factors
- Manufacture
  - Goods and Services
  - Distribution
- Physician
  - Demographic Factors
  - Economic Factors
  - Disease Incidence
- Competitive Factors
- Communications

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Today's Challenges – Sales

- Globalization
  - Increased demand to understand lessons learned across different product lines and geographies
  - Increased requirement to understand local needs to sell more effectively, but to act across the enterprise
- Customer saturation with sales literature
- Need for continually updated information about drug efficacy, interactions, contraindications and adverse effects
- Greater emphasis on economic and health care aspects of specific drugs and therapies by customers with high bargaining power
- Increased demand for sharing information and knowledge gained regarding comparative drug efficacy for clinical targets
Prescription Drug Channels

- "Brand" Manufacturers
- Repackers/Marketers
- "Generic" Manufacturers
- Wholesalers
- Chain Warehouses
- Group Purchase Depots
- Hospitals
- Independent Pharmacies
- Chain Drug Stores
- Mail Order Pharmacy Services
- HMOs
- Dispensing Physicians
- Nursing Homes
- Government
- Patient
The Industry’s Expectations for the 21st Century

- Managed Care
- Redefining of the Industry’s Basic Customers
- Need for R&D to Provide Unique and Cost-effective Drugs
- A Substantial Slowdown In Growth
- A Substantial Reduction in Profitability
- Continuing Efforts at Cost Containment
- Need for R&D to Provide Unique and Cost-effective Drugs
- Increasing Role For OTC Drugs
- Increasing Role For Generics
- Increasing Role For OTC Drugs
- Increased Government Intervention