

THE PHARMACEUTICAL INDUSTRY: AN OVERVIEW

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Focus Areas

- Brief historical review of the U.S. pharmaceutical industry.
- Societal benefits and challenges associated with the pharmaceutical industry.
- Overview of drug product marketing and sales issues.
- Interactions between health professionals and the pharmaceutical industry.

Historical Development

- 1700's
 - Patent medicines and remedies
 - Apothecaries dispense pills and potions
- 1800's
 - Pharmaceutical manufacturers are established in seaports (e.g., Philadelphia, New York)
 - Civil War increases demand for drugs

Historical Development

- 1900 – 1940
 - 1910's – Fat and water soluble vitamins
 - 1921 – Insulin extracted from the pancreas
 - 1930's – Sulfonamides
 - 1940's – Penicillin (Initially isolated in 1928)
 - World War II begins era of research and development; large scale production begins

Historical Development

- 1950 – Present
 - Technological innovations lead to new expensive products
 - The U.S. accounted for nearly 65% of the world wide drug innovations
 - Antineoplastics, Cardiovascular agents, Diagnostic agents, Antiulcer drugs, Hormones, Ophthalmic agents, Antihistamines, Bronchodilators, Oral Contraceptives, Analgesics, Antidepressants, Antibiotics

Pharmaceutical Industry

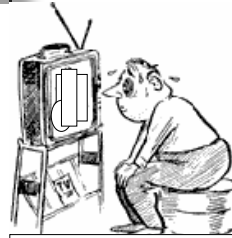
- PhRMA Companies
 - Pfizer, GlaxoSmithKline, Merck
 - Branded Products, Research Intensive
- Biotechnology Companies
 - Amgen, Biogen, Immunex
- Generic Drug Companies
 - Mylan, Teva, Watson

Top 10 Pharmaceutical Manufacturers

(Source: www.imshealth.com)

Rank	Company	2003 U.S. Sales in Billion \$	Ticker Symbol
1	Pfizer	29.2	PFE
2	GlaxoSmithKline	18.6	GSK
3	Johnson & Johnson	15.2	JNJ
4	Merck and Company	14.1	MRK
5	AstraZeneca	10.4	AZN
6	Bristol-Myers Squibb	9.6	BMJ
7	Novartis	9.5	NVS
8	Amgen	7.7	AMGN
9	Wyeth	7.6	WYE
10	Lilly	7.5	LLY
	Total	129.4	

Industry Trends



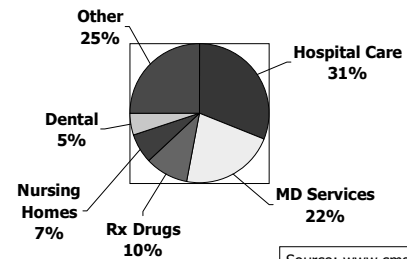
"In a surprise move today, everything merged"

Mergers and Acquisitions are Strategies to Enhance Research Pipeline and Shareholder Value

Value of Pharmaceuticals

- Medical, Social and Economic
 - Decrease morbidity and mortality
 - Improve quality of life
 - Increase productivity of Americans
 - Assist in reducing overall health care costs

Health Care Expenditures \$1.00 Spent in 2001

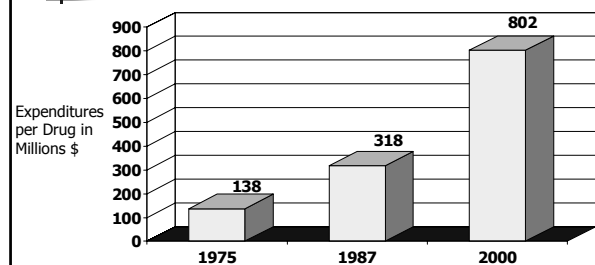


Source: www.cms.hhs.gov

DRUG DEVELOPMENT: OVERWHELMING ODDS

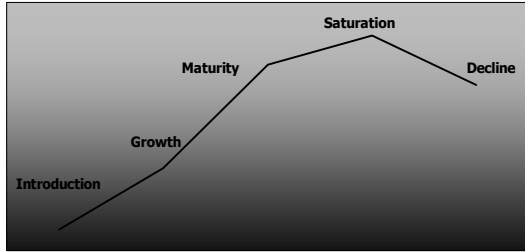
	Non-clinical Testing	Phase I	Phase II	Phase III	FDA	Phase IV
Years	3.5	1	2	3	1.5	
Test Subject	Laboratory and animal studies	40 - 100 Healthy Volunteers	200 - 500 Patient Volunteers	1,000 - 3,000 Patient Volunteers	Review process / approval	Additional post-approval trials
Purpose	Pharmacology Toxicology	Safety PK PD	Efficacy ADRs Dose-response	Benefits vs. risk under typical clinical conditions		
Success Rate	5,000 - 10,000 new compounds synthesized	6 - 9 enter trials			1 approved	
	Discovery	Development			Registration	Marketing

Drug Development Costs



Source: www.pharma.org

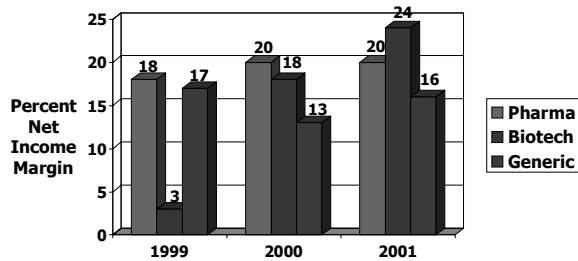
Product Life Cycle



Drug Patents

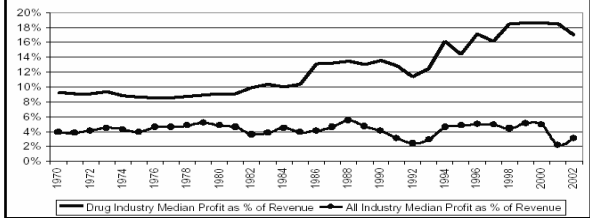
- U.S. Patents protect property rights to inventors of new products for 20 years from the date of application filing
- Pharmaceutical manufacturers typically apply for a patent when a promising compound is discovered
- May take up to 3 years for a patent to be issued
- Considering another 10 or more years for testing and review, patent protection lasts about 7 years after FDA approval

Average Annual Profit Margins



Source: www.cms.hhs.gov

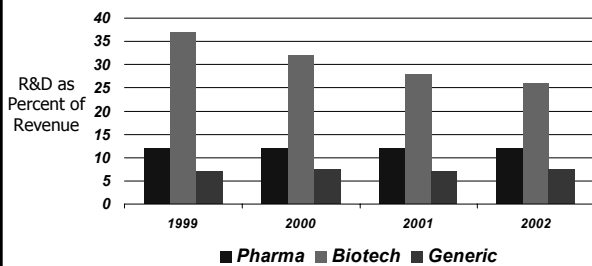
Profitability of Fortune 500 Drug Industry and All Fortune 500 Industries, 1970 to 2002



Source: Public Citizen update of Stephen W. Schondelmeyer calculation, *Competition and Pricing Issues in the Pharmaceutical Market*, PRIME Institute, University of Minnesota, based on data found in *Fortune* magazine, 1958 to 1999; *Fortune* magazine, April 17, 2003.

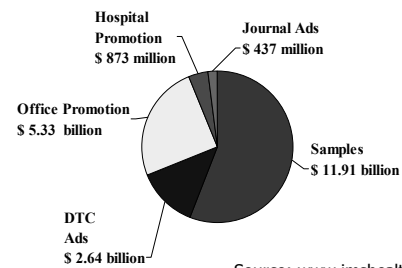
Source: www.citizen.org

Average R&D as Percent of Revenues



Source: www.cms.hhs.gov

Promotional Spending \$ 21.2 Billion in 2002



Source: www.imshealth.com

Indirect Marketing Influence – Direct-to-Consumer Advertising



Direct-to-Consumer Advertising

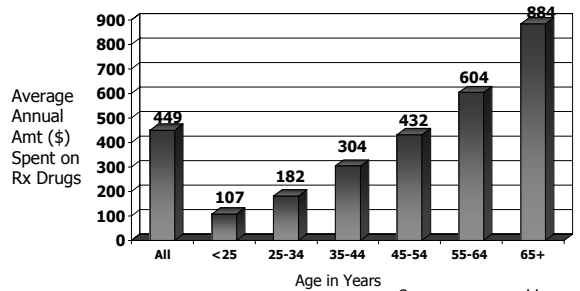
Pro

- Education of public about disease states and medications
- Some physicians report benefit since patients ask better questions
- Promote consumer involvement and empowerment
- Economic benefit to pharmaceutical industry and advertising industry

Con

- Print, radio, television and internet advertising
- Focus on population that has less sophistication than traditional targets (i.e., those prescribing, dispensing and administering drugs)
- Use of athletes and celebrities
- Manipulation of prescriber
- Lack of reliable studies to demonstrate benefit

Average Out-of-Pocket Drug Expense



Prescription Drugs via Internet

Lipitor 40mg Cost (\$)

Costco.com 95.37
Drugstore.com \$94.99
CVS.com 109.99

Celebrex 200mg (\$)

Costco.com 80.07
Drugstore.com 76.99
CVS.com 92.99

Nexium 40mg (\$)

Costco.com 122.77
Drugstore.com 120.99
CVS.com 147.99

Source: Richmond Times-Dispatch April 18, 2004

Drug Importation Controversy



Product Quality Concerns

- Counterfeit Drugs – labeling or adulteration issues
- Wholesalers (Amerisource Bergen, Cardinal Health McKesson) comprise 90% of the market
- Use of barcodes and radio-frequency identification

Consumer Concerns

- Increased number of new and expensive drugs
- Increased aging population on chronic drug therapy without adequate insurance coverage
- Decreasing coverage by private insurers with increasing co-payments for branded drugs

Generic Drugs

- A copy of the innovator drug with the same active ingredients and comparable strength, quality and therapeutic effectiveness
- Average Prescription price for trade vs. generic product was \$76.29 vs. 22.79
- Hatch-Waxman Act of 1984 and drug substitution laws at the state level supported generic drug use

Generic Drug Industry

- Companies
 - Barr, Bertek, ENDO, Eon Labs, Fougera, Geneva, Global, IVAX, Teva, Watson
- Patent Issues
 - a new generic alternative discounts the innovator product by approximately 40% and captures approximately 40% market share initially
 - a generic drug captures approximately 70% market share after 3 years

Consumer Response - Implications for Physicians



Source: www.ag.state.mn.us

Pharmaceutical Sales Representatives

- 90,000 - 95,000 Employed in U.S.
- Estimate Cost of \$ 150,000 per Representative per Year (salary, bonus, incentives, training, automobile, other expenses)
- Approximately One Representative for every Two General Practice Physicians
- Promotional Messages Restricted to FDA Labeling

Office of Inspector General Compliance Guidance for Pharmaceutical Manufacturers (June 2001)

PhRMA Code (July 1, 2002)

- General Interaction with Healthcare Professionals (Focus on information)
- Entertainment (Avoid)
- Continuing Education (Support conference, but not individual participants)
- Consultants (Avoid token arrangements)
- Educational and Healthcare Practice-related Items (For healthcare benefit of patients and value of \$100 or less)

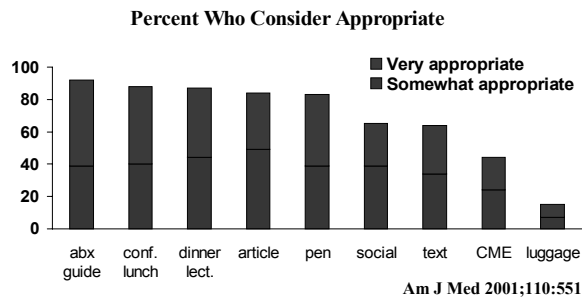
Drug Samples

- Widespread industry practice
- Distribution controlled by Prescription Drug Marketing Act of 1987
- Sale is forbidden
- Drug use control issues

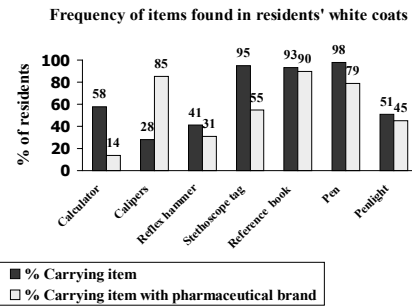
www.nofreelunch.org



Housestaff Attitudes Toward Promotions



Residents and Brand Promotion



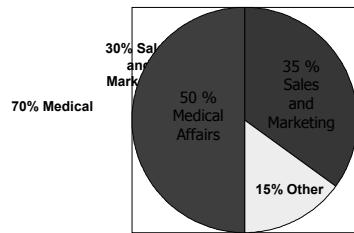
New Age Representatives

- Specialist/Liaison Positions
 - Medical Science Liaison, Clinical Education Specialist, Regional Scientific Manager
- Pharmacists (Pharm.D.) or Physicians
- Collaboration with Sales Force
- Lack of Financial Incentives for Sales
- Ability to discuss "off-label" indications
- Primary Focus is on Thought Leaders

Thought Leaders

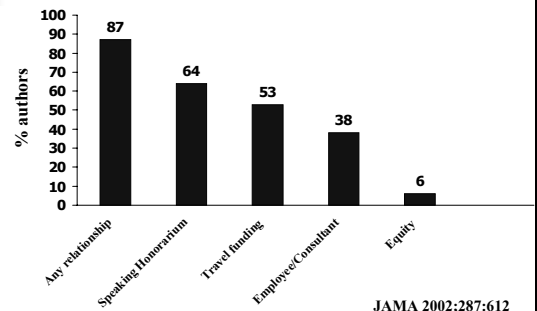
- Other Nomenclature
 - Key Opinion Leader
 - Subject Matter Expert
 - Thought Leader
 - Influence Leader
- Focus
 - Local
 - Regional
 - National

Medical Science Liaison Reporting Structure



Source - Drug Information Journal, 2000;34:1049-1052

Authors of Clinical Practice Guidelines and Relationships with the Pharmaceutical Industry



JAMA 2002;287:612

Corporate Philanthropy

Other Common Oxymorons

- Managed Care
- Authentic Replica
- Clearly Ambiguous
- Plastic Silverware
- Unbiased Opinion

Industry Challenges

- Product Pipeline Issues
- Expensive and Unpredictable Research
- Negative Industry Publicity
- Legislative Issues
- Globalization of Marketplace
- Current Marketing Practices
- Mergers and Acquisitions
- FDA Relationship
- Projections for Increased Spending on Drugs

Pharma's Political Influence

- \$ 29 Million in Contributions to National Parties and Candidates in Last Election (10th Largest Amount of 80 Industries)
- \$94.1 Million Spent in 2003 for 675 Lobbyists in Washington

Challenge to All Health Professionals

- Remember Covenantal Relationship with Patients
- Weight the Ethical Issues
- Be Alert to Conflicts of Interest
- Develop a Personal Code of Conduct