

## THE PHARMA, BIOTECH AND DEVICE COLLOQUIUM

Princeton University
Princeton, NJ
June 7, 2005



# KEYS TO RESTORING THE FINANCIAL STRENGTH OF THE PHARMA INDUSTRY

David Moskowitz, RPh, MBA
Senior Vice President and Healthcare Senior Analyst
Friedman, Billings, Ramsey Group, Inc.



#### **Disclaimer**

- Friedman, Billings, Ramsey Inc. conducts equity research on Astra Zeneca Plc. (AZN), Bristol Meyers Squibb (BMY), Merck (MRK), Pfizer (PFE), Wyeth (WYE), Schering-Plough (SGP) and Eli Lilly (LLY).
- The analyst(s) responsible for this research report has received and is eligible to receive compensation, including bonus compensation, based on Friedman, Billings, Ramsey & Co. Inc.'s ("FBRC") overall operating revenues, including revenues generated by FBRC's investment banking department.
- Our brokers and analysts may make recommendations to their clients and our affiliates may make investment decisions that are contrary to the recommendations contained in a research report. Such recommendations or investment decisions would be based on the particular investment strategies, risk tolerances and other investment factors particular to a client or an affiliate.
- In the normal course of its business, FBRC seeks to perform investment banking and other services for various companies and to receive compensation in connection with such services. As such, investors should assume that FBRC intends to seek investment banking or other business relationships with the companies.
- Additional information on the securities mentioned in this report is available upon request. The information concerning the relationship of FBRC and the assigned analyst(s) to this issuer is accurate. Because of individual client objectives, the report should not be construed as advice designed to meet the particular investment needs of any investor. Any opinions expressed herein are subject to change. The report is not to be construed as an offer or the solicitation of an offer to buy or sell the securities herein mentioned. From time to time, FBRC, its affiliated entities and their respective directors, officers, employees or members of their immediate families may have a long or short position in the securities mentioned in this report. These securities may be sold to or purchased from customers or others by FBRC acting as principal or agent. This publication has been issued and approved by FBRC under a compliance routine approved by Friedman, Billings, Ramsey, International Ltd., its UK FSA Regulated affiliate, for distribution to UK and European non-private clients.
- Commentary regarding the future direction of financial markets is illustrative and is not intended to predict actual results, which may differ substantially from the opinions expressed herein. References to "median", "consensus", "street", etc., estimates of economic data refer to the median estimate of economists polled by Bloomberg L.P.



## Major Pharmaceutical Stock Performance (12/29/00 - 5/26/05)

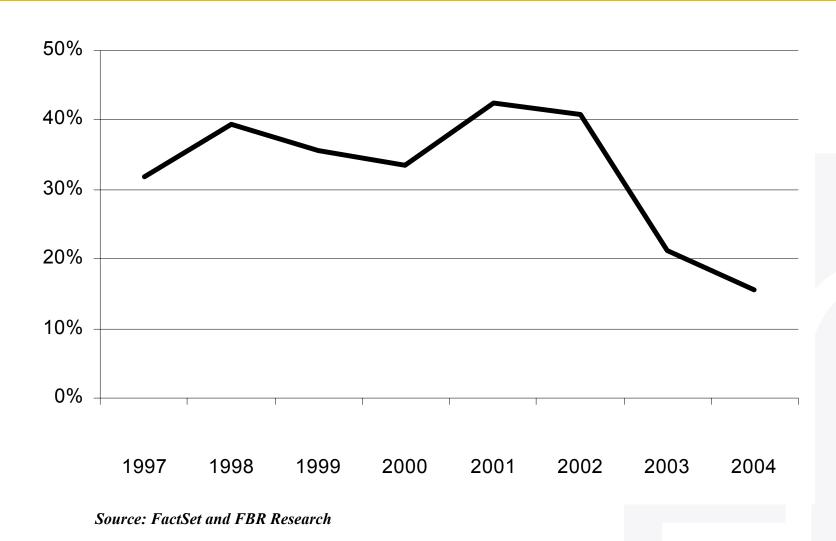


Includes: ABT, AVE, AZN, BMY, GSK, JNJ, LLY, MRK, NVS, PFE, SGP, SNY/AVE, WYE

\*As of market close on 5/26/2005 Source: FactSet and FBR Research

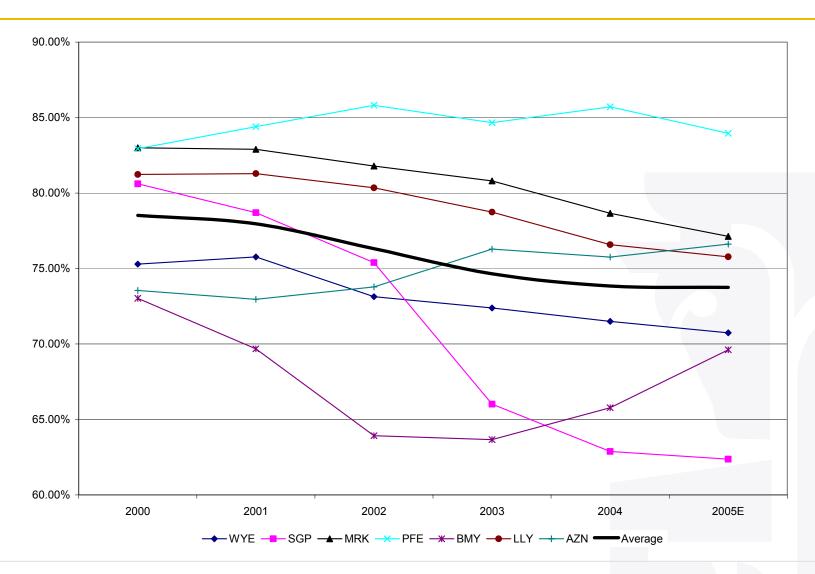


### Average Return on Equity of Major U.S. Pharma



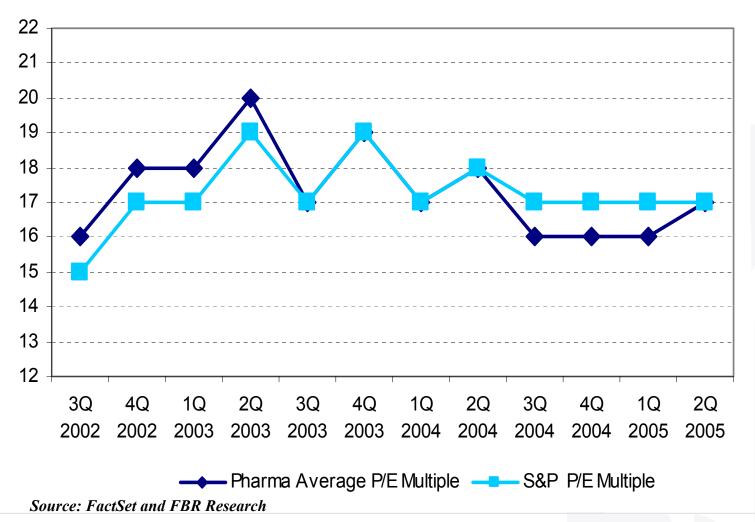


#### Major Pharma Gross Margins





### Historical P/E Comparison—S&P 500 vs. FBR Index of Major Pharmaceutical



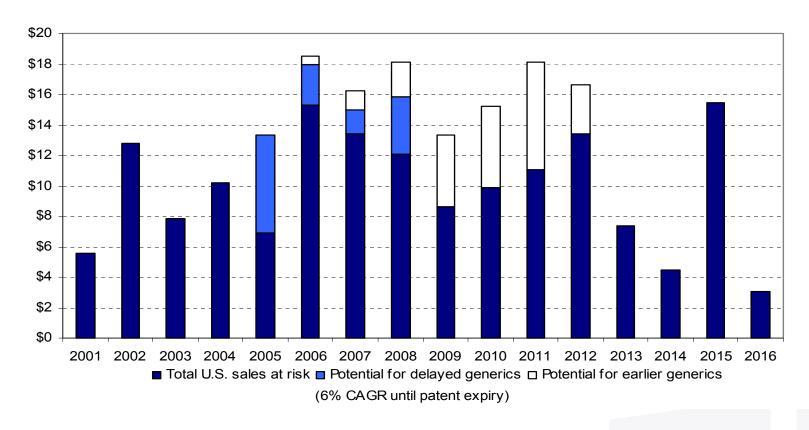


#### Major Factors Affecting Profitability

- Brand drug patent expirations/challenges
- Formulary management
- Fewer new product launches
- Rising cost of clinical trials
- In-licensing deals
- Company specific issues



### Estimated Sales of Major Drug Products Facing Patent Expiration/Challenges (\$ in billions)

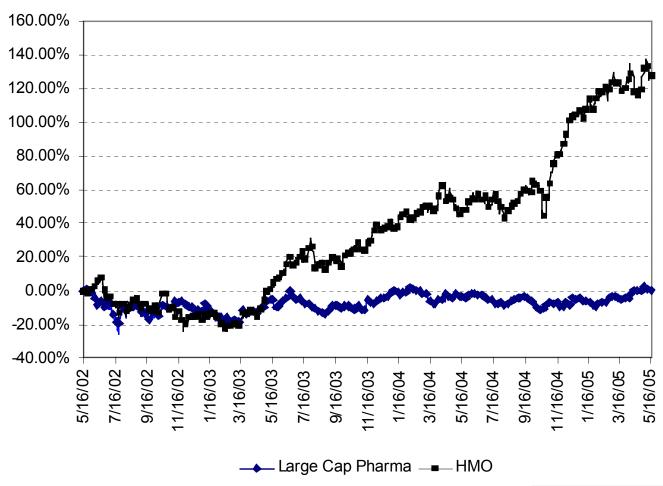


\*Products with \$100 million in U.S. sales or more

Source: FDA Orange Book, Company reports, NDC Health, and FBR Research



### Major Global Pharmaceutical Stock Performance vs. AMEX Healthcare Payer Index (HMO)

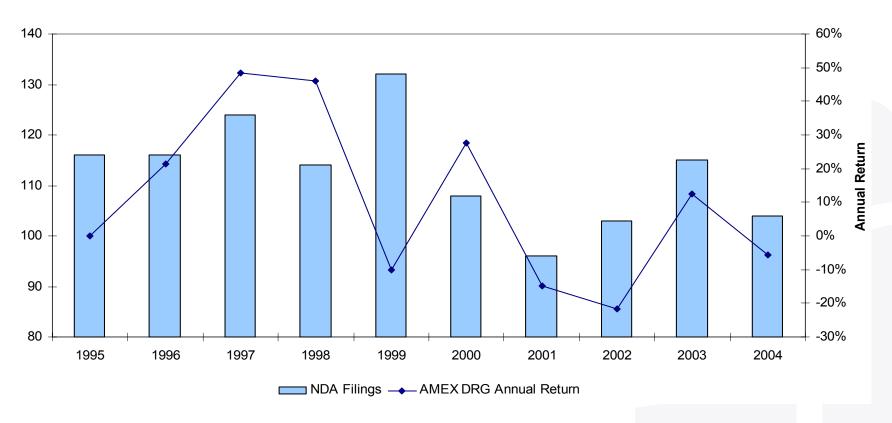


Includes: ABT, AZN, BMY, GSK, JNJ, LLY, MRK, NVS, PFE, SGP, SNY/AVE, WYE

\*As of market close 5/20/2005 Source: FactSet and FBR Research



### Total Drug Industry NDA Filings vs. AMEX DRG Index



Source: FDA, FactSet, Bridge, and FBR Research



#### Rising Drug Development Costs

- Tufts University Estimate \$800M per drug (CAGR13.25%)
- FBR estimated R&D growth (2000-2008 CAGR 9.6%)
- Average 16.5% of drug company sales
- Late-stage trials more expensive 30% of R&D expense for clinical trials
- More patients/more requirements per patient
- FDA getting more safety conscious emphasis on followup and safety evaluations – more Phase IV studies
- "Output is decreasing per company and per dollar" (FBR 2005 Pharma Management Survey)



#### **In-Licensing On The Rise (need footnotes)**

#### **Drivers:**

- R&D productivity crisis
- Increased exposure to patent expiry
- Misaligned corporate strategies and product portfolios
- Change in R&D technologies outpace technology adoption rates

#### **Statistics:**

- In-licensed product revenue grew from 16% to 22% of top-ten drug company revenues from 1996 2001
- Pharma companies spent \$2.8 billion on biotech in-licensing deals in 2001 (Datamonitor)
- The number of in-licensing deals quadrupled from 1996-2001 (IMS Health)

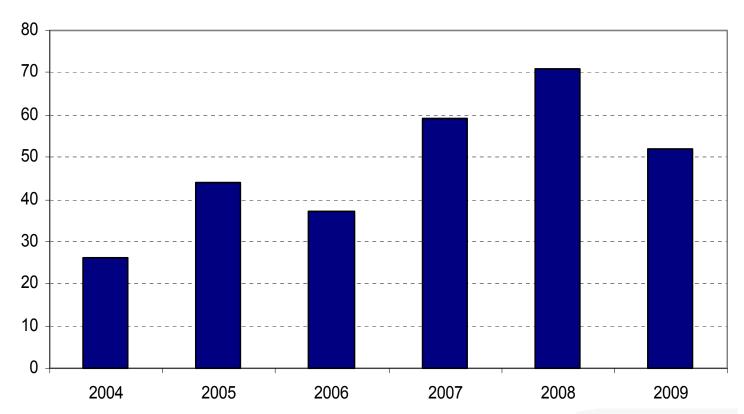


#### What's being done?

- Stronger IP protection
- Medicare drug benefit increases patient access
- In-licensing: Additional revenues offset lower profitability and may improve ROI
- Cost efficiencies
- Drug development efficiencies
- Outsourcing (CAGR 15.5% '03-'08)
- Signs of pipeline productivity increases



# NDA Filings for Top Drug Companies (2004–2009)





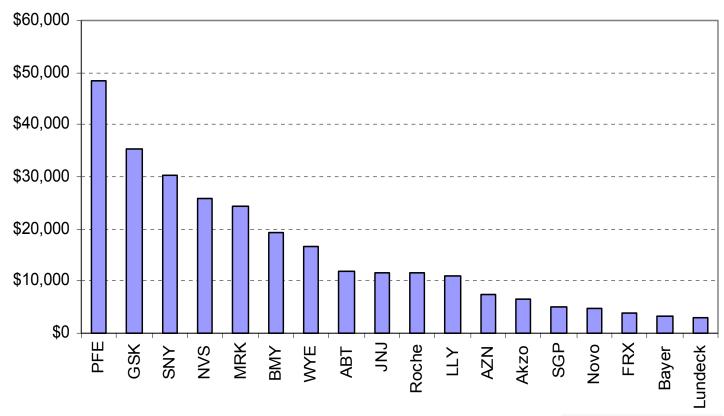
# Drug Pipeline Productivity (year-over-year change)

					2004
Company	Pipeline NPV (millions)	Phase III	Phase II	Total	Launches
ABT	\$5,839	-1	-2	-3	0
GSK	\$5,602	8	28	36	1
Roche	\$5,287	2	1	3	0
WYE	\$4,620	-1	-2	-3	1
JNJ	\$4,369	2	1	3	0
BMY	\$4,273	2	1	3	1
Akzo Nobel/Organon	\$2,976	4	-3	1	0
FRX	\$2,204	1	0	1	0
SNY-AVE	\$1,327	3	11	14	3
MRK	\$1,173	2	-4	-2	1
NVS	\$1,152	4	3	7	1
NVO	\$1,037	1	-1	0	0
Bayer	\$682	-2	-2	-4	0
Lundbeck	\$384	1	-1	0	0
SGP	-\$882	0	2	2	1
AZN	-\$3,951	0	1	1	0
LLY	-\$15,547	0	-1	-1	3
PFE	-\$25,900	-1	10	9	3
Total change	-\$5,356	25	42	67	15



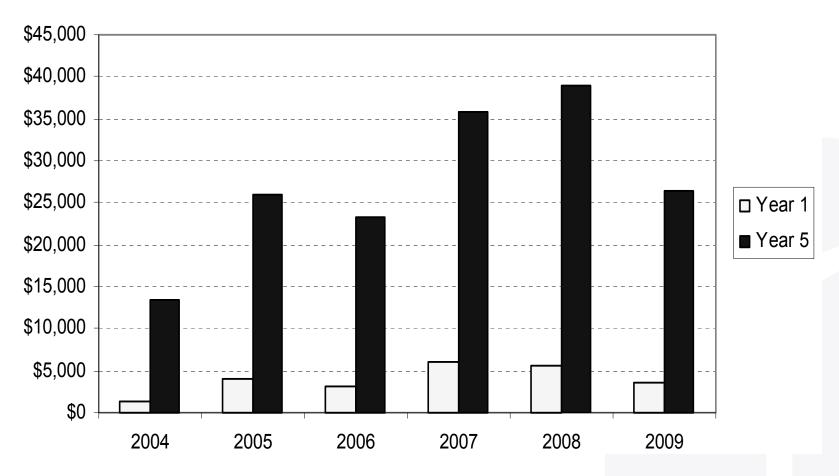
#### **Estimated Drug Development Pipeline NPV**

by Company (avg. 19% of total market cap)



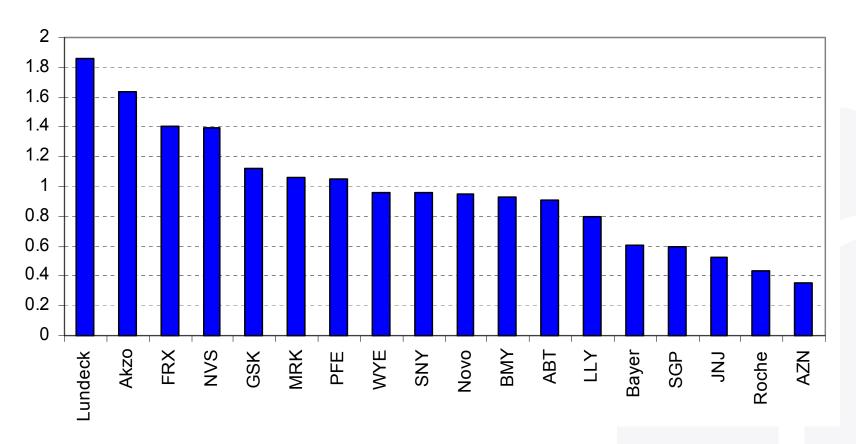


### Estimated Sales Following Launch of Products Filed in the Specified Year after Year 1 and Year 5





#### Ratio of Estimated Drug Company Pipeline NPV to 2004 Sales





### **Estimated Present Value of Drug Industry Revenues from the Medicare Rx Drug Benefit**

	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013
Sales estimates with Part D Benefit										
Total U.S. Rx expenditures (billions)	192.7	210.03	228.99	253.70	277.07	303.53	331.94	362.95	396.51	436.86
Normal Growth rate	8.6%	8.6%	8.6%	8.6%	8.6%	8.6%	8.6%	8.6%	8.6%	8.6%
Demographic growth 65+	1.0%	1.1%	1.2%	1.5%	2.4%	1.9%	1.8%	1.6%	3.9%	3.2%
Medicare bill increment in drug spending			1.7%							
Discount rate	10.00%	10.00%	10.00%	10.00%	10.00%	10.00%	10.00%	10.00%	10.00%	10.00%
2004 dollars	192.7	190.94	189.25	190.61	189.24	188.47	187.37	186.25	184.98	185.27
	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013
Without Part D Benefit										
Total U.S. Rx expenditures (billions)	192.7	210.03	228.99	249.81	272.82	298.87	326.85	357.38	390.43	430.16
Normal Growth rate	8.6%	8.6%	8.6%	8.6%	8.6%	8.6%	8.6%	8.6%	8.6%	8.6%
Demographic growth 65+	1.0%	1.1%	1.2%	1.5%	2.4%	1.9%	1.8%	1.6%	3.9%	3.2%
Medicare bill increment										
Discount rate	10.00%	10.00%	10.00%	10.00%	10.00%	10.00%	10.00%	10.00%	10.00%	10.00%
2004 dollars	192.7	190.94	189.25	187.69	186.34	185.57	184.50	183.39	182.14	182.43
Medicare Rx Impact (billions)				\$ 2.92	\$ 2.90	\$ 2.89	\$ 2.88	\$ 2.86	\$ 2.84	\$ 2.84

Est. PV of Additional Sales From Drug Benefit \$20.13 billion

\*Based on FBR estimates

Total U.S. Rx expenditures (billions) based on NDC Health retail estimates of \$235B in 2004 less 18% to allow for manufacturer discounts and rebates (18% est. discount is based on retail \$ from NDC compared with actual company reported sales on select products).

Source: FBR Research, NDC Health, and CMS



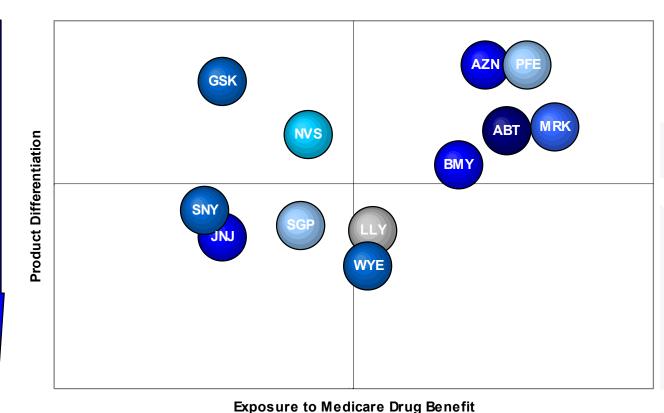
#### **Medicare Spending Estimates (2005–2014)**

	2005	2006	2010	2012	2014
Spending as a % of GDP	2.7%	3.3%	3.5%	3.7%	4.0%
Spending as a % of NHE	17.2%	20.4%	20.2%	20.3%	20.8%
Spending as a % of U.S. General Revenues	36.8%	42.8%	44.5%	45.6%	47.9%

Source: 2005 Annual Report of the Boards of Trustees of the Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Fund; CMS, Office of the Actuary, National Health Statistic Group, February 2005; FBR Research



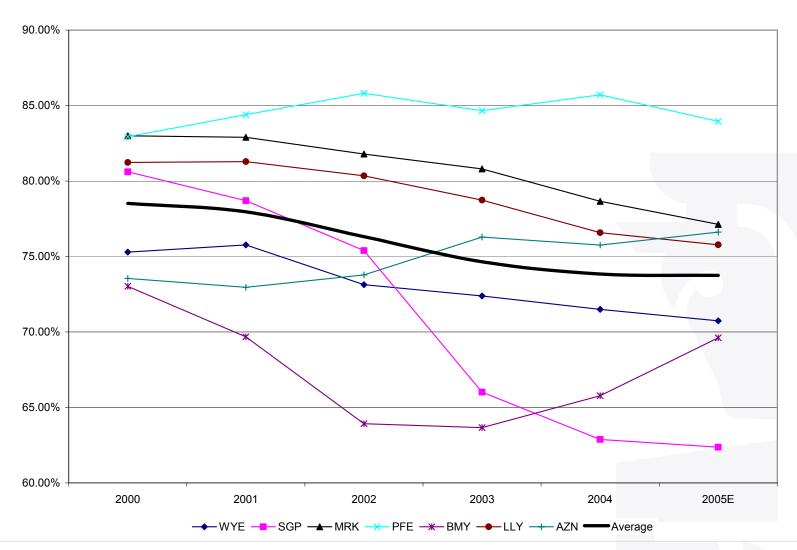
# Medicare Drug Benefit—Exposure and Opportunity Index for Major Pharma



exposure to Medicare Drug Bellen

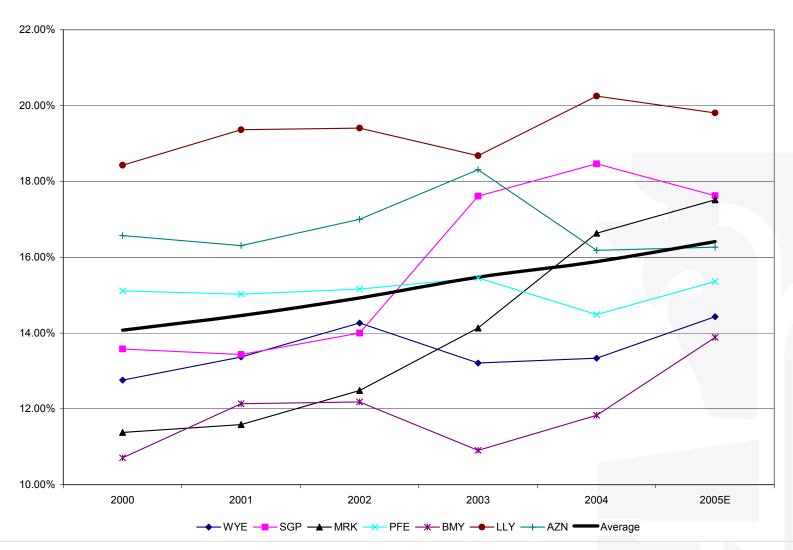


#### Major Pharma SG&A expense as a % of Sales



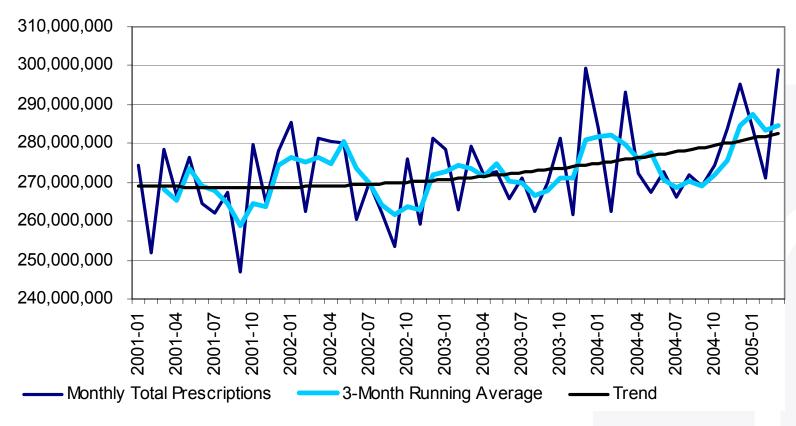


#### Major Pharma R&D expense as a % of Sales





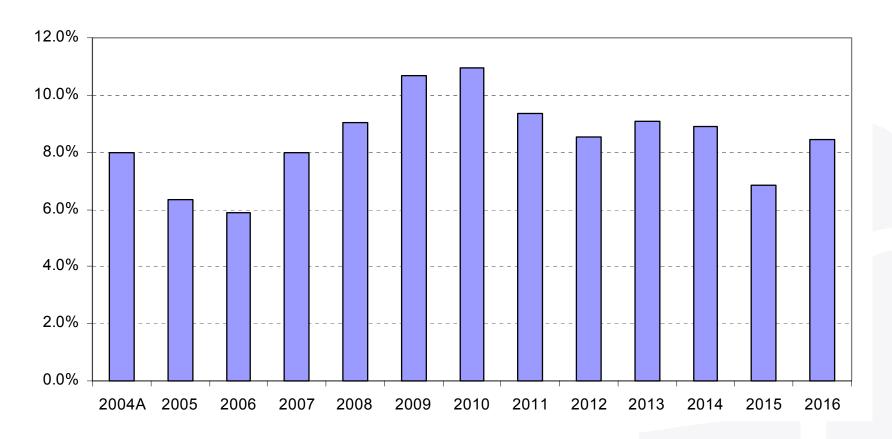
#### **Total Prescriptions (U.S.)**



Source: NDC Health and FBR Research



#### Estimated Global Sales Growth for Top Drug Companies (2004–2016)





# Trade-offs Likely To Accompany Restored Financial Strength

- Sales growth recovery anticipated after 2006
- Aging populations, improved access, baby boomers
- Gross margins likely to continue to decline due to patent losses, Medicare pricing, in-licensing, global penetration
- Profitability remains under pressure, R&D and cost efficiencies will be relied upon
- Pharmacoeconomic arguments will become more important, proof of value to patients
- New business model PCP vs. Specialty
- As always drug pipeline holds the key to long-term financial strength, on both the top and bottom lines