Connecting People, Science and Regulation®

A Look Forward on the Business/Regulatory Trends for the Pharma/Biopharma Industry

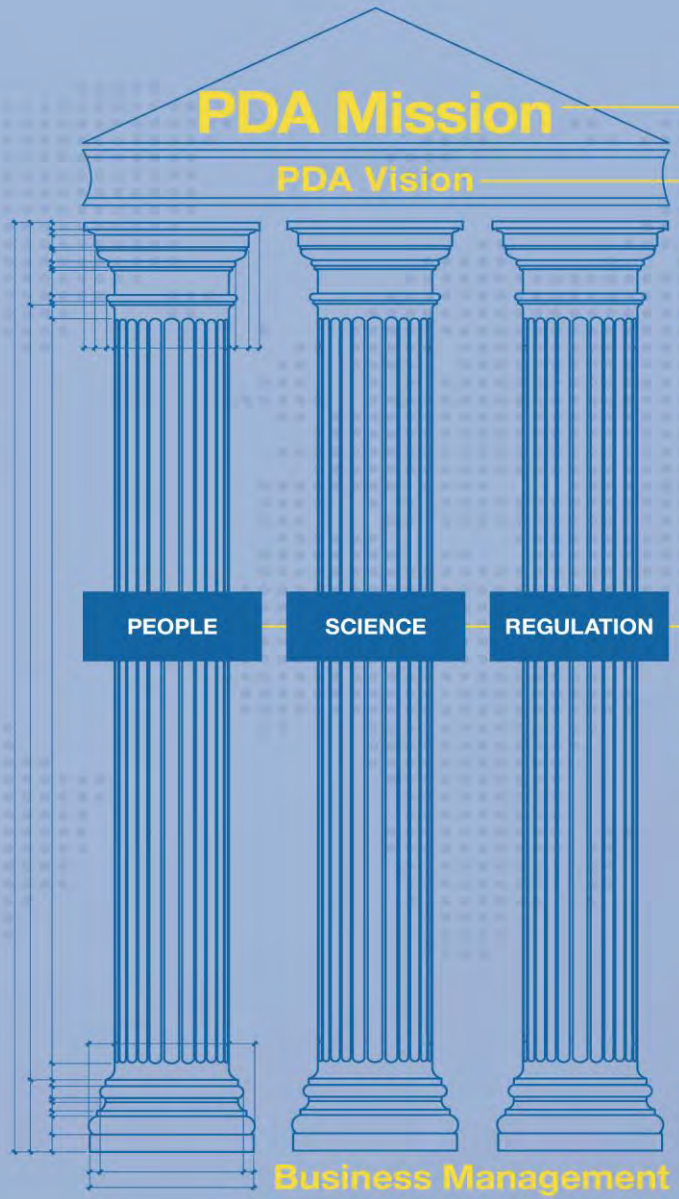
Introduction

Richard M. Johnson
Member, PDA for 24 years
President & CEO since 2009

- Ladies and Gentlemen, I am happy to be here with you.

What is PDA?

The Parenteral Drug Association (PDA) is the leading global provider of science, technology and regulatory information and education for the pharmaceutical and biopharmaceutical community. Founded in 1946 as a nonprofit organization, PDA is committed to developing scientifically sound, practical technical information and resources to advance science and regulation through the expertise of its more than 9,500 members worldwide.



MISSION
To develop scientifically sound, practical technical information and resources to advance science and regulation for the pharmaceutical and biopharmaceutical industry through the expertise of our global membership

VISION
To be the foremost global provider of science, technology, and regulatory information and education for the pharmaceutical and biopharmaceutical community

PDA: Connecting People, Science and Regulation®

PEOPLE: Enhance the value of PDA membership

SCIENCE: Be recognized as a leading organization for manufacturing science, quality and innovation

REGULATION: Our regulatory activities are scientifically and technically focused, and current information is communicated to our members

BUSINESS MANAGEMENT: Enhance business processes to provide a solid foundation and organization to sustain PDA's people, science and regulation strategies

Your Local PDA Connection

Are you curious about the issues unique to your region?

Another layer of PDA leadership resides at the grassroots level in the Chapter organizations. Regional PDA Chapters provide local services to the membership, including translations of PDA publications, networking social events, student scholarship and annual regulatory and technical conferences. Each Chapter is managed by volunteer leaders.

Get involved with your local PDA Chapter today!

Contact **volunteer@pda.org**

Overview

- Business Environment
- Pharma Manufacturing Environment
- Regulatory Environment
- Closing Thoughts

Business Changes in Pharma

- Dependence on Blockbusters
- Emerging Markets
- Loss of Patent Protection
- Lack of productivity from R&D
- Increasing Generic Competition
- Consolidation / Mergers & Acquisitions

Dependence on Blockbusters

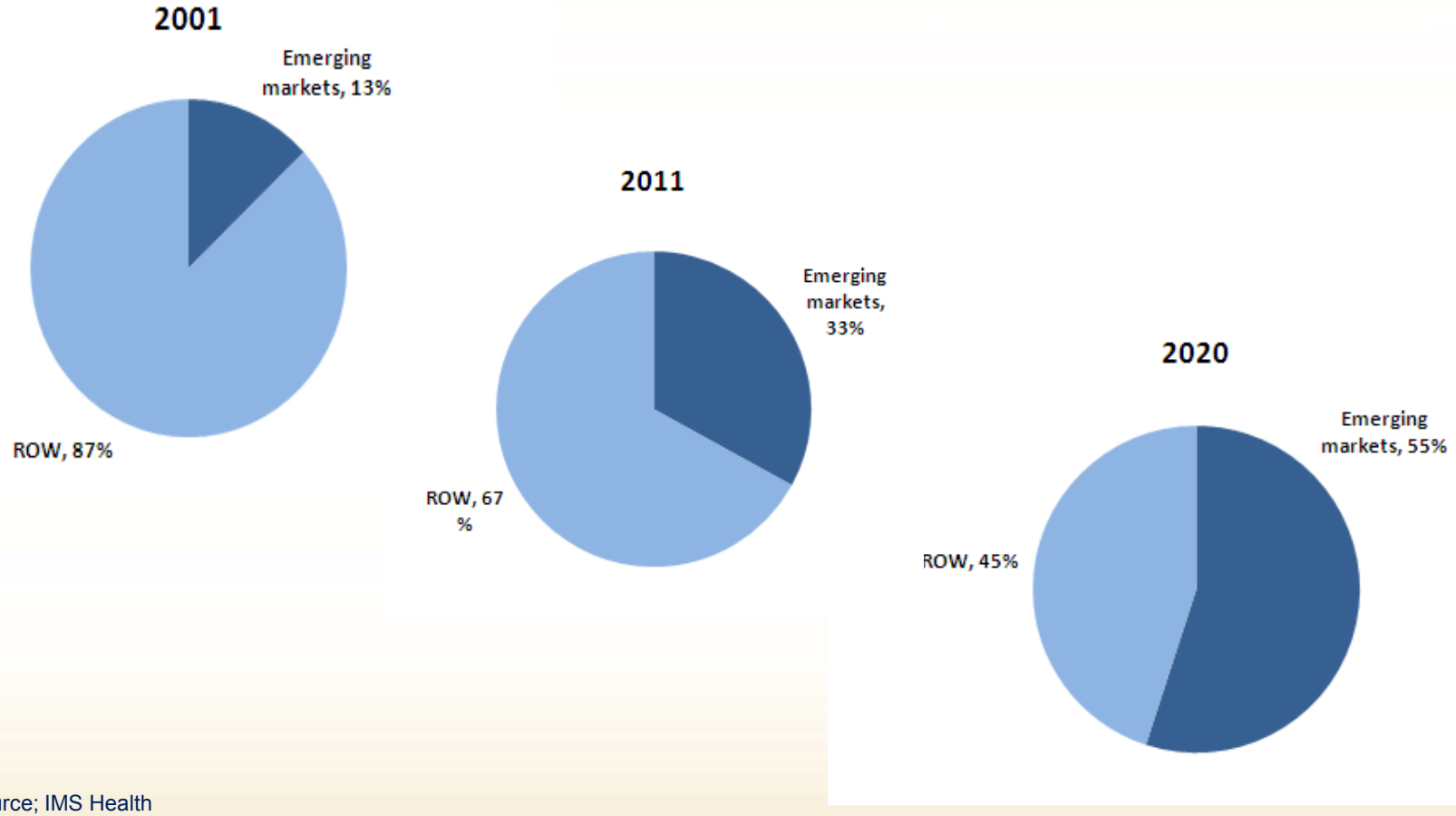
Table 2.8: Sales contributions ($m) to the top 10 companies from their 5 leading products, 2007

Company	Total Sales	Sales of Top 5 products	Revenue share of top 5 products
Pfizer	44,576	22,789	51.1%
GlaxoSmithKline	36,968	15,030	40.7%
Sanofi-Aventis	33,231	13,678	41.2%
Novartis	32,791	10,287	31.4%
AstraZeneca	30,053	17,480	58.2%
Johnson & Johnson	28,263	15,253	54.0%
Merck & Co	27,257	14,506	53.2%
Roche	26,690	13,002	48.7%
Abbott	17,276	8,904	51.5%
Lilly	16,694	10,678	64.0%

Source: IMS Health, July 2008, Copyright ©, reprinted with permission Business Insights Ltd

Diversification via Geographic Expansion

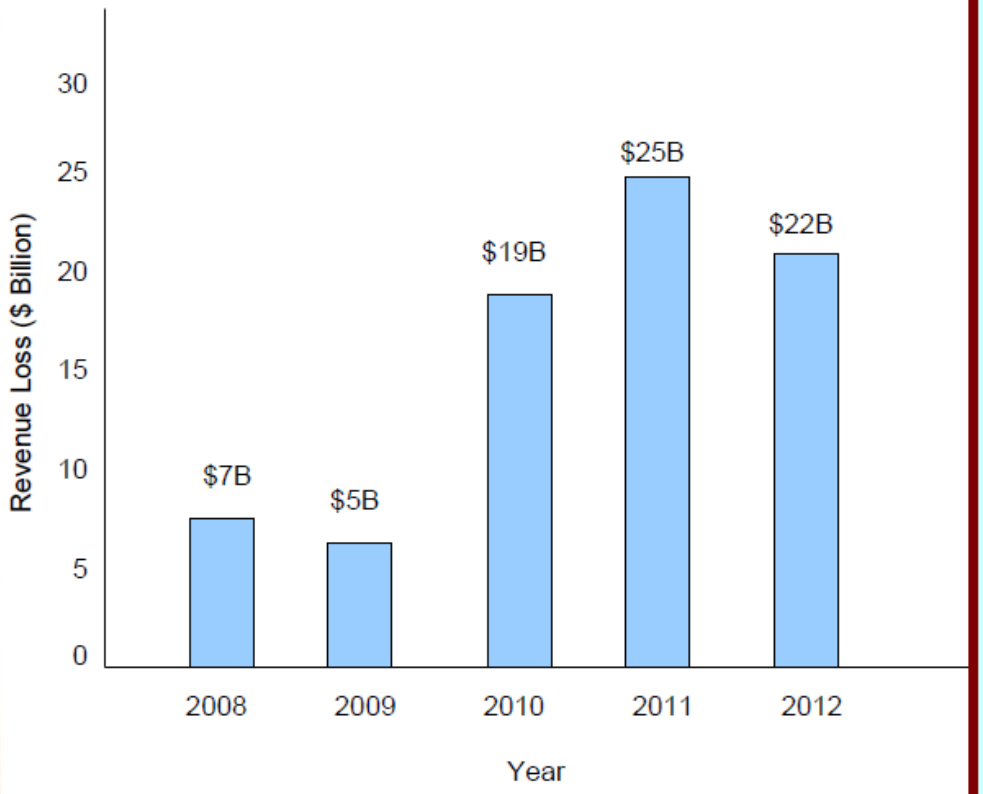
Emerging markets – share of global pharma growth:



Source; IMS Health

Patent "Cliff"

Pharma-Biotech Industry: Projected Revenue Loss due to Patent Expiry (World), 2008-2012



An estimated drop of approximately $80 billion in sales over the next five years on blockbusters such as Pfizer's Lipitor, Wyeth's Effexor, Merck's Singulair and Eli Lilly's Zyprexa is a major driver for big pharma to consolidate. In addition, there is a renewed interest in biologics as the future source of blockbusters, thereby leading to a rise of biotech acquisitions. Big pharmaceutical companies are focusing on attractive therapeutics markets like cancer, diabetes, CNS, etc. Biotech companies with existing product portfolio or at phase III stage of clinical trial are considered attractive acquisition prospects for the big pharma.

Apart from biotech companies, even large pharmaceutical companies with strong drug development pipeline and low exposure to patent expiries are attractive M&A targets. For instance, Schering-Plough's pipeline consisting mainly of biologics, with about 18 drugs in Phase III and its relative low exposure to patent expiries are the key reasons for its acquisition by Merck & Co.

Source: Frost & Sullivan

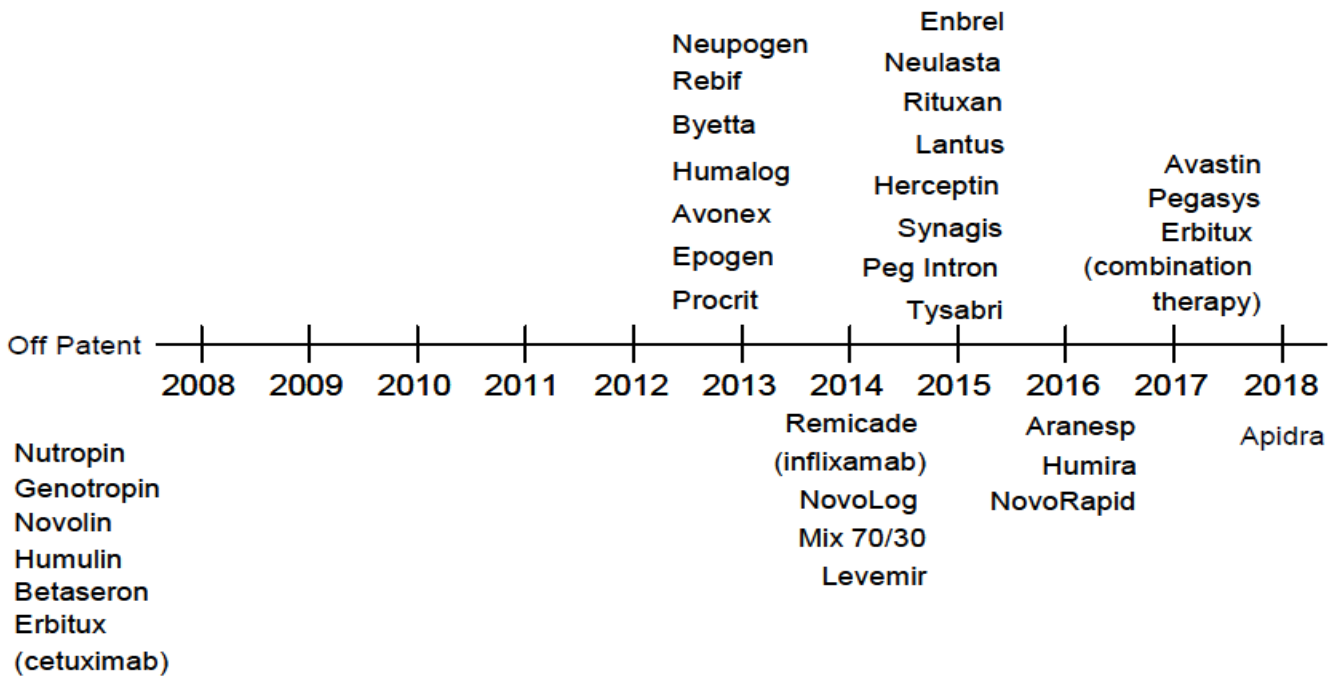
Key Product Patent Expiry

Product	2008 US$ Sales (millions)	Generic Entry
Lipitor	7.8	2011
Nexium	5.9	2014
Plavix	4.9	2011
Advair	4.4	2010
Seroquel	3.9	2011
Singluair	3.5	2012
Enbrel	3.4	2014
Neulasta	3.1	?
Actos	3.1	2010
Epogen	3.1	?
Prevacid	3.1	2009
Abilify	3.1	2014
Remicade	3.1	?
Effexor XR	3.0	2010
Lexapro	2.7	2012

B. Ryan – September 2009

Biotech Patent "Cliff"

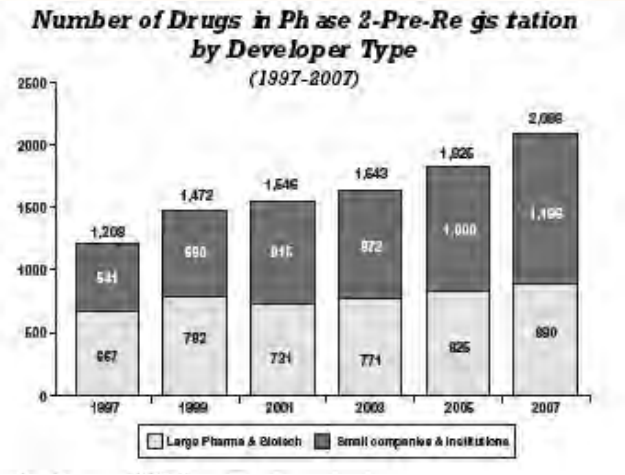
Figure 1.7: Estimated Last Patent Expiry Dates of Selected Proteins

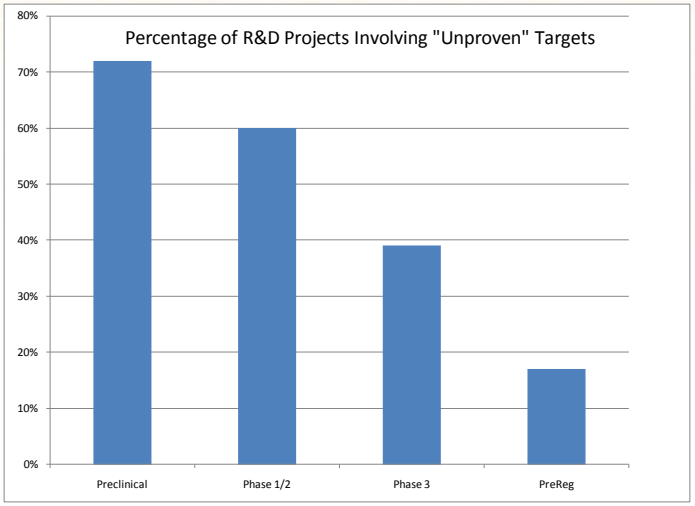


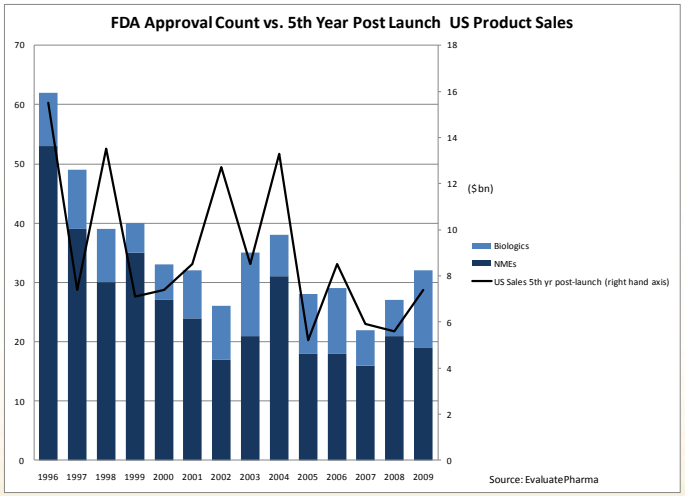
Source: Annual Reports, SEC Filings, and Business Insights

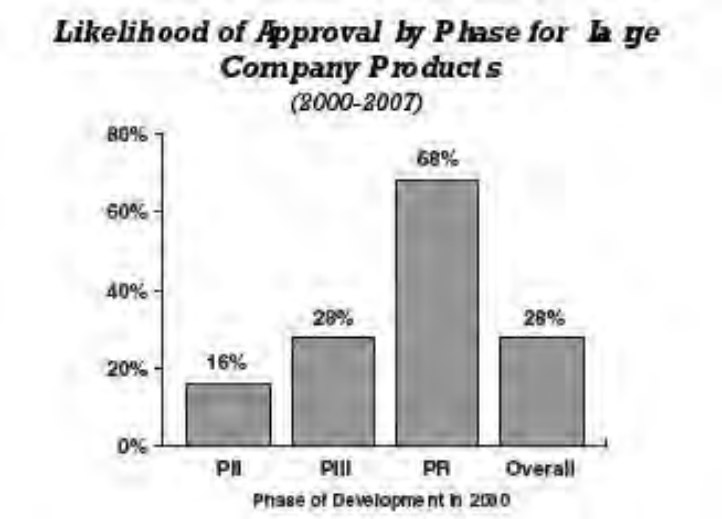
Business Insights Ltd

…And Late Stage Failures Remain High And VERY Costly



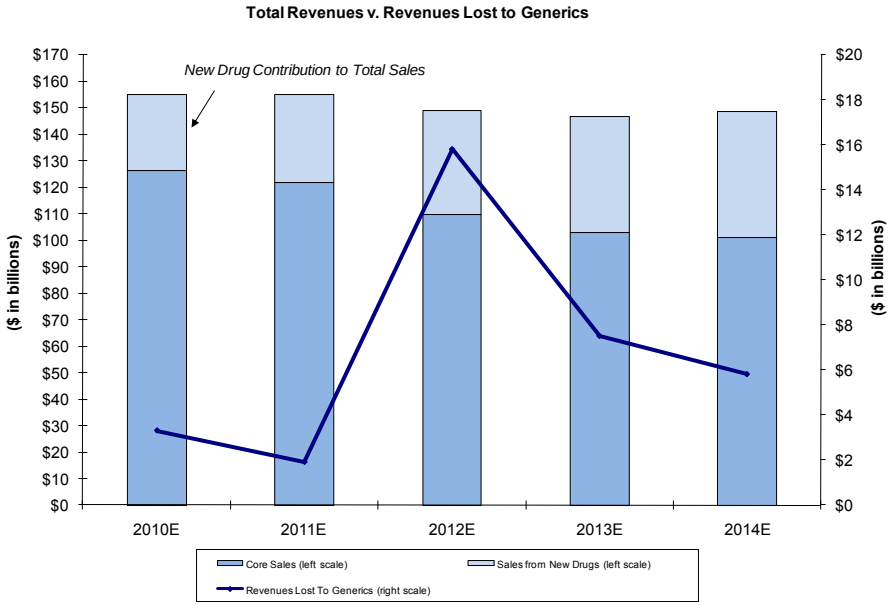






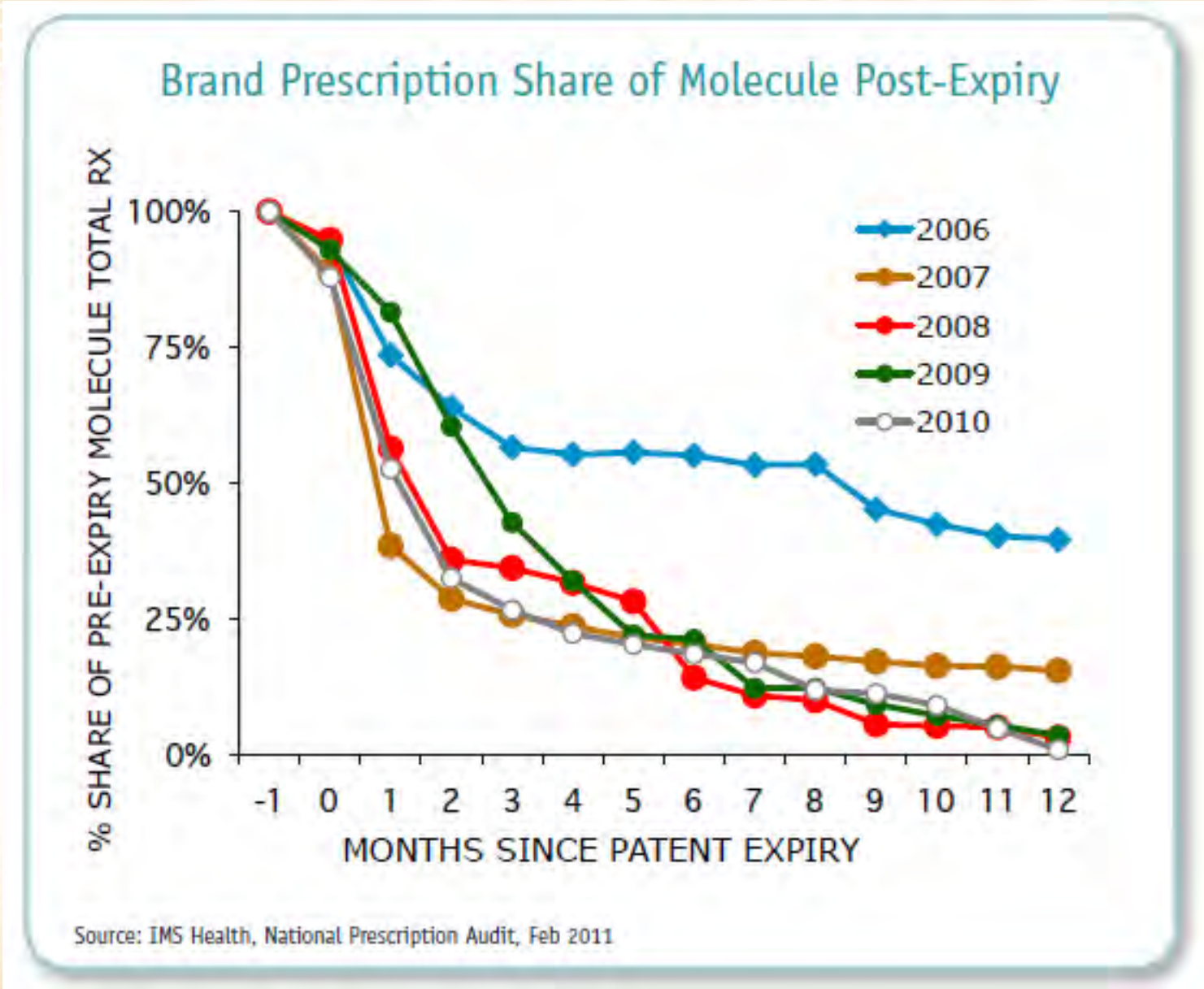
Source: B. Ryan Sept. 2010

Generic Losses Rise Dramatically in 2011-2013, Which New Drug Sales Will Fail To Offset …



… and Generic's Share of the U.S. Rx Market Continues To Climb…

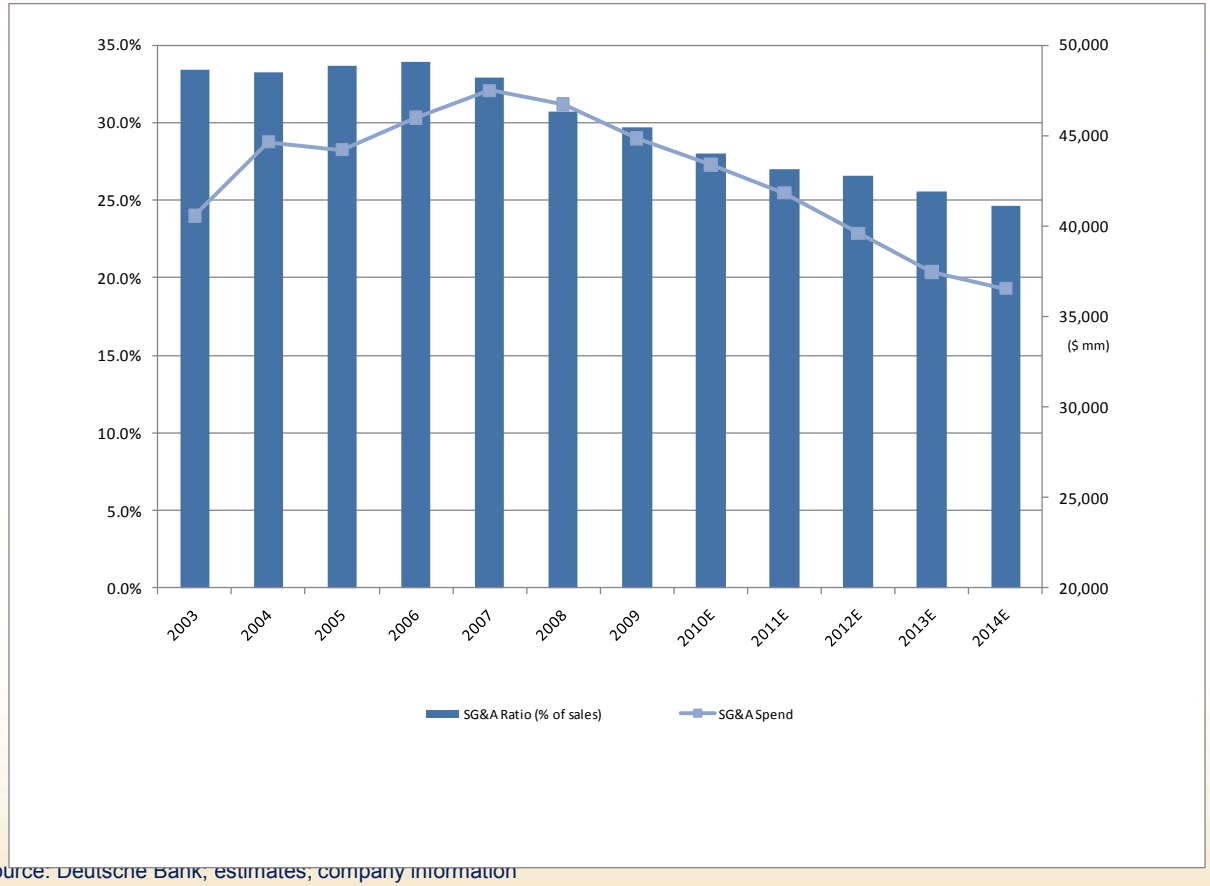
Source: Deutsche Bank B. Ryan Sept. 2010



Recent Pharma Mergers and Acquisitions

Acquirer	Target	Value ($Million)	Year
Abbott	Solvay	6,200	2009
Pfizer	Wyeth	68,000	2009
Roche	Genentech	46,800 (remaining 48% shares)	2009
Merck & Co.	Schering-Plough	41,000	2009
Novartis	Alcon	28,300	2008-2009

SG&A Cuts Are Underway, But Accelerated Cost Cutting (via consolidation) is continuing ...Enter PFE/WYE and MRK/SGP



Source: Deutsche Bank, estimates, company information

Processes have been evolving…

- From mortar and pestle to highly complex bioreactors.
- From manually intensive aseptic processes to highly automated equipment with advanced environmental controls.
- From test tubes to Raman spectroscopy.
- From Pen and Paper to Gigabytes of electronic data.

The Pharmaceutical Supply Chain has become more complex

- Globalization of Supply Chain
- More off-shore sourcing and distribution
- Increased percentage of “cold chain” products
- Increase in diversion, counterfeiting and “economically motivated adulteration”

Our concept of quality has changed…

- From test and release to Quality Assurance to Quality by Design.
- From „craftmanship" to validated processes.
- From R&D / Manufacturing/ Quality silos to Quality System Approach that reaches from beginning of new products throughout the lifecycle.

“Ready to Use” packaging

- Closures / glass-plastic containers
- Cleaned/ready to sterilize
- Sterilized/ready to use
- GMP extension to upstream suppliers

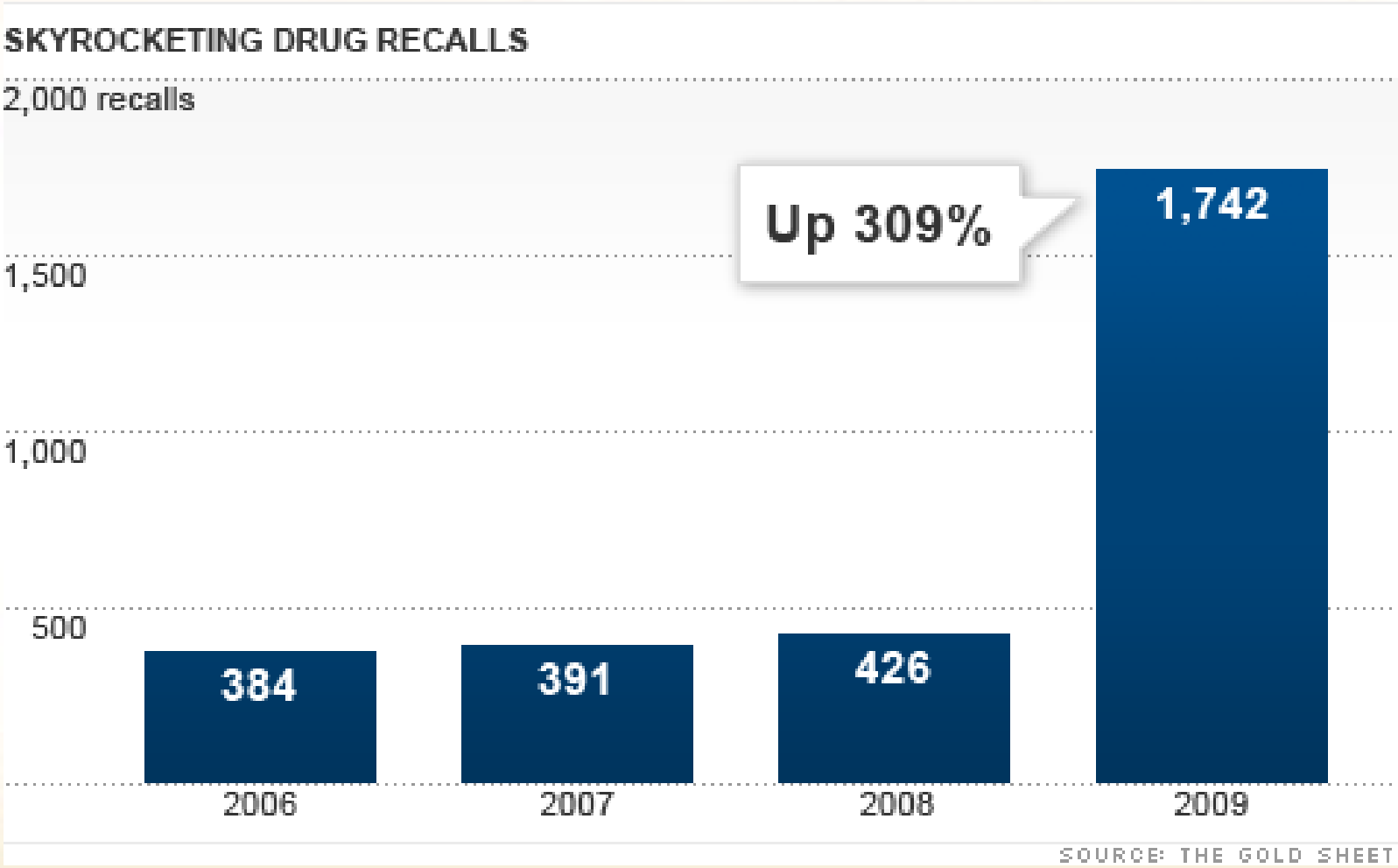
Our regulatory framework has also changed…

- 30 years ago:
  - Highly fragmented, lack of consistency,
- 20 years ago:
  - Beginnings of EU integration and international harmonization.
- Today
  - Advances in International Harmonization
- Tomorrow
  - Greater cooperation and exchange of information among global regulators

Regulatory Trends

- Enforcement pressure is increasing
  - During the fiscal year 2010 (FY 10= Oct. 2009 until Sept. 2010), 41 Warning Letters were issued, which is 60% more than during FY 09 (only 27 issued Warning Letters).

Recalls



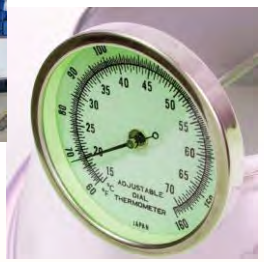
Corporate accountability across the supply chain

from Deb Autor, Esq.
Director, Office of Compliance, Center for Drug Evaluation and Research
at 2010 PDA/FDA meeting

- *FDA will hold corporate executives accountable.*
- *FDA expects firms to notify the agency when a significant problem arises that will adversely impact public health.*
- *FDA expects clear open communication from corporate officials.*

Challenges for the Pharmaceutical Industry in the 21st Century

- Globalization
- Rationalization
- Integration
- Cost Reduction
- Supply Chain Integrity



All add up to increased ***Complexity***

Globalization

- Rationalization of Manufacturing capacity is occurring at the same time that global demand for pharmaceuticals is rising.
- Growth rate is most noticeable in “pharmerging” markets
  - China, Brazil, Mexico, South Korea, India Turkey and Russia (16% CAGR 2003-07) vs. US/EU/Japan (5.6% CAGR 2003-07)
- Cost pressures are driving more manufacturing to “pharmerging” countries

Rationalization

- Pharma manufacturing has over-capacity
- Reduction of facilities is ongoing
- Impact is greatest in US and Europe
- Product rationalization is ongoing at major pharma

Integration

- Integrating merger partners
- Integrating CROs and CMOs
- Integrating Suppliers
  - APIs
  - Excipients
  - Packaging Components
  - Key Manufacturing materials

Cost Reduction

- Decline in top-line revenue adds pressure on Pharma companies to reduce expenses to maintain bottom line revenue
  - Rationalization of overcapacity
  - Pricing pressure on materials and Cost of Goods
- Government pricing pressure is increasing worldwide

Supply Chain Integrity

- Enhancing Supplier Quality Management
  - supplier selection and qualification processes,
  - on-going monitoring and management.

- Increasing Supply Chain Controls for
  - incoming materials and components,
  - supply route security and verification,
  - verification of incoming components and materials and
  - authentication of supporting documentation.

Supply Chain Integrity

- Improving Analysis and Testing Strategies and Technologies to improve the detection of adulterants
- Monitoring and Responding to Signals in the Marketplace and assessing the risk of the market/environment, including:
  - economically motivated adulteration risks,
  - as well as alert, response and communication at local and global level.

Closing Thoughts

Finally…

- The challenges that we as an industry face are many.
- PDA as an Association faces these challenges beside you.
- With your support and participation, we will continue *Connecting People, Science and Regulation.*

Finally…

- We invite you to become an active PDA member; participate in Chapter, Task Forces and committees.
- Please go to www.PDA.org to see a full list of our upcoming Global activities and events.
- Feel free to contact us if you have any questions or suggestions.

Volunteer Opportunities at PDA

volunteer@pda.org

Leadership

- PDA Executive Officers
- Director
- Scientific Advisory Board
- Biotechnology Advisory Board
- Regulatory Affairs and Quality Advisory Board
- PDA Committee Chair/Co-Chair
- Task Force Co-Chair

- Author/Contributor to the *PDA Letter*
- Author/Contributor to the *PDA Journal*
- Poster Presenter
- Attend Chapter Committee/Planning Meetings
- Technical Report Peer Reviewer

- Speaker
- Chapter Leader
- Task Force Member
- TRI Instructor
- Interest Group Leader

PDA Committees:

- Program Planning Committee
- Membership Committee
- PDA Letter Committee
- Education Committee
- Audit Committee

- PDA Membership
- Attend Global PDA Meetings
- Attend Chapter Events
- Survey Reviewer
- Interest Group Member
- Attend TRI Courses

Getting Involved

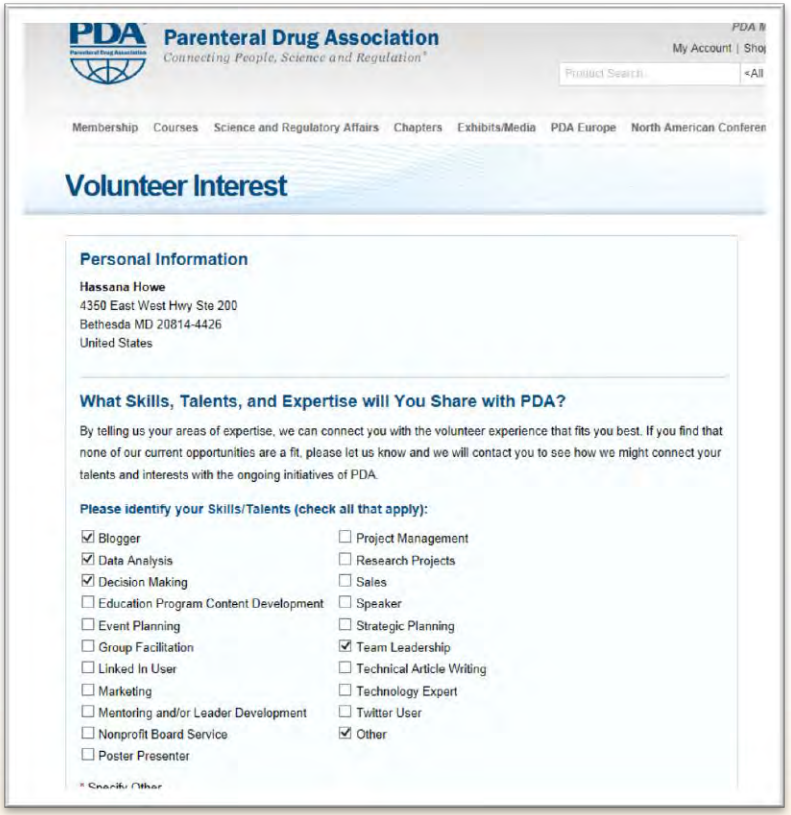
1,000

Over 1,000 volunteers worldwide actively carry out PDA's Mission

Want to get involved?

Now Available – fill out our online volunteer interest profile to get involved today!

www.pda.org/volunteer



PDA Contact Info:

PDA USA Member Relations:
4350 East West Hwy. Suite 200, Bethesda, MD USA
info@pda.org or 301-656-5900

PDA Europe Member Relations:
Adalbertstr. 9, 16548 Glienicke/ Berlin, Germany
Tel: +49 33056 2377-0 or -10 or Fax: +49 33056 2377-77 or -15
info-europe@pda.org

Speaker's Contact Information:
Richard M. Johnson, President, PDA
Johnson@pda.org