

Compliance as a Strategic Function

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Goals - Background

- Compliance leaders need expertise in three areas:
 - Compliance expertise which incorporates skills such as risk management, policy development, regulatory knowledge, investigation and monitoring/auditing.
 - Compliance leaders have strong competencies in this area.
 - Leadership expertise with skills associated with leading and motivating compliance teams.
 - Compliance leaders are beginning to develop deep expertise in this area.
 - Strategic expertise and skills required to give flight to the business and elevate the role of the compliance function within pharmaceutical firms.
 - Focus of the Session.



Goals

- Understand pharmaceutical global market trends and the role of multinational, regional and domestic firms in multiple markets.
- Understand how compliance leaders can provide a strategic advantage to firms through innovations in compliance strategies that enhance business (within the tenets of an ethical policy)?
- Understand how compliance leaders can recognize the emerging changes in the environment and be the first-to-market with innovative compliance strategies?
- Understand how multinational firms compete when their compliance policies do not match the policies of local competitors?
 - How can compliance leaders better understand their customers and develop innovative non-duplicatable compliance strategies such as brand leveraging to help their firms grow rapidly in developing markets?



Presentation Layout

- The Pharmaceutical Industry.
 - Emerging Markets.
- Data from Compliance Surveys.
- Compliance Issues.
- Addressing Compliance Needs in Emerging markets.

Trends in the Pharmaceutical Industry

- Slowdown in Growth in Developed Markets, Increased Growth in Emerging Markets.
- Traditional Focus on Sales, Commercial, Physician, Medical Professionals and Pharmacists.
 - Channels, Alliances and Institutions.
- From Internal Sourcing to External Sourcing.
 - Collaboration
 - R&D, Manufacturing, Distribution.
 - Outsourcing internal functions.
- Risk increases exponentially with partners/outsourcing firms.
 - Increase knowledge of risk management.



Our Study of Industry and Trends

- In 2013 more firms are missing their emerging market growth targets when compared to the last decade.
- Concerns about the effectiveness of current market strategies have increased.
- The Pharma business has nineteen Big Pharma firms and over 200 smaller firms.
 - As long as reimbursements were high (gross margin for this industry was over 80%), there was little need for industry consolidation.
 - The industry is under attack from the bottom (generic drugs) and the top (too many similar medicines).
 - Emerging Market Firms are Growing.



Western Pharmaceutical Firms and Emerging Markets

- Emerging markets are facing increased price pressures due to reduction in pricing power, regulatory intervention, and lower priced “good enough” products.
 - “Advanced market” strategy has worked well for the high end markets; emerging market mass markets will require a complete rethink.
 - Emerging market competitors will always have cost structures that are lower than Western firms.
 - The asymmetric effects of ethical codes – Western firms have them and Emerging market competitors do not.
 - So how do Western firms battle with our emerging market competitors?



R&D Issues

- R&D as a Growth Engine has become less reliable.
 - R&D Expenses went from \$20B in 1999 to \$70B in 2010.
 - Reduced Efficiency.
 - Pfizer had 5,000 researchers and 2.7 million square feet of space in Connecticut and only one major drug was released – Chantix.
 - Big R&D Departments Did Not Increase Innovation.
 - Bureaucracies emerged – small scientist groups were best at creating new drugs.
 - Ideal size 20-40 scientists.
 - Blockbuster Drug (everybody can use) Opportunities are Fewer.
 - Smaller diseases are the focus (e.g., Alzheimer's).
 - FDA Trials are taking longer and are more contentious.



Industry Trends

- Major Shifts in Developed Markets.
 - Reduction in Pricing in Developed Countries.
- Generics have Grown in All markets.
- Emerging Markets Pharma business is growing by about \$30 Billion a year.
 - Growth in emerging markets will be about \$200 Billion from 2013-2020.



Developed Economies

	2008	2009	2010	2011	2012	2013	2014
World output	3	-0.7	5.2	4	3.2	3.3	4
Advanced economies	0.5	-3.7	3.2	1.6	1.2	1.2	2.2
United States	0.4	-3.5	3.0	1.8	2.2	1.9	3
Euro area	0.6	-4.3	1.9	1.4	-0.6	-0.3	1.1
Germany	1.2	-5.1	3.6	3.1	0.9	0.6	1.5
France	0.3	-2.6	1.4	1.7	0	-0.1	0.9
Italy	-1	-5.2	1.5	0.4	-2.4	-1.5	0.5
Spain	0.9	-3.7	-0.1	0.4	-1.4	-1.6	0.7
Japan	-1.2	-6.3	4.4	-0.6	2	1.6	1.4
United Kingdom	0.5	-4.9	2.1	0.9	0.2	0.7	1.5
Canada	0.4	-2.8	3.2	2.6	1.8	1.5	2.4
Other advanced economies	1.7	-1.1	5.8	3.3	1.8	2.5	3.4

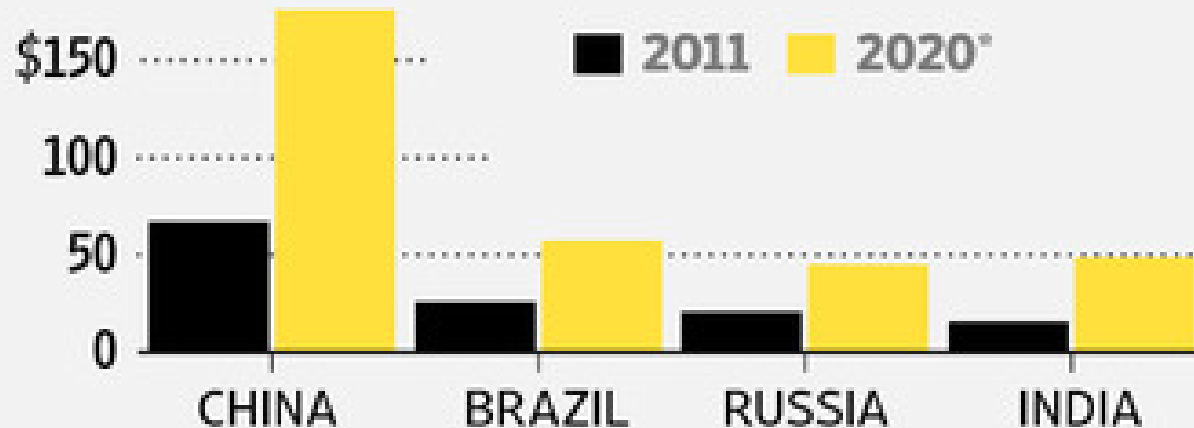
Developing Economies Growth Rates

Area	2008	2009	2010	2011	2012	2013	2014
World output	3	-0.7	5.2	4	3.2	3.3	4
Advanced economies	0.5	-3.7	3.2	1.6	1.2	1.2	2.2
Emerging and developing economies	6.1	2.8	6.4	5.1	5.3	5.7	6.4
Central and eastern Europe	3.1	-3.6	5.2	1.6	2.2	2.8	5.2
Commonwealth of Independent States	5.5	-6.4	4.8	3.4	3.4	4.0	4.8
Russia	5.6	-7.8	4.3	3.4	3.4	3.8	4.3
China	9.6	9.2	9.3	7.8	8.0	8.2	9.3
India	7.3	6.8	7.7	4.0	5.7	6.2	7.7
Indonesia, Philippines, Malaysia, Thailand and Vietnam	4.7	1.7	4.5	6.1	5.9	5.5	4.5
Middle East and North America	5.3	2.6	3.9	4.7	3.1	3.7	3.9
Latin America and the Caribbean	4.3	-1.8	4.6	3.0	3.4	3.9	4.6
Brazil	5.1	-0.6	2.7	0.9	3.0	4.0	2.7
Mexico	1.3	-6.1	3.9	3.9	3.4	3.4	3.9

Emerging Markets

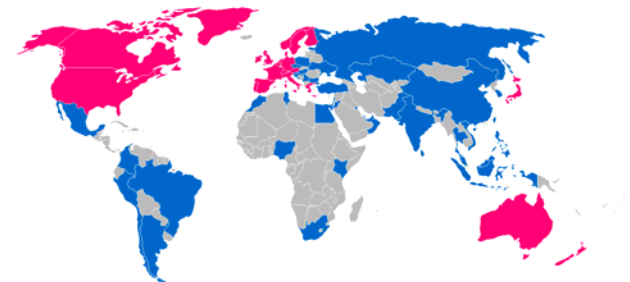
DEMAND FOR DRUGS

SALES BY SELECTED COUNTRIES, IN BILLIONS



How Did Western Firms Compete in Emerging Markets?

- Followed Advanced Country Model.
 - Attempted to Enforce Patent Laws.
 - Multinationals Buy Local Firms.
 - Sanofi-Aventis buys Medley (Brazil).
 - Pfizer buys 40% of Teuto (Brazil).
 - Daiichi Sankyo buys Ranbaxy Labs (India).
 - Abbott Buys Piramal in India.
 - Multinationals Use Local Firms as R&D partners.
 - Lilly uses Jubilant and Piramal (India) for faster R&D.
- Problems of Growth – Market Mismatch.
 - Different markets different needs.



Patent Cliff Issues: BMS

- Bristol-Myers-Squibb sold off its baby formula, ultrasound machines and surgical bandages businesses.
- The company has a third fewer employees, and half as many manufacturing plants as it did in 2006.
- Midsize Player Looking for Big Deal (e.g., Biogen Idec, Shire, Gilead Sciences).

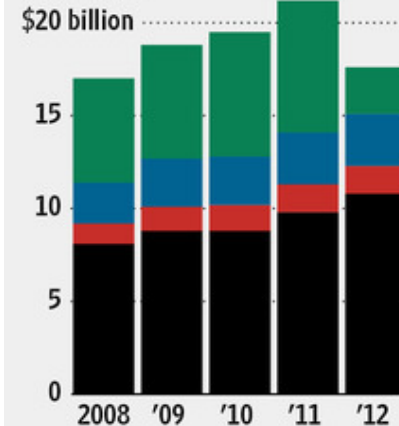
Bristol's Patent Cliff

Some top-selling Bristol drugs are losing patent protection.

Drug	Use	U.S. loss of exclusivity
Plavix	Bloodthinner	(2012)
Abilify	Antipsychotic	(2015)*
Sustiva franchise	HIV agent	(2013)†

■ Others

REVENUE



*Rights to commercialize in U.S. end in 2015

†Patent expiry is for Sustiva, but not for combination treatments

Source: Bristol-Myers Squibb
The Wall Street Journal

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MARKET STRATEGY ASSOCIATES, INC.

Source: "Bristol-Myers Stalks Deals To Bolster Its Drug Lineup", Wall Street Journal, March 4, 2013; <http://online.wsj.com/article/SB10001424127887323293704578332191493675744.html>

New Shifts -- Abbott

- Abbott Has Split into Two Firms:
 - Abbott has created a company focused on diversified medical products consisting of medical devices, established generic pharmaceuticals, diagnostic and nutritional businesses. This company, has retained the Abbott name, has sales of approximately \$22 billion and is led by Abbott CEO Miles White.



- The second company Abbvie, with current sales of around \$18 billion, has taken over Abbott's research-based drug business and a pipeline focused on specialty markets such as multiple sclerosis, immunology and hepatitis C. The research company's drug roster includes Abbott's biologic, or biotech drugs, including the rheumatoid arthritis blockbuster Humira.

abbvie

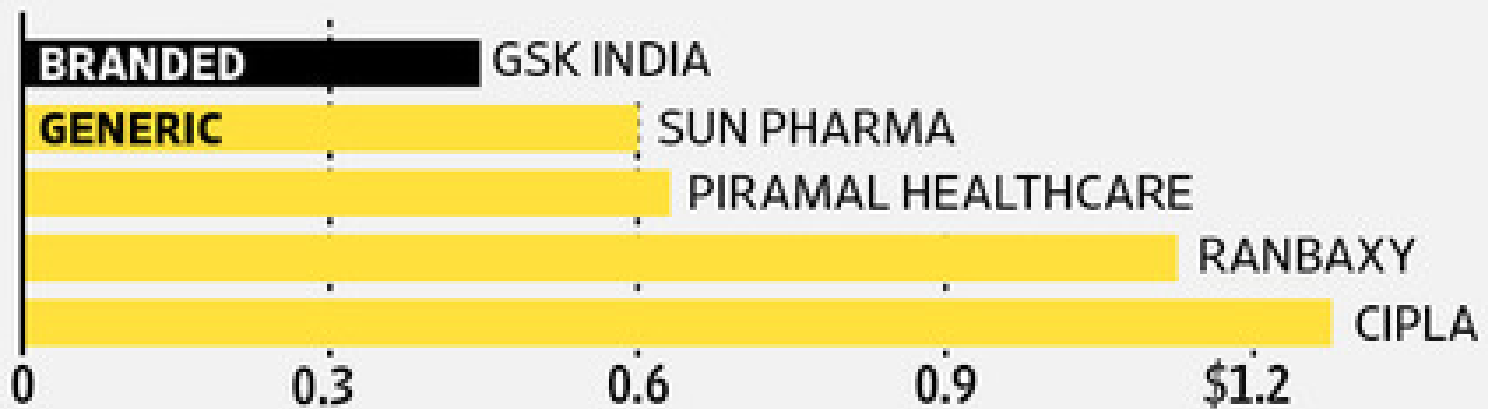
Generic Market

- Will Drive the Pharmaceutical Market.
- Will Grow from \$120 Billion in 2012 to \$180 Billion in 2018.
 - 90% of the growth will come from Emerging Markets.
 - From 37% of market share, developed countries will drop to 30% of world market share.



Results --Local Generic Firms Dominate Emerging Markets (India)

REVENUE OF INDIA'S FIVE BIGGEST DRUG MAKERS FOR THE 12 MONTHS ENDING JULY 2010, IN BILLIONS

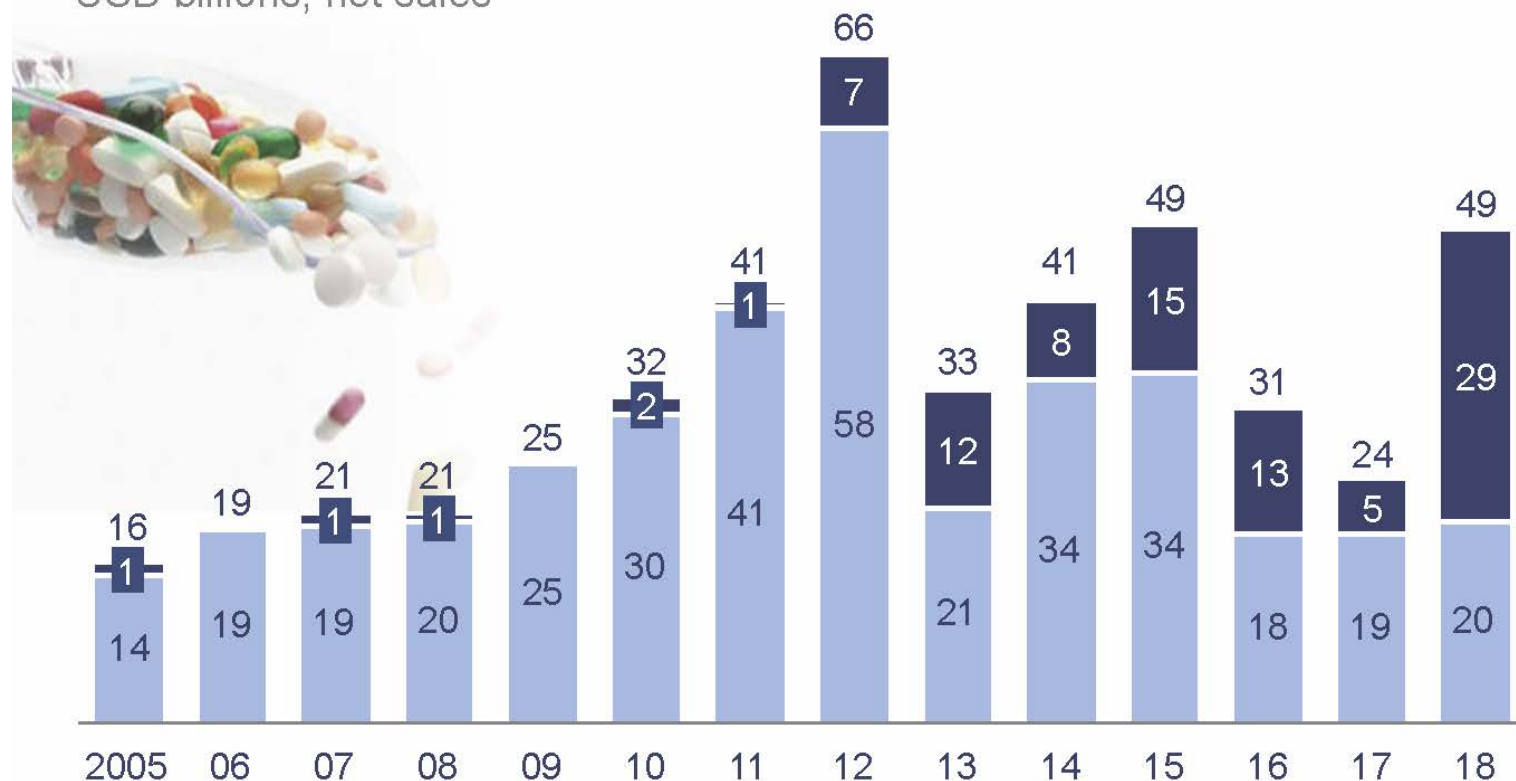


Rise of Biologics – The New Battleground

Worldwide sales of all products losing U.S. patent protection
in the year before patent expiry

USD billions, net sales

■ Biologics
■ Small molecule

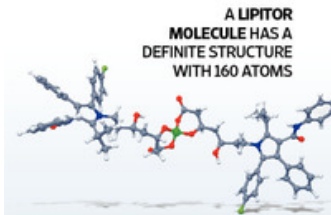


What Are Biosimilars?

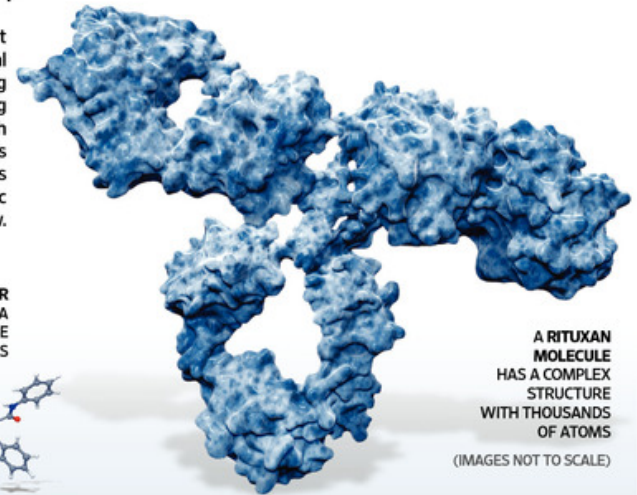


No Ordinary Generic

Chemists can make exact generic copies of conventional pills. But, scientists making 'biosimilar' drugs are copying much more complex biotech drugs. A Rituxan molecule is about 120 times larger—in terms of molar mass—than the basic chemical unit of Lipitor, below.



The Challenge of Copying Biotech Drugs



LIPITOR (ATORVASTATIN)

High cholesterol

A handful of atoms, mostly carbon and hydrogen, combined in specific, replicable formula

LESS THAN **\$10 MILLION**

Chemicals are mixed at subzero temperatures

CHEMICAL VS. BIOTECH

INDICATIONS

INGREDIENTS

COST TO COPY

HOW IT'S MADE

RITUXAN (RITUXIMAB)

Cancer, arthritis

Hundreds of amino acids bound together in a complex structure that scientists can't fully document

\$100M-\$300M

Living cells with altered DNA produce the injectable drug

A BIOSIMILAR RECIPE



1 Scientists copy key DNA sequences used to make branded drugs



2 The strands are inserted into living cells



3 The cells replicate and secrete antibodies in a bioreactor



4 Antibodies to use in treatments are filtered out

Sources: FDA; National Comprehensive Cancer Network; WSJ reporting

Images: Drug Bank (Lipitor); Genentech
Graphic by Alberto Cervantes/The Wall Street Journal

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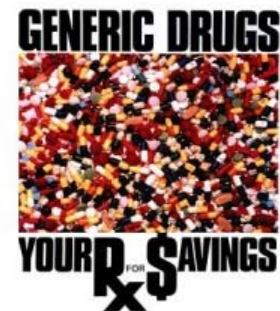
Why Are They Important?

- Sales of Biologics.
 - Expected to be \$175 Billion in 2013.
 - About one-third will lose their patent protection in the next five years.
 - In Brazil, 3% of the drugs are biologics but they account for 40% of the budget.
- Premium
 - Small molecules drop to 10% of patented prices.
 - Biosimilars drop to 73% of patented prices currently and maximum expected is 50%.
- Time to Market
 - Small molecules: 1-2 years.
 - Biosimilars: 7-8 years



The Current Situation in Emerging Countries

- Local Branded Generic Manufacturers Dominate Most Markets.
 - Global Pharma have become specialists/niche players.
- The Battle of Generics has been won by locals.
- Global Pharma wants to Attack Biosimilars.
 - Generic Versions of Biologics.
- Big Pharma have Money and Expertise to Develop Biosimilars that Local Generic Manufacturers do (may) not have.
 - Firms will need to Provide Clinical Trial data.



Five Critical Questions for Emerging Markets

- Where Will We Play?
 - High-margin, low-volume market or low margin – high volume?
- How Will We Play?
 - Same Strategies, Different Strategies
- Who Will We Play With?
 - Own Firm, Third Party
- What Will be Critical to Success?
 - Distribution, Branding
- How Will We Know That We Won?



Exercise

- How do you think that your particular market will evolve?
 - 15 minute work, followed by discussions.

COMPLIANCE STRATEGY

Our Research Objectives

- How to Enhance the Efficiency and Effectiveness of the Compliance Organization and Function in Emerging Markets.
- Conducted interviews with:
 - External Stakeholders – Medical Professionals, Associations, Hospital Executives, Insurance Firm and Governments Ministry Heads.
 - Internal Stakeholders -- Western Firms executives



External Stakeholders Results -- Pharmaceutical Industry Trends Emerging Markets

- High Price Sensitivity
 - But also Brand and Relationship Sensitive.
- Competition
 - Local Firms Will Dominate (5,000 firms in Emerging Markets).
 - Government Relationships, Provider Relationships, Distribution Channel Relationships, Low Prices
 - Big Pharma Will Need Partners (Government, Local Firms).
 - Value Focus will be needed.
 - Innovation Will Not be a Differentiator.
 - Need to Reduce Costs
 - Enhance Brand and Relationships.



External Stakeholders Results -- Evaluation of Western Pharmaceutical Firms -- Best Practices

- Thought Leadership.
- Provide Assistance in Health Management.
 - Disease Prevention and Management.
- Cutting-edge Medicine and Technology.
- Build Clinics.
- Train Doctors and Nurses.
- Free Medicine.
- Develop drugs for critical needs (e.g., malaria).



Internal Stakeholders Results – Compliance Policies

- Western Firms have among the strictest compliance policies – Emerging market firms have varying degree of flexibility.
- Compliance function is concentrated on enforcing policy rather than enhancing business.
- Commercial/marketing feel high constraints from legal and compliance departments.
- Doctors do not choose pharmaceutical products based on ethical considerations, but rather on efficacy and value.
- The emphasis on value (versus efficacy) is increasing.

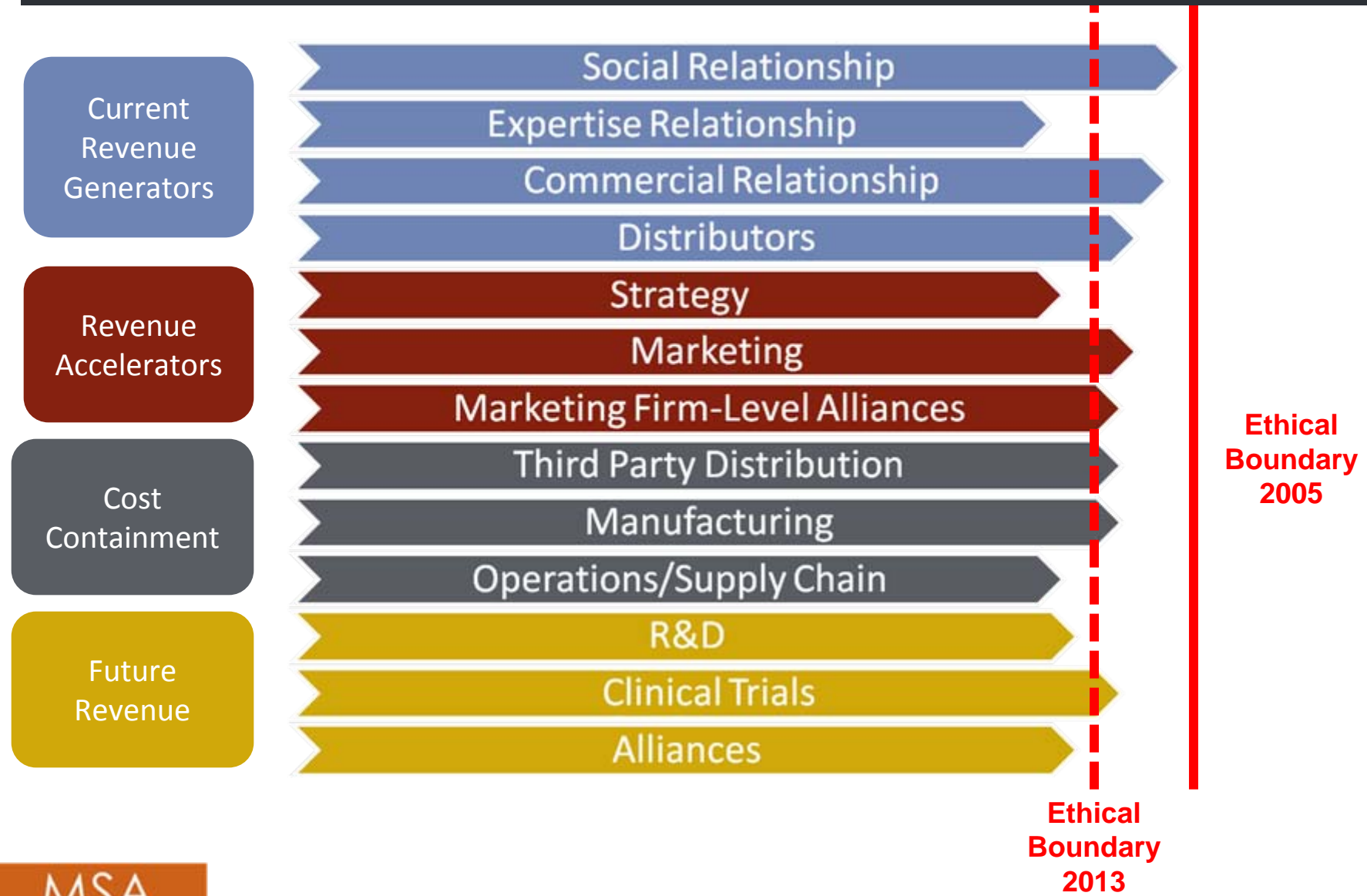


Some Results from Our Surveys

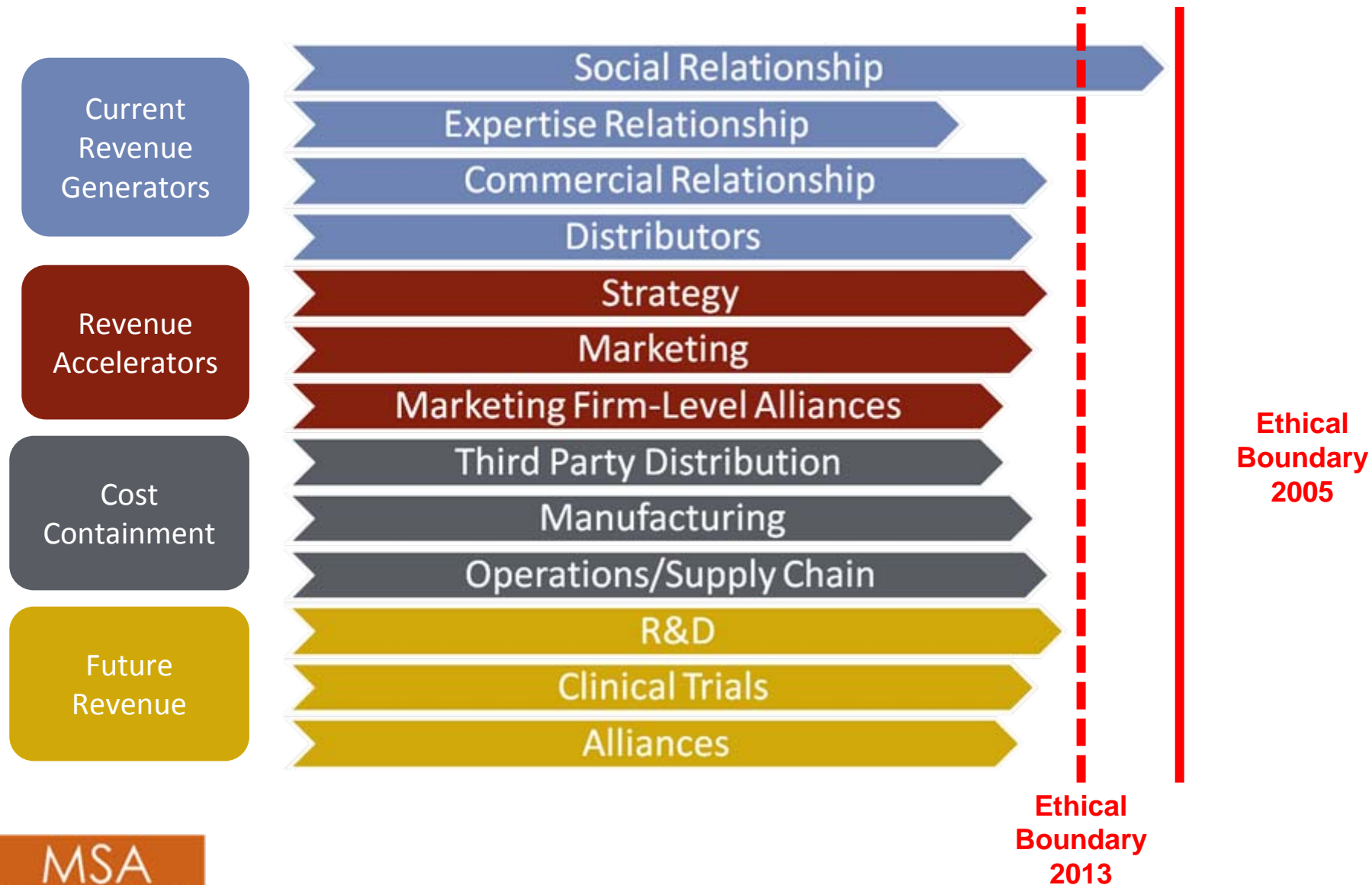
- “No” is always a Less Risky Options “Yes.”
- Not Creative -- Follow the Letter of the Law.
- Role -- Seen by Firm as a hindrance.
- Commercial/Marketing feels that Compliance Rules are too Restrictive and do not Allow them to Practice their Functions well.
- The Compliance Function does not have adequate Understanding of the Business.
- Compliance Policies have Restricted Brand Enhancing Activities.
- Medical Professionals are not Getting the Medical/Scientific Information that they need.



Pharmaceutical Firm Operational Excellence 2005



Pharmaceutical Firm Operations 2013



Exercise

- How would you address the issues raised by internal stakeholders regarding the Compliance Function?
 - 15 minute work, followed by discussions.

Summary

- Fundamental Shifts in Markets
 - Branded versus Generic
 - Advanced Markets versus Developing Markets
 - Best versus “good enough.”
- Compliance Needs to be More Strategic.

Summary

Arun Sharma



Dr. Arun Sharma is Executive Director of the JAE Leadership Institute and Professor in the Marketing Department at the School of Business Administration, University of Miami. Arun has extensive knowledge of firms through his experience in consulting, and conducting seminars. He is a well known expert in Global Market Trends, Leadership Strategies, Sustainable Competitive Strategies, and Market Strategy and his expertise is in designing and implementing corporate strategies. He has consulted and conducted seminars for companies such as Accenture, Agilent Technologies, Ambrosetti, American Express, AT&T, Bell South, Citrix, Ericsson, Exxon, Goodyear, HP, IBM, Lucent, Macy's, MasterCard, Motorola, Siemens, Sprint, Telecom Italia, Telecom Italia Mobil, Visa International, Wal-Mart and Western Union. He has extensive expertise in business and consumer markets, technology, financial, telecommunication, healthcare, consumer goods and consulting industries.

He has previously taught at the University of Illinois at Urbana-Champaign where he received his Ph.D. in marketing in 1988. Arun also has an MBA and a Bachelor of Engineering degree in Metallurgy. Prior to joining the academic world, he worked for three years in a high-technology firm where he handled product management and sales management responsibilities.

Arun has published extensively (over 80 refereed articles) and is on the review board of major journals and has received many excellence in research and excellence in teaching awards from the School of Business Administration at the University of Miami. He can be contacted at 305.284.1770, Fax: 305.667.2557 and email: asharma@bus.miami.edu.