



Mediscor PBM

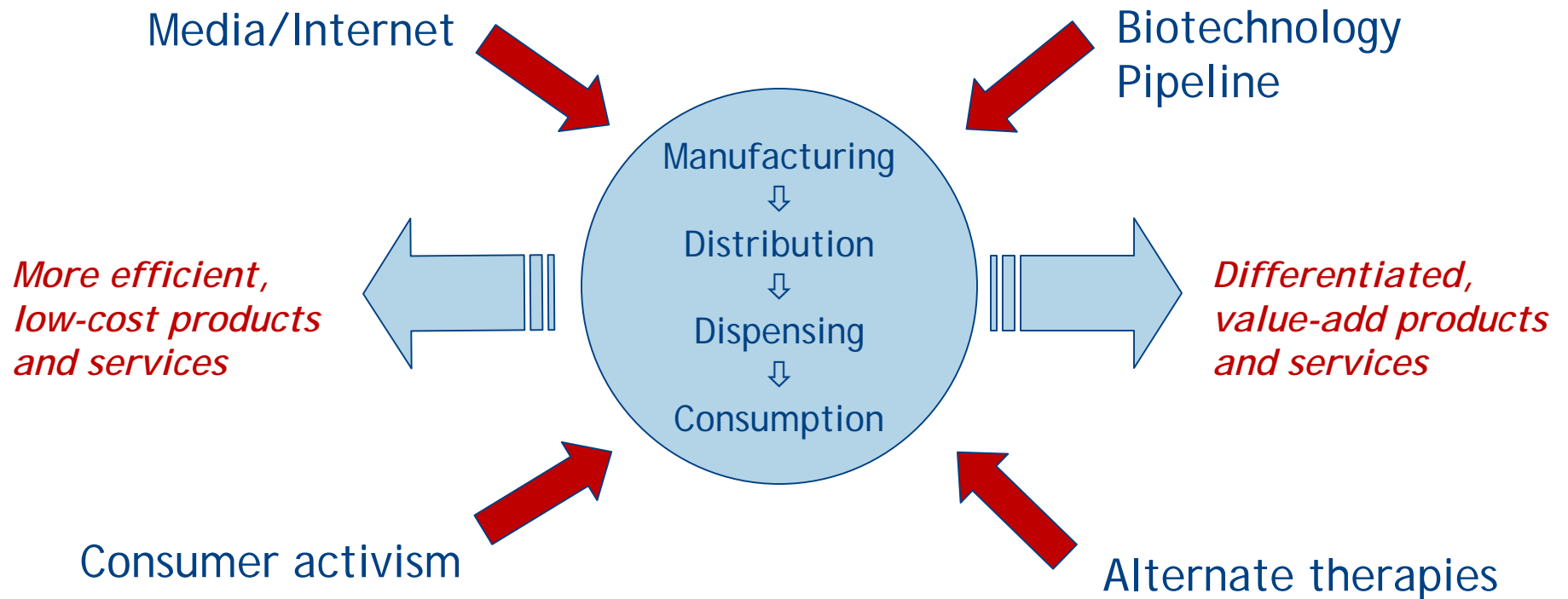
Managing the Drug Pipeline

▶ A quick environmental scan

Shows four dominant forces at play:

- Access to information explosion
- Rising use of alternative therapy
- Rising consumer activism
- Biotechnology 'Tsunami'

▶ The forces at play



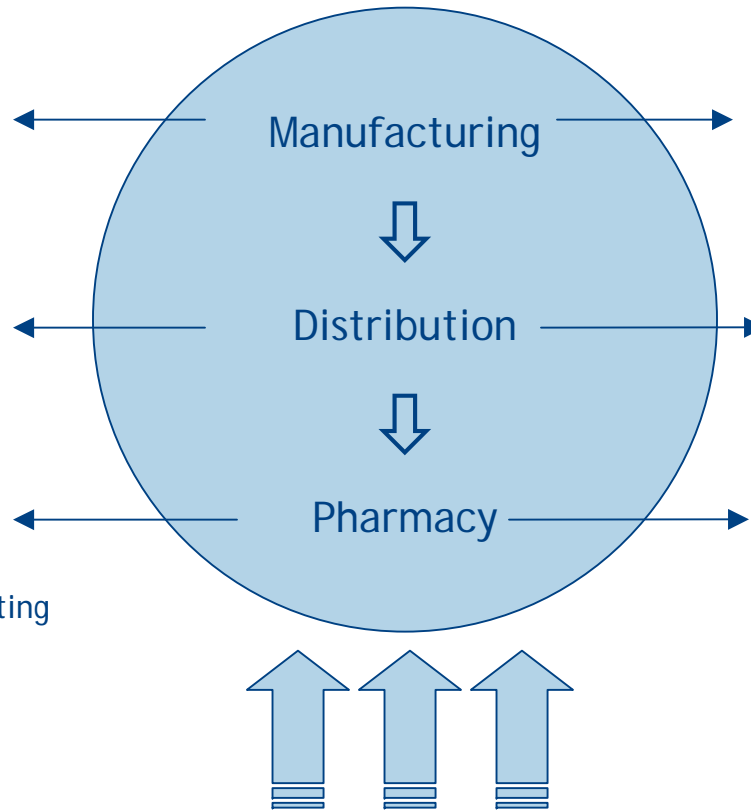
▶ The response

More efficient, low-cost products and services

Generic products
Contract manufacturing

Integrated electronic catalogs
New labeling and packaging
Use of bar coding
Unit-of-use packaging
Central fill systems

Central adjudication
Integrated ordering systems
Automated dispensing systems
Refill management systems
Electronic prescribing and Rx routing



Differentiated, value-add products and services

Contract research organisations
R&D: Biotech and pharmacogenomics
R&D: Diagnostics and drug delivery

Third-party logistics
Product tracking
Compliance packaging
Specialty distribution services
Reimbursement consulting

Patient registries
Medication management and therapeutic care services
Monitoring/testing services

Economic pressure/price transparency push

Consumer frustration with access to care
Continued payor frustration with cost of care
Changing consumer expectations and buying patterns
Legislative/regulatory solutions promulgated

▶ Key trends

- Shorter product life cycles
- Bottleneck with registrations
- New retail pharmacy models
- Electronic claims and ordering systems
- Blurring between 'product' and 'service'
- Pharma manufacturer's focus on disease management services

▶ The success of clinical drug trials

- Clinical drug trials are divided into three phases
- Each phase is designed to learn more about the safety and efficacy of the drug
- Typical success rate:
 - About 6% of first time Phase One studies make it to approval
 - About 11% of all Phase One studies make it to approval
 - About 18% of drugs in Phase Two get eventual approval
 - Almost 46% of Phase Three drugs meet with approval
- When checking a pipeline, you need to separate multiple drug candidates from multiple trials of a single drug candidate
- Companies commonly launch multiple trials of one drug, particularly when it's an autoimmune-disorder or cancer drug

▶ What's happening in the drug pipeline?

- Development of biotech compounds is explosive
- Most compounds are focused in the oncology arena
- Most compounds in development will be additive or complimentary to current therapies
- What might some of the consequences be:
 - Breakthrough treatments may provide new hope in the treatment of some diseases
 - Alternative delivery systems may arise from uniqueness of treatments

▶ So what's the issue?

- We are seeing a large number of biotechnology drugs and biologics entering the market each year
- With over 500 biopharmaceuticals in the pipeline if just 10% of these drugs make it through the pipeline there will be 50-80 new drugs entering the market each year
- Each new blockbuster enters at an alarmingly high price

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PRESCRIPTIONS



**"This is one of those new miracle drugs.
If you can afford it, it's a miracle."**

Concerns about off-label creep

- If a medicine is approved for an obscure and uncommon disease, good marketing can deliver sales well in excess of what was anticipated
- Pharma manufacturers often push for registration of a medicine across a wide range of diseases
- Off-label usage can make up a sizable chunk of pharmaceutical company's revenue

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“With this new drug, cholesterol forms outside of the body, where it can’t clog the arteries!”

▶ Most popular R&D disease states

- Asthma
- Autoimmune disorders
- Breast cancer
- Colon/colorectal cancer
- Congestive heart failure
- Crohn's disease
- Diabetes
- Head and neck cancer
- Hepatitis C
- HIV/AIDS
- Leukemia
- Lupus
- Lymphoma
- Mucositis
- Myocardial infarction
- Non-small cell lung cancer
- Organ transplants
- Osteoporosis
- Prostate cancer
- Rheumatoid arthritis
- Sepsis
- Wounds/burns

▶ Hepatitis C

- Interferons - approved
- Thymosin immune stimulator - phase 3
- Immunomodulator - phase 2/3
- Preventive vaccine - phase 2
- Antisense inhibitor - phase 2

▶ Breast Cancer

- Three vaccines - phase 2/3
- Four monoclonal antibodies - phase 2/3
- Antisense inhibitor - phase 2
- Anti-VEGF antibody - phase 2/3

▶ HIV Infection

- Two vaccines in phase 2/3 development
- Fusion inhibitors - phase 2/3
- Interferons - phase 2/3
- Gene therapy - phase 2

▶ Lymphoma

- Seven monoclonal antibodies - phase 2/3
 - Bexxar® (Coulter Pharmaceutical) - awaiting FDA approval
- Vaccine - phase 2

▶ Prostate Cancer

- Four vaccines in development - phase 2/3
- Gene therapy - phase 2/3
- Anti-VEGF antibody - phase 2
- Monoclonal antibody - phase 2

▶ Congestive Heart Failure

- Three endothelin receptor antagonists - phase 2/3
 - (Both injectable and oral dosage forms)
- Tumor necrosis factor - phase 2/3

▶ Therapeutic technologies

- Major research emphasis:
 - Monoclonal antibodies (22 NHL)
 - Antisense compounds (infectious diseases, cardiovascular disease, inflammatory conditions)
 - Endothelin receptor antagonists (cardiovascular disease)
 - Tumor necrosis factor targets (arthritis)
 - Gene therapy (HIV, cancers)
 - Vaccines
 - HIV
 - Breast cancer
 - Non-small cell lung cancer
 - Colon/colorectal cancer
 - Prostate cancer
 - Lymphoma

▶ A few of the biotech candidates

- Oralgen®
 - oral spray formulation of insulin
- IM862 (Cytran Inc.)
 - nasal drops for prostate cancer
- Patient-specific therapies
 - Provenge®, Oncophage®, T-cell Gene therapy
- Several patient administered injectables
 - Forteo®, Tenovil®, Neumega®, Zadaxin®

▶ Impact on distribution

- About 65-70 of these new targets will be a protein-based injectable formulation
 - Places a demand on refrigerator/freezer capacity
 - Product shelf life and inventory management becomes important
 - Patient instruction for administration concerns
 - Availability issues almost assured
- Patient-specific tissue-derived products
 - Express handling
 - Safety/hazardous material concerns
 - Time to delivery an issue

▶ Impact on policy formulation

- Streamlining of the approval process is required
- Need to balance availability, cost and safety
- Key challenge is to better measure the health effects of new technologies and to reimburse in ways commensurate with their added costs and benefits
- Consumer activism and public opinion will be the biggest wildcard

▶ Impact on finances

- New cardiovascular agents: +US\$20 billion
 - Cholesterol reducing agents = US\$7.6 billion
 - Avant Vaccine moves to phase II
- New gastrointestinal agents: +US\$10 billion
- New anti-infectives and respiratory therapies: +US\$8.3 billion each
- Is there room for additional blockbusters?
 - Herceptin® and Rituxan® = US\$400 million
 - Procrit®, Epogen® & Neupogen® = US\$4.6 billion

And if that's not enough...

Ablation Devices			
▼	Biosense Webster NaviStar / Celsius ThermoCool Diagnostic/ Ablation Deflectable Tip Catheters	11/5/2004	Text
▼	HerOption Uterine Cryoblation Therapy System	4/20/2001	Text PDF
▼	Hydro ThermAblator	4/20/2001	Text PDF
▼	IBI Therapy™ Dual 8™ Ablation Catheter and IBI 1500T6 (USA) Generator	11/18/2005	Text
▼	Microwave Endometrial Ablation (MEA) System	9/23/2003	Text
▼	NovaSure™ Impedance Controlled Endometrial Ablation System	9/28/2001	Text
Acoustics			
▼	Orthospec™ Extracorporeal Shock Wave Therapy	4/1/2005	Text
Adhesion Prevention			
▼	Gynecare Intergel Adhesion Prevention Solution	11/16/2001	Text PDF
Alpha-Fetoprotein			
▼	IMMULITE AFP and IMMULTE 2000 AFP	11/9/2001	Text PDF
Analyzer Systems			
▼	Bayer Immuno 1 Complexed Prostate-Specific Antigen (PSA) Assay - P990055	9/8/2000	Text PDF
▼	Roche Elecsys free Prostate-Specific Antigen (fPSA) Assay on the Elecsys 1010 and 2010 immunoassay analyzers	12/12/2000	Text PDF
▼	Roche Elecsys Total Prostate-Specific Antigen (PSA) Assay on the 1010 and 2010 immunoassay analyzers	11/22/2000	Text PDF
Aneurysm Repair Devices			
▼	EXCLUDER™ Bifurcated Endoprosthesis	11/6/2002	Text
▼	Neuroform™ Microdelivery Stent System	9/11/2002	Text
▼	Zenith AAA Endovascular Graft	5/23/2003	Text
Angioplasty			
▼	BeStent™ 2 with Discrete Technology™ Over-The-Wire and Rapid Exchange Coronary Stent Delivery Systems	10/16/2000	Text PDF
▼	Bridge™ Extra Support Over-The-Wire Renal Stent System	12/18/2002	Text
▼	Cordis Checkmate System	11/3/2000	Text PDF
▼	FX miniRAIL™ RX Percutaneous Transluminal Coronary Angioplasty PTCA Catheter	6/11/2003	Text
▼	MULTI-LINK VISION™ RX & OTW Coronary Stent System	7/16/2003	Text
▼	Novoste Beta-Cath System	11/3/2000	Text PDF
▼	PALMAZ® Balloon-Expandable Stent for Renal Arteries	7/10/2002	Text PDF



The first 22 of 780 FDA Medical Device Approvals for 2006

Where will it all end?



“AMGEN: Most advanced pipeline/best biotechnology pipeline”

“Amgen Inc., the world’s largest biotechnology company, possesses one of the most robust biotechnology pipelines in the industry. The company, which has sales approaching \$8 billion, expected to have 24 programs either in human clinical studies or entering human clinical studies in 2004. Overall, the company has about 40 programs in development, including 14 in Phase II or Phase III.

“Our efforts over the last few years have resulted in significant increases in R&D productivity,” says Kevin Sharer, chairman and CEO. “We continue to attract some of the industry’s best and brightest scientists, encouraged by Amgen’s R&D scope, capability, leadership and the commercial potential of our pipeline.”

Amgen’s global R&D organization is focused on five therapeutic areas: inflammation, oncology, metabolic disease and osteoporosis, hematology and nephrology, and neurology. As evidence of its increased R&D productivity, more product candidates have entered into development at Amgen during the past three years than in the previous 10 years combined. In 2003, the company achieved 22 regulatory approvals worldwide and had more than 35,000 enrolled in clinical studies. Pipeline expansion continues, and the company intended to put as many as nine new programs into development in 2004. ..”



▶ For more information on our Drug Pipeline product offering please contact Margot Brews our Business Development Director on +27 12 674-8015