The US Pharmaceutical Market: Trends, Issues and Outlook

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2009 Strategic management presentation

The World pharmaceutical market

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- Operating in more than 100 countries, IMS is the world's leading provider of information solutions to the pharmaceutical and healthcare industries.
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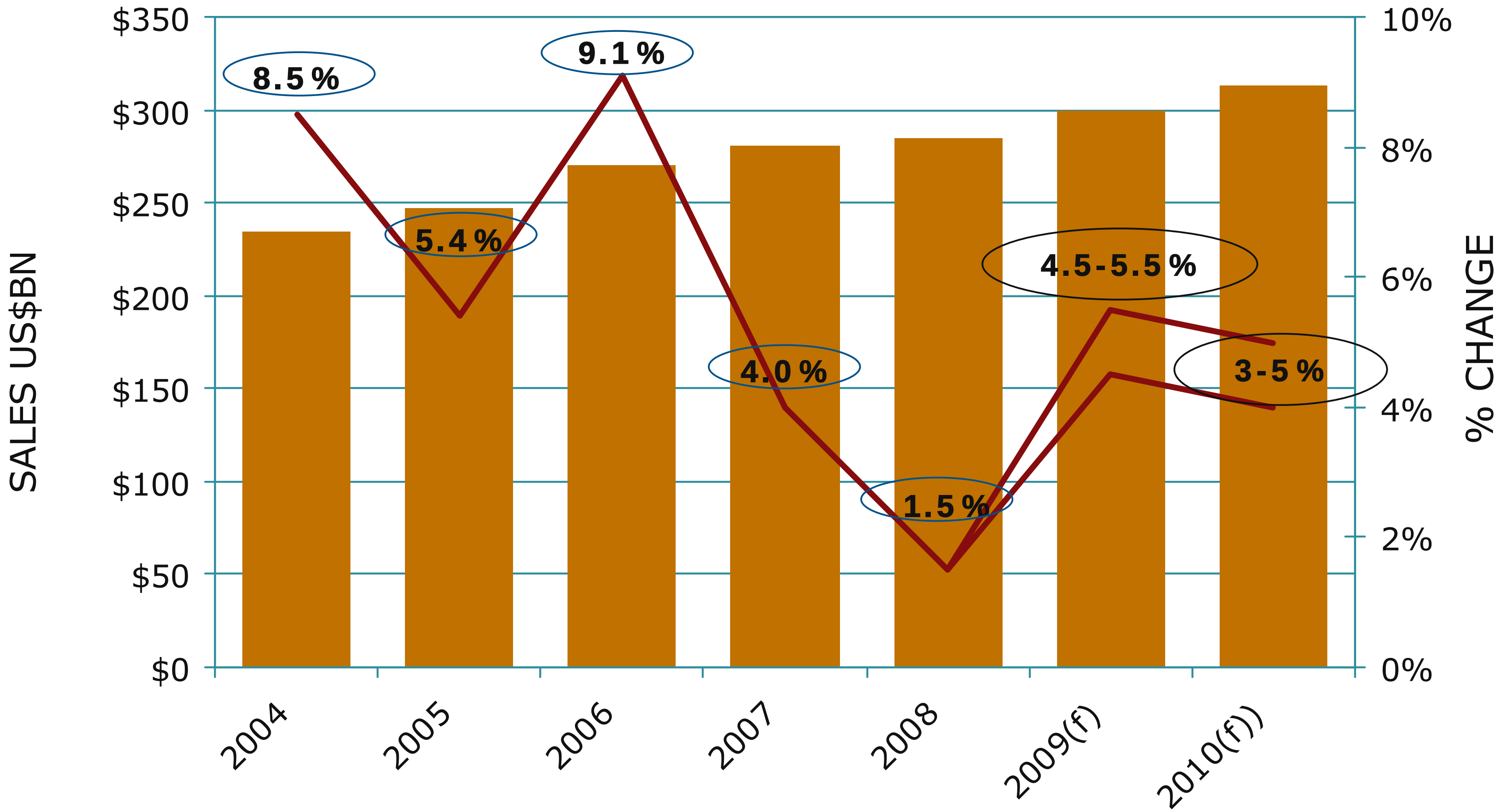
US market growth recovers to 3.6% in MAT September

Source: IMS Health, National Sales Perspectives, Sep 2009

US market sales and growth 2004-2010

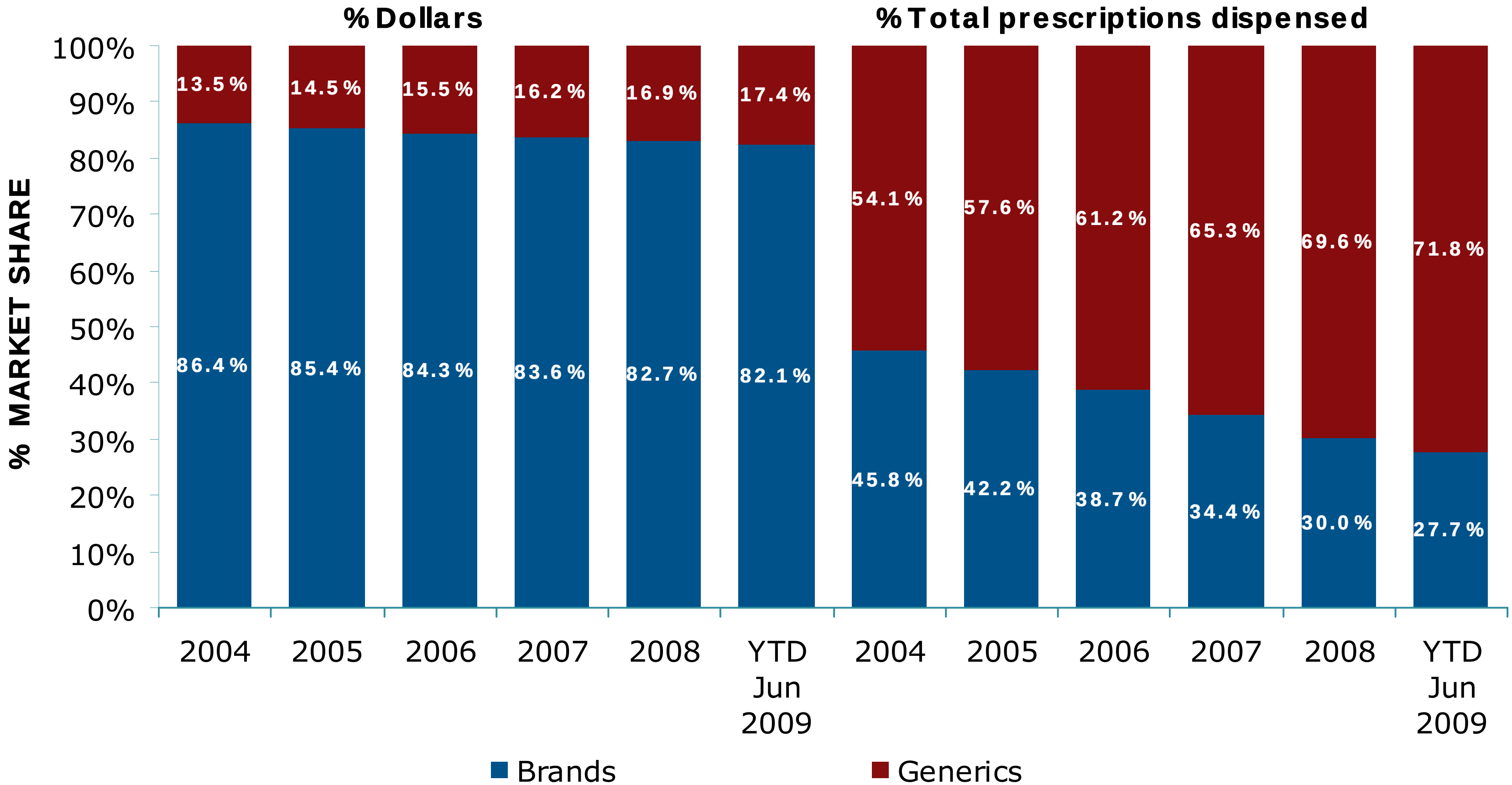


Source: IMS Health, Market Prognosis, Sep 2009

Market Forces

- Generics
- Safety & Regulation
- Innovation Drought
- Rx to OTCs
- Medicare Part D & Medicaid
- Economic Slowdown
- Healthcare Reform

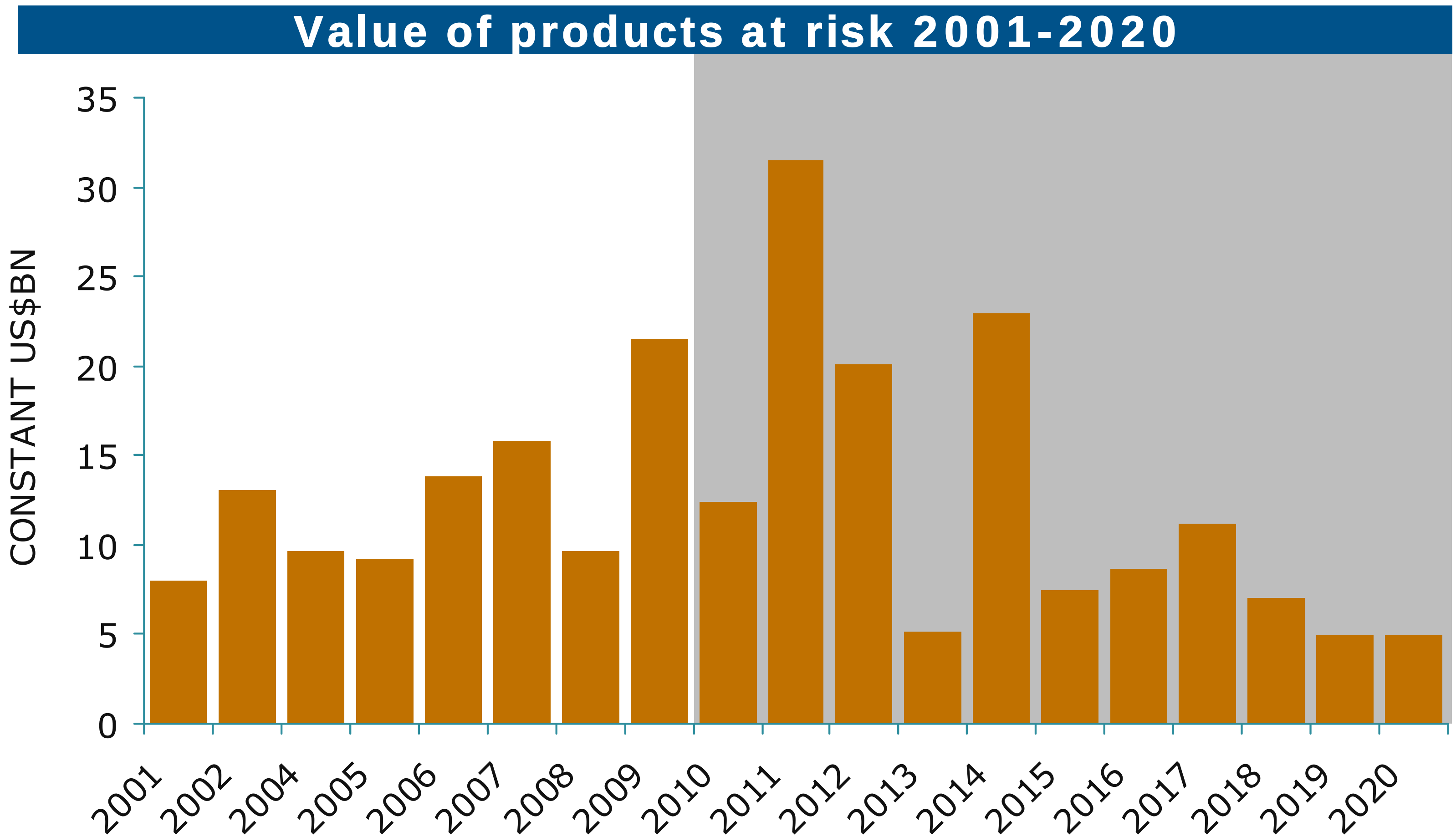
Generics hold more than 70% of scripts but 17% of sales



Source: IMS Health, National Sales Perspectives, Jun 2009, National Prescription Audit, Jun 2009, Branded generics disaggregated

Beyond 2012, exclusivity losses will level off

US sales losing protection 2001-2020



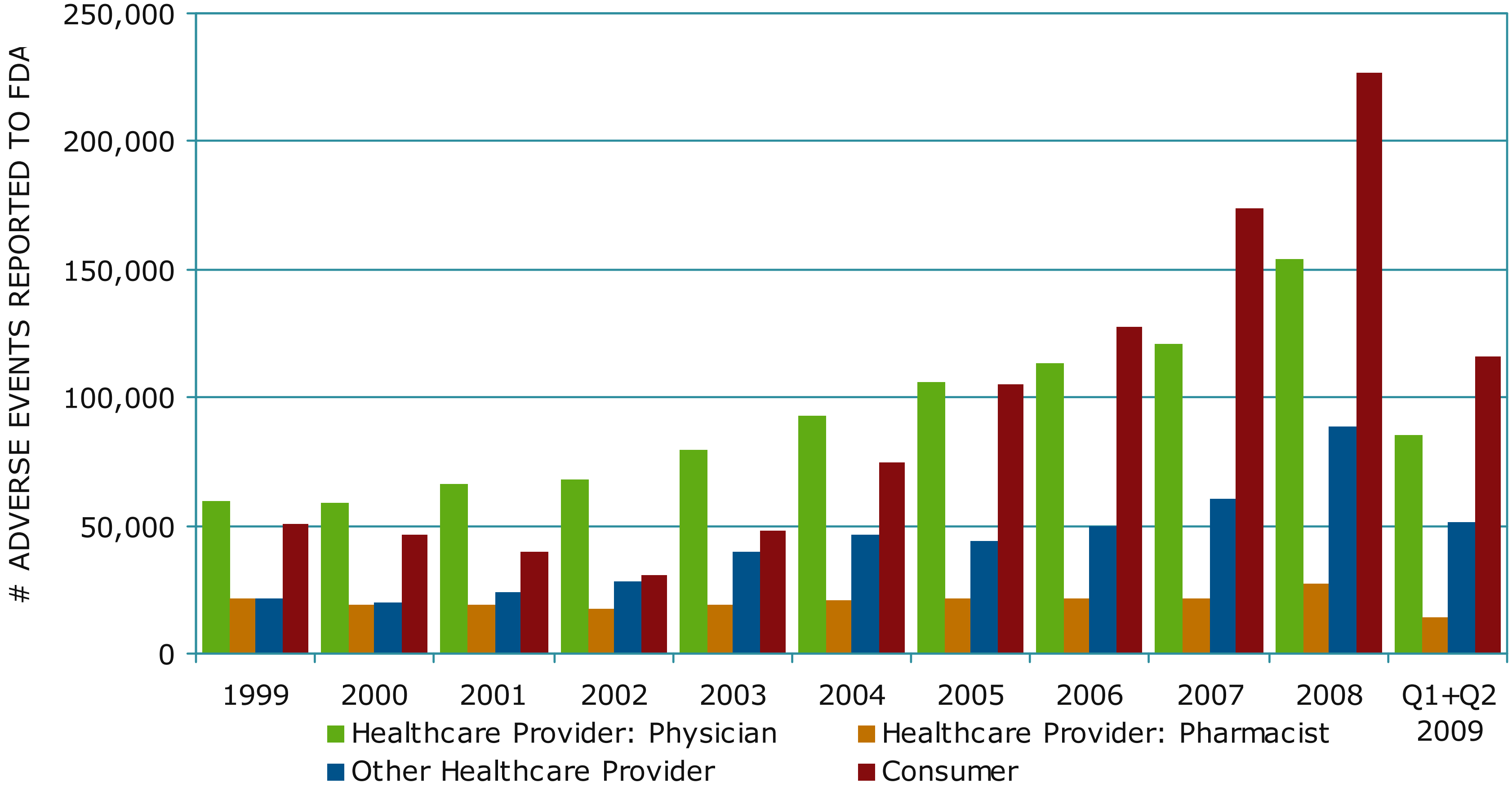
Source: IMS Health, MIDAS, Market Segmentation, MAT Jun 2009. 2009-2020 estimates equal MAT Jun 2009 sales.

FDA is actively managing product safety through REMS, a FDAAA prerogative for the agency

- Risk Evaluation and Mitigation Strategies are becoming prominent in all of FDA's safety-related actions
- Unlike standard post-marketing studies demanded by FDA with specific scope and patient populations, REMS are designed by companies and negotiated with FDA
- REMS components can include:
    - Medication guide (for new or previously approved products)
    - Communication plan
    - Elements to assure safe use (healthcare providers and patients registries)
    - Implementation system
- Medication guide-only REMS applied to multiple products in the following therapy classes:
    - Antiepileptics
    - TNF inhibitors
    - Erythropoietin stimulating agents
    - Fluoro-quinolones
- First formal class-wide REMS for long-acting opioids and botulinum toxin products pending FDA implementation

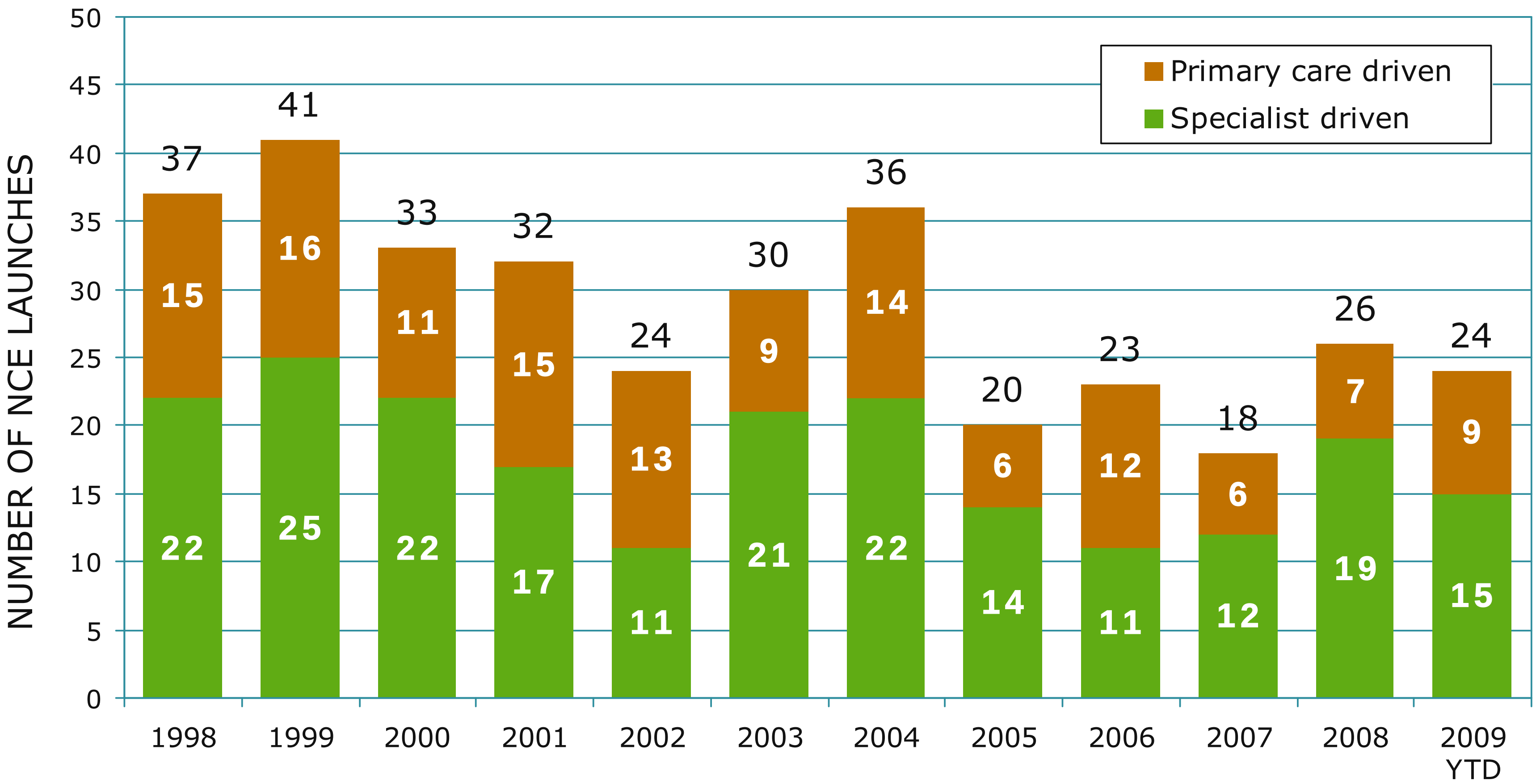
Source: FDA, IMS Market Insights Research

Patients and doctors are becoming more active in reporting adverse events to FDA or manufacturers



Source: FDA, Oct 2009

FDA approvals in 2008 are skewed towards specialist driven and niche therapies



Source: FDA, IMS Health, Market Insights Team Analysis, Oct 2009

2008 FDA approvals of NCEs took place in a challenging environment

Fewer new product submissions

24 in 2008* vs. 34 in 2007

Fewer “me-too” products

Delayed or denied market access

36 complete response or not-approvable letters

26 NCE approvals

Restricted market access

21 Risk Evaluation & Mitigation Strategies

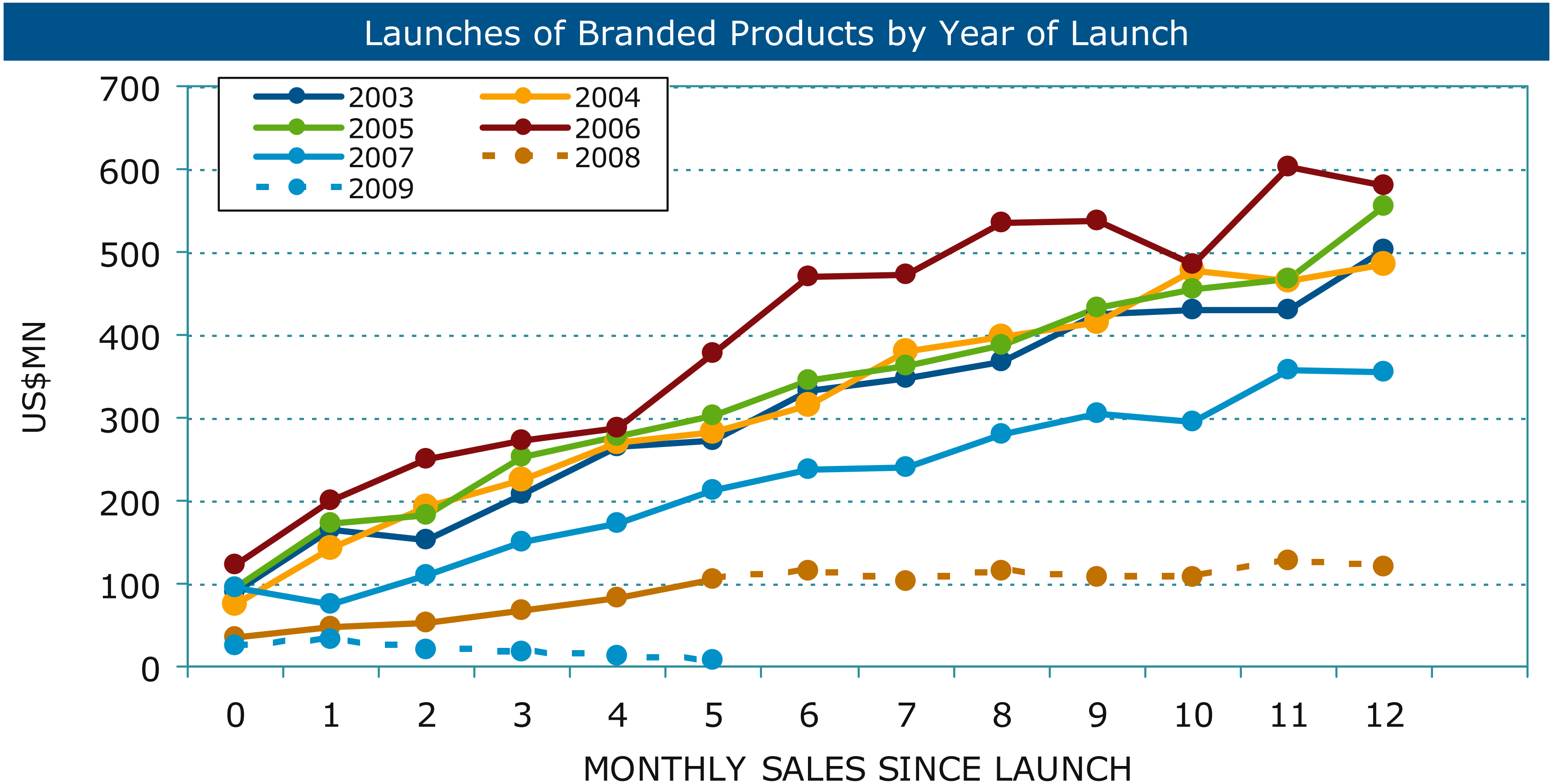
Review delays

20% of PDUFA goals missed in 2008*

FDA staff shortage

Source: IMS, Market Insights Research. *Jan-Oct 2008.

New Brand launches meet with diminishing success



Dotted lines represent incomplete data. Slope may change as more products become complete

Source: IMS Health, National Sales Perspectives, Jun 2009

Absolute growth – top 10 therapies

Dollars	AC US$mn	Total Rx dispensed	AC TRxs mn
Analogs of human insulin	1275.6	Lipid regulators	8.0
Analeptics	952.2	Codeine & comb	8.0
Angiotensin II antagonists	907.8	Proton pump inhib	6.7
Anti-platelets,oral	761.0	Seizure disorders	5.7
Antiarth,biol resp mod	712.6	Vitamin D	4.8
Antineo monoclonal antib	652.9	Anti-depressants	4.7
Codeine & comb	620.7	Analeptics	3.4
Steroid,inhaled bronch	585.0	Analogs of human insulin	3.3
HIV antiviral combination	569.2	Non-barb,oth	3.3
UT benign prostate	519.8	Benzodiazepines	2.7

Source: IMS Health, National Sales Perspectives, Jun 2009, National Prescription Audit, Jun 2009

Growth is strong in classes not impacted by patent expiration or safety

Leading classes	MAT Sep 2009 US$mn	MAT Sep 2009 % Market Share	MAT Sep 2009 % Growth
US Industry	295,379	100.0	3.6
1 Lipid regulators	16,945	5.7	-0.9
2 Antipsychotics,oth	14,278	4.8	0.8
3 Proton pump inhib	13,842	4.7	-0.9
4 Anti-depressants	11,374	3.9	-2.7
5 Angiotensin II antagonists	8,145	2.8	11.7
6 Antineo monoclonal antib	7,850	2.7	9.3
7 Seizure disorders	6,428	2.2	-33.5
8 Erythropoietins	6,353	2.2	-11.6
9 Antiarth,biol resp mod	6,150	2.1	13.5
10 Analogs of human insulin	6,000	2.0	26.8
Top 10	97,365	33.0	-1.1

Source: IMS Health, National Sales Perspectives, Sep 2009

Double-digit growth very common in next tier therapy classes

Leading classes	MAT Sep 2009		
	US$mn	% Market Share	% Growth
11 Anti-platelets,oral	5,838	2.0	15.7
12 Analeptics	5,535	1.9	22.5
13 Steroid,inhaled bronch	5,269	1.8	12.2
14 GI anti-inflam	4,744	1.6	12.8
15 Codeine & comb	4,674	1.6	14.5
16 Glitazones	4,633	1.6	3.4
17 HIV antiviral combination	4,559	1.5	16.1
18 Immune system adjuncts	3,979	1.3	-2.3
19 Anticoag,inj	3,891	1.3	12.5
20 Alzheimer-type dementia	3,812	1.3	15.2
Top 20	144,300	48.9	2.9

Source: IMS Health, National Sales Perspectives, Sep 2009

Absolute growth – top 10 products

Dollars		AC US$mn
OxyContin®	Purdue Pharma	1,094
Abilify®	Otsuka America	928
lamotrigine	Teva	745
Plavix ®	BMS Sanofi	712
Crestor ®	Astrazeneca	699
Humira ®	Abbott Pharma	561
pantoprazole sod	Wyeth-Ayerst	522
Januvia ®	Merck	465
Avastin ®	Genentech	439
Cymbalta ®	Lilly	439

Total Rx dispensed		AC TRxs mn
simvastatin	Lupin Pharma	14.8
alendronate sod	Teva	10.1
azithromycin	›ckhardt America	8.8
lisinopril	Lupin Pharma	8.5
ibuprofen (rx)	Amneal Pharma	7.6
Proair Hfa®	Teva Respiratory	7.4
Ocella ®	Teva	6.9
pantoprazole sod	Wyeth-Ayerst	6.8
lamotrigine	Teva	6.2
fluticasone prop	Apotex	5.8

Source: IMS Health, National Sales Perspectives, Jun 2009, National Prescription Audit, Jun 2009

Abilify and Plavix achieve double digit growth in MAT June 2009

	Products	Company	MAT Jun 2009 US$mn	MAT Jun 2009 % Market Share	MAT Jun 2009 % Growth
	US Industry		291,804	100.0	3.2
1	Lipitor®	Pfizer	7,668	2.6	-2.9
2	Nexium®	AstraZeneca	6,111	2.1	7.2
3	Plavix®	BMS	5,212	1.8	15.8
4	Advair Diskus®	GlaxoSmithKline	4,540	1.6	6.1
5	Seroquel®	AstraZeneca	3,965	1.4	9.2
6	Singulair®	Merck & Co	3,548	1.2	2.5
7	Abilify®	Otsuka America Ph	3,525	1.2	35.7
8	Actos®	Takeda	3,245	1.1	5.8
9	Enbrel®	Amgen	3,164	1.1	0.1
10	Remicade®	Johnson & Johnson	3,099	1.1	7.9
	Top 10		44,076	15.1	7.1

Source: IMS Health, National Sales Perspectives, Jun 2009

Double digit growth from Avastin, Cymbalta and Oxycontin

	Products	Company	MAT Jun 2009		
			US$mn	% Market Share	% Growth
11	Epogen®	Amgen	3,074	1.1	2.1
12	Prevacid®	Takeda	2,971	1.0	-7.7
13	Neulasta®	Amgen	2,965	1.0	-2.4
14	Effexor XR®	Wyeth	2,926	1.0	-1.2
15	Avastin®	Genentech,Inc.	2,789	1.0	18.7
16	Lexapro®	Forest Lab	2,734	0.9	1.5
17	Lovenox®	Sanofi Aventis	2,662	0.9	7.5
18	Cymbalta®	Lilly	2,650	0.9	19.8
19	OxyContin®	Purdue Pharma	2,644	0.9	70.6
20	Zyprexa®	Lilly	2,564	0.9	7.4
	Top 20		72,056	24.7	7.5

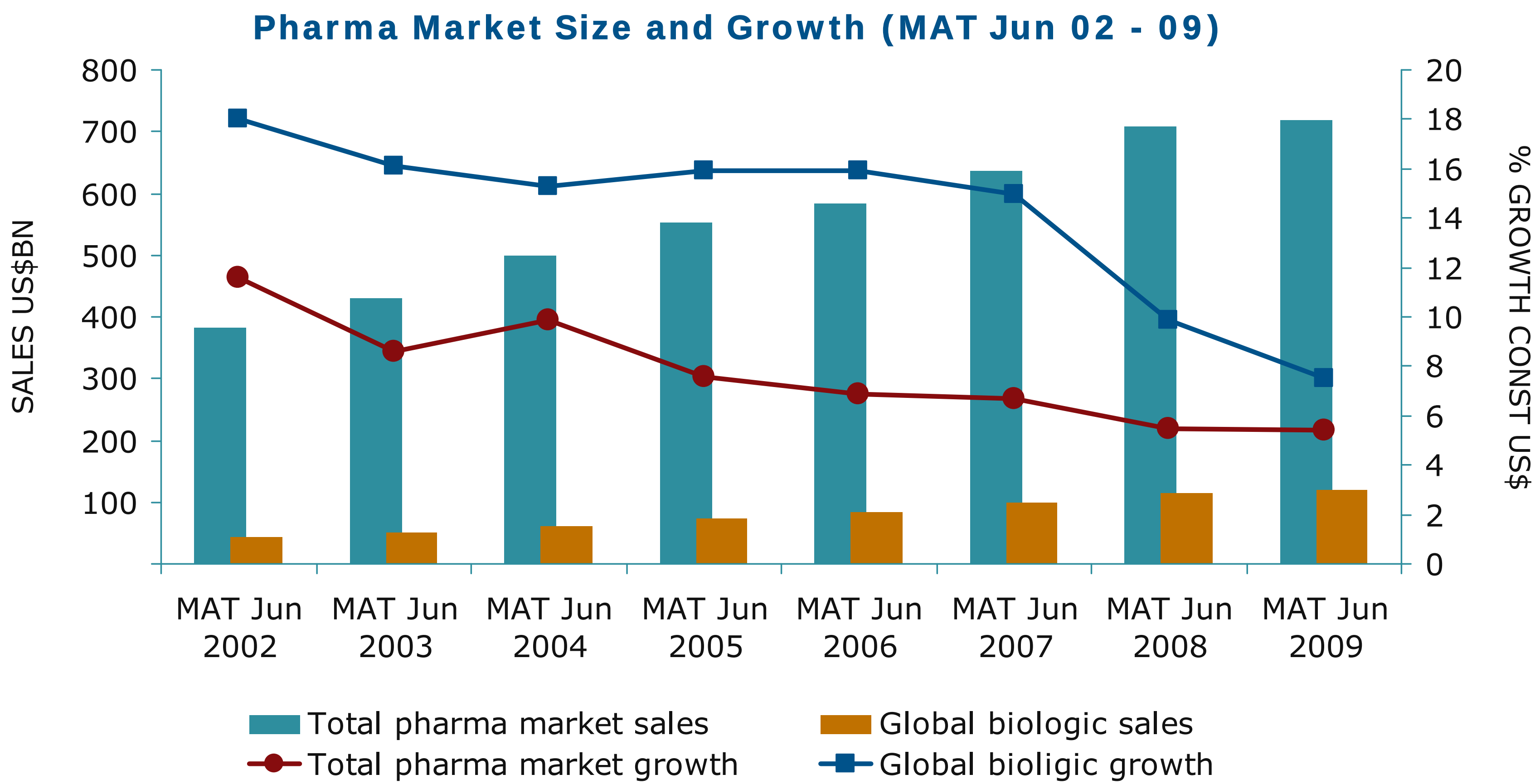
Source: IMS Health, National Sales Perspectives, Jun 2009

Absolute growth – top 10 corporations

Dollars	AC US$BN	TRx	AC TRx mn
Teva	2.3	Lupin Pharma	37.4
AstraZeneca	1.6	Teva	30.9
Lilly	1.2	Amneal Inc	26.9
Purdue Pharma	1.1	Apotex Corp	25.7
Bristol-Myers Squibb	1	Dr Reddy Inc	17.7
Boehringer Ingelheim	0.9	Mylan Labs, Inc.	15.2
Otsuka America Ph	0.9	Cadista Inc	14.4
Roche (incl Genentech)	0.8	Wockhardt America	12.2
Sanofi Aventis	0.8	Aurobindo Pharma	12.1
Mylan Labs, Inc.	0.7	Glenmark Pharma	6.8

Source: IMS Health, National Sales Perspectives, Jun 2009, National Prescription Audit, Jun 2009

Global market dynamics



Source: IMS Health, MIDAS, MAT Jun 2009

What do these terms mean?
IMS Definitions

- **Biologic**- The broad universe of 'biologics' could include many substances: single identified components, whole cells, etc. They generally include some form of polymer. They can be purified from human, animal, plant, or micro-organism sources, produced by recombinant DNA technology, or chemically synthesized.
- **Biotech**- refers to a specific sub-set of biologic molecules that are produced through recombinant DNA technology.

*If you want to view molecules that are produced by recombinant methods limit the market definition in the query to Salt = Recombinant.

IMS' definition of a biologic requires that a molecule must meet all four criteria*

Characteristic	Specification
Molecular Structure	Biologic molecules are complex macromolecules, typically with some form of polymer structure. Specific macromolecules included in this definition are proteins, nucleic acids and carbohydrates. There are certain agreed conventions where a collection of molecules can be commonly referred to as a single entity (e.g. Antisera). If all the components in such a collective entity will also be a Biologic.
Molecule Identification	Biologic molecules must be clearly identified. Any 'molecule' where the molecule name is descriptive and the actual composition of the molecule is not identified (e.g. Vegetable Extract) will not be classified as a biologic.
Active Substance	Biologic molecules must be, or are intended to be clearly defined active therapeutic ingredients in a product.
Regulatory	Biologic molecules must have undergone (or be undergoing) a regulatory human clinical trial program under the auspices of a national or regional regulatory authority.

*Vaccines are an exception to this rule, and as a general rule of thumb if molecules meet the inclusive criteria it is considered to be a biologic

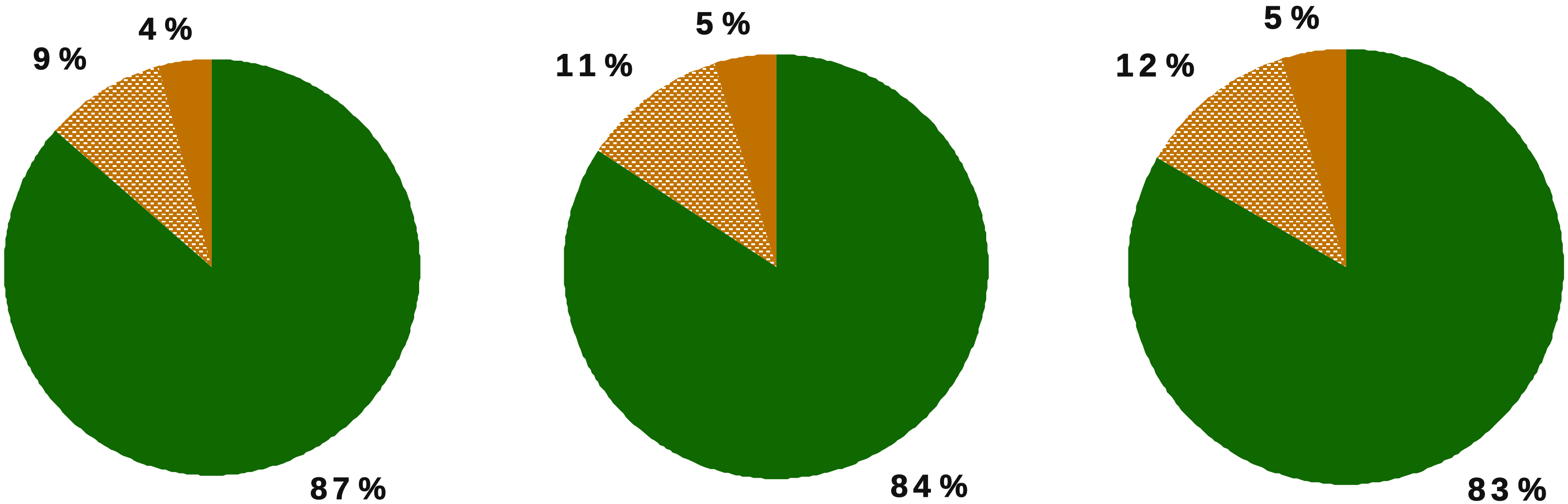
Chemical Hierarchy

- Family names are divided into Chemical Family Names and Sub-Family Names.

- Chemical Family Names Relevant to IMS Data:
  - Monoclonal Antibodies
  - Immunoglobulins
  - Vaccines
  - Nucleotide based Therapeutics
  - Human Cells and Tissues
  - Animal Cells and Tissues
  - Microorganism Cells and Fractions
  - Other Protein Polypeptides and Peptides
  - Insulins
  - Growth Hormones and Factors
  - Haematopoietic Growth Factors
  - Blood Coagulation Factors
  - Interferons
  - Enzymes
  - Heparins
  - Carbohydrates
  - Lipids
  - Plants and Plant Extracts

Global biologic products account for 17% of the global market

% Market share (US$)

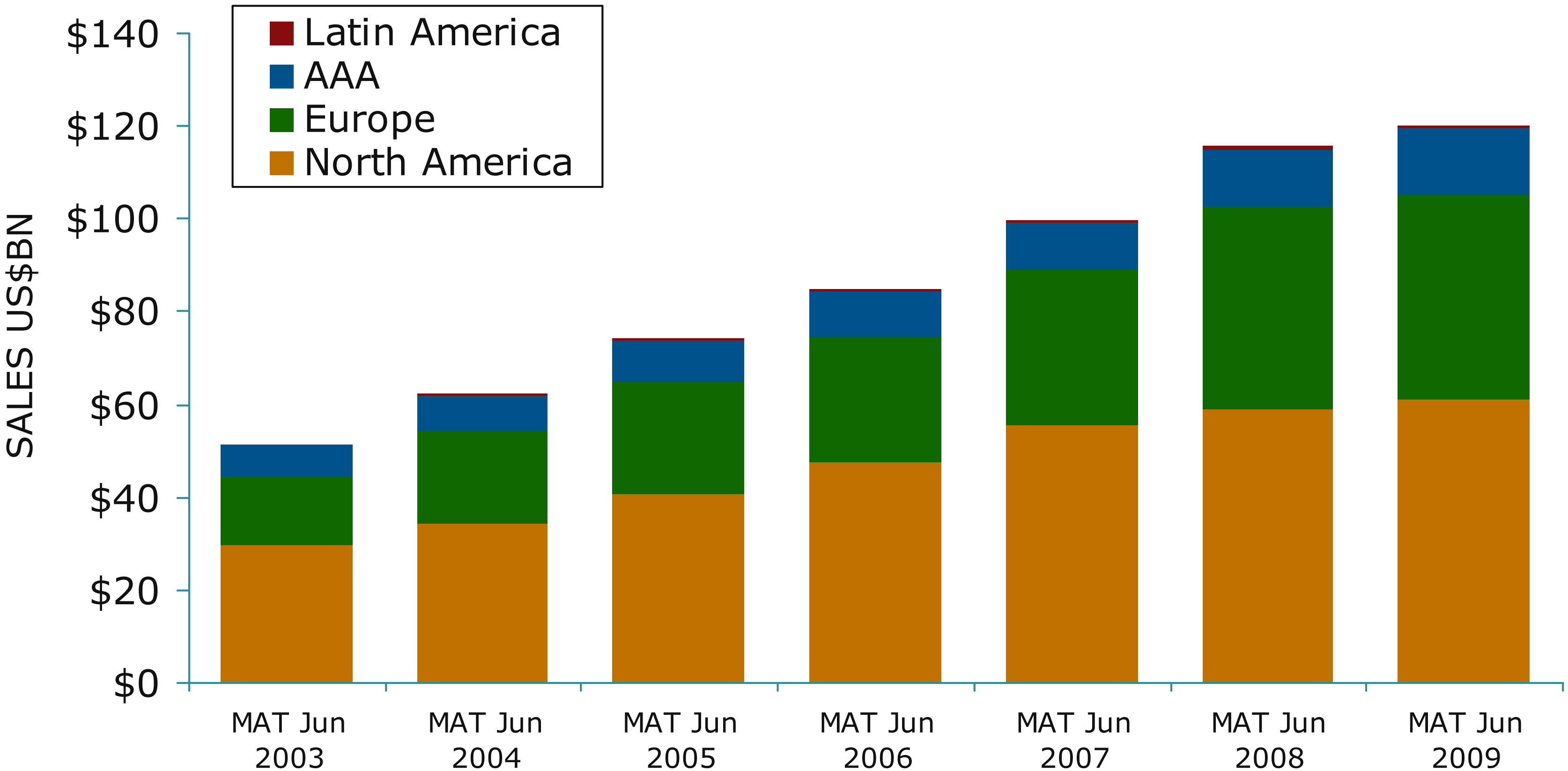


	MAT Jun 2005	MAT Jun 2007	MAT Jun 2009
Total Market =	$552bn	$636bn	$719bn

Biologics minus Biotech | Biotech | Small molecule

Source: IMS Health, MIDAS, MAT Jun 2009

Regional biologic market dynamics



Source: IMS Health, MIDAS, MAT Jun 2009

Country market Biologic dynamics

	MAT Jun 2009		Const US$	
	US$Bn	% Sales	% Growth	CAGR 05-09
Global Market	120.1	100.0	7.5	12.0
US	58.4	48.6	4.3	10.7
Germany	9.2	7.7	3.0	12.0
Japan	8.7	7.2	9.4	6.5
France	8.3	6.9	5.1	11.7
Italy	4.8	4.0	9.1	12.9
Spain	4.4	3.6	13.9	14.7
UK	3.2	2.7	19.0	14.7
Canada	2.5	2.0	13.8	14.5
Russian Fed	1.9	1.5	22.4	52.2
China	1.7	1.5	24.3	19.8

Source: IMS Health, MIDAS, MAT Jun 2009

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Global biologic leading therapy classes

Therapy classes 1-10	MAT Jun 2009		Constant US$	
	US$Bn	% Market Share	% Growth	CAGR 05-09
Oncologics	17.8	14.8	12.5	22.4
Autoimmune agents	15.5	12.9	18.2	21.3
Antidiabetics	13.9	11.5	15.9	17.9
Erythropoietins	10.7	8.9	-9.3	-3.2
Immunostim. agents excl. interf.	8.6	7.2	6.3	10.0
Pure vaccines	8.2	6.8	-8.8	20.4
Heparins	6.4	5.3	7.9	8.6
Interferons	5.8	4.8	11.1	7.9
Blood coagulation	4.3	3.6	9.2	12.3
Polyvalent immuno-glob – I.V	3.1	2.6	8.0	10.1

Source: IMS Health, MIDAS, MAT Jun 2009

Global biologic leading therapy classes

Therapy classes 11-20	MAT Jun 2009		Constant US$	
	US$Bn	% Market Share	% Growth	CAGR 05-09
Growth hormones	2.8	2.3	5.4	6.3
Immunosuppressive agents	2.2	1.8	24.2	11.7
Antivirals, excl anti-HIV prods	2.0	1.6	5.2	3.6
Combinations of vaccines	1.8	1.5	-2.0	7.0
Ocular antineovascularisation prods	1.8	1.5	30.5	195.9
Specific immunoglobulins, antiviral	1.6	1.4	4.6	11.0
Hypothalamic hormones	1.6	1.3	7.1	7.5
Gonadotrophins	1.4	1.2	4.9	6.8
Other alimentary tract and metabolism	1.2	1.0	19.3	24.4
Parathyroid hormones and analogues	0.8	0.7	8.8	20.8

Source: IMS Health, MIDAS, MAT Jun 2009

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Global biologic leading products 1-10

Constant US$

Rank		US$Bn MAT Jun 2009	% Market Share	% Growth	CAGR 05-09
	Global	120.1	100.0	7.5	12.0
1	Enbrel	5.5	4.6	7.1	13.5
2	Remicade	5.1	4.2	13.1	16.2
3	Avastin	4.5	3.7	34.9	70.7
4	Mabthera	4.4	3.7	10.4	15.7
5	Humira	4.4	3.7	38.7	43.4
6	Lovenox	4.3	3.6	6.0	10.7
7	Herceptin	3.7	3.1	9.5	35.3
8	Lantus	3.7	3.1	25.1	29.8
9	Neulasta	3.6	3.0	0.2	12.7
10	Epogen	3.0	2.5	1.9	0.9
	Top 10	42.2	35.1	13.8	19.7

Source: IMS Health, MIDAS, MAT Jun 2009

Global biologic leading products 11- 20

Rank	US$Bn MAT Jun 2009	% Market Share	Constant US$ % Growth	Constant US$ CAGR 05-09
Global	120.1	100.0	7.5	12.0
11 Aranesp	2.9	2.4	-21.0	-2.1
12 Erypo	2.5	2.1	-9.9	-10.1
13 Copaxone	2.3	1.9	28.9	20.9
14 Avonex	2.0	1.7	11.0	7.3
15 Novorapid	1.9	1.6	25.0	30.9
16 Lucentis	1.8	1.5	31.1	---
17 Rebif	1.7	1.4	13.8	13.2
18 Neorecormon	1.5	1.3	-11.5	-2.2
19 Betaferon	1.5	1.2	11.9	11.4
20 Humalog	1.4	1.2	16.7	12.0
Top 20	61.7	51.4	10.7	15.0

Source: IMS Health, MIDAS, MAT Jun 2009

Global biologic leading corporations 1-10

Rank		US$Bn MAT Jun 2009	% Market Share	Constant US$ % Growth	Constant US$ CAGR 05-09
	Global	120.1	100.0	7.5	12.0
1	Roche	18.5	15.4	11.9	22.4
2	Amgen	14.1	11.8	-5.3	3.8
3	Sanofi-Aventis	10.4	8.6	10.9	15.4
4	Novo Nordisk	7.2	6.0	12.8	14.8
5	Johnson & Johnson	6.1	5.1	-0.1	-1.8
6	Abbott	5.7	4.7	27.8	26.2
7	Lilly	5.4	4.5	7.2	7.8
8	Wyeth	4.1	3.4	5.8	14.2
9	Novartis	4.0	3.3	8.7	9.3
10	Schering-Plough	3.2	2.7	5.2	7.8
	Top 10	78.6	65.5	7.2	11.6

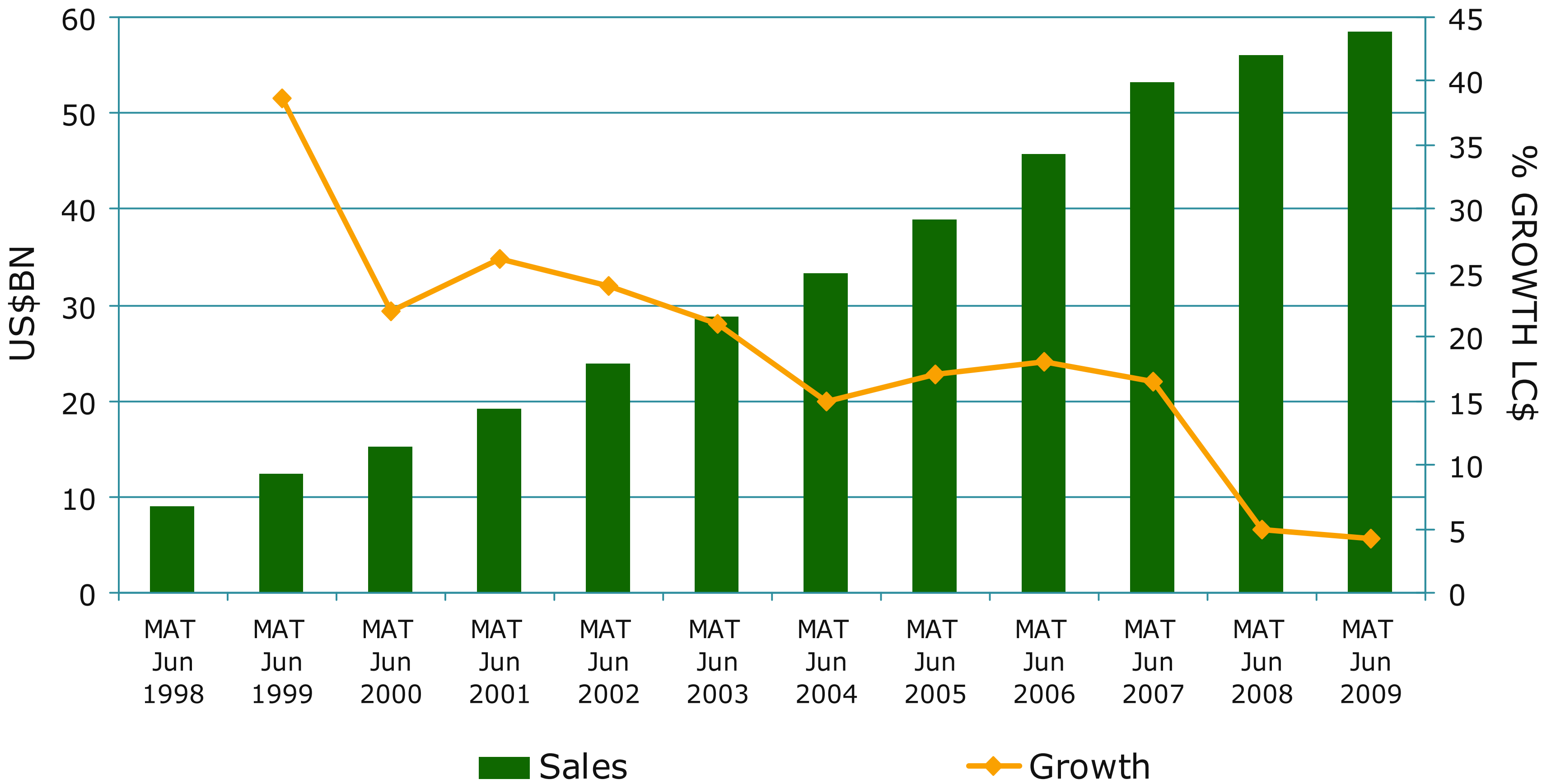
Source: IMS Health, MIDAS, MAT Jun 2009

Global biologic leading corporations 11-20

Rank	US$Bn MAT Jun 2009	% Market Share	Constant US$ % Growth	Constant US$ CAGR 05-09
Global	120.1	100.0	7.5	12.0
11 Merck KGaA	3.2	2.7	11.1	13.7
12 Merck & Co.	3.2	2.6	-18.7	28.6
13 GlaxoSmithKline	2.6	2.2	3.0	10.4
14 Baxter Int.	2.3	1.9	5.2	13.7
15 Bayer	2.2	1.8	2.7	5.9
16 Biogen Idec	2.2	1.8	20.7	10.8
17 Teva	1.9	1.6	28.1	22.1
18 AstraZeneca	1.9	1.6	1.6	4.4
19 CSL	1.4	1.1	14.1	9.3
20 Takeda	1.3	1.1	7.1	6.7
Top 20	100.8	83.9	6.6	11.8

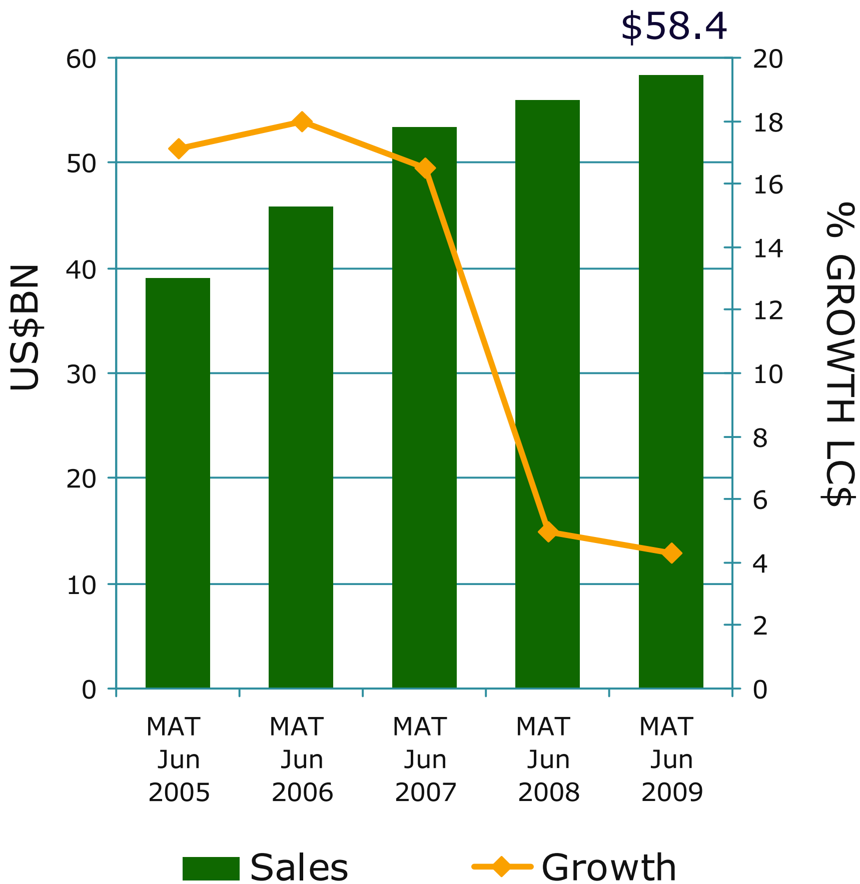
Source: IMS Health, MIDAS, MAT Jun 2009

US biologic growth over time



Source: IMS Health, MIDAS, MAT Jun 2009

US biologic dollar sales $58bn, but growth rate is low at 4%



Key Factors

– Safety events

– Economy

– 5 biotech NCEs launched in the US in 2008

– Biosimilar legislation continues to be debated

– Concentrated market, top 10 companies encompass 90% of current market sales

– Antidiabetics and expanded indications drive growth

– Products continue to target areas of unmet need

Source: IMS Health, MIDAS, MAT Jun 2009

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Leading 1-10 US biologic therapy classes

MAT Jun 2009

Rank		US$mn	% Market Share	% Growth	CAGR 04-08
	US Biotech Market	58,406	100.0	4.3	13.9
1	Autoimmune agents	8,653	14.8	11.7	20.7
2	Oncologics	8,153	14.0	7.2	26.4
3	Antidiabetics	7,039	12.1	21.7	24.3
4	Erythropoietins	6,157	10.5	-13.1	-1.2
5	Vaccines	4,496	7.7	-18.4	20.9
6	Multiple Sclerosis therapies	4,359	7.5	24.4	14.3
7	Immunostim AG EX Intfron	3,874	6.6	-2.7	13.1
8	Heparins	2,935	5.0	12.6	13.4
9	Polyval immuno-globl I.V.	1,504	2.6	7.3	14.8
10	Blood Coagulation	1,379	2.4	11.3	17.5
	Top 10	48,549	83.1	4.5	15.0

Source: IMS Health, MIDAS, MAT Jun 2009

Leading 11-20 US biologic therapy classes

MAT Jun 2009

Rank		US$mn	% Market Share	% Growth	CAGR 04-08
	US Biotech Market	58,406	100.0	4.3	13.9
11	Growth hormones	1,149	2.0	3.0	19.7
12	Specf imm-glob antiviral	1,015	1.7	1.5	15.3
13	Ocular Antineovascular Prods	949	1.6	15.6	---
14	Anti-virals excl Anti-HIV	640	1.1	2.5	-5.5
15	Hypothalamic hormones	537	0.9	6.7	7.6
16	Osteoporosis Products	506	0.9	1.3	36.0
17	Other Opthalmologicals	451	0.8	20.7	51.0
18	Gonadotrophins	442	0.8	4.0	9.5
19	Immunosuppressive Agents	381	0.7	0.2	-3.1
20	Respiratory Agents	372	0.6	-3.4	106.5
	Top 20	54,991	94.2	4.6	15.2

Source: IMS Health, MIDAS, MAT Jun 2009

Leading 1-10 US biologic products

			MAT Jun 2009		% Growth Constant US$	
			US$bn	% Market Share	2008	CAGR 04-08
	US Biotech Market		58,406	100.0	4.3	13.9
1	Enbrel	Amgen	3,020	5.2	-0.1	18.4
2	Remicade	Centocor	2,959	5.1	7.7	12.9
3	Epogen	Amgen	2,934	5.0	1.8	-0.2
4	Neulasta	Amgen	2,831	4.8	-2.7	20.9
5	Avastin	Genentech	2,663	4.6	18.4	121.0
6	Lovenox	Sanofi-Aventis	2,542	4.4	7.2	14.5
7	Mabthera	Roche	2,433	4.2	8.7	14.8
8	Lantus	Sanofi-Avnetis	2,295	3.9	27.4	37.5
9	Humira	Abbott	2,219	3.8	31.5	46.0
10	Aranesp	Amgen	1,618	2.8	-32.3	15.0
	Top 10		25,514	43.7	5.0	18.1

Source: IMS Health, MIDAS, MAT Jun 2009

Leading 11-20 US biologic products

			MAT Jun 2009		% Growth Constant US$	
			US$bn	% Market Share	2008	CAGR 04-08
	US Biotech Market		58,406	100.0	4.3	13.9
11	Erypo	Johnson & Johnson	1,605	2.7	-11.5	-13.0
12	Copaxone	Teva	1,511	2.6	32.5	18.8
13	Herceptin	Genentech	1,322	2.3	6.3	31.9
14	Varivax	Merck & Co.	1,206	2.1	4.4	41.3
15	Avonex	Biogen Idec	1,200	2.1	14.0	4.6
16	Novorapid	Novo Nordisk	1,064	1.8	33.8	46.6
17	Humalog	Lilly	970	1.7	21.3	11.2
18	Lucentis	Genentech	949	1.6	15.6	---
19	Synagis	Medimmune	914	1.6	2.0	17.4
20	Neupogen	Amgen	873	1.5	-4.9	1.4
	Top 20		37,127	63.6	6.3	15.2

Source: IMS Health, MIDAS, MAT Jun 2009

Leading 1-10 US biologic corporations

		MAT Jun 2009		% Growth Constant US$	
		US$bn	% Market Share	2008	CAGR 04-08
	US Biotech Market	58,406	100.0	4.3	13.9
1	Amgen	11,419	19.6	-6.8	11.1
2	Roche (Genentech)	9,243	15.8	9.8	32.7
3	Sanofi-Aventis	5,460	9.3	13.0	19.3
4	Johnson & Johnson	4,916	8.4	0.3	-2.1
5	Lilly	3,413	5.8	6.5	11.4
6	Novo Nordisk	2,848	4.9	22.9	27.6
7	Abbott	2,797	4.8	21.8	18.5
8	Merck & Co.	2,435	4.2	-21.8	35.9
9	Teva	1,613	2.8	30.3	20.8
10	Biogen Idec	1,200	2.1	14.0	4.6
	Top 10	45,341	77.6	3.9	15.0

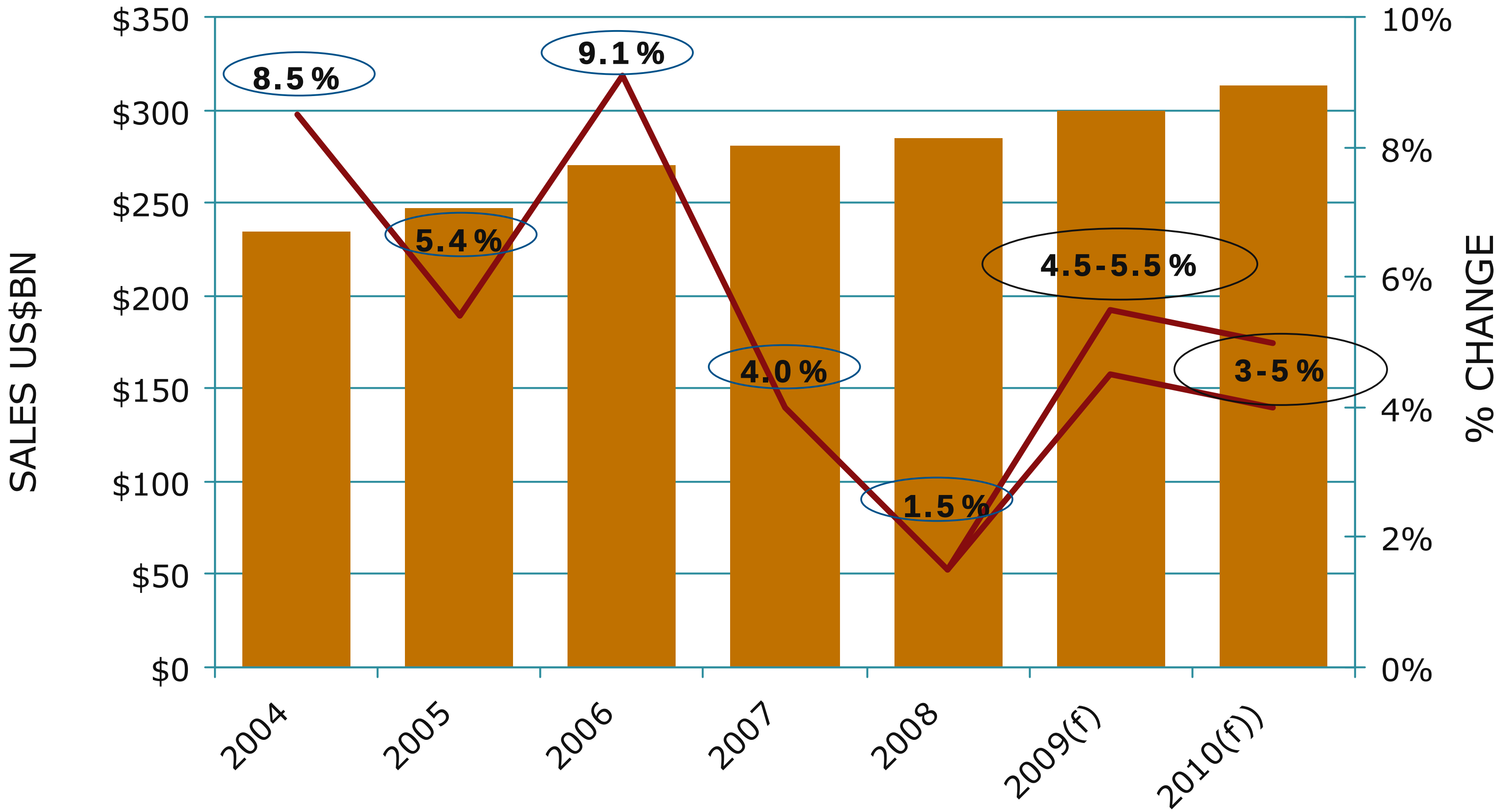
Source: IMS Health, MIDAS, MAT Jun 2009

Leading 11-20 US biologic corporations

		MAT Jun 2009		% Growth Constant US$	
		US$bn	% Market Share	2008	CAGR 04-08
	US Biotech Market	58,406	100.0	4.3	13.9
11	Merck KGaA	1,029	1.8	20.3	14.1
12	AstraZeneca	1,028	1.8	2.8	11.5
13	Bayer	1,026	1.8	8.0	2.7
14	Novartis	$952	1.6	-5.3	-5.0
15	Baxter Int	$944	1.6	12.3	17.8
16	Wyeth	$855	1.5	-12.8	3.6
17	GlaxoSmithKline	$779	1.3	-18.1	14.3
18	Schering Plough	$766	1.3	-8.0	-2.9
19	Amylin	$714	1.2	2.7	---
20	CSL	$590	1.0	21.2	9.8
	Top 20	54,025	92.5	3.4	13.6

Source: IMS Health, MIDAS, MAT Jun 2009

US market sales and growth 2004-2010



Source: IMS Health, Market Prognosis, Sep 2009

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Thank you

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