

2004/05 Report Card for the Ontario Drug Benefit Program

Drug Program Branch Mandate

- To develop and manage drug programs to ensure that optimal pharmaceutical services are provided for the protection and improvement of Ontarians' health.
- To manage a reimbursement system for prescription drugs.

Strategic Goals

- To ensure on-going access to cost-effective drug therapies through the recommendations of the Drug Quality and Therapeutics Committee (DQTC) and innovative management approaches;
- To manage pharmaceutical expenditures under Ontario Drug Benefit (ODB) and present options for new program features and future program designs;

Strategic Goals

- To promote optimal drug therapy through the development and use of therapeutic guidelines and other evidence-based approaches;
- To maintain a high level of performance of the Health Network System which adjudicates claims;
- To maintain strong working relationships with other governments, drug manufacturers, pharmacists, physicians, third-party insurers, and consumers;
- To provide information to health care professionals and consumers about the ODB program.

Strategic Goals

- To make effective and efficient use of human, financial and technological resources in order to meet program objectives;
- To provide effective and efficient customer service to all our clients;
- To monitor ODB program performance through measures of efficiency, effectiveness and customer satisfaction.

Growth Factors

- newer and more expensive drugs;
- aging population;
- new clinical evidence (indications) and better treatment outcomes involving drug therapy;
- new diseases and new areas of pharmacology;
- increased utilization (overall and per patient);
- restructuring of health system (shift to outpatient care);
- continued pressure for manufacturers to increase market share.

Report Card Framework

I. Program Overview

Program overview and utilization trends

II. Financial

Financial indicators and cost trends

III. Formulary Listings

Process and Type of Listing

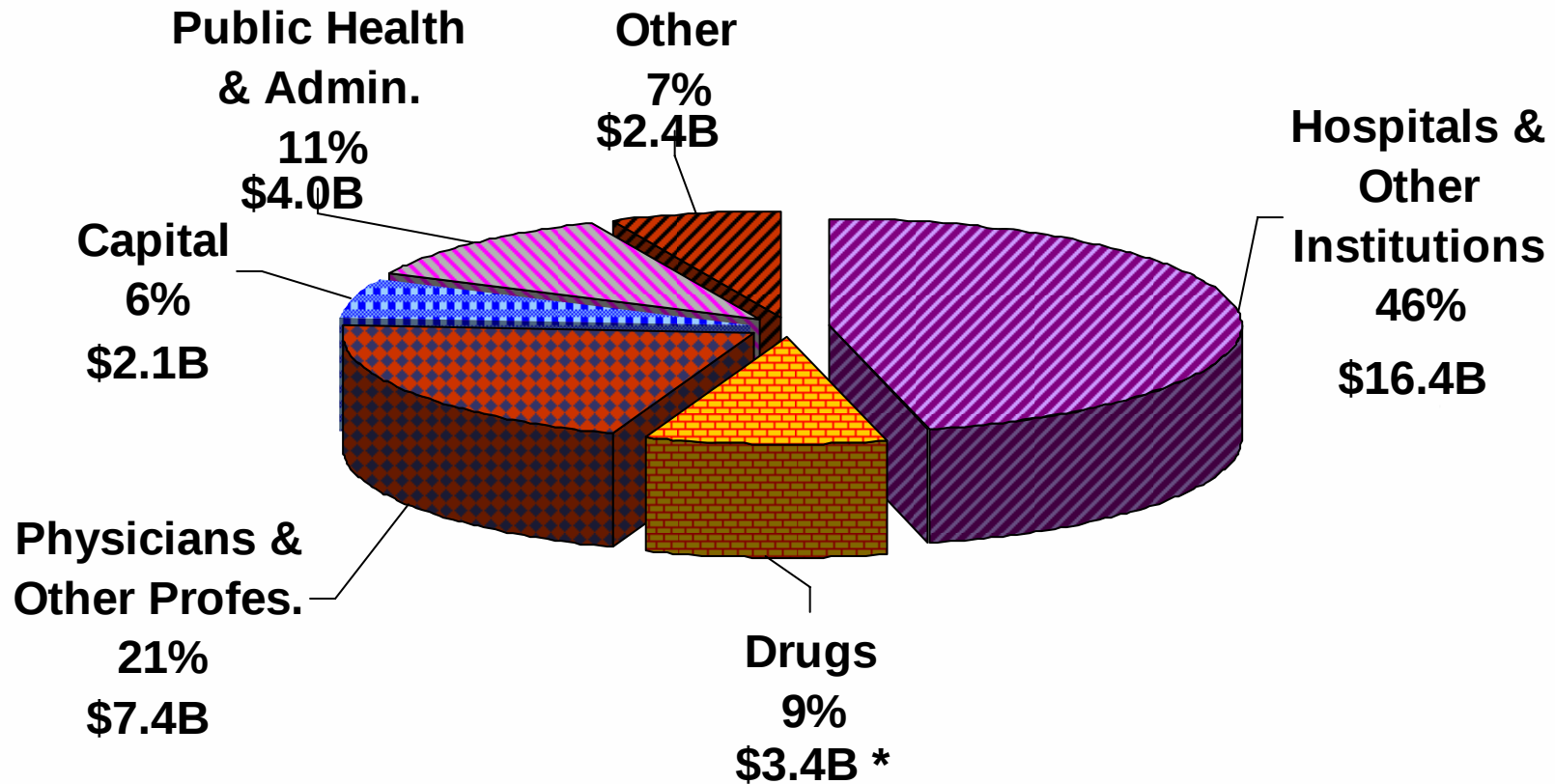
IV. Achievements

Accomplishments and Looking Ahead

Definitions

- **Beneficiary**: Eligible person who had at least one claim during the fiscal year
- **Claim**: Every time a pharmacist fills a prescription, initial or refill
- Figures include MOHLTC and MCSS programs unless otherwise specified

Provincial Health Expenditures - Total \$35.7 Billion, Ontario 2004

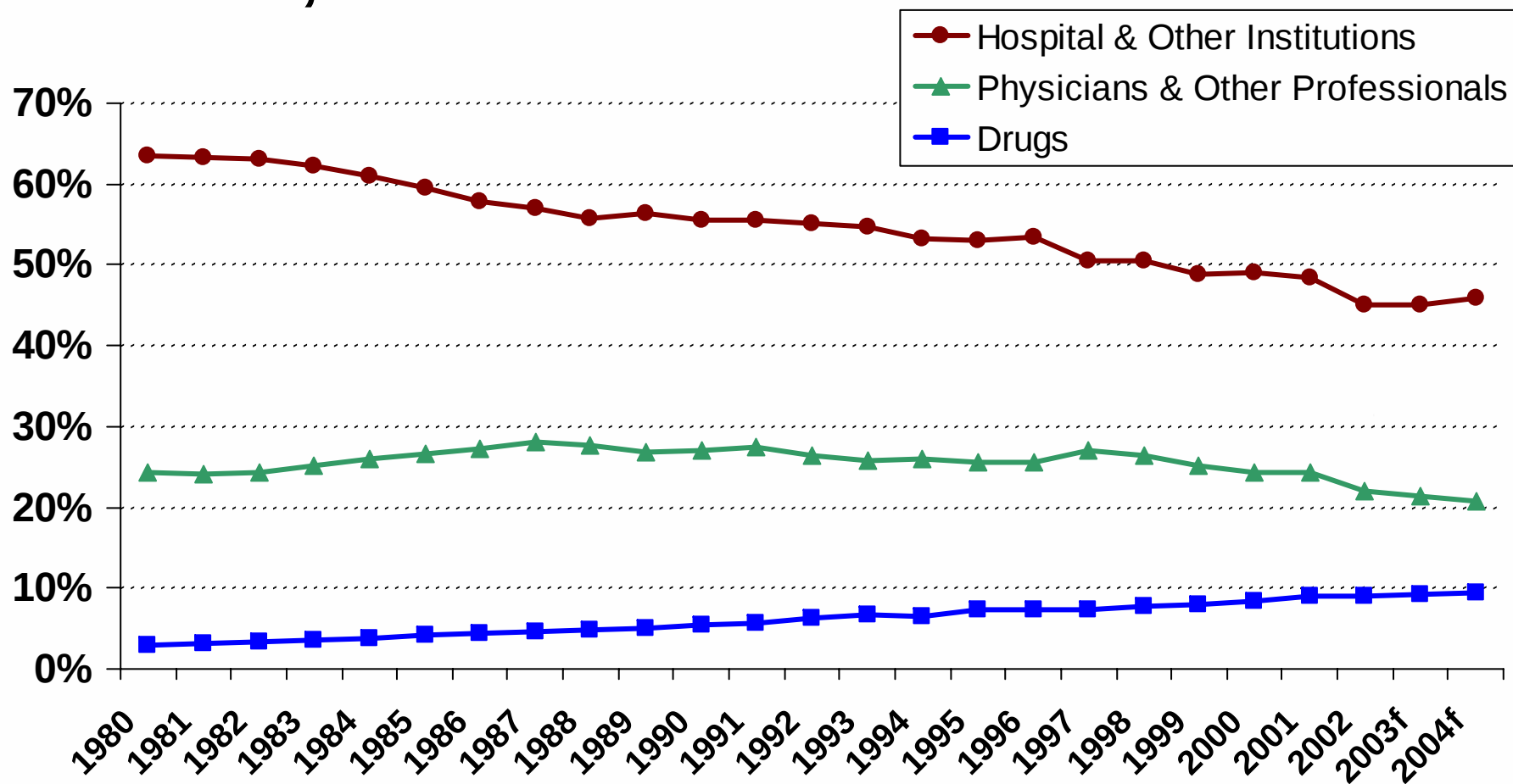


Source: Forecast from the Canadian Institute for Health Information, 2005

* Includes ODB Programs (\$3.2B) + Other Public Programs (\$0.15B)

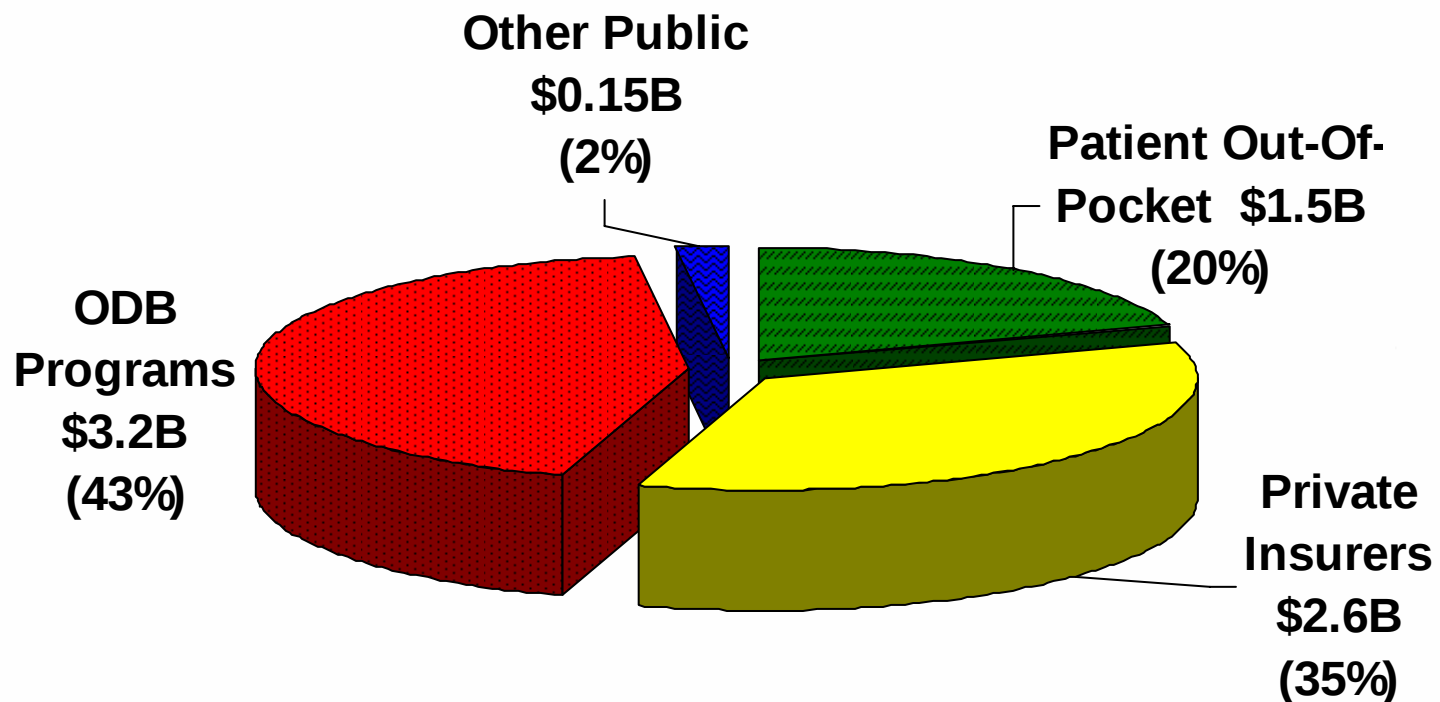
Provincial Health Expenditures

Ontario, 1980-2004



Source: Actual and forecasted data from the Canadian Institute for Health Information, 2005

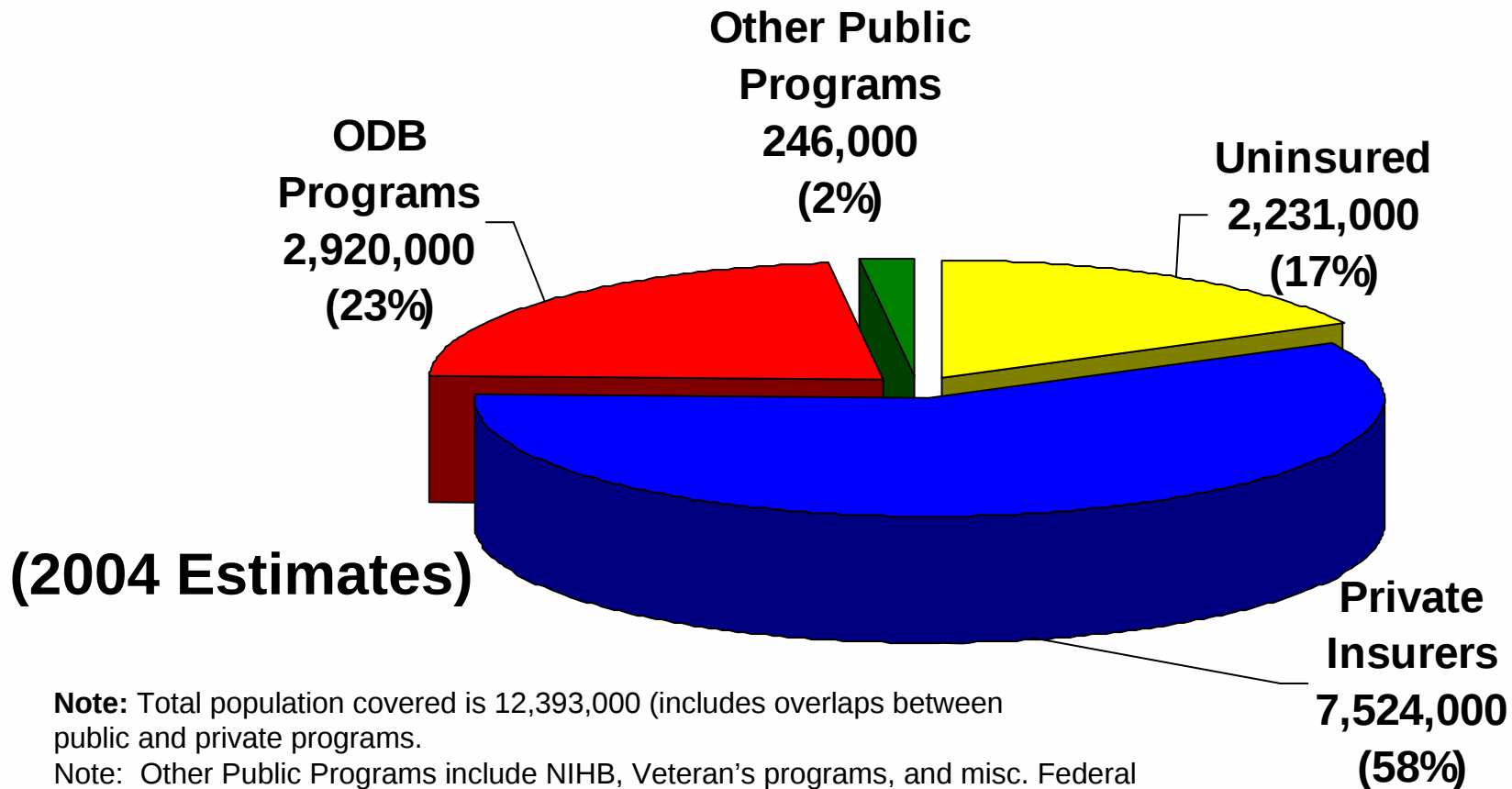
Ontario 2004 Drug Costs - Total \$7.4 Billion Public, Private & Beneficiary Costs



Source: Canadian Institute for Health Information (CIHI)

Note: Other Public Programs include NIHB, Veteran's programs, and misc. Federal Programs (e.g. RCMP, etc.)

Ontario Population Covered by Public and Private Insurance



Note: Total population covered is 12,393,000 (includes overlaps between public and private programs).

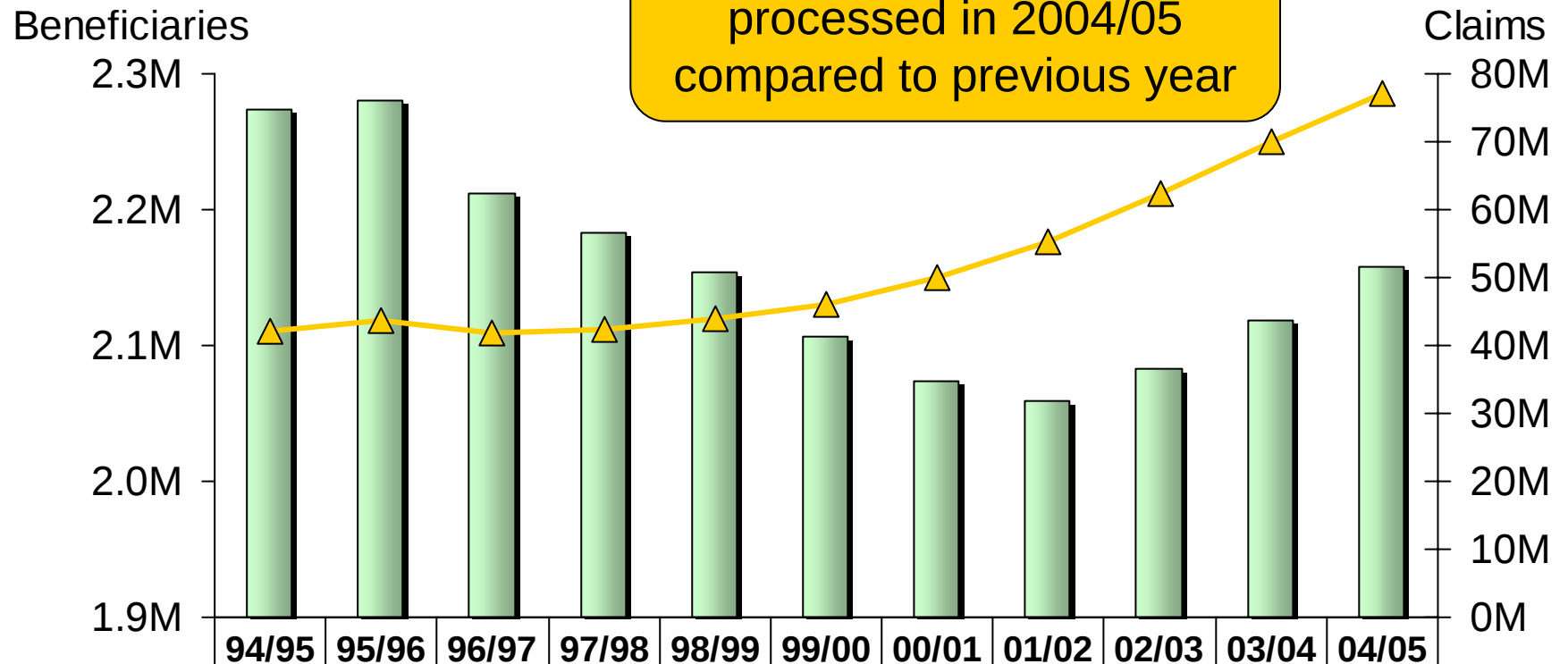
Note: Other Public Programs include NIHB, Veteran's programs, and misc. Federal Programs (e.g. RCMP, etc.)

Source: Drug Programs Branch calculation based on data from Applied Mgmt/Fraser Group (2000), internal ODB statistics and Statistics Canada.

ODB Beneficiaries & Claims

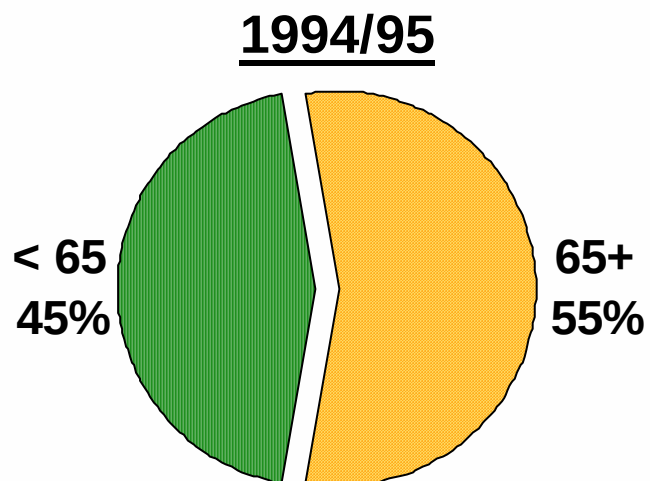
1994/95-2004/05

10% more claims
processed in 2004/05
compared to previous year

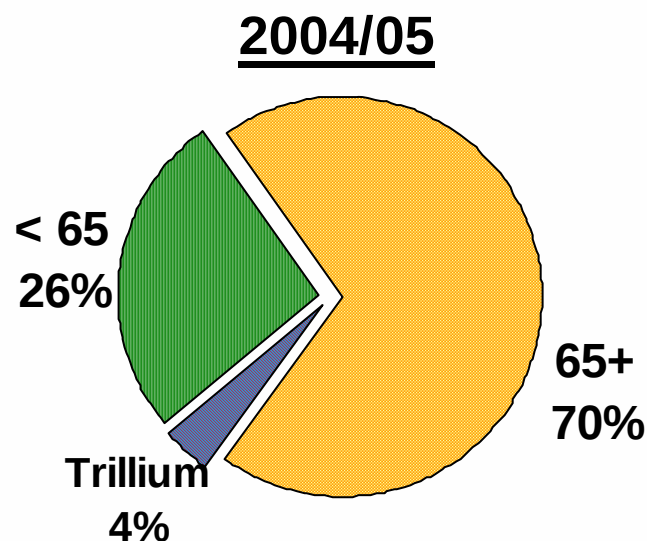


Age Breakdown of ODB Beneficiaries

1994/95 vs. 2004/05



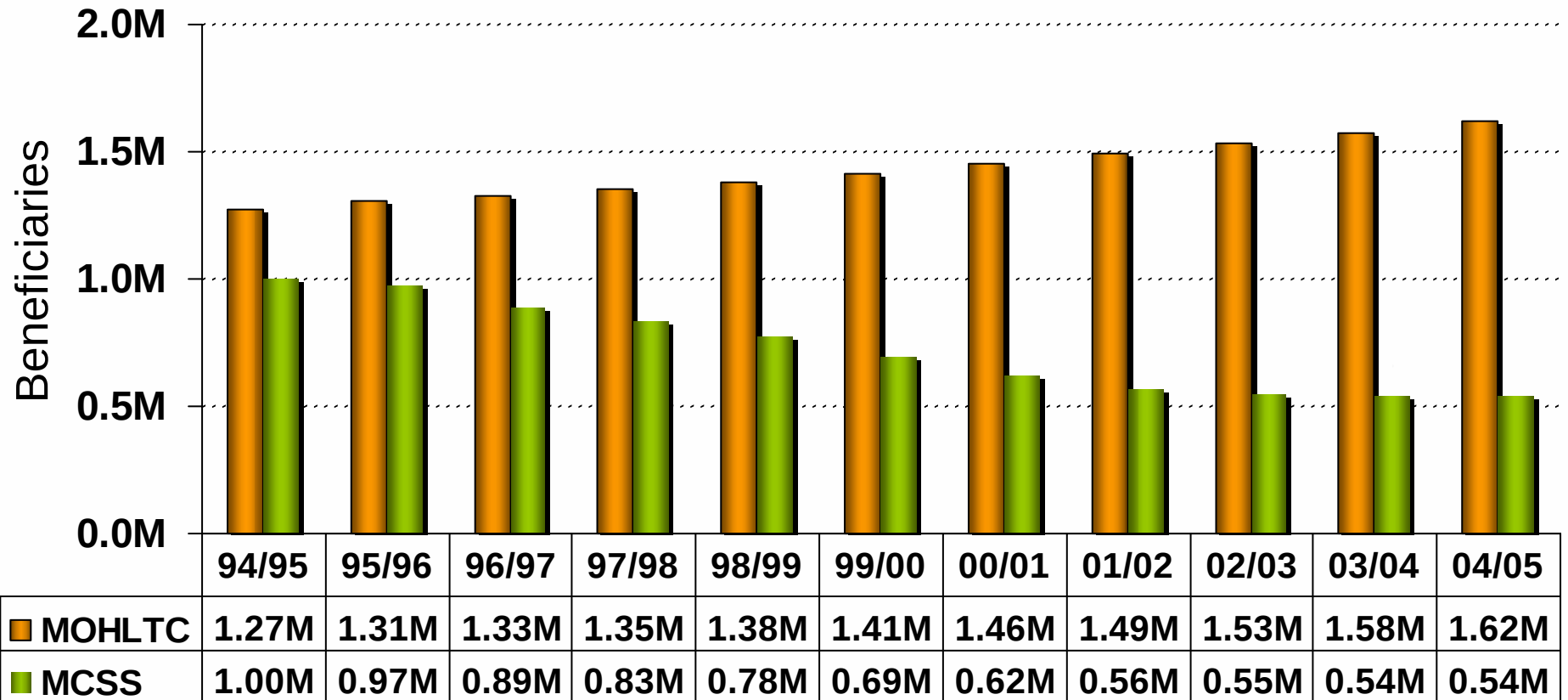
<65	1,012K
65+	1,262K
Total	2,274K



<65	571K
Trillium	81K
65+	1,506K
Total	2,158K

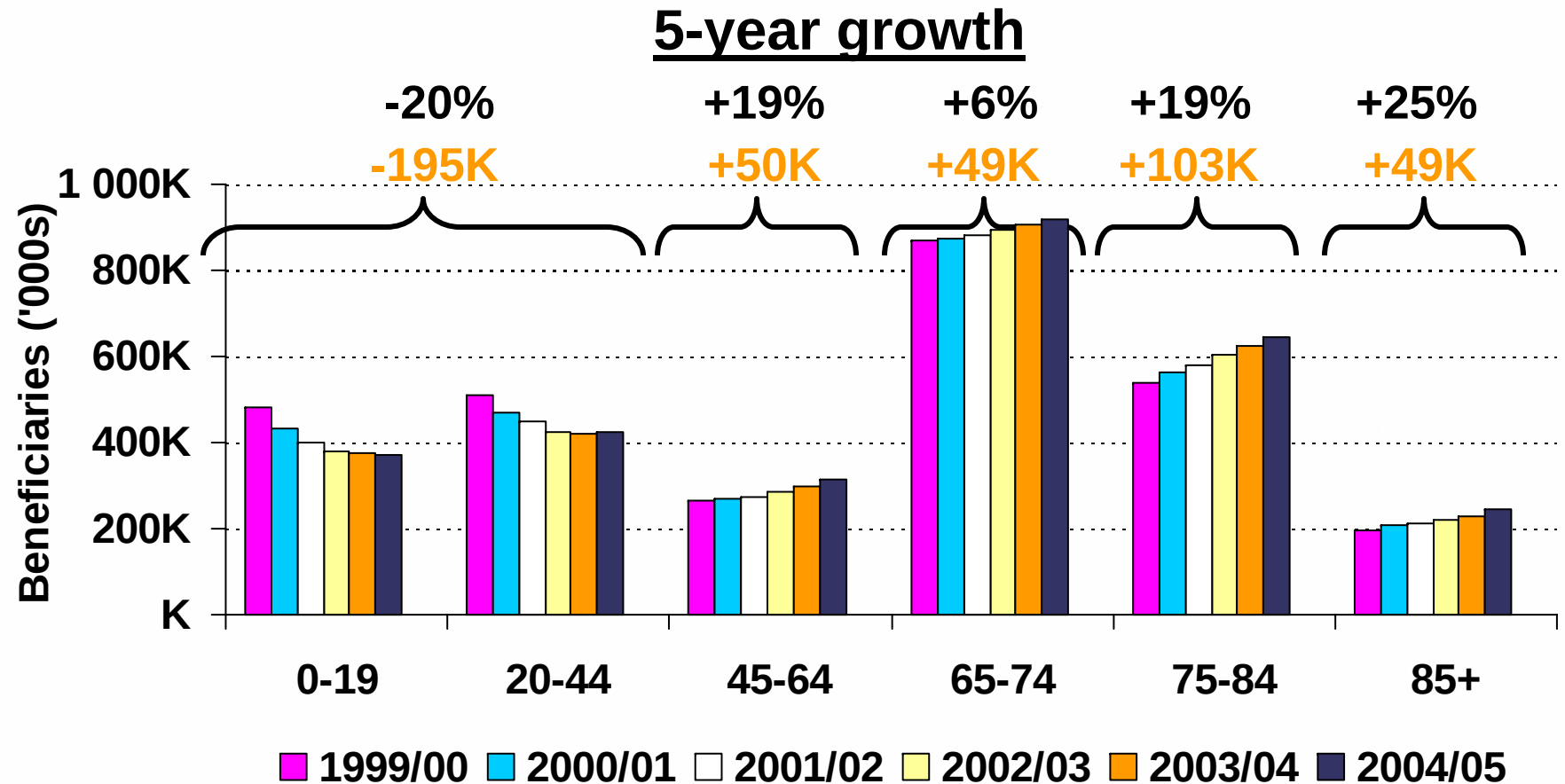
Excludes
Trillium pre-
registration.

ODB Beneficiaries by Source of Finance 1994/95-2004/05



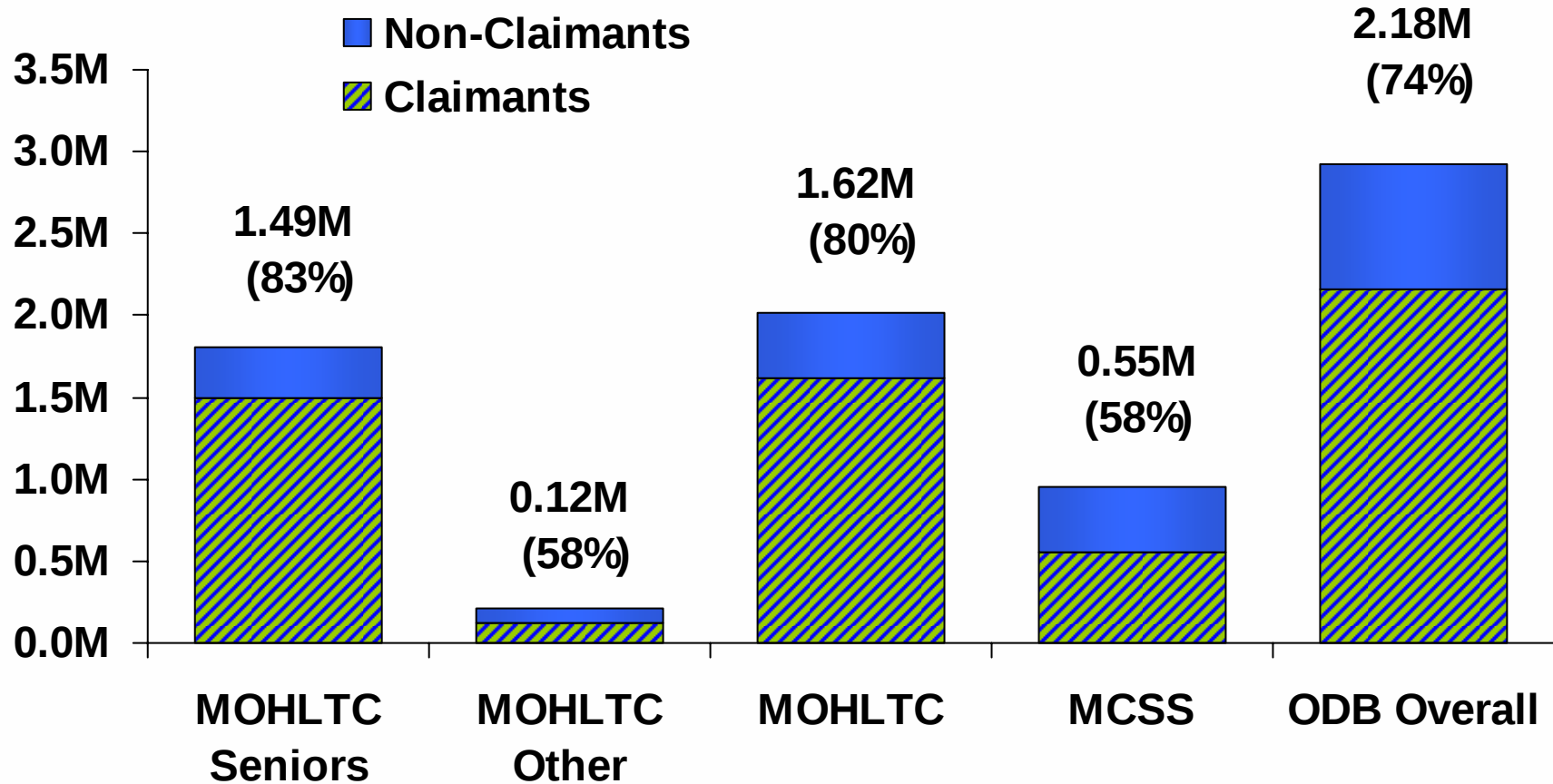
From 1994/95 to 2004/05, the total number of beneficiaries decreased by 5%.

Age Distribution of Eligible Beneficiaries 1998/99-2004/05



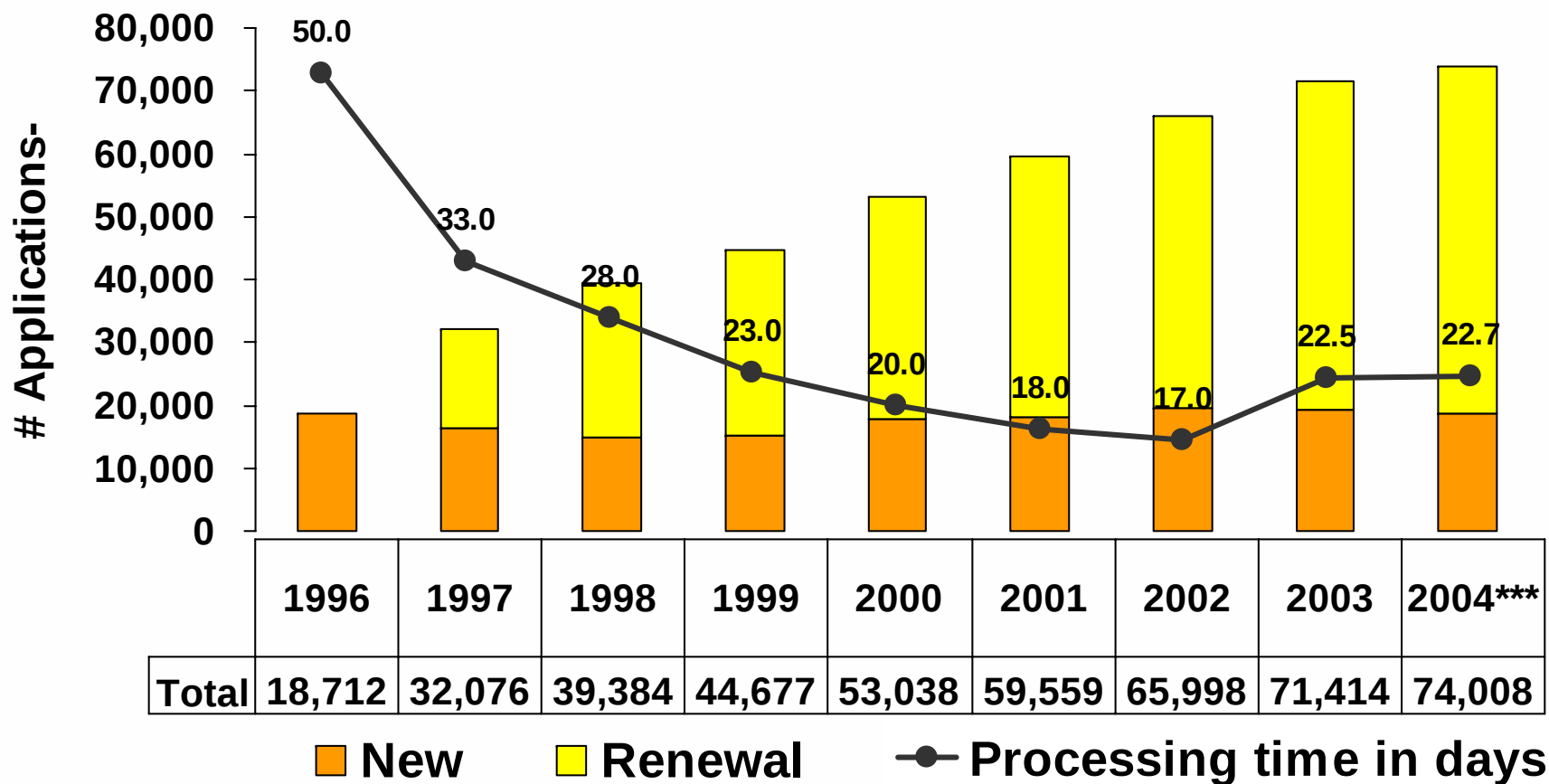
ODB Beneficiaries by Program

2004/05



Labels are the number of active beneficiaries and their percentage of the total.

Trillium Applications* & Processing Time, 1996 – 2004 Benefit Years**



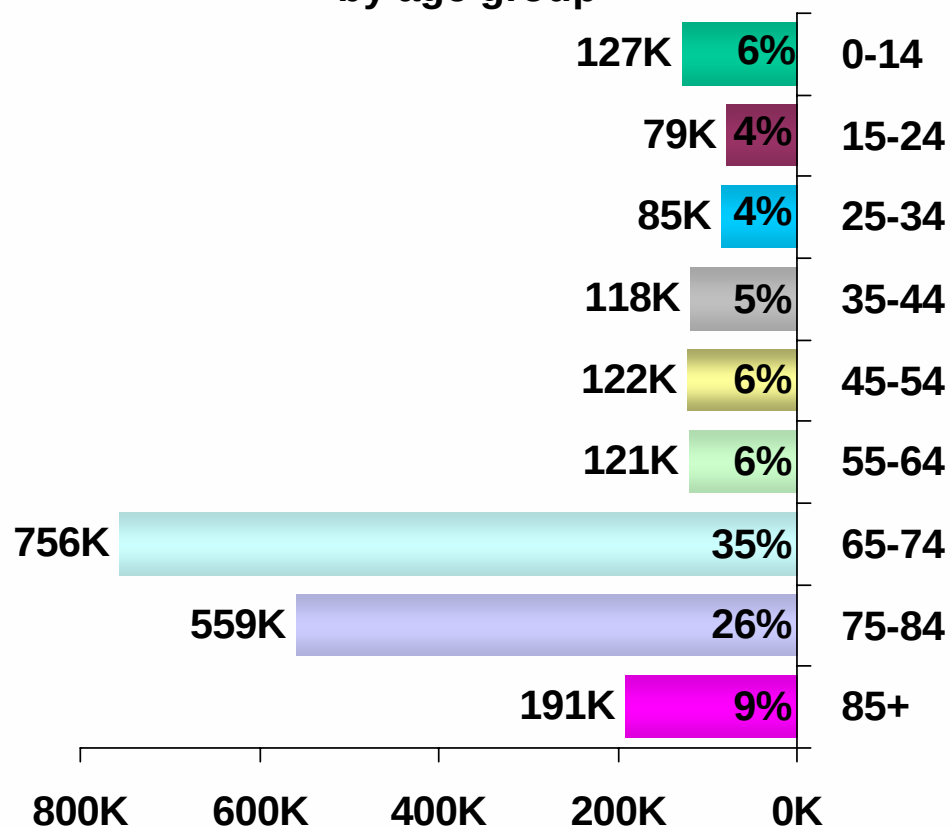
* Number of applications represents households, not individuals.

** Trillium benefit year starts August 1 and ends July 31 the following year.

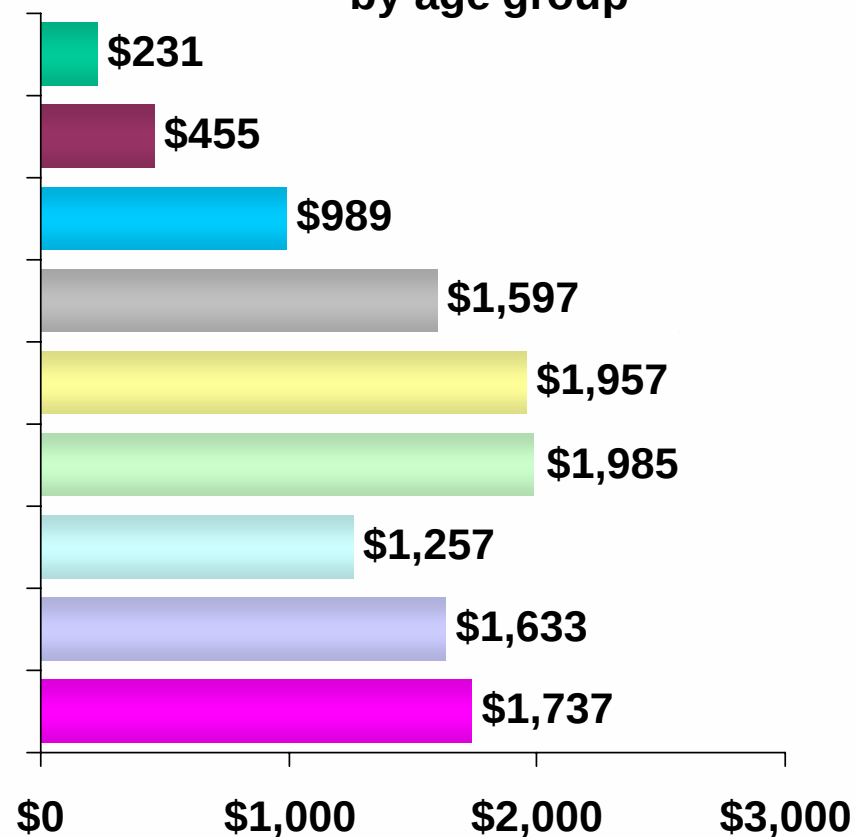
*** 2004 new application data are based on actual data as of June 15, 2005 and an estimate to the end of the benefit year.

Beneficiary Distribution & Government Share by Age, 2004/05

Distribution of beneficiaries
by age group

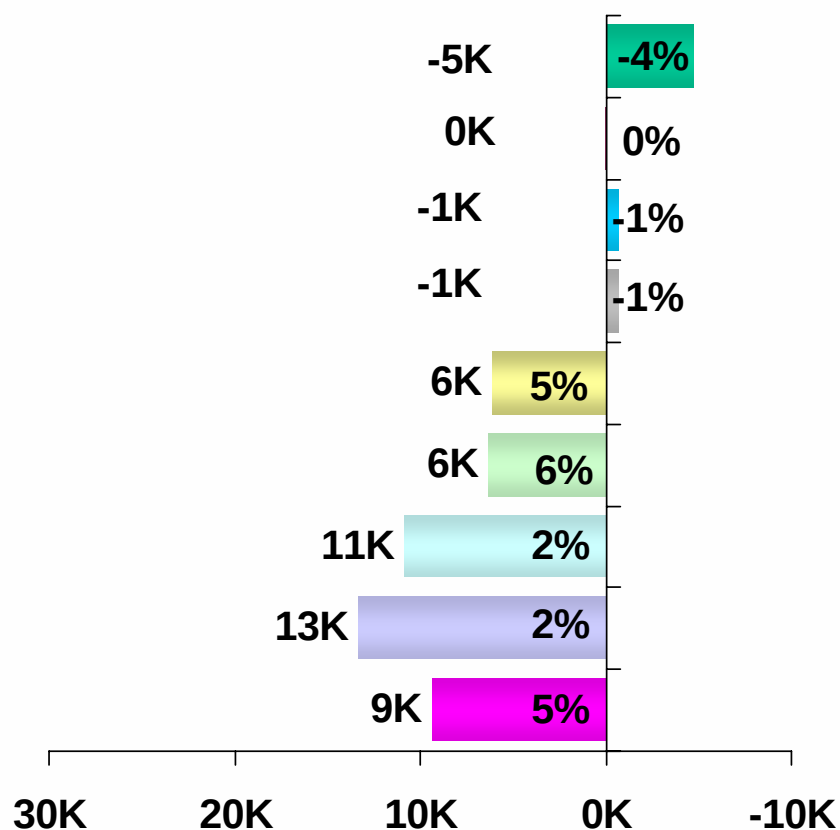


Government share per beneficiary
by age group

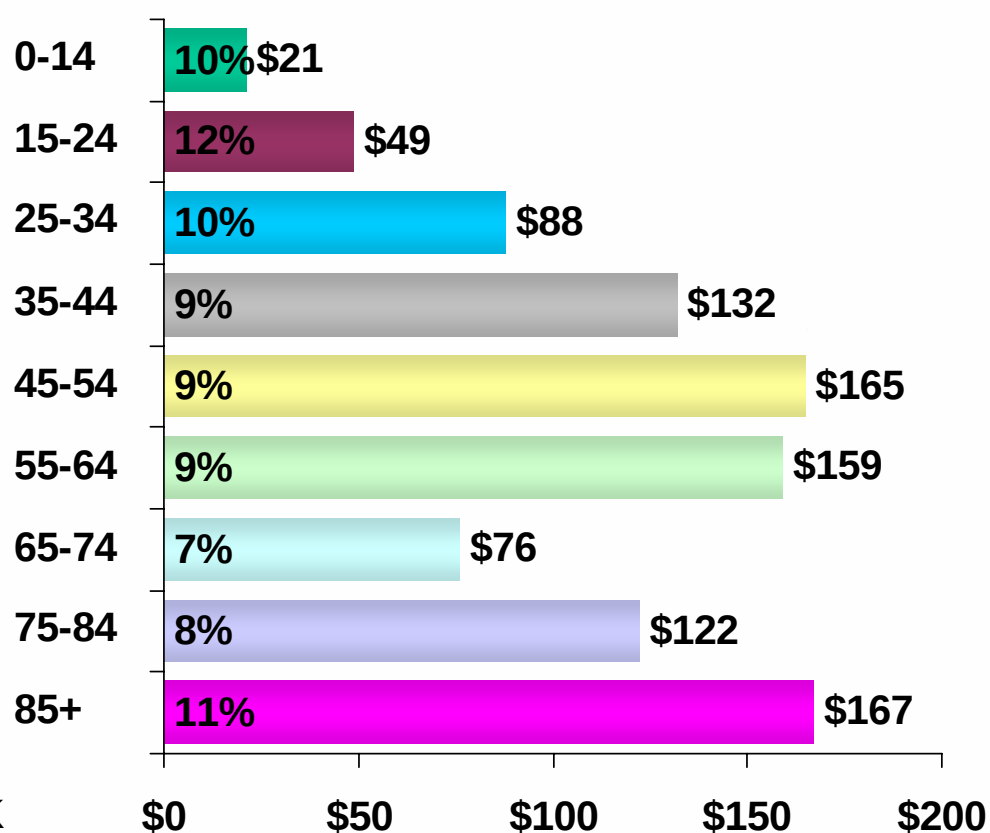


Change in Beneficiaries & Government Share by Age, 2003/04-2004/05

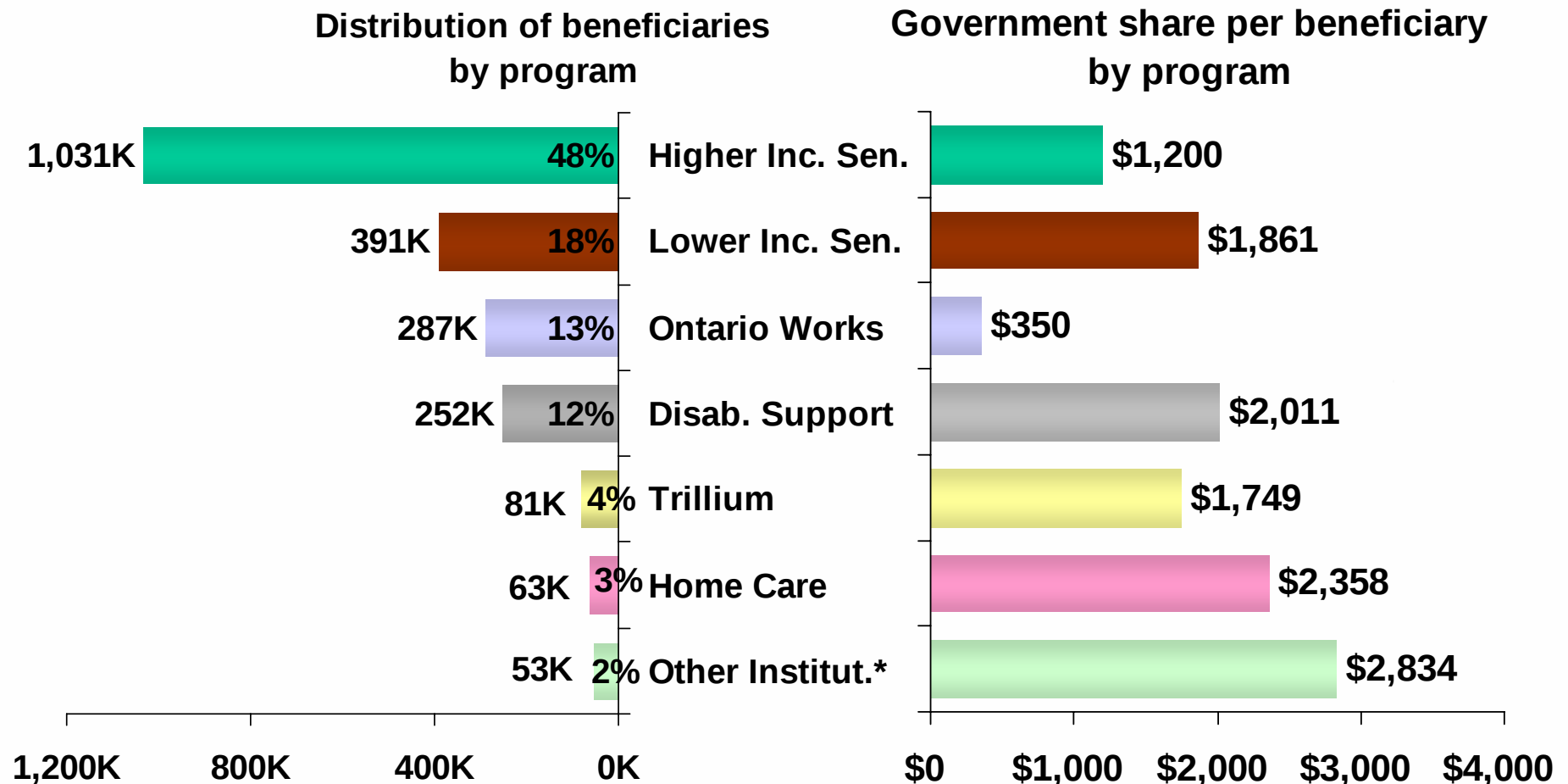
Change in beneficiaries
by age group



Change in government share per
beneficiary by age group

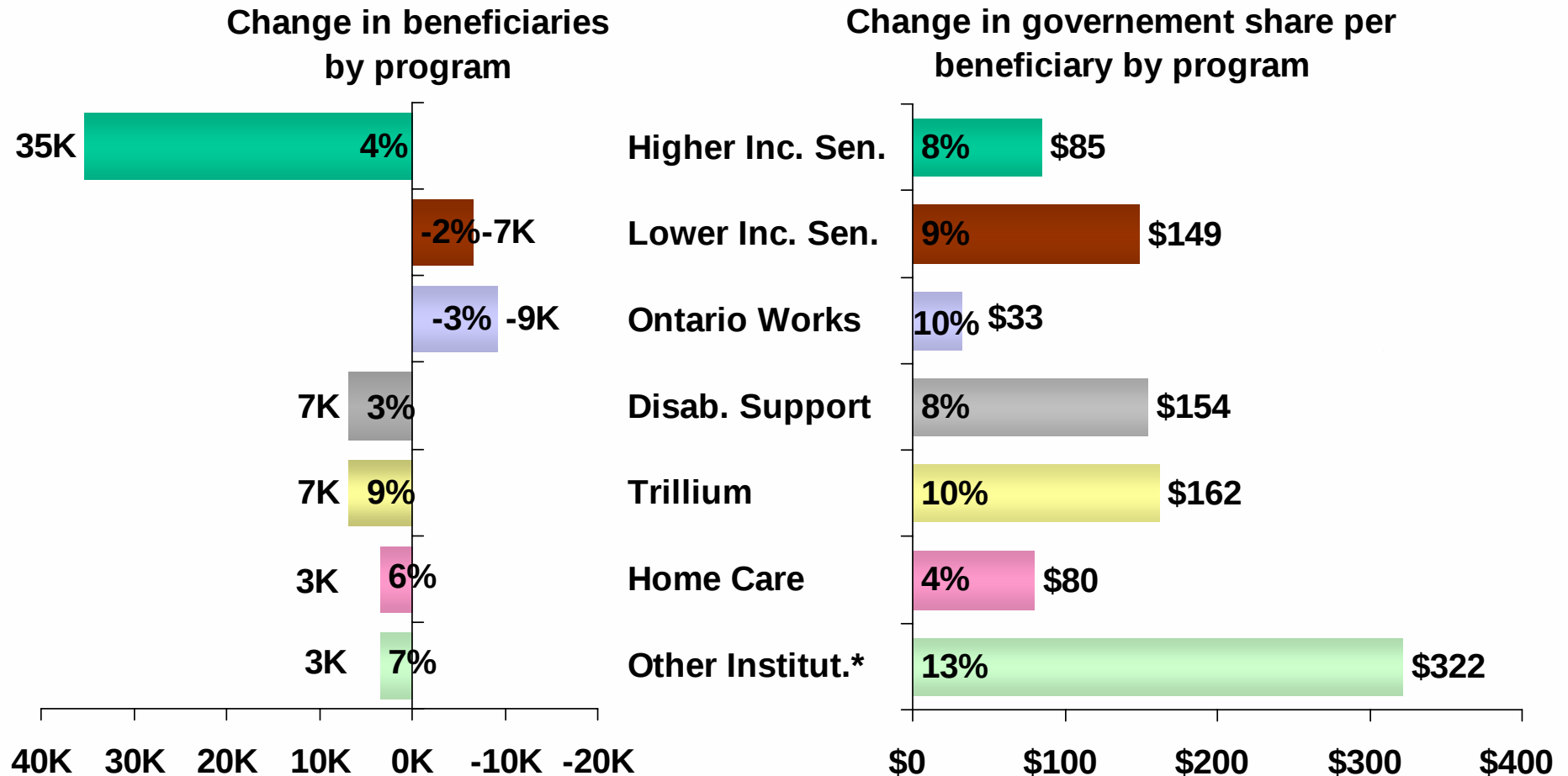


Beneficiary Distribution & Government Share by Program, 2004/05



*Special Care & Long-Term Care

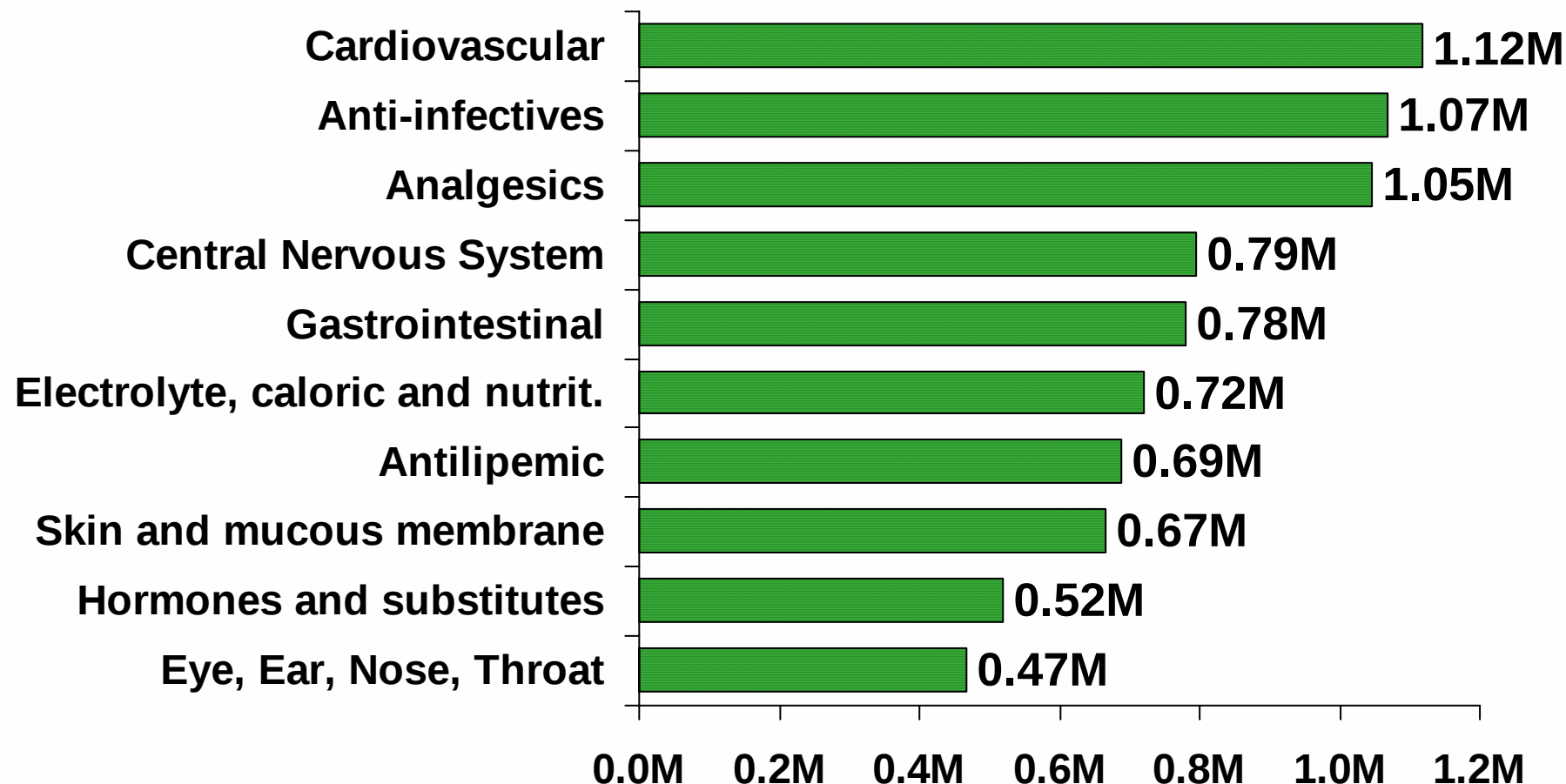
Change in Beneficiaries & Government Share by Program, 2003/04-2004/05



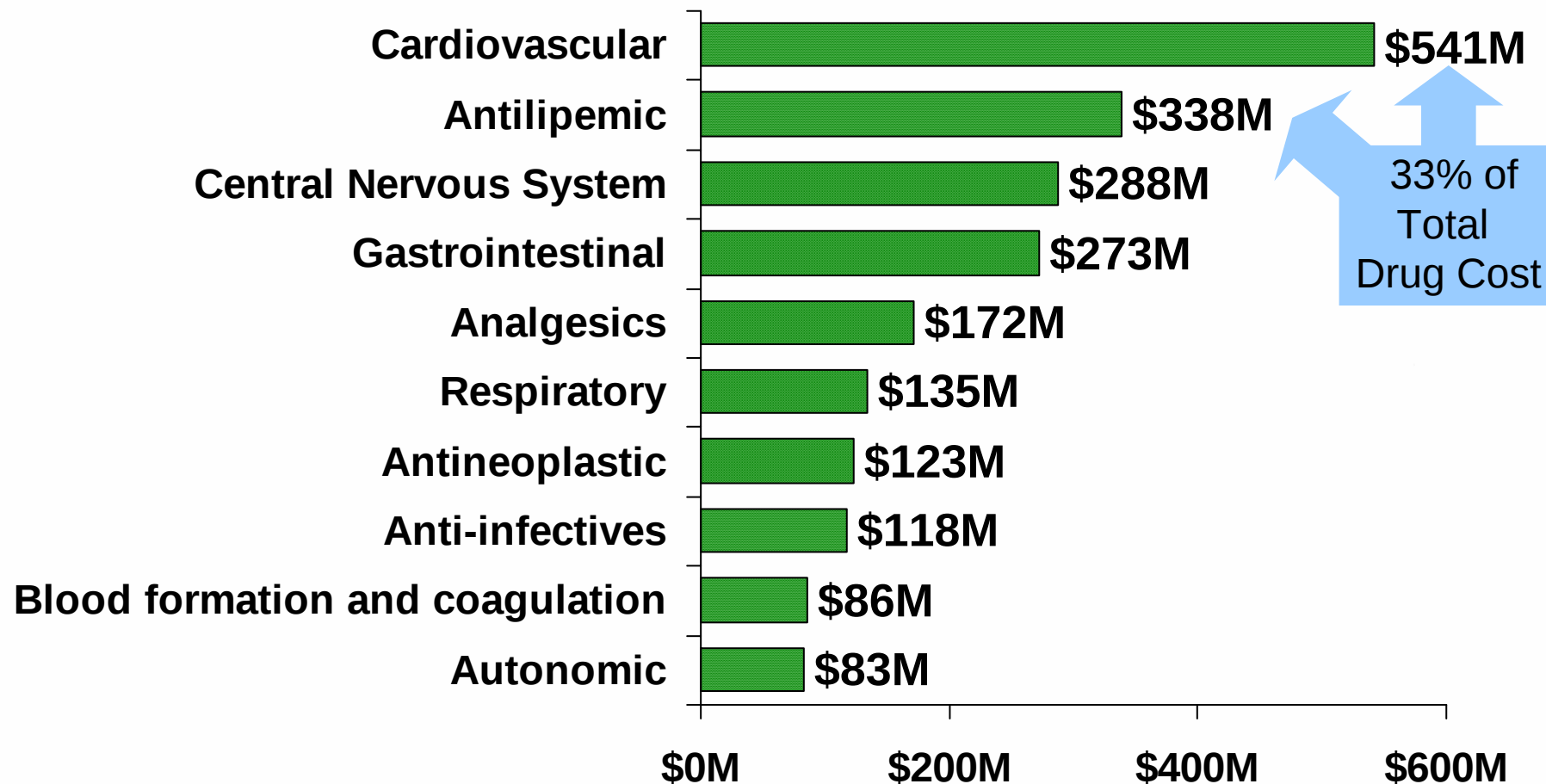
*Special Care & Long-Term Care

Top-10 Therapeutic Classes

By Number of Users, 2004/05



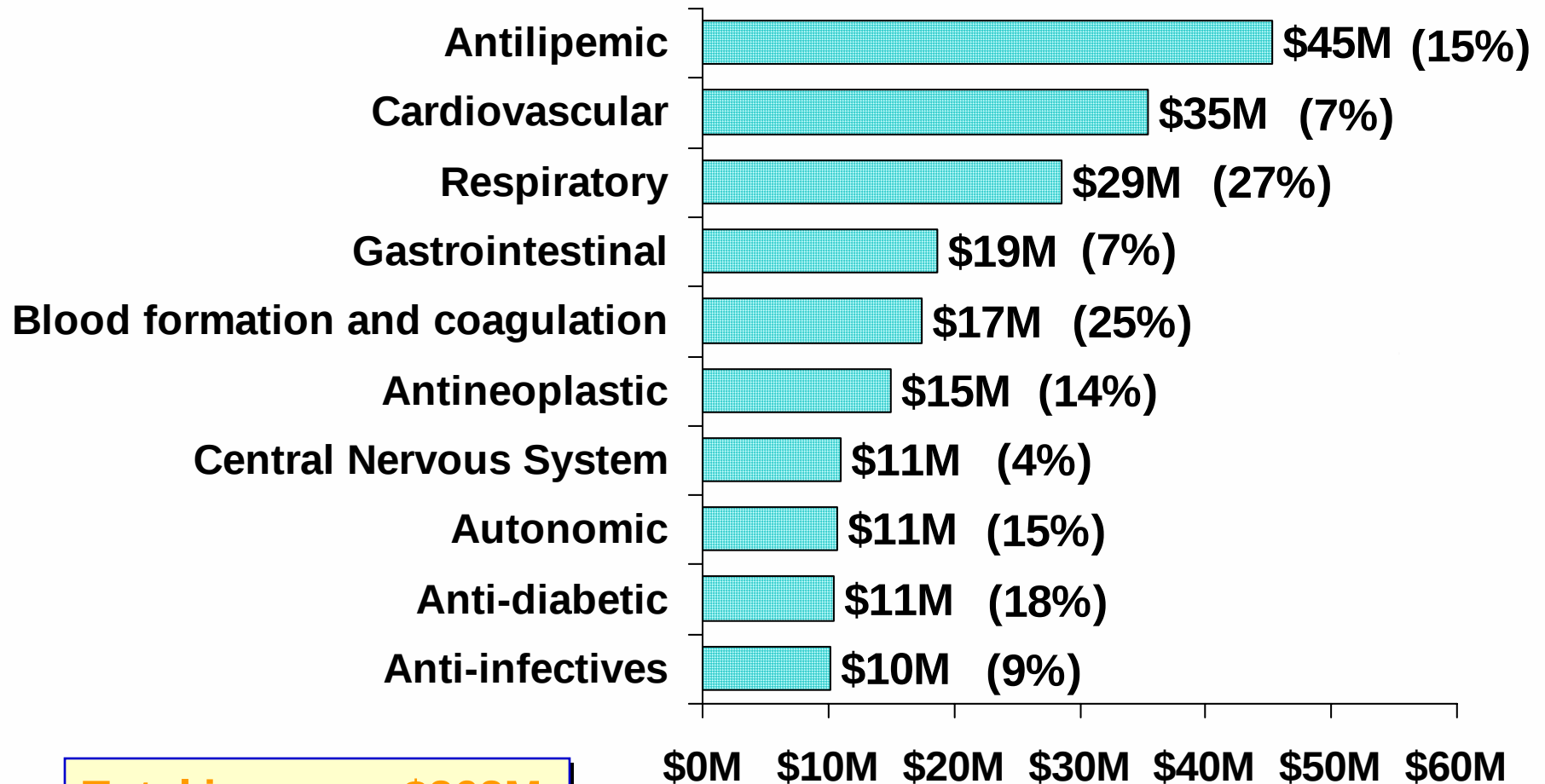
Top-10 Therapeutic Classes By Drug Cost, 2004/05



Total Drug Cost: \$2.65B

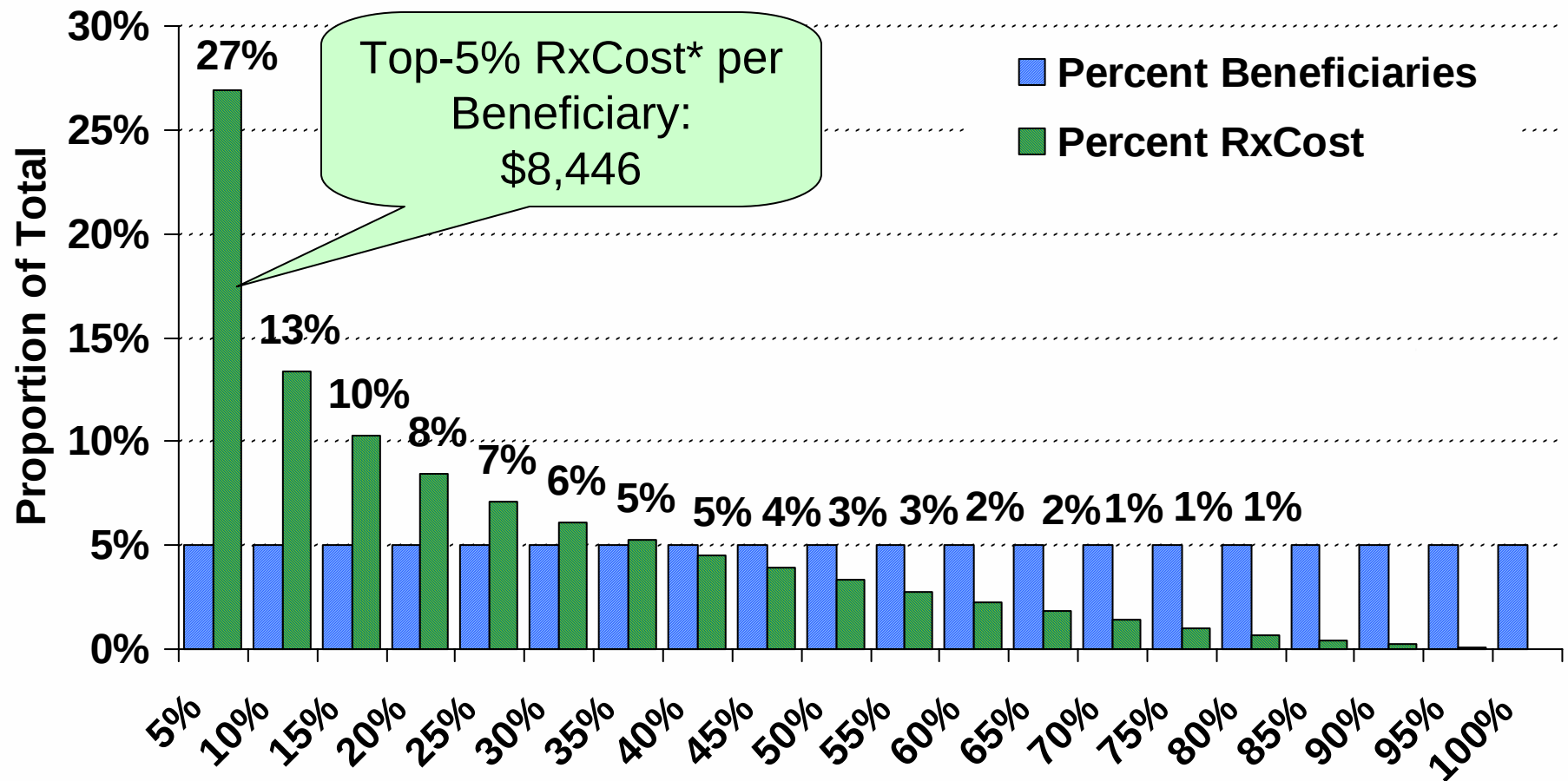
Fastest Growing Classes

By Drug Cost, 2003/04-2004/05



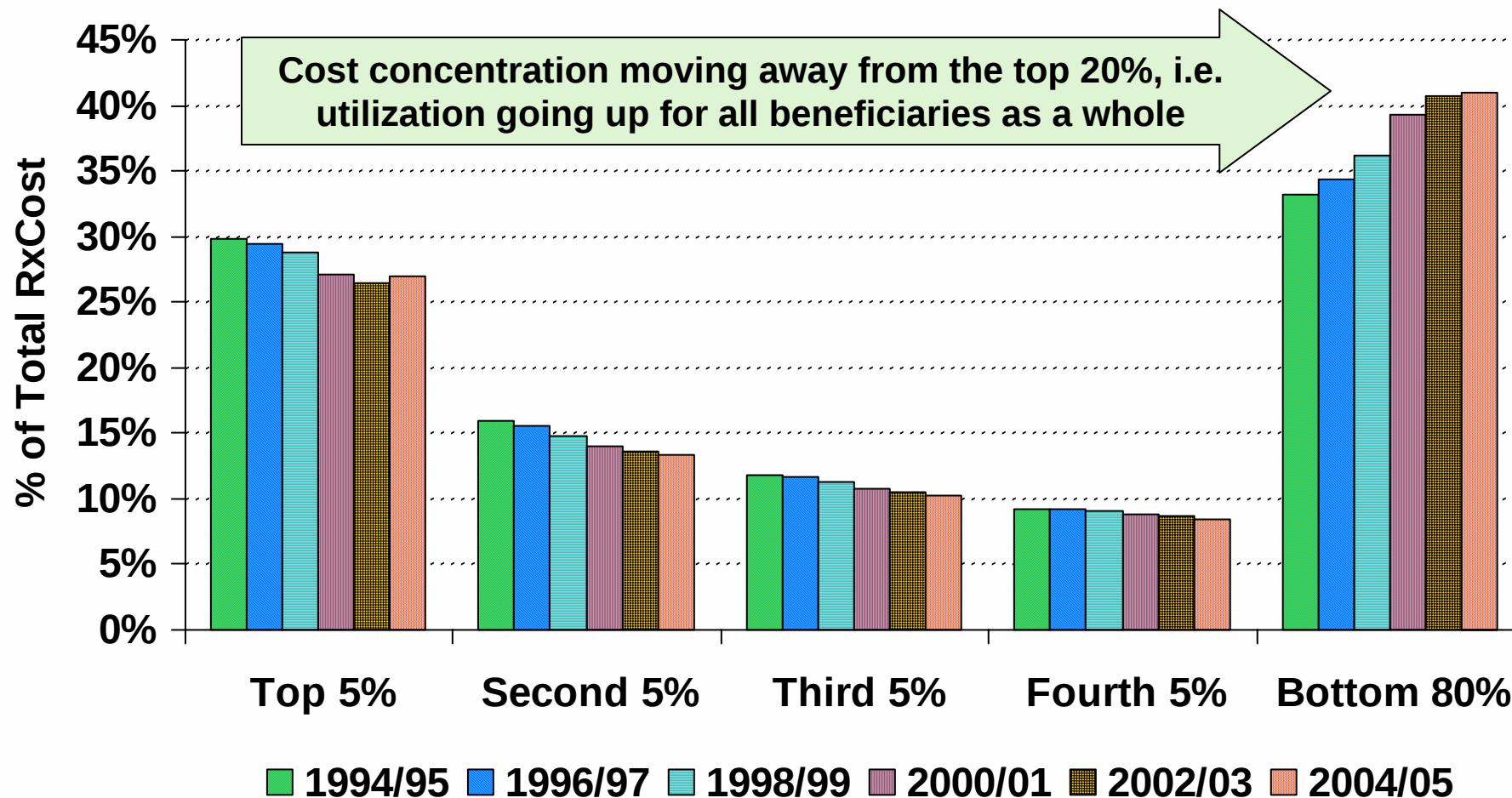
Cost Concentration, 2004/05

From Most to Least Costly Beneficiary

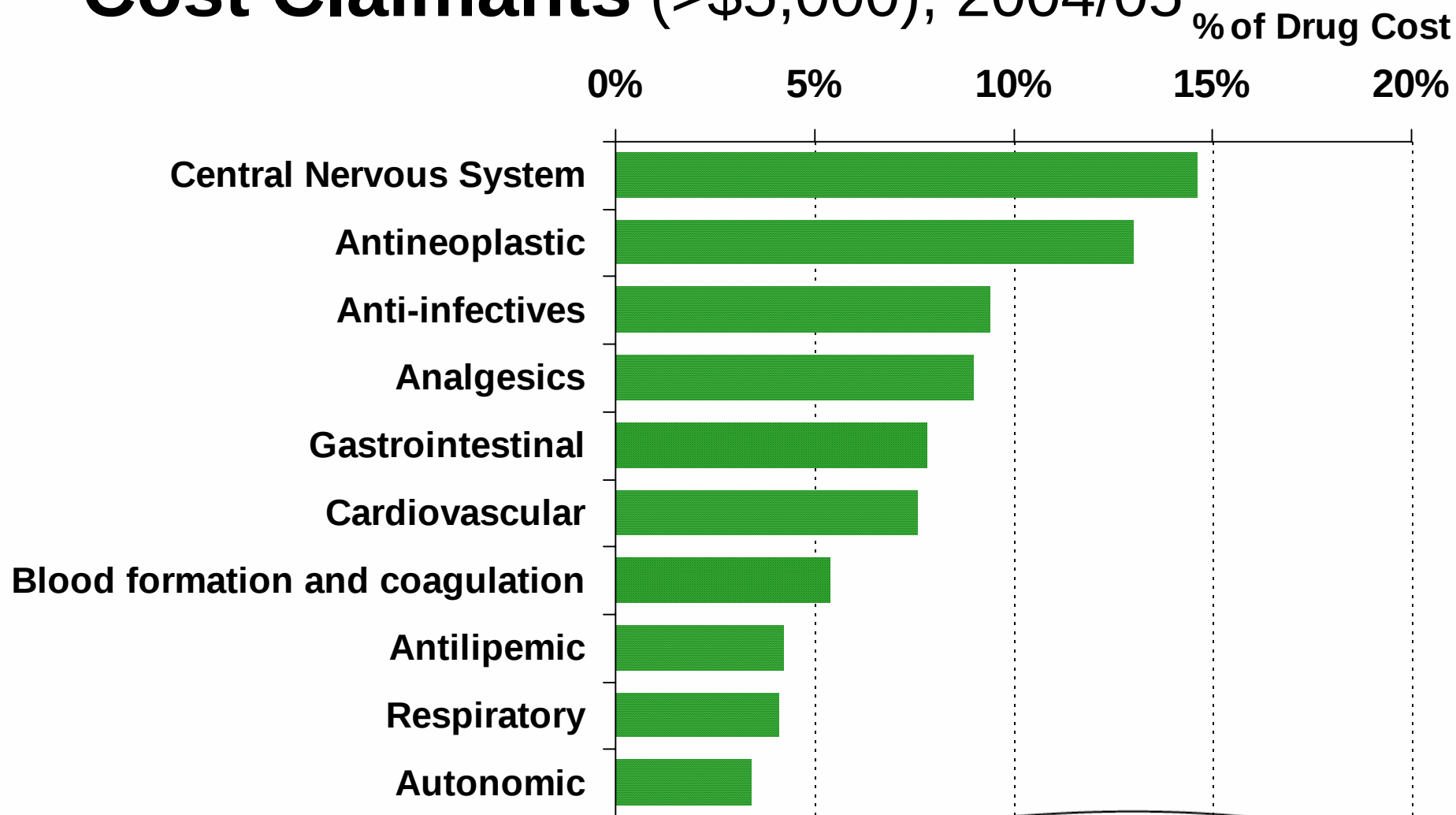


* RxCost = Drug Cost + Markup + Dispensing fee

Trend in Cost Concentration 1994/95-2004/05



Top Therapeutic Classes for High Cost Claimants (>\$5,000), 2004/05



Highlights of Overview

- Drugs are one of the fastest growing component of healthcare spending, and represent 10% of public expenditures.
- In past years, there was a large decline of beneficiaries covered under MCSS programs, while the number of seniors covered under MOHLTC kept growing.
- Cardiovascular and Antilipemic drugs account for a third of total program expenditures, which is related to the prevalence of heart and cardiovascular problems.
- A small portion (10%) of beneficiaries account for a large proportion of expenditures (40%).

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Definitions

- Drug Cost = Cost at formulary prices
- Markup = Pharmacy Markup + Wholesale Markup
- RxCost = Drug Cost + Markup + Dispensing Fee
- Gov't Cost = RxCost – Recipient Cost
- Figures includes MOH and MCSS programs unless otherwise specified.

ODB Financial Statistics

2003/04-2004/05

	2003/04	2004/05	% Change
Drug Cost	\$2,391M	\$2,653M	11%
+ Markup	\$216M	\$232M	7%
+ Dispensing Fee	\$444M	\$491M	10%
= RxCost	\$3,051M	\$3,376M	11%

	2003/04	2004/05
Markup as % of Total Drug Cost	8.3%	8.0%
Est. % of Cost-To-Operator Claims	18%	17%

ODB Financial Statistics

2003/04-2004/05

	2003/04	2004/05	% Change
Drug Cost	\$2,391M	\$2,653M	11%
+ Markup	\$216M	\$232M	7%
+ Dispensing Fee	\$444M	\$491M	10%
= RxCost	\$3,051M	\$3,376M	11%
– Deductible	\$334M	\$364M	9%
= Government Cost	\$2,717M	\$3,012M	11%
<i>MOHLTC</i>	<i>\$2,167M</i>	<i>\$2,404M</i>	<i>11%</i>
<i>MCSS</i>	<i>\$550M</i>	<i>\$608M</i>	<i>11%</i>

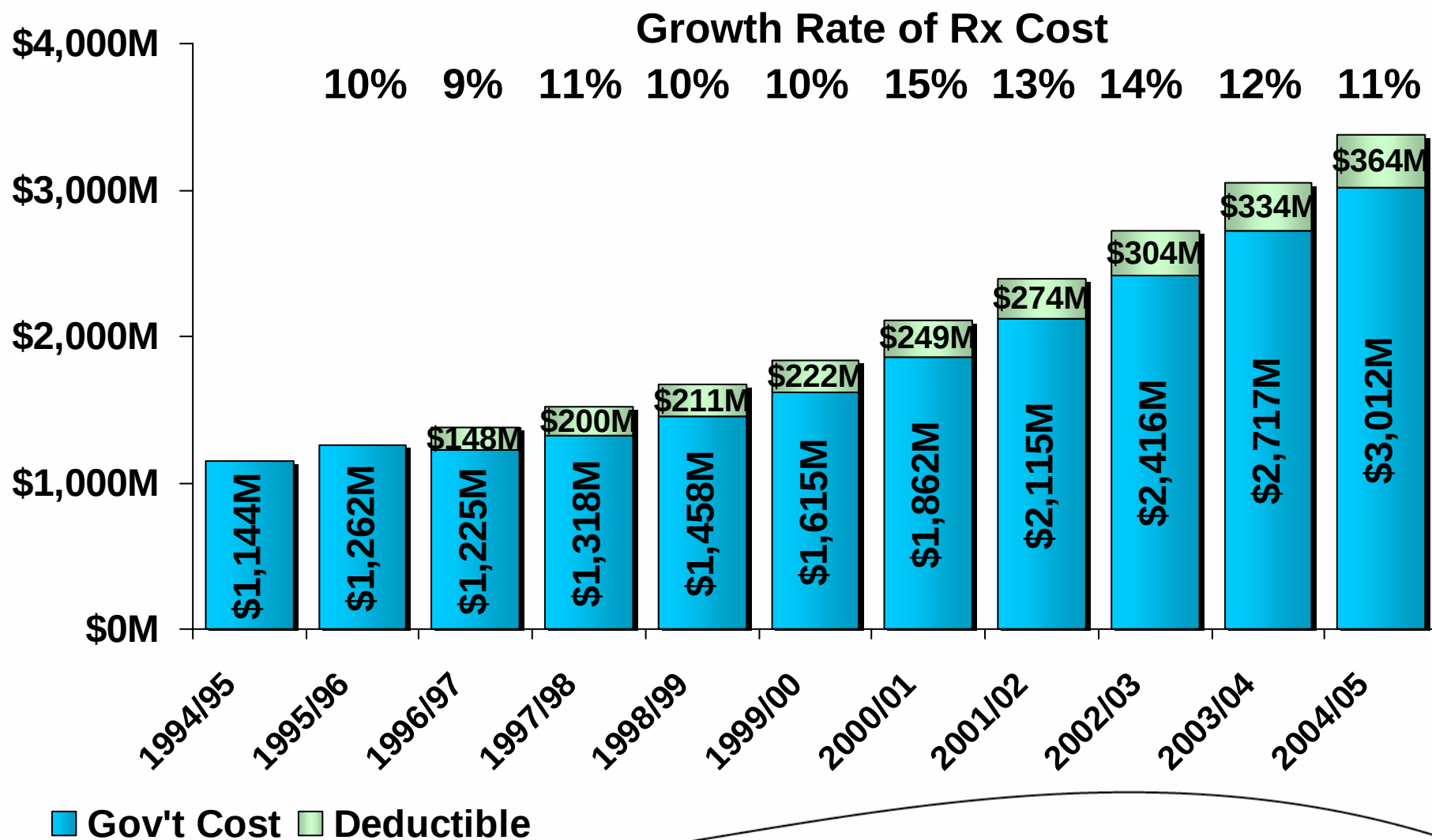
ODB Financial Statistics

2003/04-2004/05

		2003/04	2004/05	% Change
RxCost	Total	\$3,051M	\$3,376M	11%
	<i>Brand</i>	<i>\$2,316M</i>	<i>\$2,522M</i>	<i>9%</i>
	<i>Generic</i>	<i>\$735M</i>	<i>\$854M</i>	<i>16%</i>
Beneficiaries		2.12M	2.16M	2%
Average	RxCost per Beneficiary	\$1,440	\$1,564	9%
	RxCost per Claim	\$43.59	\$43.74	0%
	Claims per Beneficiary	33.0	35.8	8%

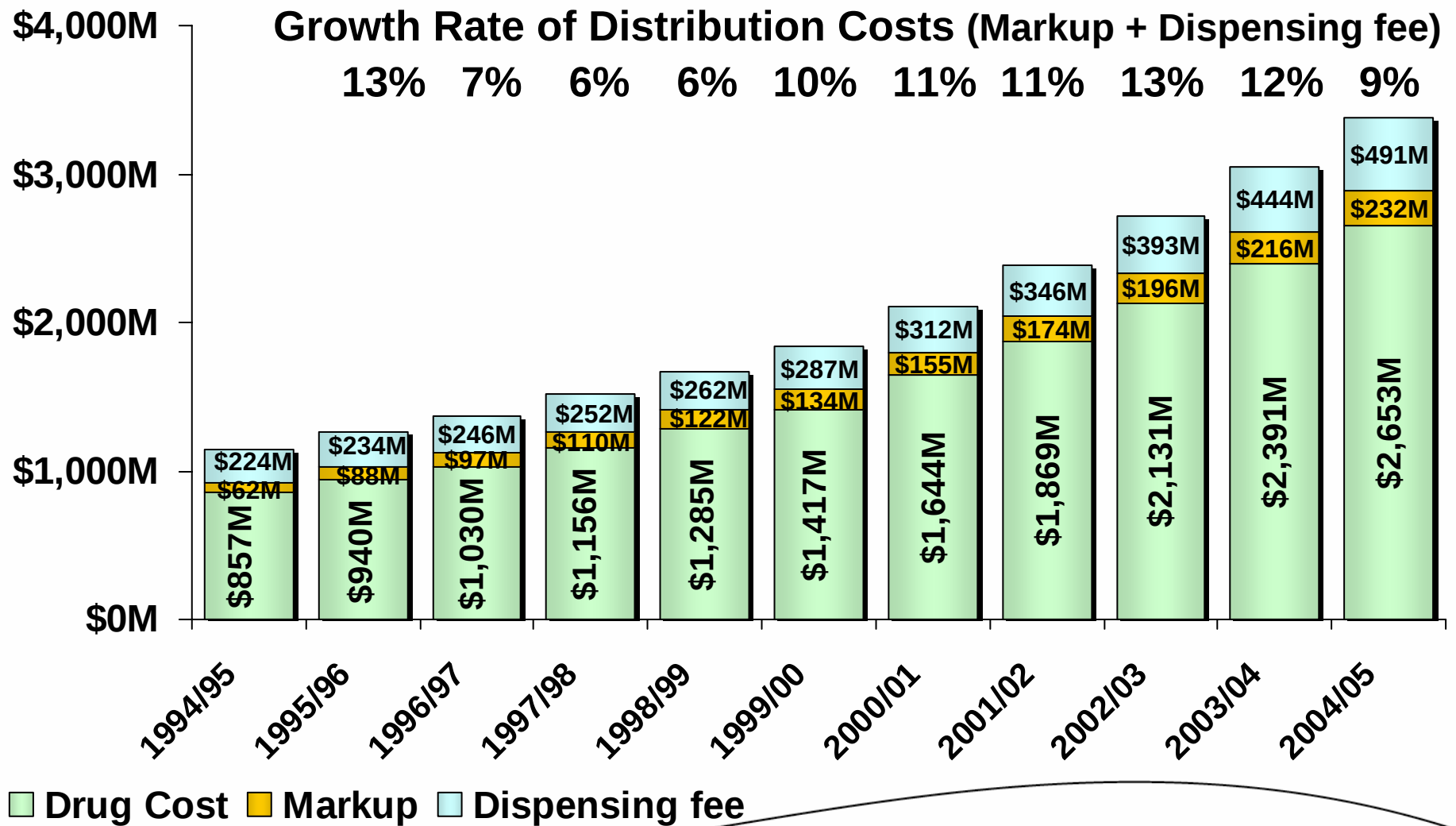
Government & Beneficiary Cost

1994/95-2004/05



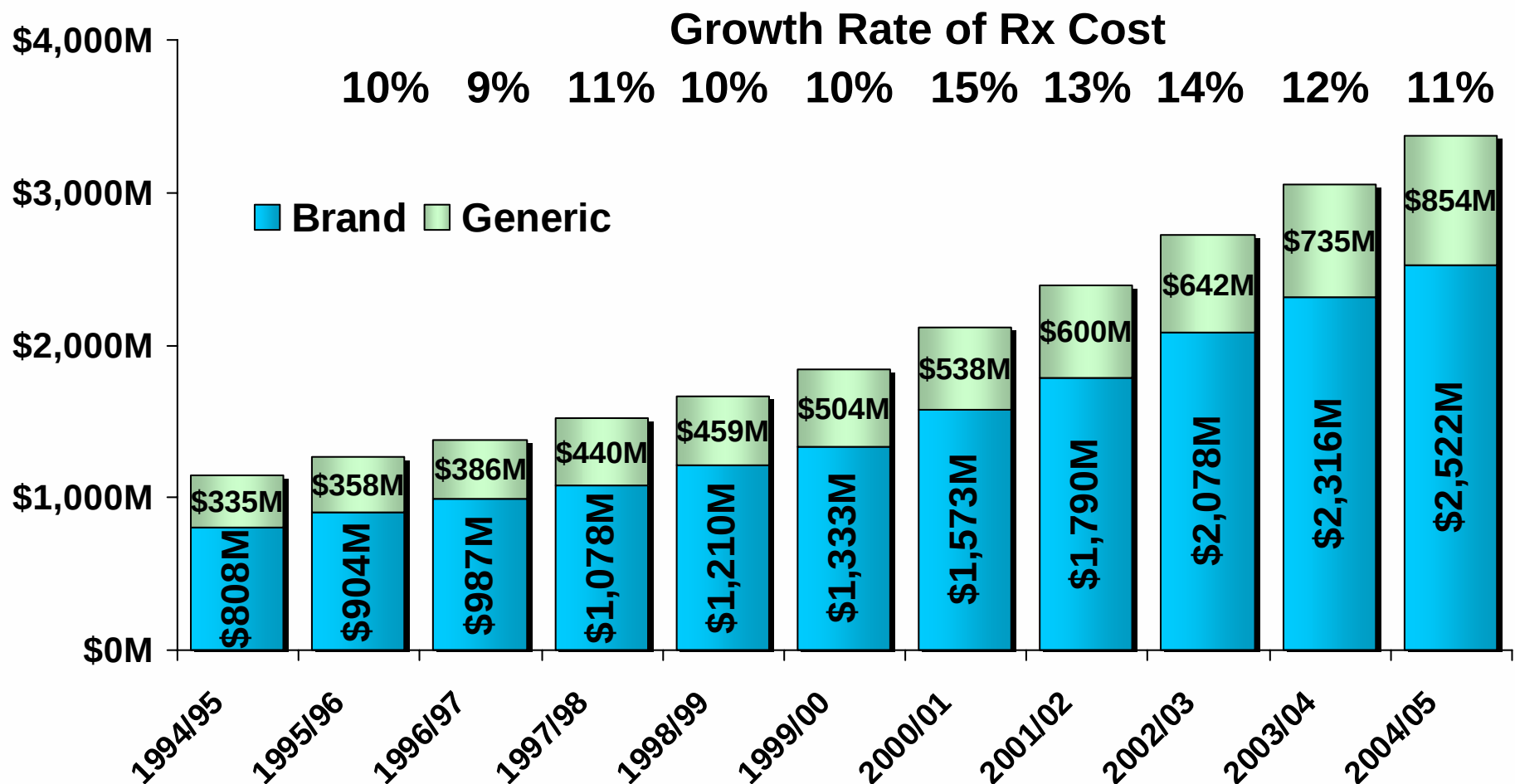
Rx Cost by Type of Spending

1994/95-2004/05



Brand vs. Generic Rx Cost

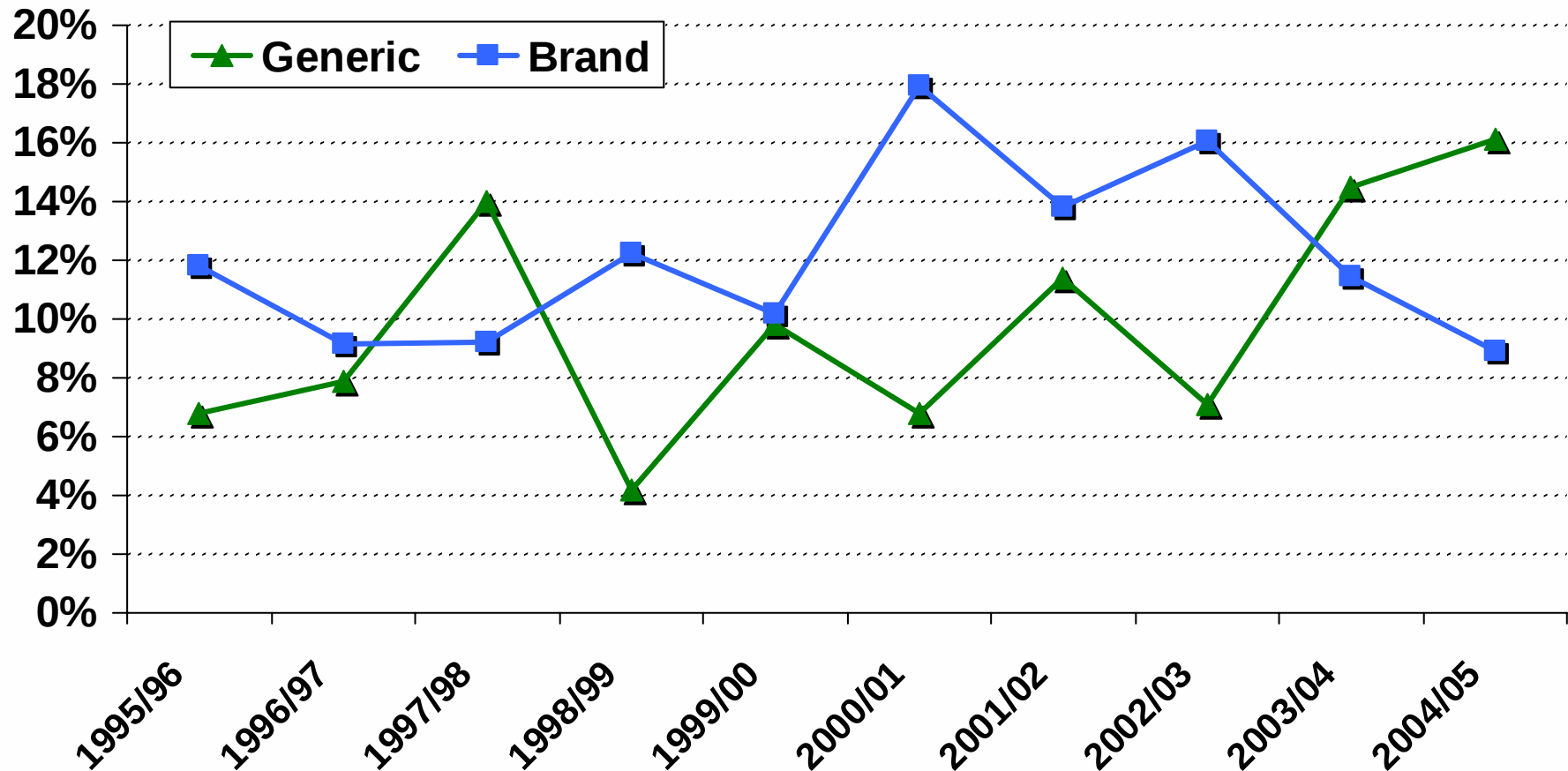
1994/95-2004/05



Note: Figures are approximations. Pharmacy compounded products were classified as generics. They accounted for approx. \$28 million in 2004/05

Brand vs. Generic Rx Cost

Annual Growth, 1995/96-2004/05



Note: Figures are approximations. Pharmacy compounded products were classified as generics. They accounted for approx. \$28 million in 2004/05

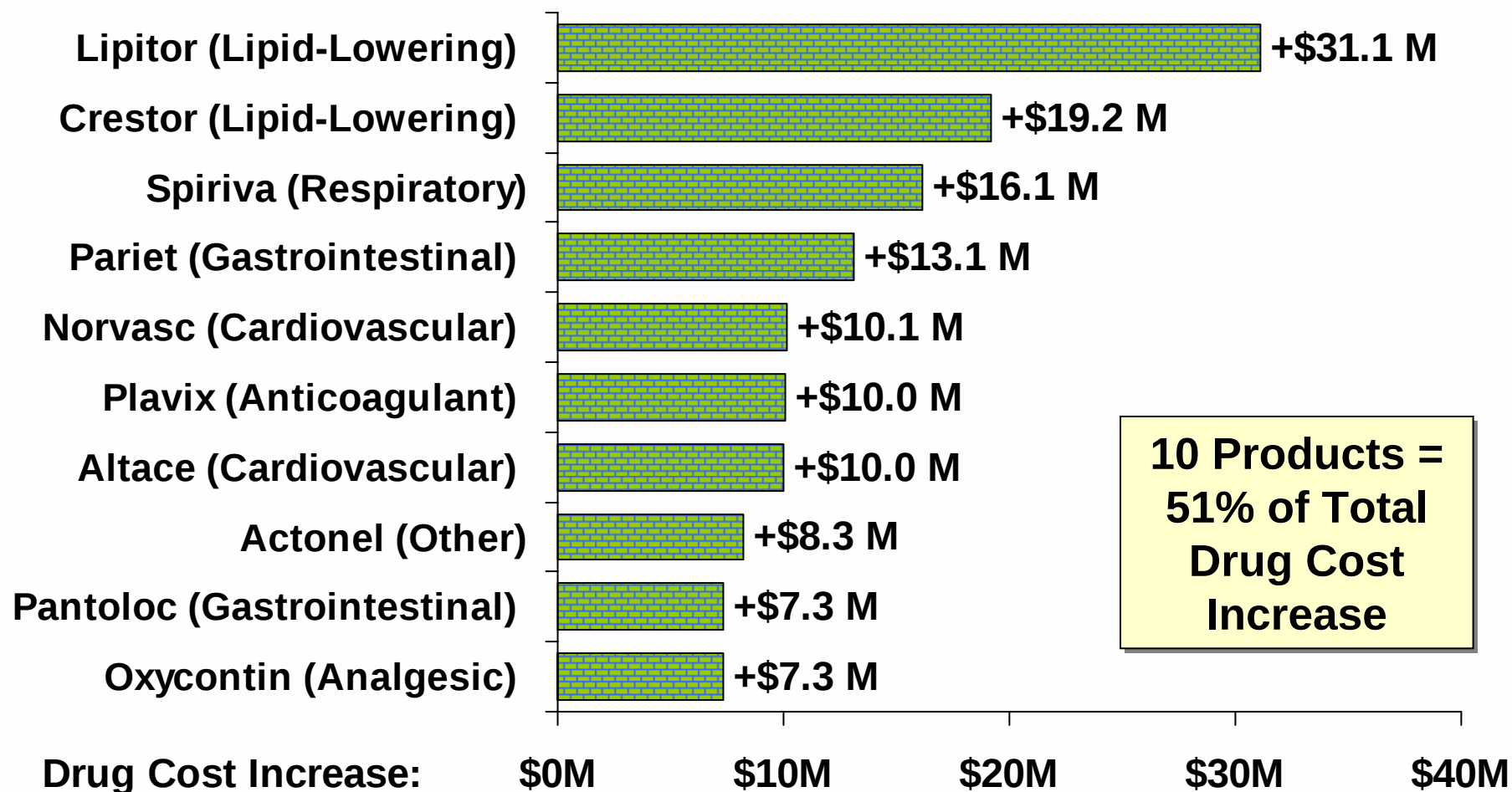
Top-10 Chemicals by Drug Cost

2004/05

Rk	Drug Name	Class	Drug Cost	% Total Drug Cost
1	Atorvastatin (Lipitor)	Lipid-Lowering	\$201M	7.6%
2	Omeprazole (Losec) – LU	Gastrointestinal	\$97M	3.7%
3	Amlodipine besylate (Norvasc)	Cardiovascular	\$97M	3.6%
4	Ramipril (Altace)	Cardiovascular	\$90M	3.4%
5	Diagnostic Agent – Diabetes	Diagnostic Agents	\$77M	2.9%
6	Olanzapine (Zyprexa)	Anti-psychotic	\$74M	2.8%
7	Simvastatin (Zocor)	Lipid-Lowering	\$56M	2.1%
8	Diltiazem HCl (Tiazac)	Cardiovascular	\$42M	1.6%
9	Donepezil HCl (Aricept) – LU	Autonomic Agents	\$42M	1.6%
10	Pantoprazole (Pantoloc) – LU	Gastrointestinal	\$41M	1.5%
TOTAL Top-10			\$817 M	31%

Fastest Growing Brand Products

By Drug Cost, 2003/04-2004/05



Top-10 Products* Launched Since 2000

By Drug Cost, 2004/05

Rk	Drug Name	Class	Drug Cost	% Total Drug Cost
1	Fluticasone Propionate (Flovent HFa)	Respiratory	\$30.6M	1.15%
2	Rabeprazole Sodium (Pariet)	Gastrointestinal	\$29.4M	1.11%
3	Rosuvastatin Calcium (Crestor)	Antilipemic	\$26.4M	0.99%
4	Simvastatin (Apo-Simvastatin)	Antilipemic	\$26.3M	0.99%
5	Tiotropium Bromide Monohydrate (Spiriva)	Respiratory	\$23.3M	0.88%
6	Simvastatin (Gen-Simvastatin)	Antilipemic	\$22.0M	0.83%
7	Infliximab (Remicade) – Section 8	Other	\$16.6M	0.63%
8	Galantamine Hydrobromide (Reminyl) – LU	Autonomic	\$13.7M	0.52%
9	Etanercept (Enbrel) – Section 8	Other	\$12.2M	0.46%
10	Imatinib Mesylate (Gleevec) – Section 8	Antineoplastic	\$12.1M	0.46%
TOTAL Top-10			\$212.6M	8.01%

** This analysis includes all generic and brand products launched since 2000*

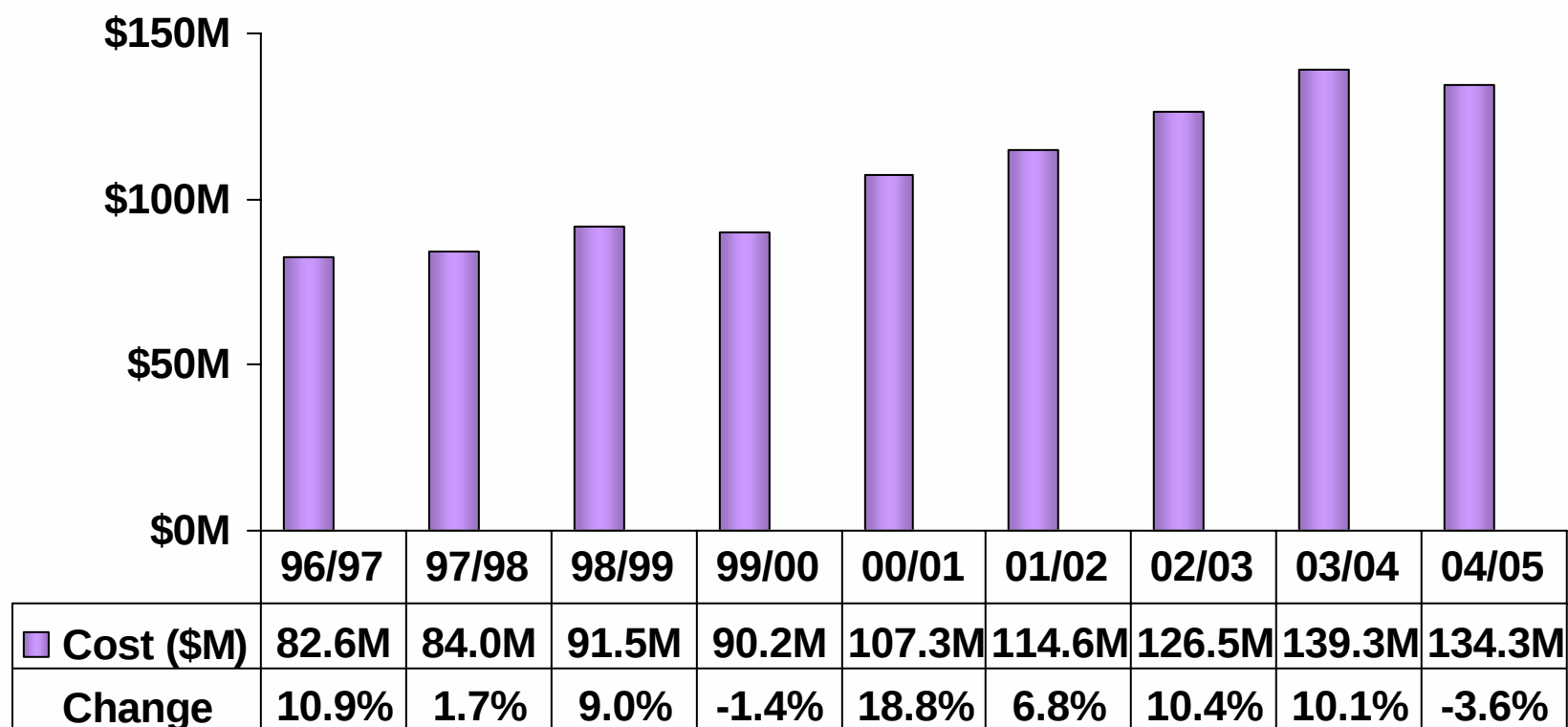
Top-10 Brand Products* Launched Since 2000, by Drug Cost, 2004/05

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6	Galantamine Hydrobromide (Reminyl) – LU	Autonomic	\$13.7M	0.52%
7	Etanercept (Enbrel) – Section 8	Other	\$12.2M	0.46%
8	Imatinib Mesylate (Gleevec) – Section 8	Antineoplastic	\$12.1M	0.46%
9	Rivastigmine (Exelon) – LU	Autonomic	\$9.6M	0.36%
10	Olanzapine (Zyprexa Zydis)	CNS	\$9.3M	0.35%
TOTAL Top-10			\$183.3M	6.91%

** This analysis includes all brand products launched since 2000*

Special Drugs Program Cost

1996/97-2004/05



Highlights of Financials

- Government Cost was \$3,012M, a 11% increase over 2003/04
- \$723M was paid as dispensing fees plus mark-ups. Beneficiaries paid \$364M in deductible
- The average RxCost per claim remained stable at nearly \$44, but the average number of claims per beneficiary went up 10% to 35.8
- The 10 fastest growing products accounted for 51% of the total Drug Cost increase

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Accomplishments and Looking Ahead

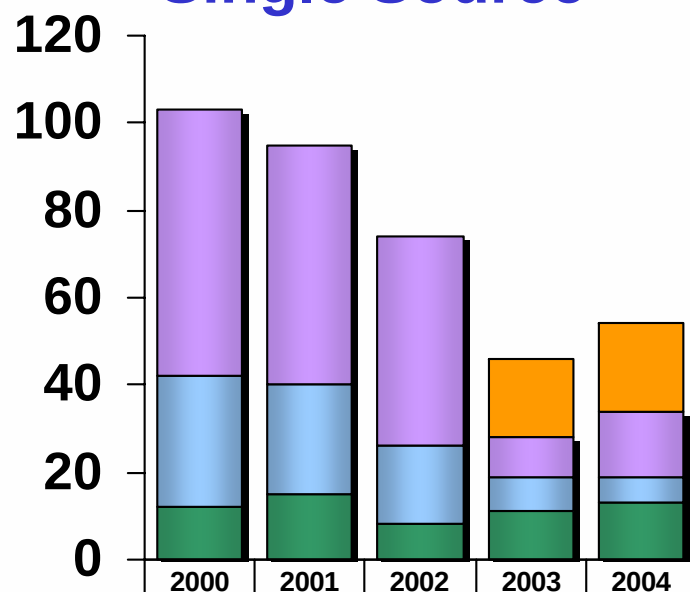
Definitions

- **General Benefit**: Reimbursement for the drug product is without restrictions
- **Limited Use Products**: Reimbursement for certain drugs is dependent on specific clinical criteria
- **Individual Clinical Review (Section 8)**: Individual requests for coverage of drug products not listed in the formulary are reviewed on a case by case basis

DQTC Recommendations

Submissions for First Review, 1999-2004

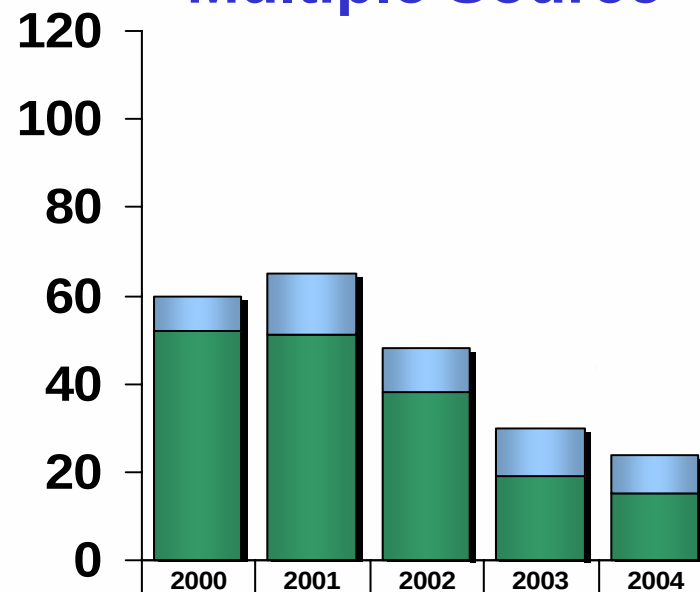
Single Source



No Reimbursement*	-	-	-	18	20
ICR*	61	55	48	9	15
Limited Use	30	25	18	8	6
General Benefit	12	15	8	11	13

* Negative listing recommendations prior to 2003 were not broken down into ICR and no reimbursement.

Multiple Source



Rejected	8	14	10	11	9
Interchangeable	52	51	38	19	15

Note: Reviews of oral solid dosage forms were streamlined starting in 2002 and no longer require DQTC review.

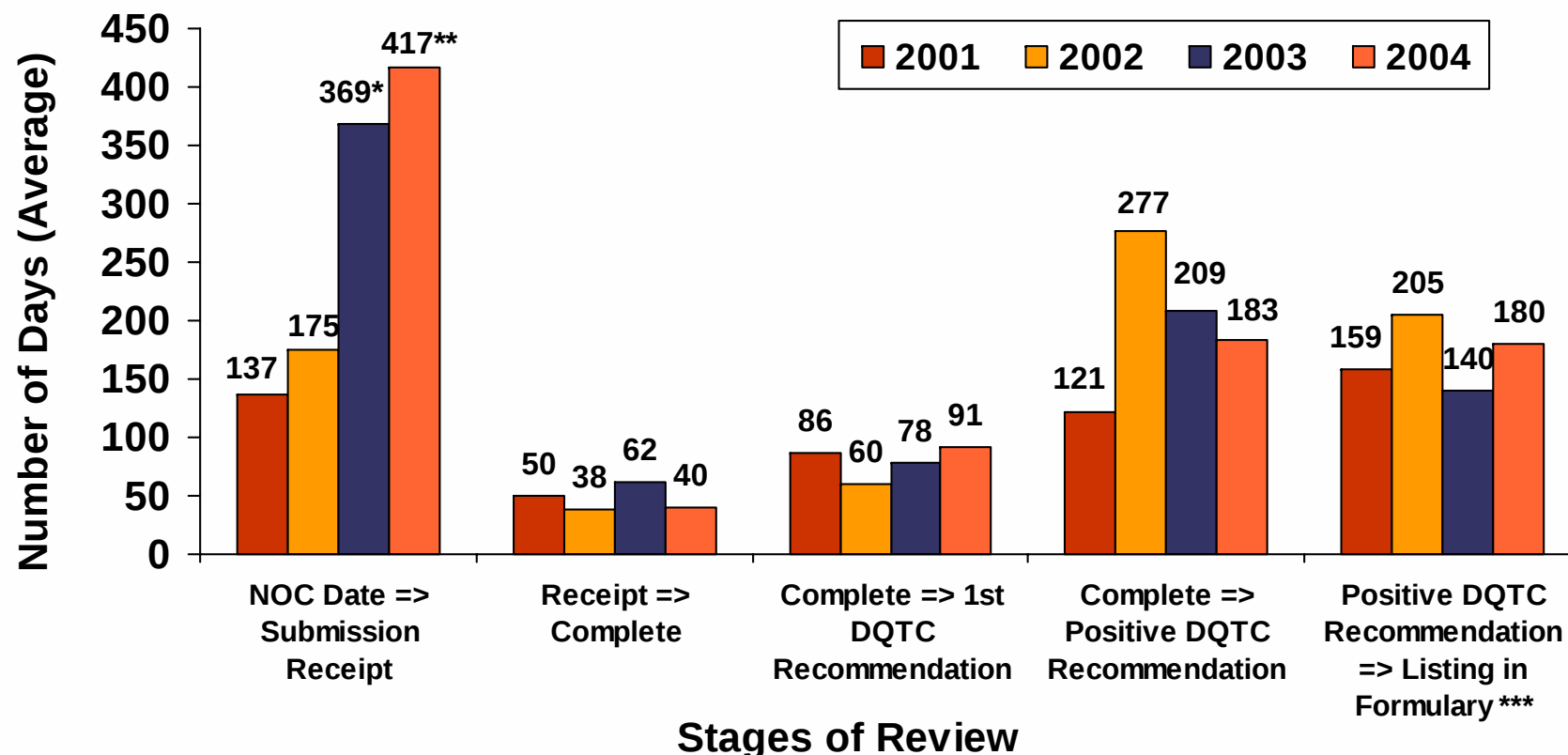
CDR Submissions – ODB Perspective

- Overall, DQTC recommendations have been consistent with final CEDAC recommendations
- DQTC recommendations communicated to manufacturers as of December 31, 2004 for CDR Submissions:

General Benefit	Limited Use	Section 8	No reimbursement
1	1	4	3

Average Timelines between a CEDAC and DQTC recommendation = 15.9 business days
(Range: 9 – 40 days)

Average Review Timelines for All Single Source Drug Products Listed in 2004

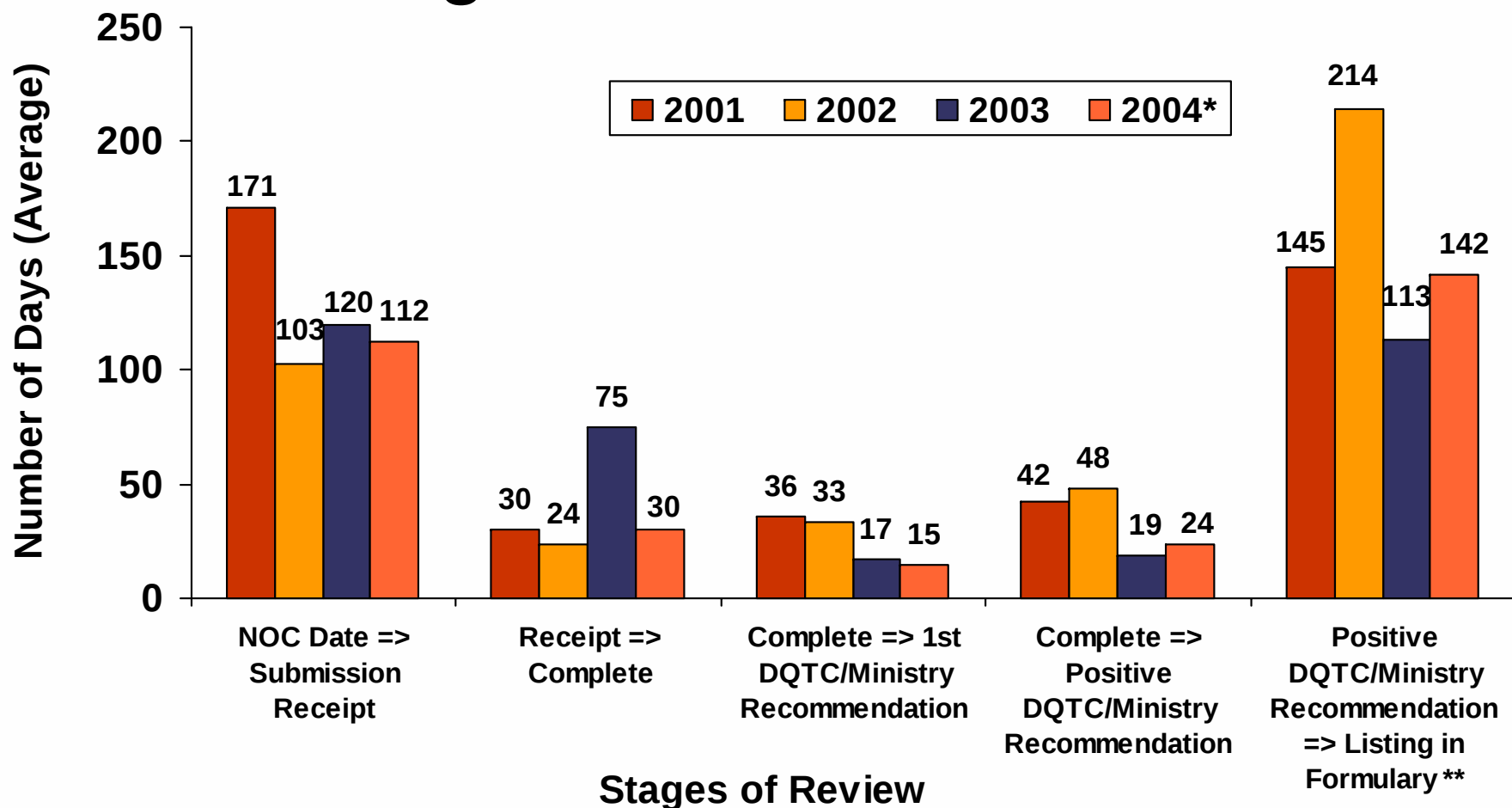


* 10 products had significant lag time (>730 days) from NOC receipt to submission

** 6 products had a significant lag time (>730 days) from NOC receipt to submission

*** One quarterly update was delayed in early 2004 due to a change in Government

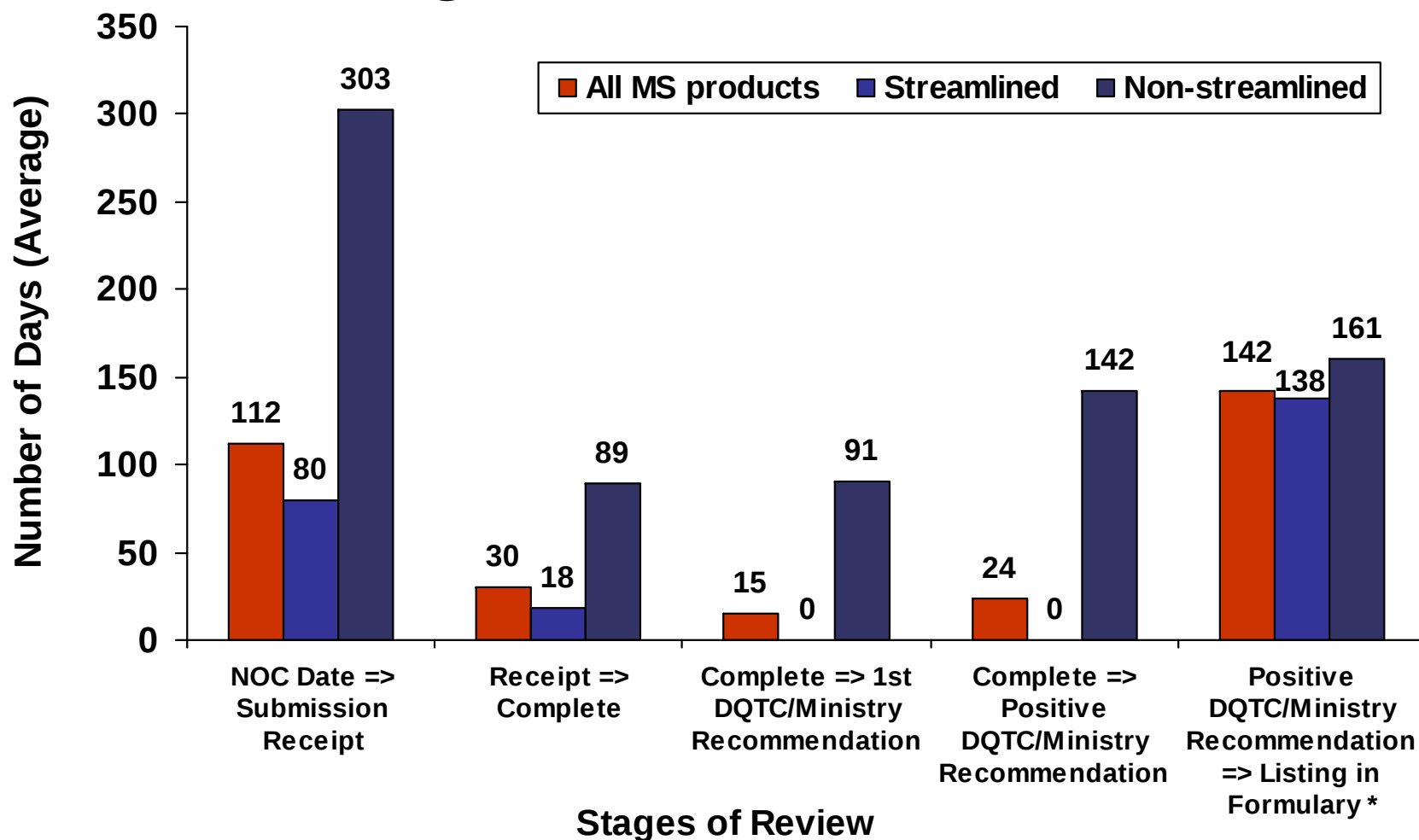
Average Review Timelines for All Multiple Source Drug Products Listed in 2004



* Introduction of monthly generic approvals process in July 2004

** One quarterly update was delayed in early 2004 due to a change in Government

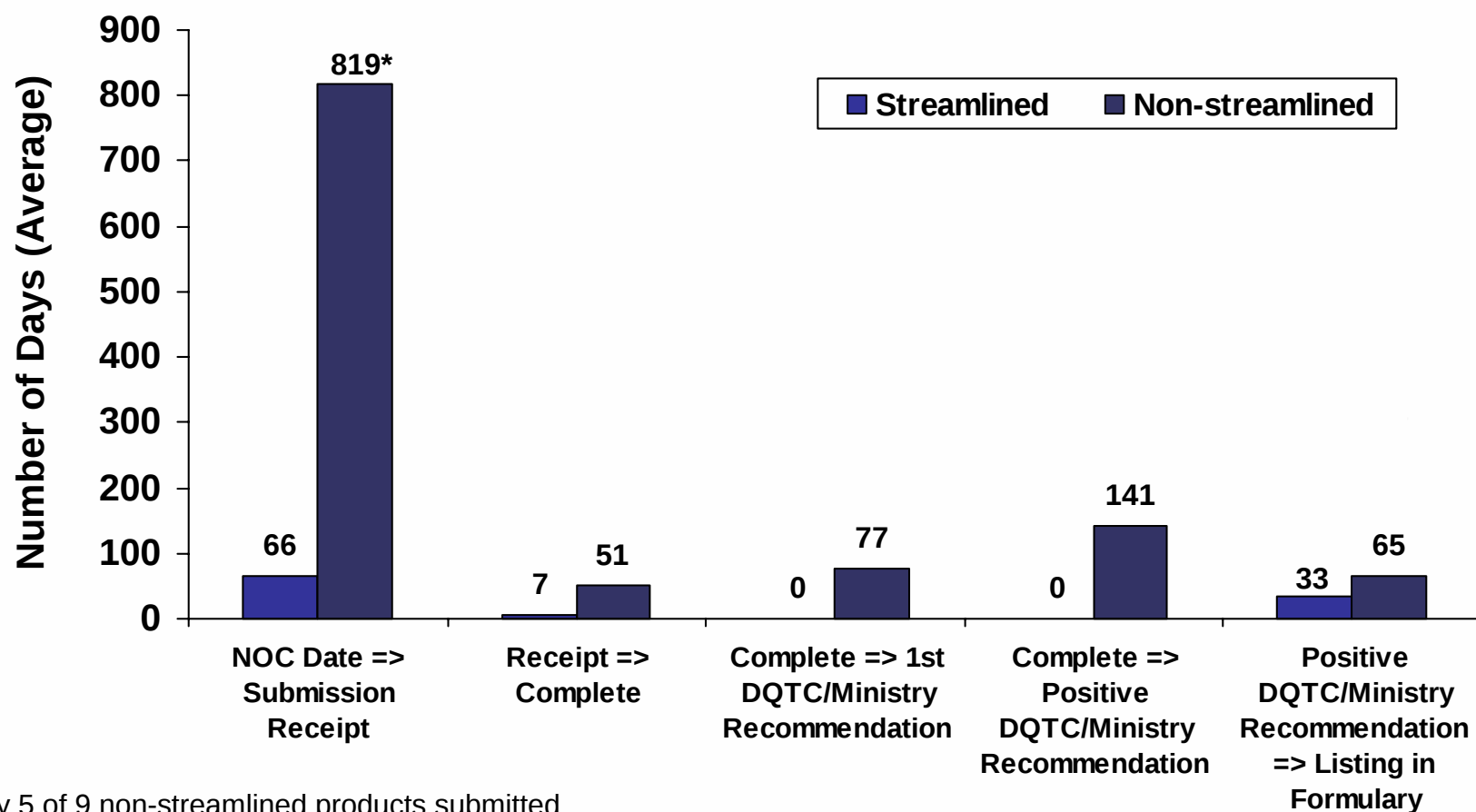
Streamlined vs. Non-Streamlined Multiple Source Drug Products Listed in 2004



* One quarterly update was delayed in early 2004 due to a change in Government

Monthly Generic Formulary Updates (August – December 2004)

Streamlined vs Non-Streamlined Multiple Source Drug Products

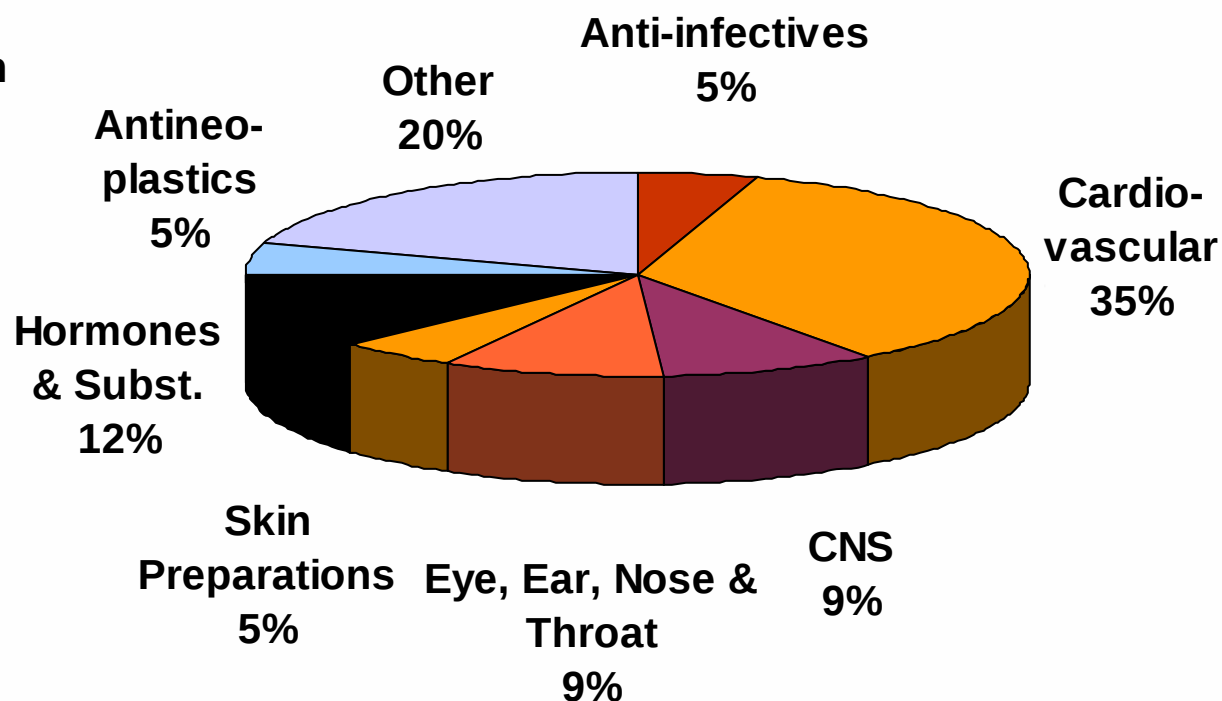


* Only 5 of 9 non-streamlined products submitted received a NOC from Health Canada (i.e. other submissions were “old” drugs) with 2 products having a significant lag time (>730 days) from NOC receipt to submission

Stages of Review

Written Agreements by Therapeutic Class, 2004/05

- Forecasted cost provided by manufacturers for each of the first three years of new single-source drugs listed
- 192 agreements are in effect as of Formulary 38, Update F (Feb. 22, 2005)



Top-10 Chemicals, 2004/05

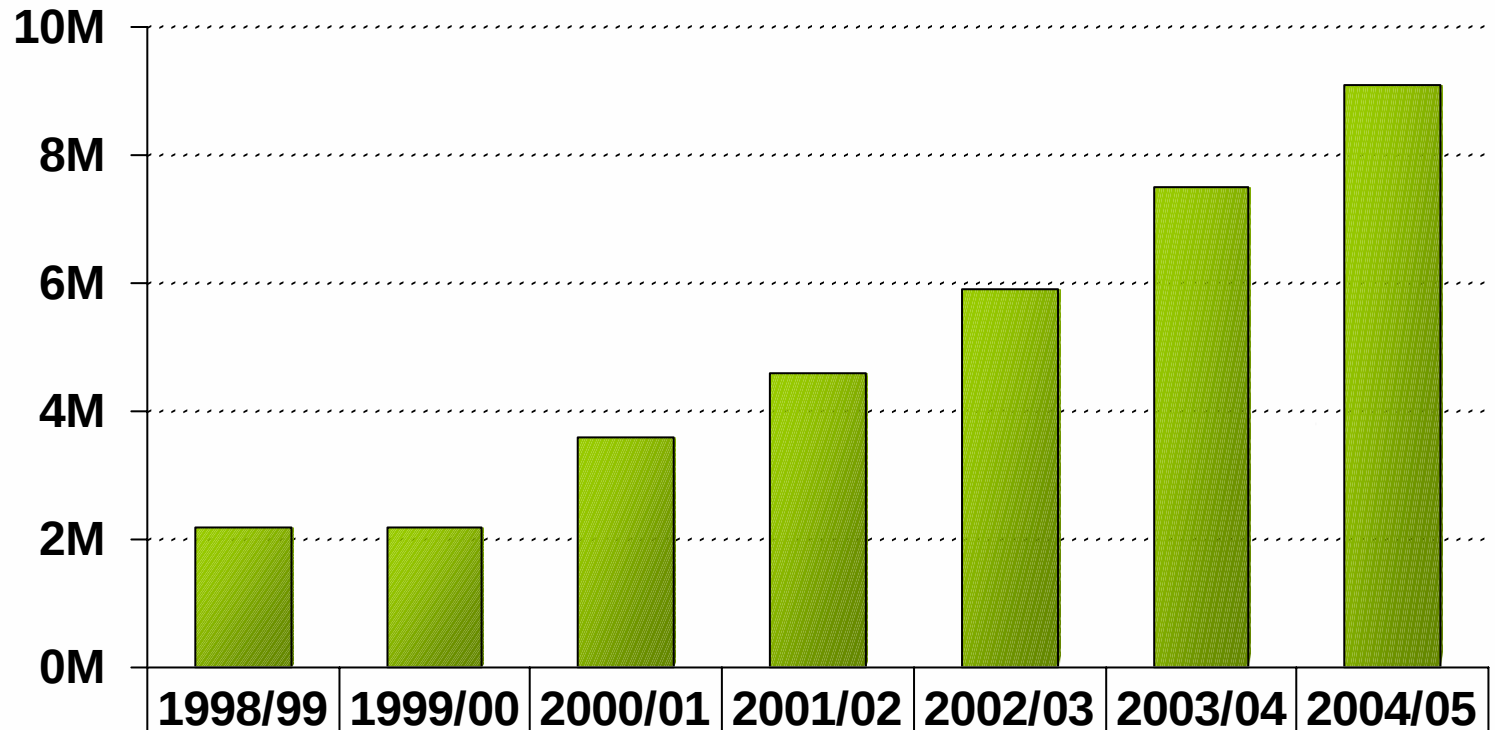
by Number of Claimants (thousands)

Rk	Drug Name	Class	Claimants	% Claimants
1	Acetaminophen & Caffeine & Codeine (Tylenol No.3)	Analgesic	416K	19.3%
2	Atorvastatin (Lipitor)	Lipid-Lowering	380K	17.6%
3	Ramipril (Altace)	Cardiovascular	326K	15.1%
4	Amoxicillin	Antibiotic	317K	14.7%
5	Hydrochlorothiazide	Diuretic	293K	13.6%
6	Levothyroxine sodium (Synthroid)	Hormones	253K	11.7%
7	Diagnostic Agents - Diabetes	Diabetes	247K	11.5%
8	Lorazepam (Ativan)	Central Nervous System	241K	11.2%
9	Amlodipine Besylate (Norvasc)	Cardiovascular	220K	10.2%
10	Furosemide	Diuretic	208K	9.7%

All these drugs are General Benefits

Limited Use Products

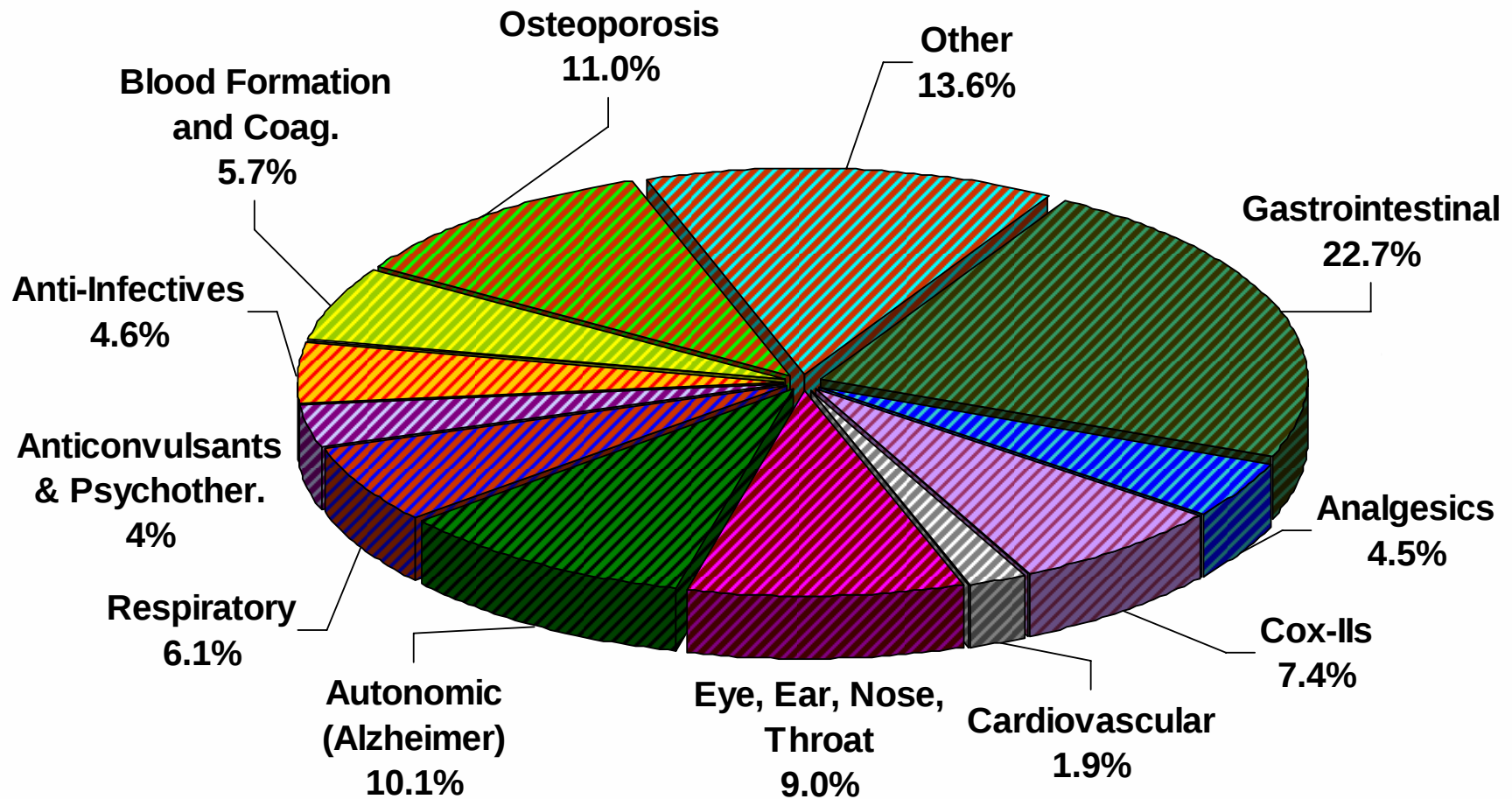
Number of Claims, 1998/99-2004/05



■ Claims (million)	2.2M	2.2M	3.6M	4.6M	5.9M	7.5M	9.1M
% of Overall ODB	4.9%	4.8%	7.2%	8.3%	9.4%	10.7%	11.8%

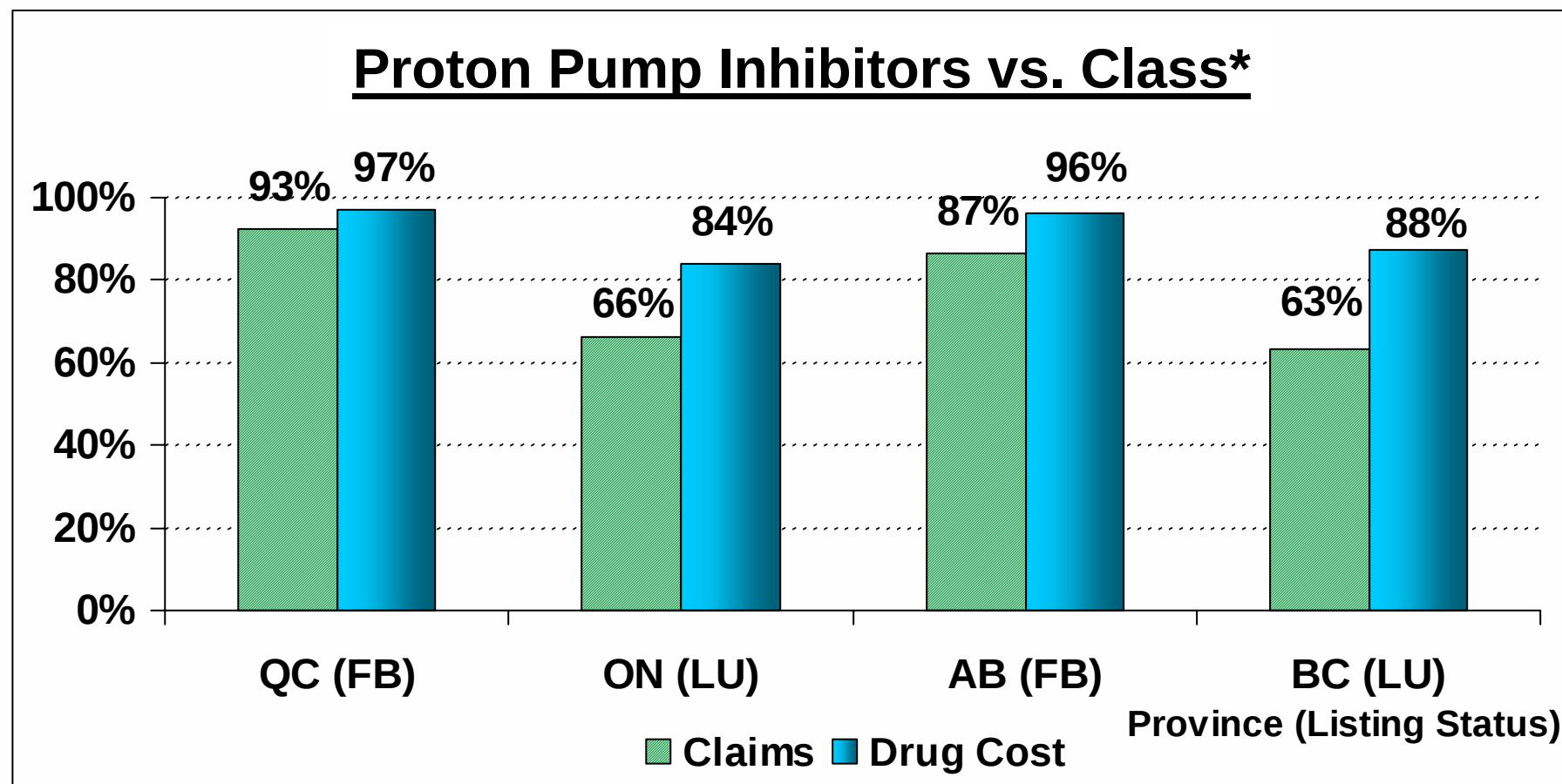
Limited Use Products

Claims by Class, 2004/05



Limited Use Products vs. Entire Class

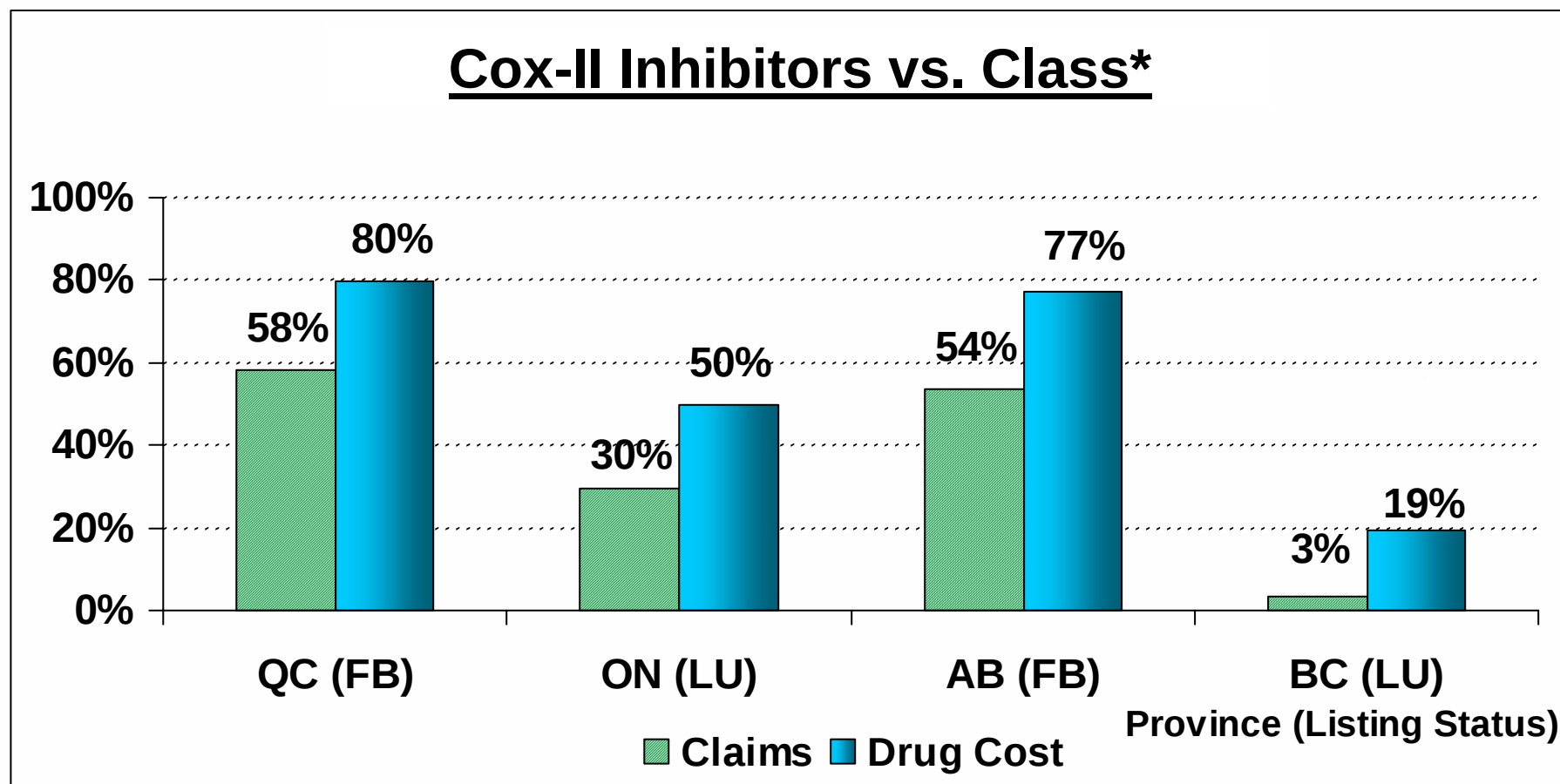
By Province, 2004/05



*The class is defined as Proton Pump Inhibitors and Histamine H2 Receptor Antagonists.

Limited Use Products vs. Entire Class

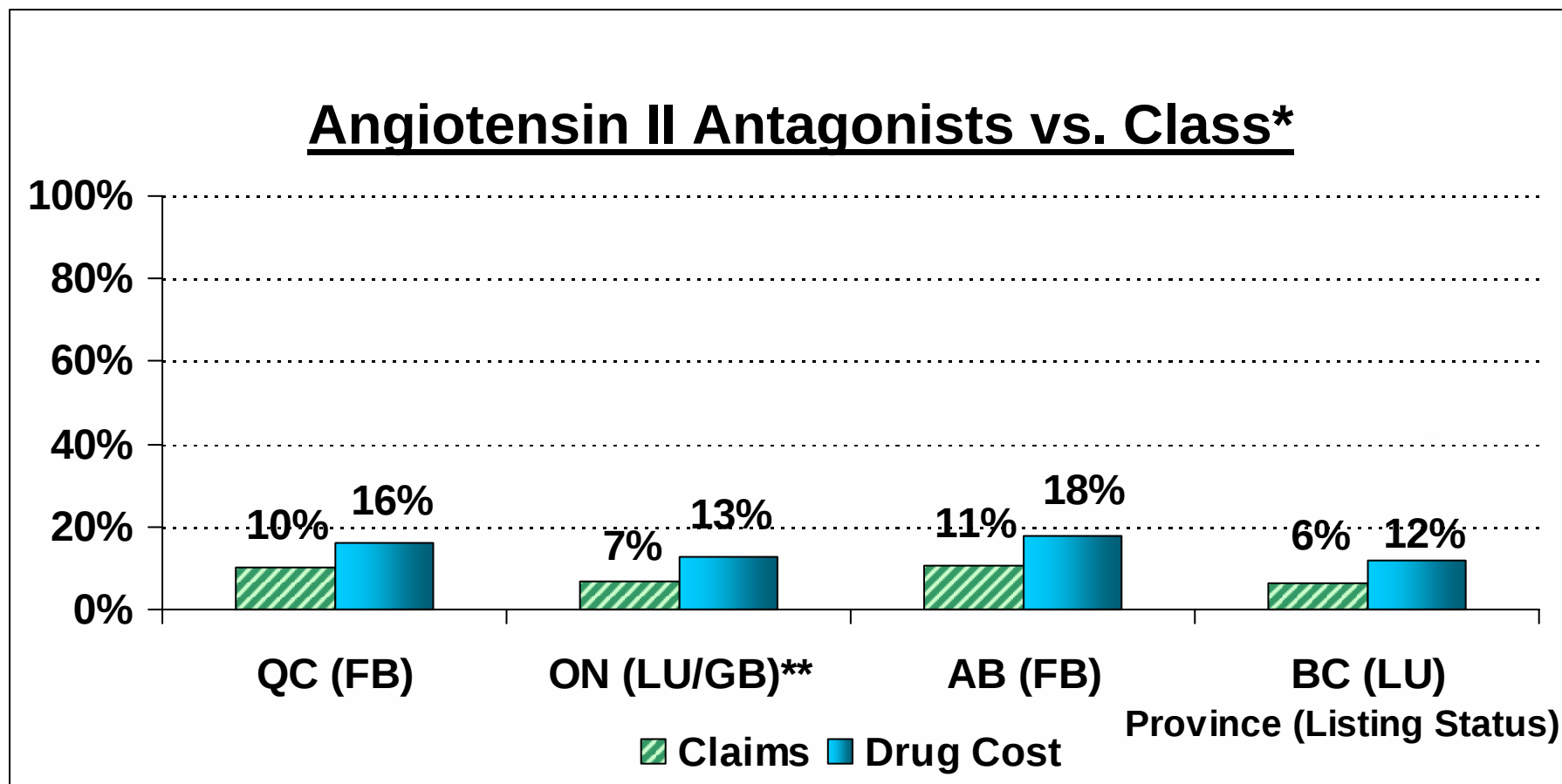
By Province, 2004/05



*The Limited Use drugs are Celebrex and Vioxx. The class is all Non-Steroidal Anti-Inflammatory Drugs (excluding ASA).

Limited Use Products vs. Entire Class

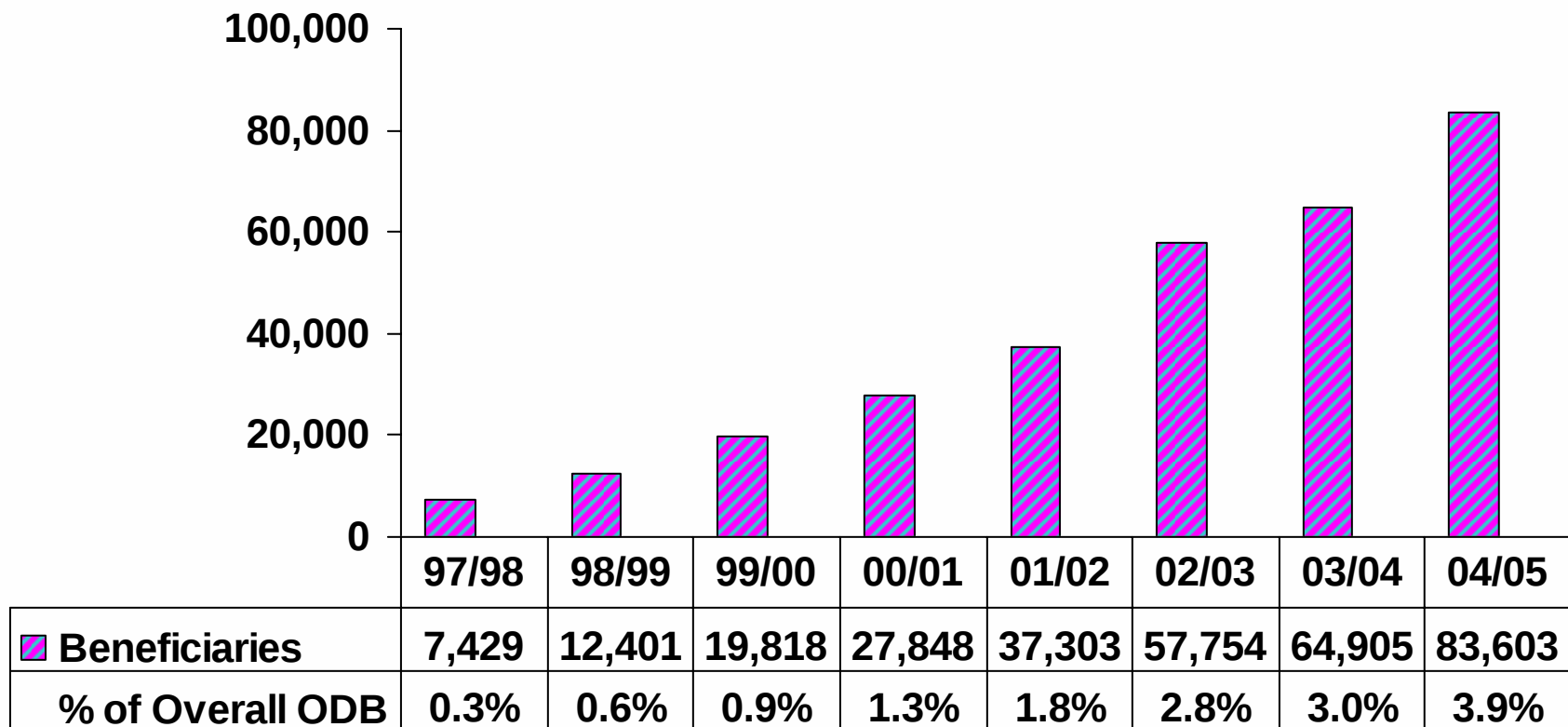
By Province, 2004/05



* The class is defined as Angiotensin II Antagonists, ACE-Inhibitors, Calcium Channel Blockers, Diuretics and Beta Blockers.

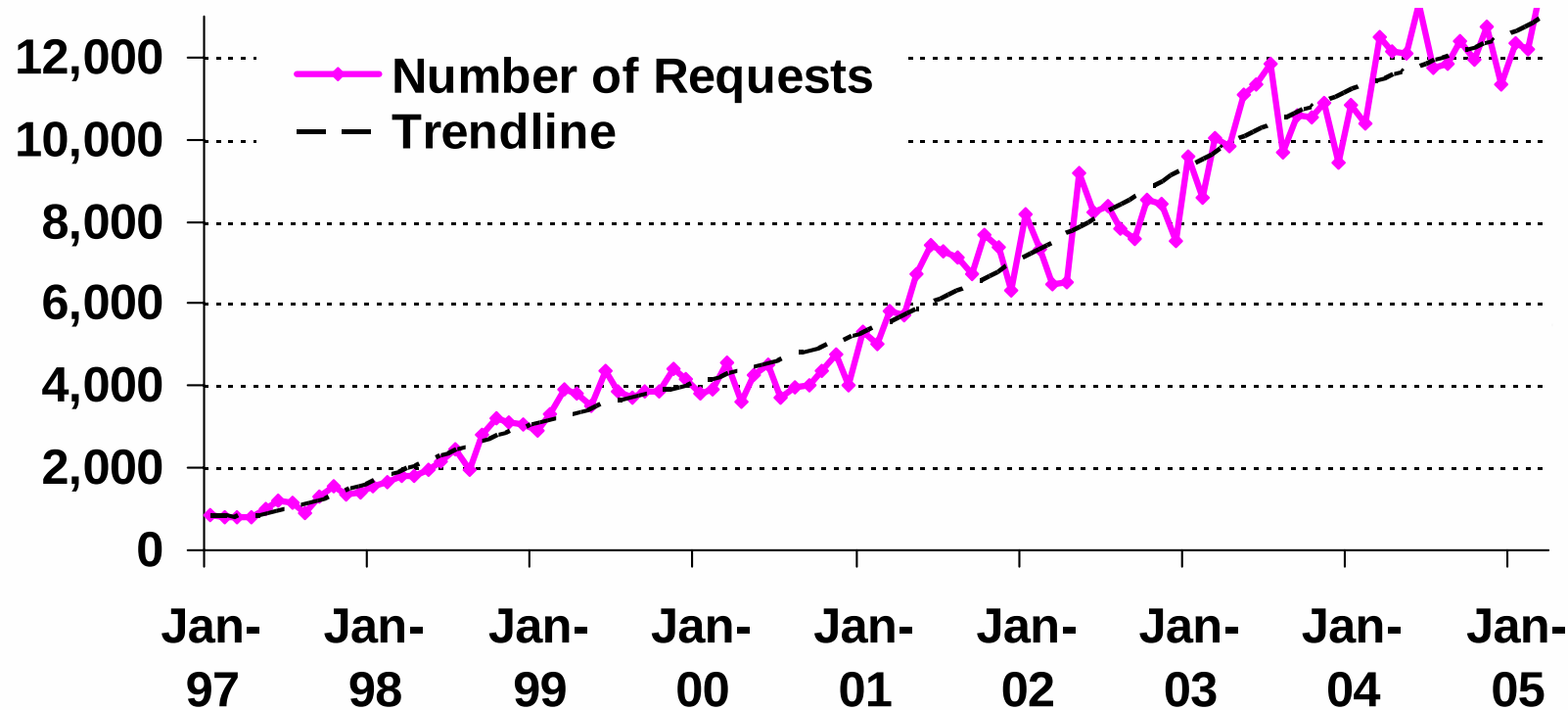
** Angiotensin II Antagonists moved from LU to GB (general benefit) in April 2004

Individual Clinical Review Beneficiaries 1997/98 - 2004/05



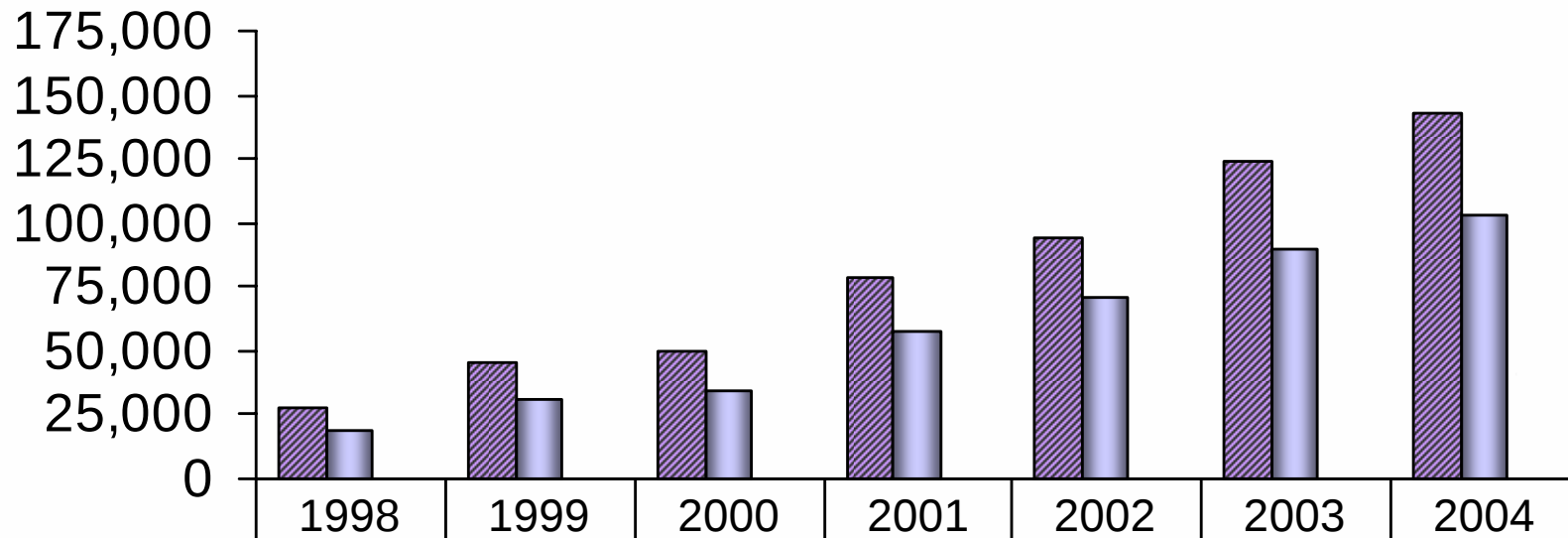
Monthly ICR Requests

January 1997 - March 2005



ICR Requests & Approval Rate

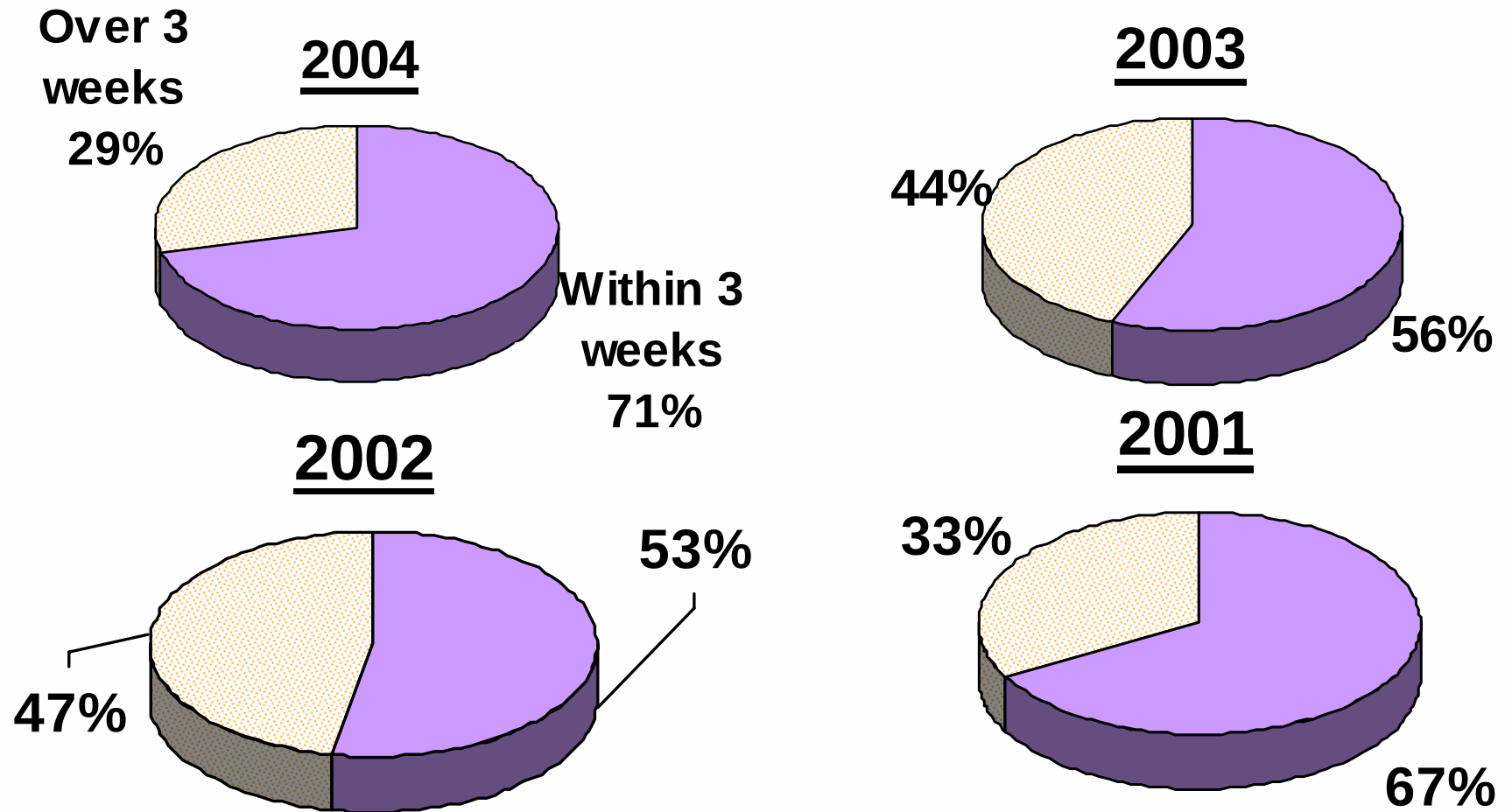
1998 - 2004



Received	27,472	45,694	49,518	78,855	94,212	123,515	143,370
Approved	18,924	30,487	34,110	57,628	70,907	90,095	102,512
% Increase	108%	66%	8%	59%	19%	31%	16%

% Approved	n/a	69%	67%	69%	73%	75%	72%
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ICR Response Time, 2001 - 2004



ICR Top-10 Requested Drugs

2004/05

Rk	Drug	Requests	Approved	% Approved	Gov't Cost
1	Plavix	46,543	39,968	85.9%	\$29.5M
2	Avandia	14,032	9,649	68.8%	\$8.3M
3	Eprex	10,189	6,330	62.1%	\$20.1M
4	Actos	6,843	5,048	73.8%	\$4.7M
5	Remicade	4,161	3,203	77.0%	\$17.8M
6	Gabapentin	3,824	2,296	60.0%	\$0.3M
7	Neupogen	2,639	1,902	72.1%	\$7.7M
8	GlucNorm	2,592	1,588	61.3%	\$0.4M
9	Enbrel	2,190	1,397	63.8%	\$13.2M
10	Singulair	1,934	810	41.9%	\$0.6M
Top-10 Total		94,947	72,191	76.0%	\$102.6M

ICR Top-10 Requested Drugs, by Government Costs, 2004/05

Rk	Drug	Beneficiaries	Rx	Gov't Cost
1	Plavix	41,229	328,797	\$29.5M
2	Eprex	2,342	9,870	\$20.1M
3	Remicade	990	5,017	\$17.8M
4	Gleevec	448	3,203	\$13.2M
5	Enbrel	1,079	8,587	\$13.2M
6	Pegetron	1,025	6,559	\$9.3M
7	Avandia	10,075	58,130	\$8.3M
8	Neupogen	1,201	3,930	\$7.7M
9	Rebif	425	3,756	\$6.6M
10	Sandostatin	367	3,347	\$6.5M
Total Top 10 Section 8		58,253	431,196	\$132.3
% Top 10 Section 8 / Total Section 8 FY 2004/05		69.7%	71.2%	71.0%

Highlights of Formulary

- In 2004, the DQTC recommended the listing of 19 single source products; 13 as General Benefits and 6 as Limited Use Benefits.
- The average time from the receipt of a complete single source drug submission to Formulary listing was 363 days in 2004*.
- The top 10 drugs by the number of recipients receiving therapy are all General Benefit.
- The number of Limited Use claims has more than quadrupled in the past five fiscal years.
- 143,370 requests were processed through the Individual Clinical Review (ICR) mechanism in 2004, and 72% of those requests were approved.
- Extension of the approval period for new and existing non-formulary oral hypoglycemic requests (for up to 5 years) helped to mitigate the rate of growth in ICR requests in 2004.

* One quarterly update was delayed in early 2004 due to a change in Government.

Report Card Framework

I. Program Overview

Program overview and utilization trends

II. Financial

Financial indicators and cost trends

III. Formulary Listings

Product and Type of Listing

IV. Achievements

Accomplishments and Looking Ahead

Formulary Updates

- Edition 38, Update C - April 6, 2004
 - 109 drug product additions, 2 nutrition products
 - A2RBs moved to General Benefit
- Edition 38, Update D – July 20, 2004
 - 85 drug product additions, 4 nutrition products
- Edition 38, Update E – November 4, 2004
 - 24 drug product additions, 1 nutrition, 1 diabetic testing agent
 - Glaucoma and diabetes Formulary Modernization reviews implemented
 - Atrovent CFC to HFA conversion
- Edition 38, Update F – February 22, 2005
 - 42 drug product additions, 1 diabetic testing agent
- e-Formulary launched – December 20, 2004

Drug Review Process

Common Drug Review (CDR)

- Developed process for integration of permanent CDR process into DPB/DQTC's process
- Active participation at national level on Advisory Committee on Pharmaceuticals (ACP)
- Timely processing of CDR submissions and final CEDAC recommendations
- Monitor timelines to ensure they meet Ontario's needs

Generic Streamlining

- Participated in F/P/T committee on generic streamlining
- Implemented monthly generic formularies (in July 2004)

Drug Review Process

Formulary and Section 8 Modernization Reviews

- HRT and testosterone reviews completed
- PPI review underway
- Long-term approvals implemented for oral hypoglycemic agents and selected drugs used in the management of chronic conditions
- Section 8 reviews completed for Neupogen, Viread, Concerta, Eprex in cancer

Cancer Drugs

- DQTC/Cancer Care Ontario subcommittee to review cancer drugs established and met monthly (starting winter 2005)
- Communications, guidelines and procedures completed

Program Delivery

Trillium

- Plan for reengineering renewal process developed;
- System changes to support consent and electronic income verification from Canada Revenue Agency (plan developed in 2003/04);
- Agreement with Canada Revenue Agency signed;
- Revisions to new applications and renewal forms completed.

Section 8

- Ongoing recruitment of staff;
- Implementation of long-term renewals for diabetes, psychiatric and other medications;
- RFP process for Document Management system completed.

Emergency Department (ED) Access to ODB Drug Profile

- Agreement with Canada Health Infoway;
- e-health councils, provincial associations, hospitals in various regions consulted and selected sites visited;
- Business requirements, conceptual architecture and privacy impact, business impact assessments completed;
- User group of front-line hospital ED and administration staff met monthly (started winter 2005);
- System development work well underway:
 - CapGemini for viewer and mid-tier
 - Greenshield for back-end and consent management services
 - Smart Systems for Health Agency for portal and registration management services
- Communications planned and existing documents revised;
- Regulation changed.

Pharmaceutical Strategy

National

- Principles, options and costing for national pharmacare developed for discussion of Ministers and First Ministers;
- Ongoing collaboration on approach for “orphan drugs”;
- Priorities and directions for National Pharmaceutical Strategy developed by Task Group of Drug Plan Directors.

Provincial

- Developed policy options for Government consideration “to manage drug program growth”:
 - Income testing seniors’ drug benefits
 - “Best practices” support for drug prescribing and use
 - Reference-based pricing
 - Lower generic pricing
 - Medication management by pharmacists
 - Pharmacy information system

Stakeholder Relations

- Regular meetings with pharmaceutical manufacturers and associations;
- Meetings with Ontario Pharmacists Association and Ontario College of Pharmacists;
- Quarterly meetings with Limited Use Tripartite Committee;
- Meetings with Physician Services Committee, Drugs & Pharmacotherapy Committee;
- Meetings with Canadian Life & Health Insurance Associations and private insurers;
- Workshop held with Rx&D;
- Provincial consultations and User Group on ED Access to ODB Drug Profile;
- Meetings with Cancer Care Ontario (CCO) and Ontario HIV Treatment Network;
- Regular meetings with Drug Plan Directors of other provinces, Health Canada, PMPRB and CIHI.

Looking Ahead

- Pharmaceuticals Strategy – national and provincial policy options;
- Formulary Modernization – class reviews, Limited Use, Section 8, post-marketing evaluations;
- Medication Management – pharmacists in family health teams, enhanced role of community pharmacists;
- Drug Pricing – purchasing and policy options for patented and non-patented drugs;
- E-Pharmacy – potentially for the provision of medication profiles beyond the Emergency Department Access project, expansion of claims data information and e-prescribing.