



Forecasting and Managing Medication Expenditures – 2009 Update

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Overview

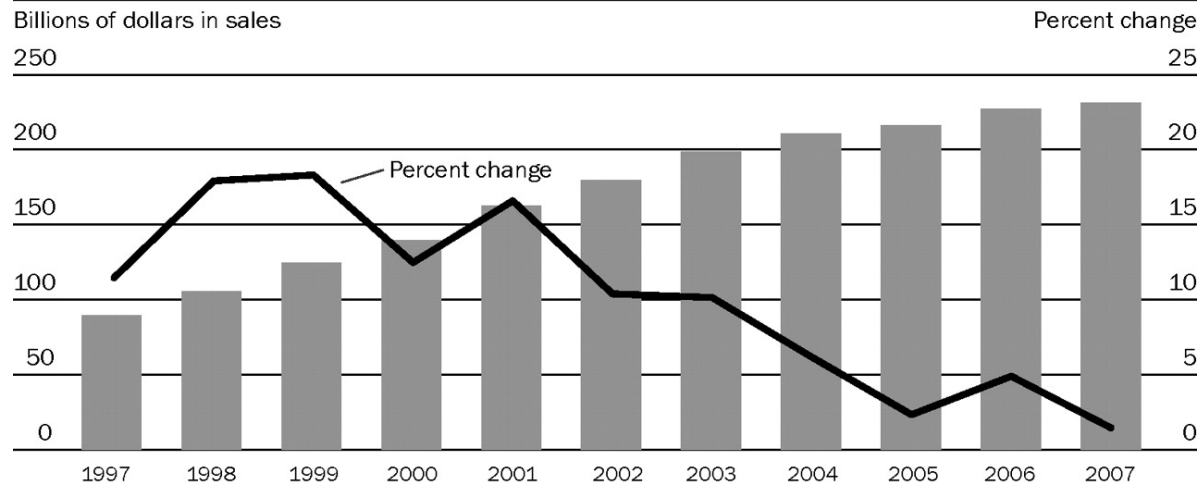
- Discuss trends in US health care and pharmaceutical expenditures
- Outline drivers of pharmaceutical expenditures and discuss the 2009 forecast of pharmaceutical expenditures
- Discuss financial management tactics to respond to future cost containment pressure

Total US Health Care Expenditures

| Year | 1970 | 1980 | 1990 | 2000 | 2004 | 2005 | 2006 | 2007 |
|----------------------------------|-------------|-------------|-------------|-------------|-------------|-------------|-------------|-------------|
| Total, Billions \$ | \$74 | \$253 | \$714 | \$1,353 | \$1,854 | \$1,980 | \$2,112 | \$2,241 |
| Population (millions) | 210.2 | 230.4 | 253.8 | 282.5 | 293.5 | 296.2 | 299.1 | 302.0 |
| NHE Per Capita | \$356 | \$1,100 | \$2,814 | \$4,789 | \$6,319 | \$6,387 | \$7,062 | \$7,421 |
| NHE as % GDP | 7.2% | 9.1% | 12.3% | 13.8% | 15.9% | 15.9% | 16.0% | 16.2% |

Pharmaceutical Expenditures and Growth

EXHIBIT 1
Size And Growth Of The U.S. Retail Pharmaceutical Market, 1997-2007



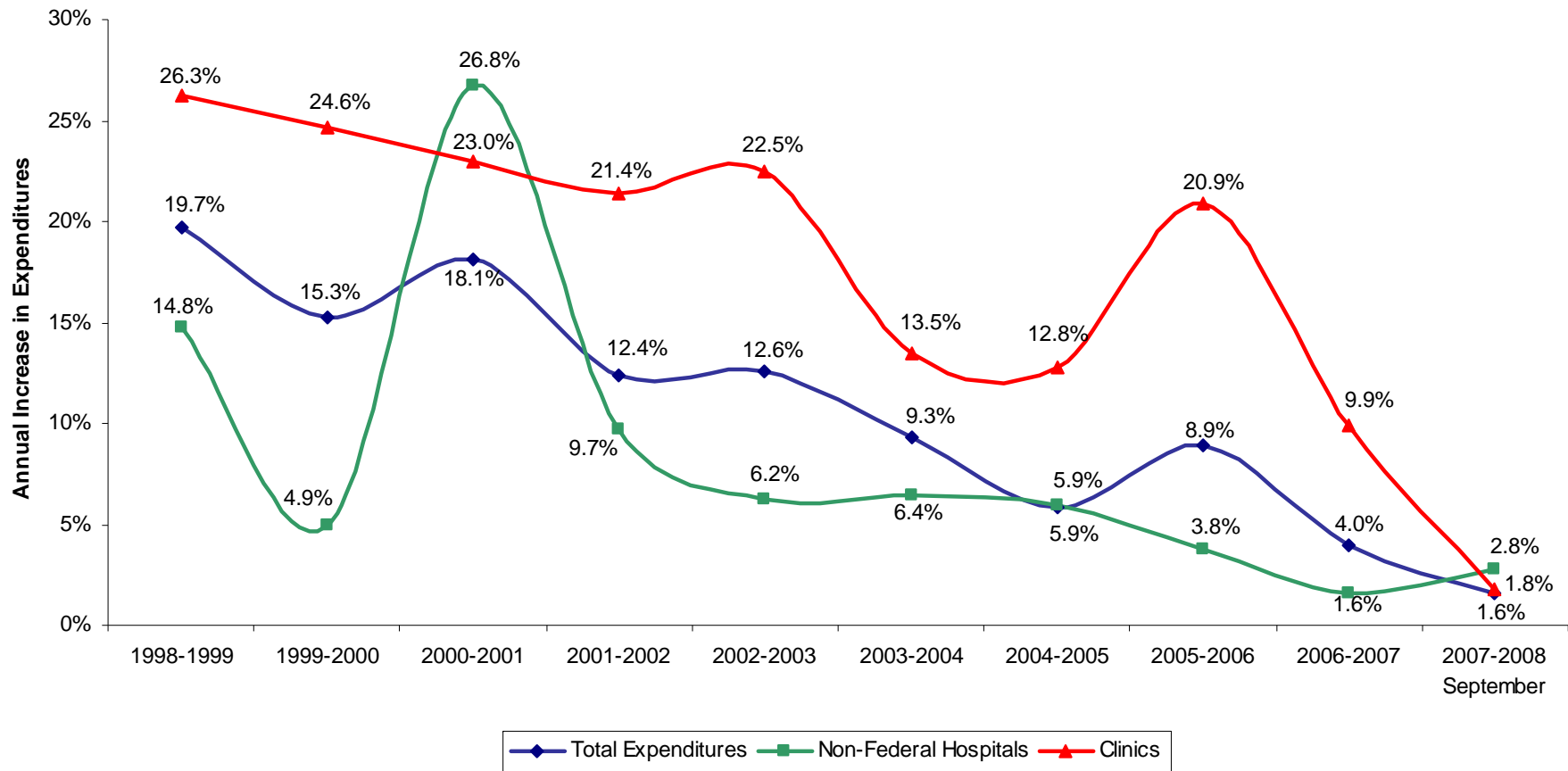
SOURCE: IMS Health, National Sales Perspectives, December 2007 (sales deflated by implicit gross domestic product deflator, \$2000).

NOTES: Dollar figures (bars) relate to the left-hand y axis. Percent change (line) relates to the right-hand y axis.

| Year | 1970 | 1980 | 1990 | 2000 | 2004 | 2005 | 2006 | 2007 |
|--------------------------------|-------|--------|--------|---------|---------|---------|---------|---------|
| Drug Expenditures, Billions \$ | \$5.5 | \$12.0 | \$40.3 | \$120.6 | \$188.8 | \$199.7 | \$216.8 | \$227.5 |
| Growth, % (vs previous period) | 7.5% | 8.2% | 12.8% | 11.6% | 11.9% | 5.8% | 8.6% | 4.9% |

Figure from Aitken et al. *Health Affairs* 2009;28:w151-160w. Data from IMS.
 Table adapted from Hartman et al. *Health Affairs* 2009;28:246-261. Data from CMS.

Growth in Pharmaceutical Expenditures by Channel



Top 10 Drug Classes in Hospitals

| Drug Class | 2007 Total (\$ Thousands) | Change From 2006 | 2008 Expenditure YTD Sep 2008 (\$ Thousands) | Change YTD Sep 2007 vs YTD Sep 2008 |
|---------------------------|------------------------------|---------------------|--|---|
| Antineoplastic Agents | 3,321,432 | 6.6% | 2,643,867 | 6.7% |
| Hemostatic Modifiers | 3,308,712 | 4.4% | 2,608,358 | 5.6% |
| Anti-infectives, Systemic | 3,062,470 | 2.6% | 2,483,304 | 8.8% |
| Blood Growth Factors | 2,531,955 | -11.2% | 1,768,352 | -9.3% |
| Biologicals | 1,552,058 | 22.2% | 848,084 | -25.5% |
| Diagnostic Aids | 1,472,772 | -1.3% | 1,106,300 | -1.6% |
| Hospital Solutions | 1,468,450 | 23.8% | 1,318,090 | 20.7% |
| Psychotherapeutics | 1,134,477 | 1.3% | 894,739 | 5.2% |
| Gastrointestinal | 1,078,886 | 2.9% | 897,556 | 11.6% |
| Respiratory Therapy | 984,172 | 9.9% | 780,038 | 6.2% |
| Total | 27,312,317 | 1.6% | 21,052,543 | 2.8% |

Top 15 Drugs in Hospitals

| Drug | 2007 Total (\$ Thousands) | Change From 2006 | 2008 Expenditure YTD Sep 2008 (\$ Thousands) | Change YTD Sep 2007 vs YTD Sep 2008 |
|------------------------------------|------------------------------|---------------------|---|--|
| Enoxaparin (Lovenox) | 1,048,526 | 9.8% | 879,178 | 12.0% |
| Epoetin Alfa (Epopgen, Procrit) | 730,900 | -17.3% | 484,944 | -14.8% |
| Immune globulin (various products) | 946,596 | 16.9% | 674,202 | 17.9% |
| Infliximab (Remicade) | 648,490 | 4.5% | 524,805 | 8.9% |
| Pegfilgrastim (Neulasta) | 645,804 | -1.1% | 509,217 | 4.7% |
| Darbepoetin Alfa (Aranesp) | 642,712 | -20.2% | 377,725 | -26.2% |
| Piperacillin/Tazobactam (Zosyn) | 558,606 | 15.7% | 505,017 | 23.1% |
| Rituximab (Rituxan) | 545,972 | 2.2% | 451,872 | 11.0% |
| Bevacizumab (Avastin) | 405,844 | 17.5% | 349,318 | 15.6% |
| Iohexol (Omnipaque) | 374,108 | 0.5% | 259,004 | -10.3% |
| Filgrastim (Neupogen) | 356,556 | 1.2% | 276,905 | 3.8% |
| Eptifibatide (Integrilin) | 325,467 | 1.6% | 236,097 | -3.0% |
| Iodixanol (Visipaque) | 320,255 | 3.9% | 240,487 | -0.8% |
| Linezolid (Zyvox) | 313,352 | 13.8% | 280,918 | 20.7% |
| Oxaliplatin (Eloxitan) | 284,879 | 4.4% | 229,835 | 7.7% |
| Total | 27,312,317 | 1.6% | 21,052,543 | 2.8% |

Top 15 Drugs in Clinics

| Drug | 2007 Total (\$ Thousands) | Change From 2006 | 2008 Expenditure YTD Sep 2008 (\$ Thousands) | Change YTD Sep 2007 vs YTD Sep 2008 |
|-----------------------------------|------------------------------|---------------------|--|--|
| Epoetin Alfa (Procrit, Epogen) | 3,786,237 | -8.2% | 2,668,665 | -7.3% |
| Pegfilgrastim (Neulasta) | 2,153,770 | 7.0% | 1,690,977 | 4.6% |
| Darbepoetin Alfa (Aranesp) | 2,147,785 | -18.5% | 1,158,329 | -32.6% |
| Infliximab (Remicade) | 1,851,287 | 11.2% | 1,514,484 | 10.4% |
| Bevacizumab (Avastin) | 1,754,629 | 37.4% | 1,501,741 | 16.3% |
| Rituximab (Rituxan) | 1,647,649 | 13.8% | 1,347,430 | 11.4% |
| Trastuzumab (Herceptin) | 1,035,280 | 9.4% | 820,421 | 6.9% |
| Oxaliplatin (Eloxatin) | 1,031,455 | 10.0% | 809,380 | 5.1% |
| Docetaxel (Taxotere) | 783,094 | 8.4% | 666,224 | 14.3% |
| Ranibizumab (Lucentis) | 759,963 | 121.3% | 589,386 | 1.4% |
| Varicella vaccine (Varivax) | 692,617 | 194.8% | 569,569 | 19.1% |
| Human papiloma vaccine (Gardasil) | 666,439 | 545.4% | 469,317 | -5.5% |
| Zoledronic acid (Zometa, Reclast) | 537,129 | -2.5% | 466,183 | 17.7% |
| Gemcitabine (Gemzar) | 527,083 | 8.6% | 425,591 | 8.2% |
| Paricalcitol (Zemplanr) | 456,384 | 10.2% | 392,264 | 19.5% |
| Total | 33,427,450 | 9.9% | 25,456,822 | 1.8% |

Factors Driving Pharmaceutical Expenditure Growth

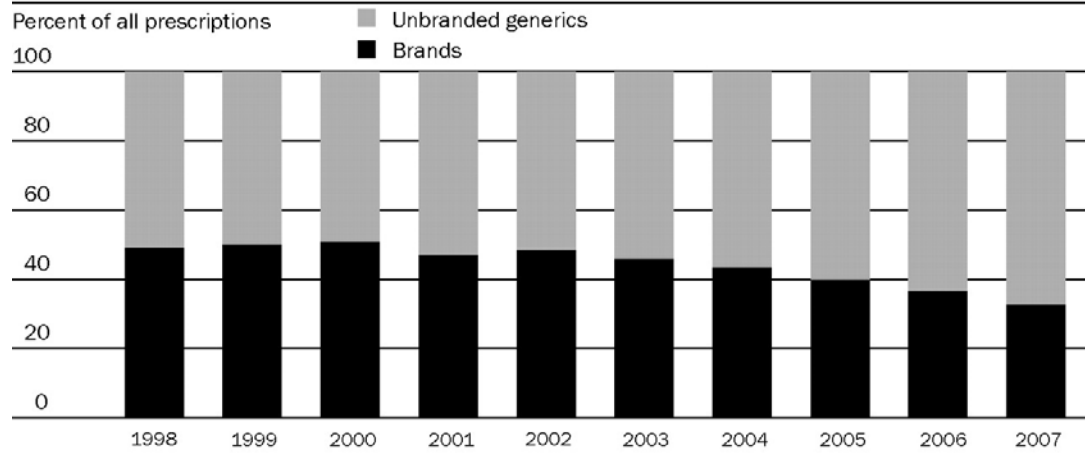
- Price
- Utilization
 - Per capita utilization of prescription drugs
- “Mix” and new technology
 - Some innovative products used to treat previously untreated disease; true innovation
 - Many marginally improved, “me too” products that gain preference over older agents for various (sometimes irrational) reasons
 - Increasing intensity of drug therapy; add-on therapies vs replacements (triple drug tx vs single drug tx)

Explanations for Recent Deceleration in Growth (1)

- Increase in generic drug availability and utilization
- Shift in co-pay differentials; gap widening
 - 2000: \$7 generics, \$13 preferred, \$17 non-preferred
 - 2005: \$10 generics, \$22 preferred, \$35 non-preferred
 - 2008: \$6 generics, \$29 preferred, \$40 non-preferred

EXHIBIT 4

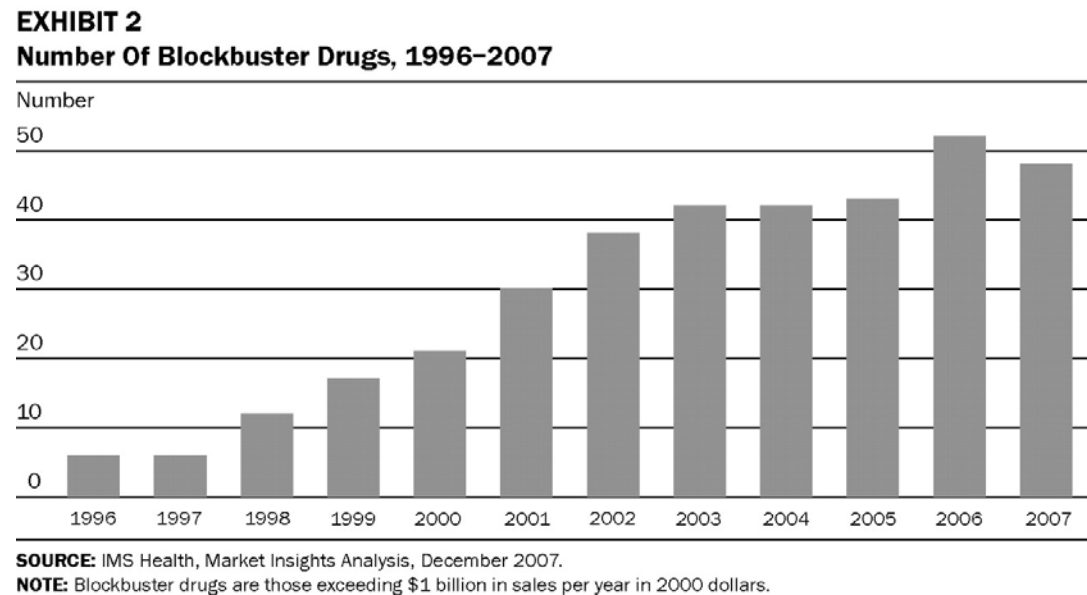
Brand-Name And Generic Drugs' Share Of Total Retail Dispensed Prescription Drugs, 1998-2007



SOURCE: IMS Health, National Prescription Audit, December 2007.

Explanations for Recent Deceleration in Growth (2)

- Diminished innovation
- Reduction in number of blockbuster drug products approved by FDA
- Recently, lower spend on individual blockbusters



Explanations for Recent Deceleration in Growth (3)

- Ongoing impact of prescription to OTC status
 - Non-sedating antihistamines
 - Proton pump inhibitors
- Consumer safety concerns
 - Increase in number and significance of new “black box” warnings
 - Meta analyses demonstrating safety concerns (e.g., rosiglitazone)
 - Continued increase in number of market withdrawals

Explanations for Recent Deceleration in Growth (4)

- Lower growth of Medicare Part D
 - Decrease in growth after huge jump in initial spending
 - More aggressive contracting and better performance of plans
- Improved performance of Medicaid prescription drug programs
 - Following big drop with implementation of Medicare Part D, continued decline
 - Improved formulary management (Medicaid programs finally catching up with commercial insurer strategies!)
- Impact of overall economic downturn on commercial side
 - Increase in unemployment
 - For those employed, decrease in generosity of insurance (higher out-of-pocket expenses)
 - Decrease in clinic visits

Summary of Factors Potentially Affecting Future Growth

- Continued growth of generic products with substantial products coming (see 2009 forecast for details)
- Ongoing slowing of innovation with fewer market entries as weak economy has reduced R&D investments (see 2009 forecast for details)
- Continued impact of economic downturn on employment, etc. (potentially affected by HC reform or incremental changes in publicly funded programs)
- Continued impact of demographic changes

Projection of US Health Care and Pharmaceutical Expenditures

| Year | 2002 | 2004 | 2006 | 2010 Proj. | 2014 Proj. | 2017 Proj. |
|---|-------------|-------------|-------------|-----------------------|-----------------------|-----------------------|
| Total National Health Expenditures (NHE), Billions \$ | \$1,603 | \$1,852 | \$2,105 | \$2,725 | \$3,523 | \$4,277 |
| NHE Growth from Previous Year | - | 6.9% | 6.7% | 6.7% | 6.6% | 6.7% |
| Prescription Drug Expenditures, Billions \$ | \$157.6 | \$188.8 | \$216.7 | \$284.6 | \$393.7 | \$515.7 |
| Drug Expenditure Growth from Previous Year | - | 8.4% | 8.5% | 7.6% | 8.9% | 9.6% |

Source: Data from CMS. National Health Expenditure Projections 2007-2017. Available at <http://www.cms.hhs.gov/NationalHealthExpendData/Downloads/proj2007.pdf>. Accessed July 1, 2009. See also Keehan et al, *Health Affairs* 2008;27: w145-w155.

2009 Forecast of Pharmaceutical Expenditures by Channel

- Use with caution... not a “multiplier”
- Clinics include prescriber offices and hospital outpatient clinics where meds are administered

| Setting | Inflation Rate Forecast |
|-----------------------|-------------------------|
| Outpatient | 0 to 2% |
| Clinics | 1 to 3% |
| Non-federal hospitals | 1 to 3% |

Not out of the woods yet...

- Many factors may act to increase future expenditures and require vigilance
 - Isolated areas of substantial expenditure growth
 - New, very expensive biologics; small numbers of patients, huge cost
 - Orphan drugs
 - Antimicrobials
 - Continued impact of medication shortages
 - H1N1 novel influenza
 - Potential impact of FDA reform
 - Response to decreases in medication use leading to poorer outcomes and resulting increases in total cost of care



Response to Trends: Tactical Approach to Financial Management for Pharmacy Leaders

Improved Financial Planning (1)

- Systematic, step-wise approach to budgeting for medications, identifying cost containment targets and conducting financial management
- Resources
 - Annual forecast of expenditures and trends in *AJHP*
 - Summary of budgeting process in *AJHP*, January 15, 2005
 - Andy Wilson’s new book “Financial Management for Health-System Pharmacists” (2009, ASHP)

Improved Financial Planning (2)

- Key messages
 - Data, data, data
 - Focus your attention on key drivers of cost; 60-80 products account for 80-90% of hospital drug budget
 - Consider diffusion patterns of newer products
 - Creative cost containment tactics
 - Moderation of trend vs actual reduction in expenditure
 - Monitor performance monthly; trend analysis, variance reporting
 - Financial performance metrics
 - Cost per day vs cost per discharge
 - Watch volume of cost-driving service elements
 - Use benchmarks with caution (“compass vs thermometer”)

Evidence-based “Tool Kit” (1)



- Variety of tools used to ensure the safe, rational, efficient and ethical use of health care interventions in the treatment of patients
- Some passive tools that do not involve direct interventions on prescribing
- Some active tools involve direct intervention on prescribing

Evidence-based “Tool Kit” (2)



- **Passive tools**
 - Prescriber education and cost awareness campaigns
 - Clinical practice guidelines
 - Medication use evaluation, report cards
- **Active tools**
 - Medication formulary and restrictions
 - Prior authorization
 - Generic and therapeutic interchange
 - Protocol-based independent pharmacist prescribing
 - IV to PO
 - Renal dose adjustment
 - Collaborative practice agreements
 - Antimicrobial stewardship program

Value of Clinical Pharmacy Services

- Impact of clinical pharmacists accepting responsibility for both clinical and financial implications of medication use
- 1988 to 1995, n = 104 studies
 - Schumock GT, Meek PD, Ploetz PA, Vermeulen LC. *Pharmacotherapy* 1996;16:1188-1208.
- 1996 to 2000, n = 59 studies
 - Schumock GT, Butler MG, Meek PD, Vermeulen LC, et al. *Pharmacotherapy* 2003;23:113-132.
- 2001 to 2005, n = 93
 - Perez A, Doloresco F, Hoffman JM, Meek PD, Touchette DR, Vermeulen LC, Schumock GT, American College of Clinical Pharmacy. Economic evaluations of clinical pharmacy services: 2001-2005. *Pharmacotherapy*. 2009;29:128. (See <http://www.accp.com/> for full report.)

Clinical Pharmacy Services R.O.I.

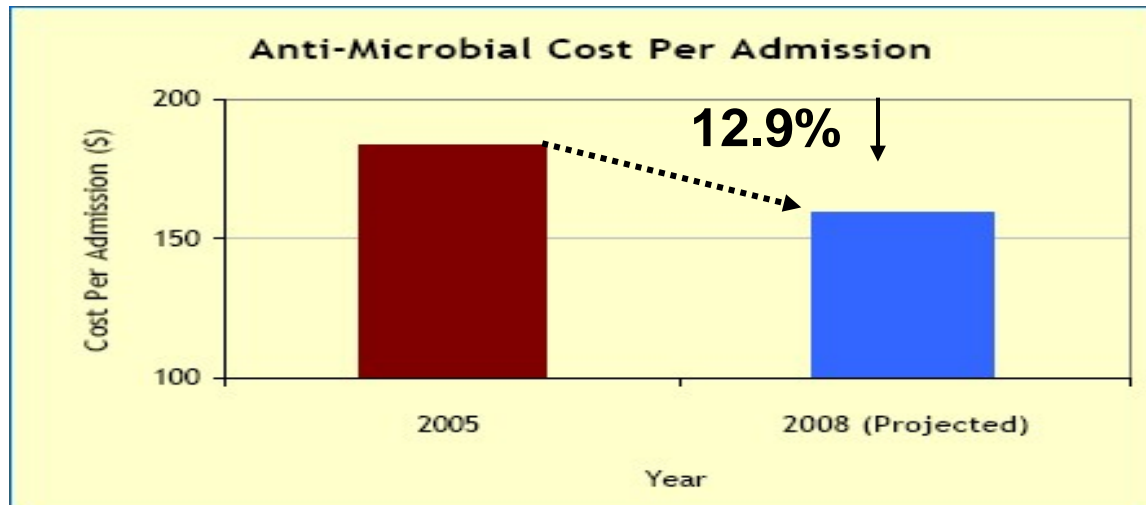
“Highest R.O.I. in Healthcare”

| R.O.I. | 1988-1995 N = 7 | 1996-2000 N = 5 | 2001-2005 N = 15 |
|---------|--------------------|--------------------|---------------------|
| Lowest | \$1.08 : \$1 | \$1.7 : \$1 | \$2 : \$1 |
| Highest | \$75.84 : \$1 | \$17.01 : \$1 | \$12 : \$1 |
| Median | \$4.09 : \$1 | \$4.68 : \$1 | \$6.40 : \$1 |
| Mean | \$16.70 : \$1 | \$5.54 : \$1 | \$6.70 : \$1 |

Antimicrobial Stewardship Program (1)

- Huge portion of inpatient budget in antibiotics, antifungals
- Commitment of resources to stewardship program
 - Separate subcommittee of P&T
 - Pharmacist and Infectious Disease faculty member employed by pharmacy
 - Daily activities
- Data resource for infection control

Antimicrobial Stewardship Program (2)



- Goal: Maximize appropriate utilization of antimicrobial and antifungal therapies to control both resistance and expense
- Antimicrobial portion of inpatient drug budget: 22.9% (FY05), 20.5% (FY08)
- Cost-avoidance in 2009 Budget = \$600,000
- Team consists of a clinical pharmacist, an ID physician, infection control and microbiology
- Methods
 - Development of evidence-based guidelines
 - Cereplex software to identify targeted interventions
 - Daily interdisciplinary rounds
 - Restriction of specific antibiotics and antifungals to ID approval

“Internal” Prior Authorization of Clinic Administered Injectables (1)

- Policy response #1, ban on “brown-bagging” of infused medications
 - Exceptions on case-by-case basis, often economic issues (WRT patient out of pocket expense)
- Policy response #2, prior authorization program for all clinic administered injectable medications with cost of >\$5,000 per year
 - Currently infliximab, omalizumab, plerixafor, botox, palivizumab, natalizumab
 - Future IVIG, albumin, rituximab

“Internal” Prior Authorization of Clinic Administered Injectables (2)

- Key components of program
 - Pharmacy department-based program
 - Center for Drug Policy develops guidelines for use
 - Subcommittee of P&T reviews and approves guidelines and oversees program
 - Pharmacy staff reviews requests for medications
 - Appeals process for denials
 - Independent of insurance or ability to pay
 - Inpatient application; essential for management of transition of care

Cancer Chemotherapy Management (1)

- Risks and cost of cancer chemotherapy create substantial challenges
- Recent emergence of biologics (EGFR inhibitors, VEGF inhibitors, etc) raise stakes
- While national standards are prominent in cancer care (guidelines from ASCO, NCCN), variation in care common
- Questionable value from substantial investments (life expectancy gains of days, months for tens of thousands of dollars in added cost)
- Huge reimbursement challenges
- Increasing interest in cost-effectiveness by oncologists

Cancer Chemotherapy Management (2)

- Cost containment focusing on supportive care (n/v, pain, infection, anemia, neutropenia) common
- Efforts to limit chemotherapy decision making needed
- Chemotherapy Review Council developed to manage safety, reduce variability and open dialogue regarding cost

Cancer Chemotherapy Management (3)

- Individual groups of oncologists apply for “core” status of specific chemo regimens
 - Specific disease, stage, etc.
 - Specific routes, doses and dosing intervals
 - Evidence (phase III trials; no abstracts)
 - Cost and reimbursement analysis
 - Far more restrictive than P&T Committee
- If approved by Chemo Council, can be ordered
- If not approved, must seek patient-specific approval before use (appeal process)

Cancer Chemotherapy Management (4)

- Results
 - Decrease from approx. 500 combinations to under 300 “core” recipes
 - In 2 years, fewer than 50 patient-specific requests with 30% denial rate
 - More consistency in prescribing
- Status as sub-committee of P&T
- Expanding to supportive care review
- Critical venue for debate over “productive” vs “unproductive” treatment and cost/value issues

Summary

- Substantial deceleration in expenditure growth for pharmaceuticals in all channels
- Likely continued decline in rate of growth for short-term
- Many factors may put pharmaceutical expenditures in spotlight again
- Vigilance, improved financial management, creative cost-containment will remain critical for pharmacy leaders



Questions?

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