Introduction to the US Health Care System

What the Business Development Professional Should Know

PLEXUS VENTURES
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Understanding of the US Health Care System

Evolution of the US health care system to its current state can be understood as:

- desire for the most advanced health care, by the population
- persistent search for the least costly health care, by "payers" (employers, government) and their agents (health plan administrators)
- fundamental belief that the solution to these conflicting goals is through regulated competition in the private sector, and not a one-payer, government-run program

As a result, the existing health care framework is quite complex and not well integrated

Agenda

I. Some Differences Between US and Japanese Systems
II. History of Changes in the US Health Care System
III. Healthcare Funding Mechanisms and Implications
IV. Key Players in the Health Care System
    A. Employers
    B. Managed Care Organizations
    C. Government
V. Focus on Drug Prices and Costs
VI. Pharmaceutical Company Marketing Strategies
VII. Conclusions

I. Healthcare Structure and Expenditures: US and Japan

2004 Data

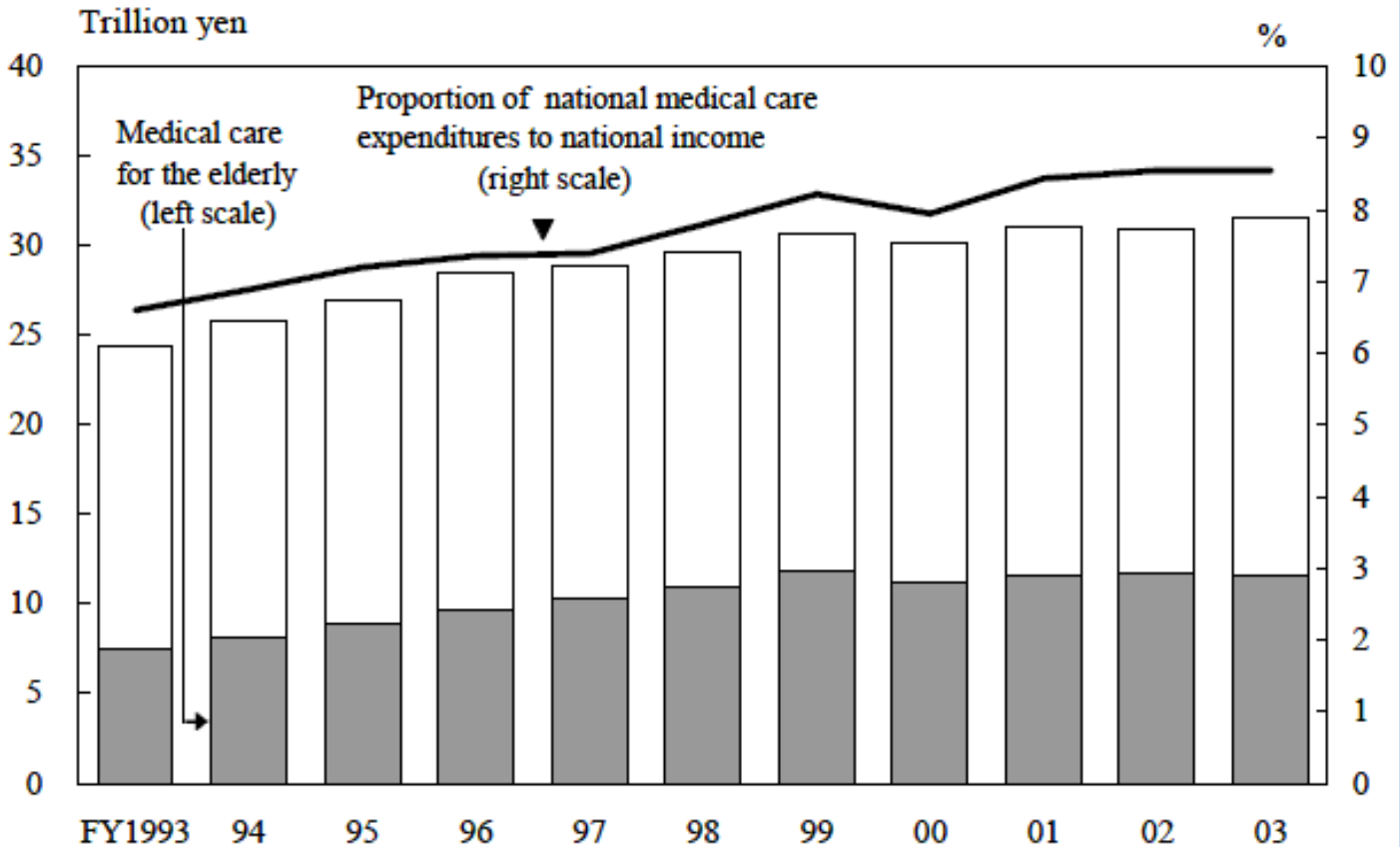
	US		Japan
Population	299 million		128 million
% 65+ years old	12.2%		19.5%
No. of Active Physicians	692,000		268,000
Physicians per 100,000	231.4		209.7
No. of Hospital Beds	965,256		1,631,553
Beds per 100,000	322.8		1,227.8
Ave. Length of Stay	4.8 days		40.1 days[1]
Healthcare as % of GDP	16%	⟺	8%
Total Healthcare Expenditures per capita	$6,280	⟺	$2,662
Government Expenditure as % of Total Healthcare Expenditure	45%	⟺	81%
% of Population with Healthcare Insurance	84.4%	⟺	100%

US has a high cost healthcare system with non-universal coverage and is supported primarily by private funds

[1]MHLW, 2002 Survey

Japan's Medical Care Expenses Have Gradually Increased to 8.5% of GDP

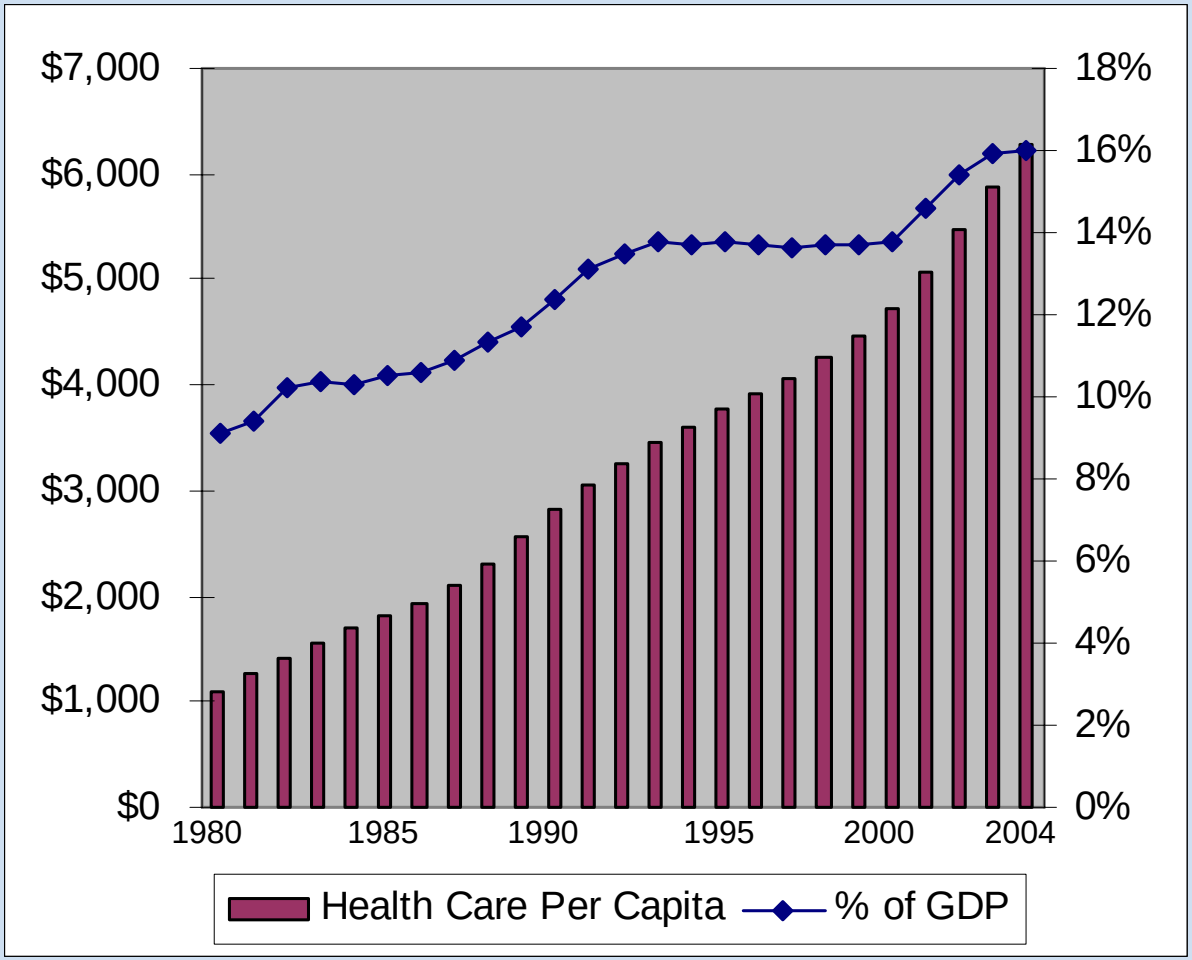
Figure 15.4
Trends in Medical Care Expenditures



Source: Ministry of Health, Labour and Welfare.

A major concern is that the declining birth rate, low immigration and growing elderly population together will make universal health coverage a great burden on working people

US Medical Care Expenses Have Recently Accelerated to 16% of GDP



Major concerns are that health care insurance is becoming unaffordable to individuals, and that US companies are losing their cost competitiveness to global companies that enjoy government-sponsored health care

II. Cost Control has been a Goal for Decades

Virtually all changes to US medical care since 1960 have aimed to reduce cost

1960-87: "Golden Age of American Medicine". Fee-for-service system meant that physicians and hospitals charged fees, which private insurance companies or the government paid. Annual increases in expenditures were 4.5%.

1987-92: Rapid growth in health care expenditures >10% per year, due to new and high cost technologies. Deregulation in "supply-side" healthcare, resulting in more hospitals and more competition for patients.

- DRGs (diagnosis related groups) introduced that paid a fixed reimbursement for each procedure in the hospital; hospital length of stay sharply declined

1992-97: Emergence of "Managed Care", pushed by employers wanting to reduce the cost of employer-sponsored health insurance. These plans achieved lower cost by:

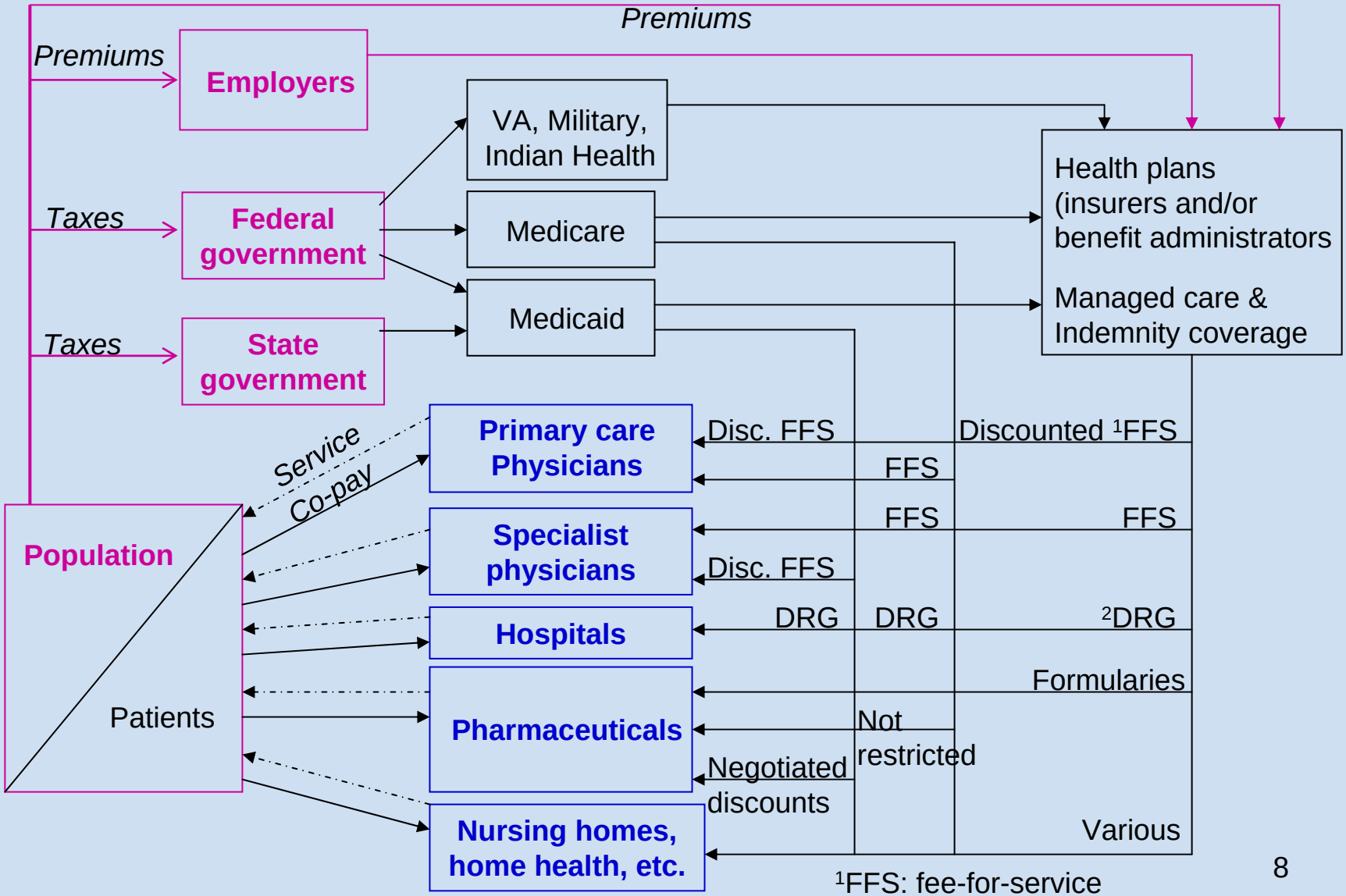
- Limiting employees' choice of doctors and hospitals to a certain network
- Limiting direct access to specialists
- Limiting access to new and expensive medical technology, including new pharmaceuticals

These plans then formed contracts with selected physicians and hospitals who agreed to cut their fees in exchange for increased patient visits. They thus became "sub-contractors" and could lose their contracts if they didn't obey the managed care organization's (MCO) clinical practice guidelines specifying how patients with a given illness would be treated. Annual increases in expenditures were much lower than 4.5%, and in 1996 were 0%

The 1990's were a period of dramatic change for both providers and patients

Source: Reinhardt, U., The United States Health-care System: Recent History and Prospects, Oct. 2001

III. US Healthcare Funding Mechanisms



1FFS: fee-for-service
2DRG: diagnosis related group

Implications of the Healthcare Financing Structure

- Physicians and hospitals receive the majority of their fees from payers (employers, government) and from the health plans the payers offer their members; the patients themselves pay a very small portion of the cost of treatment

- By controlling funding, the payers have significant control over the providers; patients end up with very little influence, aside from choosing among the health plans of their employer
  - Employees still have the opportunity to change employers if the health plan offered is not attractive

- Both employers and the government use managed care organizations (MCOs) to administer programs for their employees/members. MCOs use their “intermediary” position to reduce costs in the system, while making some profit themselves.

- Physicians often need to select from a restricted drug formulary when treating patients; an individual doctor may see patients from a number of different health plans, all with different drug formularies

IV. Key Player: Employers

"Automaker GM spends $5 billion on health care annually, which is more than it spends on steel"[1]

Employers offer their employees more affordable health care coverage than they could obtain independently

Employers can direct their employees into low cost health plans, first by offering them a choice of managed care alternatives only, and second by lowering the premiums for the least cost alternative

Employers were successful in getting their employees to accept restrictions in health care access, at a time of economic recession in the US – the early 1990's; employees were more concerned with keeping their jobs than about the details of their health plan

As the economy improved, however, the need to attract and retain employees required offering an attractive total compensation package, including benefits such as a flexible health plan

Employers tend to be inconsistent in pursuing lowest cost health care, due to the desire to provide attractive benefits to employees; more attention is paid in times of financial distress

[1]Intel Corporation Chairman Craig Barrett, "Third Health IT Summit", September 2006.

Key Player: Managed Care Organizations

Managed Care Organizations had 208 million members (2/3 of the US population) enrolled in 2005

Managed care organizations do not “treat patients”; rather, they seek a profit by administering healthcare benefits to their members at a per person fee (paid mostly by employers) that is higher than the cost of the health care resources consumed by patients

A variety of methods are used to control health care costs:

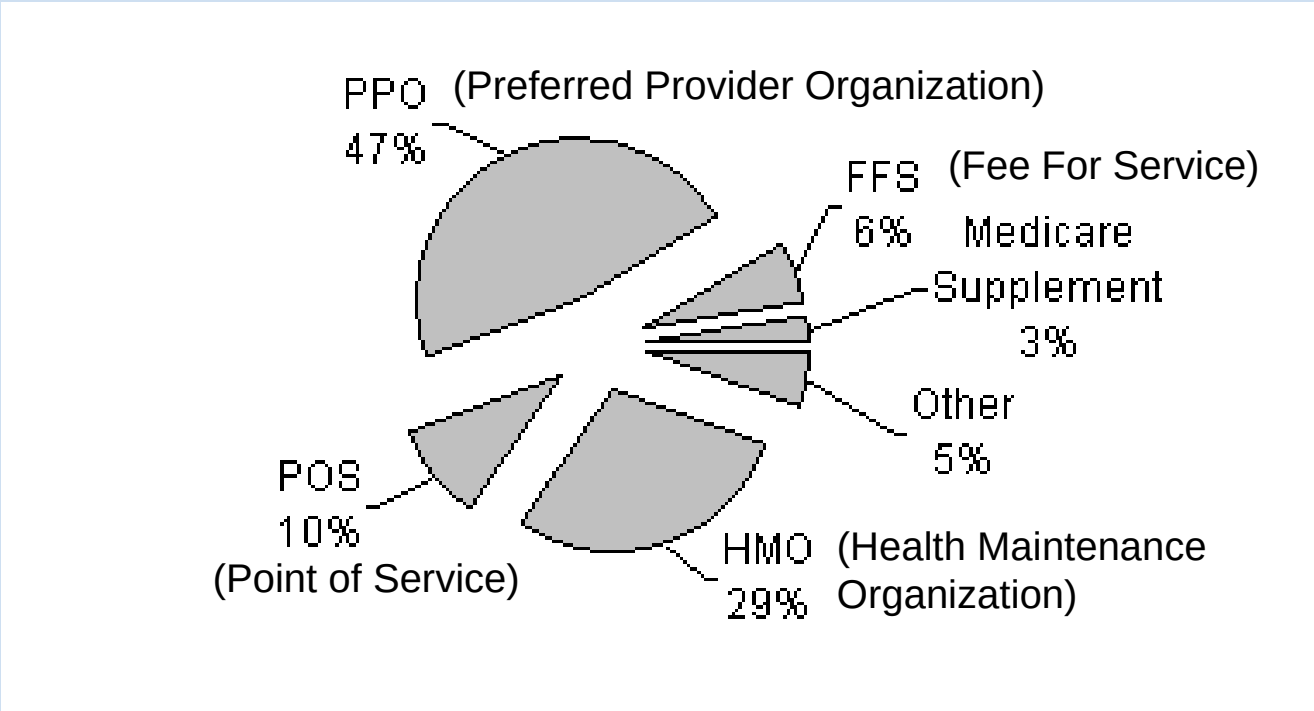
- Obtain contracts with employers to manage healthcare benefits for their employees
- Educate patient members in prevention of disease and “wellness”
- Ensure that physicians follow proven treatment protocols
- Negotiate lower fees with “suppliers” of healthcare: physicians, hospitals, pharmaceutical companies

In the past, MCOs required members to make sacrifices in order to save money for the MCO, which generated negative feelings among its members

- Hospital stays limited to 24 hours after normal delivery, and 48 hours after C-section

In addition, many employers are unhappy that premiums have continued to rise rapidly even under managed care, and are demanding more pricing transparency

Percentage of Private MCO Enrollment by Plan Type - December 2005



After over 10 years of growth, the most popular managed care types are the ones (PPO, POS) that allow the patients a wide choice of physicians; HMOs offer the least choice

Source: AIS's Directory of Health Plans, 2006

Key Player: Federal and State Governments

Medicare ($309 billion in health care expenditures in 2004)

- Federal program covering individuals 65 years old and over
- Financed by federal income taxes, payroll tax paid by employers and employees, and individual enrollee premiums (Part B and Part D)
- Four coverage areas: Part A: hospitalization; Part B: physician services; Part C: managed care; and Part D: prescription drugs (new in 2005; no formularies…yet)
- Gaps: incomplete coverage for nursing homes and preventive care; no coverage for dental, hearing or vision
- Most seniors enroll in supplementary insurance to cover gaps ("Medi-Gap Insurance")

Medicaid ($291 billion in 2004)

- State program covering low-income and disabled people
- Financed 50/50 federal and state; pharmaceutical companies must pay rebates to the state amounting to the difference between the required discount (-15% off the manufacturer's selling price) and the lowest price ("best price") given to any US customer
- Comprehensive benefits, including prescription drugs (some states have formularies)

Veterans Administration ($28 billion in 2004)

- Federal program covering military veterans, financed by federal income taxes
- Provides low-cost care in government-owned hospitals and clinics

Government Programs are Constantly Being Reviewed and Adjusted

Government is increasing its influence in health care delivery:

President Clinton identified the US population's dissatisfaction with healthcare systems and costs during his first term (1993-97), but failed to develop a popular solution

President Bush supported adding prescription drug coverage into the Medicare program, called Medicare Plan D, which previously only covered doctor and hospital visits

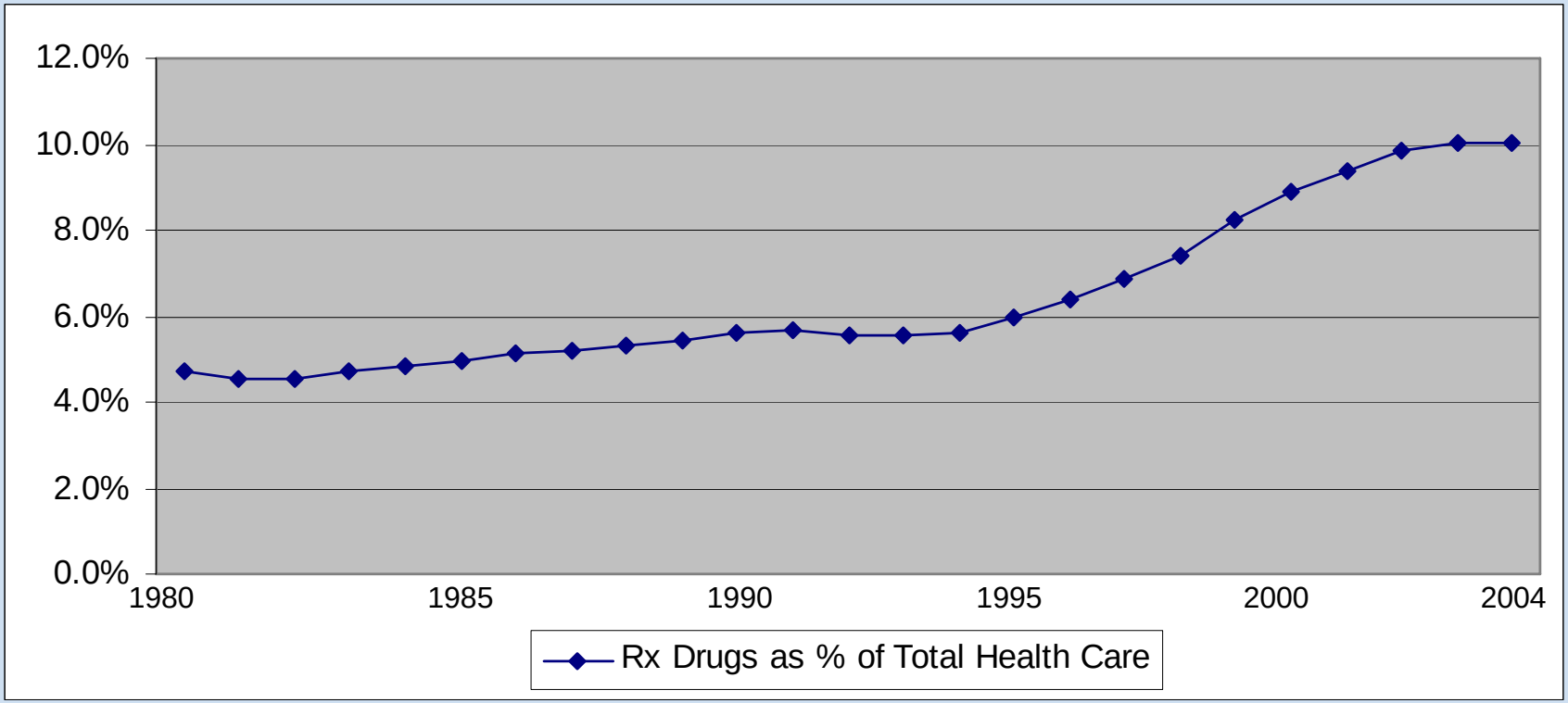
Medicare Plan D:

- pays a variable portion of the drug cost, based on the patient's annual purchases
- has no price controls, mandatory discounts or formulary restrictions
- is lprojected to cost the government some $560 billion over 10 years
- short-term impact: higher usage of chronic care medications that the elderly use
- longer-term impact: potential for mandatory price concessions and restrictive formularies

V. Drug Pricing Practices in the US

- Unlike most industrialized countries, the US does not directly control prices, relying instead on market mechanisms and linkages that ensure the prices paid by public programs are similar to market-determined rates in the private sector
- Companies are free to set any "list price" on their products
  - Reaction from politicians, patient groups and the press are considered when deciding initial prices
- Due to competitive reasons, companies will often discount, rebate, or both
  - Discount: reduces the price for every unit purchased; shows up on the invoice to the purchaser
  - Rebate: a percentage applied to total sales of the drug over a given period, and usually increases as volume exceeds certain pre-established levels; less transparent to anyone but the MCO administrator
- Companies can sometimes secure a more favorable position in the co-pay tiers by giving rebates to the MCO

Drug Costs Represent an Increasing Portion of US Health Care Expenditures



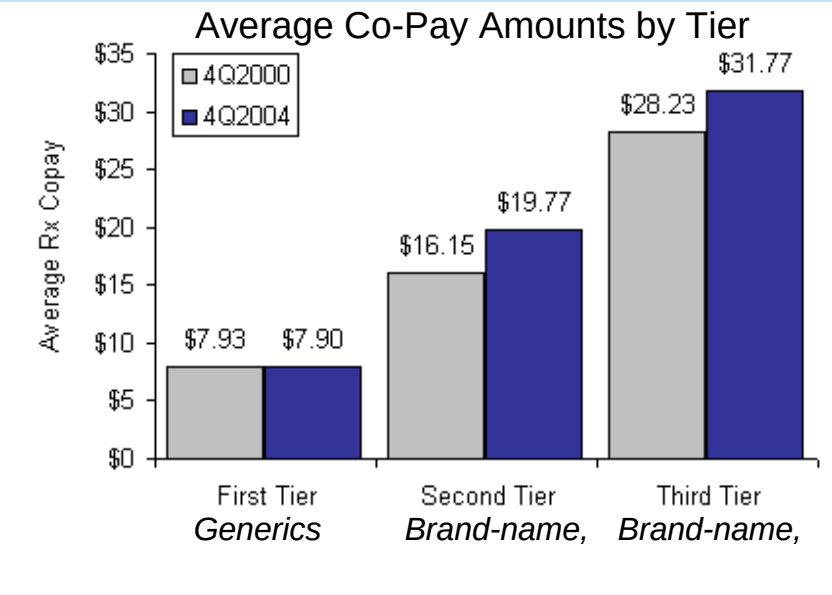
- Increase from 1995 is a result of more prescription volume, and switching from older drugs to newer, more expensive drugs.
- In 1990, 2/3 of the drug expenditure were paid “out-of-pocket” by patients themselves; in 2000, the figure was less than 1/3, with health plans absorbing the difference.

Drug costs often attract attention due to their high growth compared to other health care expenditures

Enlisting the Patient to Help Control Costs

"For the last few years, employers have been boosting workers' premiums, copays, deductibles and coinsurance levels in order to reduce the plan sponsor's share of health benefits costs. This year (2005), the focus is turning to ways to develop incentives and other programs aimed at helping workers reduce their own health care expenditures."[1]

A good example of turning more decision-making over to patients is the "Tier System" for prescription drug coverage. There has been a perception among certain groups (e.g. employee unions) that restricted formularies deny patients access to all the best medicines. Therefore MCOs have designed programs that avoid restrictive formularies, but achieve a similar result.



Co-payments can be even lower if patients have their prescriptions filled by mail order pharmacies and in 3-month quantities.
Mail order pharmacies are much larger than retail pharmacies, have lower costs, and are willing to contract with MCOs

[1] Managed Care Week, Jan. 17, 2005.

VI. Pharmaceutical Company Marketing Strategies to Succeed in the US

Companies seek to ensure availability of their products to as many patients as possible, and have created diverse sales and lobbying organizations to do this:

- National (HQ) and Regional Managed Care Account Managers
- State Government Relations Managers
- Group Purchasing Organization (GPO) Account Managers
- Hospital Sales Representatives

The marketing messages for these customers are focused on cost-effectiveness of the products

There will often be contracts signed, calling for discounts/rebates if certain targets are achieved

Once availability is ensured, then traditional sales representatives promote the product benefits to physicians in order to increase demand ("pull-through"); "direct-to-the-consumer" (DTC) advertising may also be used

Developing and communicating a credible cost-effectiveness message to the "Payer" and "Health Plan" customers is an essential role of marketing in the US

VII. Summary: Things to Keep in Mind When Negotiating Compounds for the US Market

- If you are introducing a product within an established class (e.g. angiotensin II inhibitors), MCOs may add your product only in place of an existing drug, or at a co-pay tier that limits usage
- Cost-effectiveness (the benefits of the drug vs. the price) will be an important factor in the success of your product; the Phase 3 clinical plan should include the prospective collection of data to support a cost-effectiveness argument
- In recent years, companies followed Pfizer's lead in greatly increasing the number of sales reps, and created specialty sales forces (e.g. diabetes, oncology, cardiovascular, etc.). Now, companies are following Pfizer's "****Cut" strategy by reducing the number of reps, increasing the products they promote, and therefore eliminating certain specialty sales forces; exception: oncology

Favorable Aspects of US Healthcare System for Pharmaceutical Companies

- Largest pharmaceutical market
  - Highest return on R&D and marketing investments
  - Intense competition
- Relatively free pricing
  - Able to obtain “premium for innovation”
- Multiple decision influencers over drug availability
  - Not a “winner take all” situation
- Similar development and regulatory process between US and Europe
- Single official language
- Employee mobility between companies
  - Easy to hire people with expertise
  - May be difficult to retain qualified people

Less Favorable Aspects of US System for Pharmaceutical Companies

- Multiple influencers over drug availability
  - Employers, managed care administrators, hospital pharmacists, state Medicaid departments, etc.
  - Pharmaceutical companies need to respond to needs of many groups
- Government becoming a bigger purchaser of drugs, particularly for elderly and poor
  - Likely to demand pharmaceutical price concessions in the future
- Generic drugs encouraged by law
  - Automatic substitution of generic for branded drug
  - Under certain health plans, patients may receive any drug within a class – doctor allows pharmacist to choose
- Poor reputation of the pharmaceutical industry by average people
  - Image at same level as tobacco companies
- Politicians quick to allow “illegal” purchase of drugs, via Canada/ Mexico and internet (e.g. State of Illinois imported drugs for its employees from Canada)
  - Do not want to be seen as “friendly” to pharmaceutical industry
- High number of law suits alleging injury due to side effects (e.g. Merck’s Vioxx)