Can Pharmaceuticals Cost-Effectively Meet the Challenges of Treating & Preventing Disease?

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Educational Objectives

- Explain economic and quality factors in the management of disease
- Demonstrate impact of disease on productivity and quality of life
- Explain the role of Medicare Modernization Act and disease
- Identify value of patient/consumer in managing conditions/diseases
Trends in U.S. Health Care

- Aging Society
- Finance/Reimbursement
- Corporatization
- Technology (Genomics)
- Outcomes vs. Cost
<table>
<thead>
<tr>
<th>Disease</th>
<th>Prevalence</th>
<th>Estimated Annual Cost</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alzheimer’s Disease</td>
<td>4 Million Adults</td>
<td>$100 Billion</td>
</tr>
<tr>
<td>Arthritis</td>
<td>70 Million Adults</td>
<td>$65 Billion</td>
</tr>
<tr>
<td>Asthma</td>
<td>14 Million Total</td>
<td>$12.7 Billion</td>
</tr>
<tr>
<td>Cancer</td>
<td>8.9 Million Total</td>
<td>$156.7 Billion</td>
</tr>
<tr>
<td>Congestive Heart Disease</td>
<td>4.9 Million Adults</td>
<td>$24.3 Billion</td>
</tr>
<tr>
<td>Coronary Heart Disease</td>
<td>12.9 Million Adults</td>
<td>$129.9 Billion</td>
</tr>
<tr>
<td>Depression</td>
<td>18.8 Million Adults</td>
<td>$44 Billion</td>
</tr>
<tr>
<td>Diabetes</td>
<td>17 Million Total</td>
<td>$98 Billion</td>
</tr>
<tr>
<td>Hypertensive Disease</td>
<td>50 Million Adults</td>
<td>$50.3 Billion</td>
</tr>
<tr>
<td>Irritable Bowel Syndrome</td>
<td>30 Million Total</td>
<td>$30 Billion</td>
</tr>
<tr>
<td>Osteoporosis</td>
<td>10 Million Adults</td>
<td>$17 Billion</td>
</tr>
<tr>
<td>Schizophrenia</td>
<td>2.2 Million Adults</td>
<td>$32.5 Billion</td>
</tr>
<tr>
<td>Stroke</td>
<td>4.7 Million Adults</td>
<td>$51.2 Billion</td>
</tr>
</tbody>
</table>
Health Expenditures as a Percentage of Gross Domestic Product 2003

OECD 2003
Drugs as a Percentage of Healthcare Costs 2003

U.S.  Sweden  Germany  U.K.  Canada  Japan  France  Italy

12.9%  13.1%  14.6%  15.8%  16.9%  18.4%  20.9%  22.1%

OECD 2003
Pharmacists/1000
<table>
<thead>
<tr>
<th>Category</th>
<th>Expenditure</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diagnostic</td>
<td>$ 5 Billion</td>
</tr>
<tr>
<td>Over the Counter</td>
<td>$ 25 Billion</td>
</tr>
<tr>
<td>Rx</td>
<td>$179 Billion</td>
</tr>
<tr>
<td>Total Pharmaceutical Market</td>
<td>$209 Billion</td>
</tr>
</tbody>
</table>

Projected Rx Market by 2004 ~$250 Billion
Employers as Healthcare Purchasers: An Evolving System
Individual Risks That Impact Overall Health Care Costs, Absenteeism and Productivity

For every 100 employees:

- 60 are sedentary
- 50 have high cholesterol
- 50 feel distressed or depressed
- 27 have cardiovascular disease
- 25 smoke
- 24 have high blood pressure
- 20 are at least 20% overweight
- 10 have diabetes

Ref: Statistics from the National Center for Health Promotion
Pharmaceutical Development

Pre-1940
• Basically Nonexistent

1940 - 2000
• Complex Drug Development
• Cellular Structure Analysis
• Molecular and Immunological Sciences
# Prevalence and Medicines in Development for Selected Major Diseases in the United States

<table>
<thead>
<tr>
<th>Disease</th>
<th>Prevalence</th>
<th>Development</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alzheimer’s Disease</td>
<td>4,000,000</td>
<td>26</td>
</tr>
<tr>
<td>Arthritis</td>
<td>40,000,000</td>
<td>28</td>
</tr>
<tr>
<td>Asthma</td>
<td>14,000,000</td>
<td>21</td>
</tr>
<tr>
<td>Cancer</td>
<td>8,000,000</td>
<td>402</td>
</tr>
<tr>
<td>Congestive Heart Failure</td>
<td>4,900,000</td>
<td>18</td>
</tr>
<tr>
<td>Coronary Heart Disease</td>
<td>13,900,000</td>
<td>42</td>
</tr>
<tr>
<td>Depression</td>
<td>17,600,000</td>
<td>26</td>
</tr>
<tr>
<td>Diabetes</td>
<td>15,700,000</td>
<td>25</td>
</tr>
<tr>
<td>Hypertensive Disease</td>
<td>50,000,000</td>
<td>11</td>
</tr>
<tr>
<td>Osteoporosis</td>
<td>10,000,000</td>
<td>14</td>
</tr>
<tr>
<td>Schizophrenia</td>
<td>1,500,000</td>
<td>16</td>
</tr>
<tr>
<td>Stroke</td>
<td>4,000,000</td>
<td>18</td>
</tr>
</tbody>
</table>

Source: Pharmaceutical Industry Profile 2000
Pharmaceutical Growth Drivers

- Consumer Demand
- Enhanced Product Development (>7500)
- Human Genome Project (# Drug Targets from 500 to 10,000)
Biotechnology — Manipulation and Exploration

- Genetic
- Molecular
- Enzyme
Complex Drug Development/Treatment
Chronic Conditions and Costs

- 15 Conditions account for 56% of increased healthcare spending 1987-2003
- 5 Conditions account for 1/3 of costs
  - Heart Disease, Pulmonary, Mental Disorders, Cancer, Hypertension
- Prescription drugs and procedures account for a significant amount - as much as 70%

Source: Thorpe KE, Health Affairs, August 2004
Prescriptions Filled in the US Retail Pharmacy Sector

- 1995: 2.1 Billion
- 2003: 3.4 Billion

IMS - 2004
Generics and Biologics Continue to Post Strong Dollar Growth
(MAT June 2003 vs. Mat June 2002)

Source: IMS HEALTH; Retail and Provider Perspective™, 2003
Biotechnology will Play a Major Role in Treatment and Cost:

More than 80% of biotech products are being developed for Chronic Conditions

Source: Biotechnology Research PhRMA 2004
Reasons for Rising Drug Demand and Utilization

- Growth in third-party coverage based on low copays
  - More people are able to afford prescription drugs
- More attention devoted to disease prevention and improved diagnosis
- Increasing commitment to evidence-based medicine
- Aging of America
- Increased prevalence and incidence of chronic conditions

- Types of Prescriptions: 27%
- Number of Prescriptions Dispensed: 47%
- Manufacturer Price Increases: 26%

Pharmaceutical Spending & Utilization

Top 5% of prescription drug users account for 50% of drug spending

Bottom 95% of prescription drug users account for 50% of drug spending

Institute of Medicine Report - Crossing the Quality Chasm: A New Health System for the 21st Century

- Evidence-Based Practice
- Consumer Involvement
- Payment Restructuring
- Informatics
- Interdisciplinary Approach
- Chronic Disease/Condition

IOM: Crossing the Quality Chasm, March 1, 2001
Commitment to Improve Care in Six Areas

- Safe
- Effective
- Patient Centered
- Timely
- Efficient
- Equitable

IOM: Crossing the Quality Chasm, March 1, 2001
Rules to Guide Patient-Clinician Relationship

- Based upon continuous healing relationship
- Care should be customized based on patient needs/values
- Control should reside with patient
- Patient should have access to all information

IOM: Crossing the Quality Chasm, March 1, 2001
Rules to Guide Patient-Clinician Relationship (Continued)

- Clinical decisions should be evidence-based
- Care system should be safe
- Health system more transparent
- System should anticipate need, not just react

IOM: Crossing the Quality Chasm, March 1, 2001
Rules to Guide Patient-Clinician Relationship (Continued)

- System should not waste resources
- Cooperation among clinicians
Redesign of Health Insurance Benefits, Payment and Performance Improvement IOM Project

Will address four categories of high value services that are not adequately addressed:

- Prevention
- Management of chronic condition
- Care Coordination
- End of life care
Redesign of Health Insurance
Benefits, Payment and Performance Improvement
IOM Project (Continued)

- Address payment schedule fee-for-service vs. pay for performance
- Effectiveness of QIP
Leadership is Needed

Academic Health Centers need to prepare work force to do their work differently and evolve new types of health care delivery organizations.

IOM: Crossing the Quality Chasm, March 1, 2001
IOM Report on Health Professions Education: A Bridge to Quality
Education for Health Professions is in Need of a Major Overhaul
Problems Identified

- Uneducated to work in teams for treatment of chronic disease
- Not trained to use and apply evidence-based information
- Unable to address diverse population
- Inability to analyze root cause of errors and quality problems
- Lack of training in adequately using informatics in care of patients

IOM: Health Professions Education, April 8, 2003
Health Professions Education Report
“Needed Competencies”

I. Provide Patient-Centered Care
II. Work in Interdisciplinary Teams
III. Employ Evidence-Based Practice
IV. Apply Quality Improvement Strategies
V. Utilize Informatics

IOM: Health Professions Education, April 8, 2003
Priority Areas

- Self-Management/Health Literacy
- Cancer Screening
- Hypertension
- Immunization
- Major Depression (screening)
- Pregnancy and Childbirth
- Tobacco Dependence
- Obesity

Priority Areas (Continued)

- Severe and Persistent Mental Illness
- Pain Control
- Stroke
- Asthma
- Diabetes
- Ischemic Heart Disease
- Care Coordination (cross cutting)
- Medication Management

Do We Achieve Optimal Value With Pharmaceuticals in the Treatment of Chronic Conditions?
Value of Medicine

- Direct value
  - Ability to improve
    - Morbidity and mortality
    - Quality of life
    - Symptom relief
  - Ability to prevent or mitigate complications/expenditures

- Indirect value
  - Normal, productive lives
  - Reduced absenteeism/presenteeism
  - Improved employee productivity
  - Improved workforce health
Presenteeism – A Hidden Cost Associated with Productivity Loss for Selected Chronic Conditions

- Allergy
- Arthritis
- Asthma
- Depression
- Diabetes
- Hypertension
- Migraine

Passage of Medicare Prescription Drug Improvement and Modernization Act of 2003 suggests “Yes” to the Value Question
Medication Therapy Management Services Will Target Chronic Care

- Diabetes
- Asthma
- Congestive Heart Failure
- Hyperlipidemia
- Hypertension
Pharmaceuticals and Improved Productivity

Hours Worked in a 2-Week Period

- Depression
- Anxiety
- Migraine
- Hypertension

Pretreatment vs. Posttreatment

Foundation for Managed Care Pharmacy, 2001
HOWEVER,

- Only 27% of patients with hypertension are under control
- 46% of diabetics have $\text{HbA}_{1c}$ levels $< 7$
- Only 14% with coronary heart disease reach stable levels
- $\frac{1}{2}$ tobacco users are adequately counseled
- Similar statements for Asthma, Atrial Fibrillation, Depression, Chronic Heart Failure etc…

Source: Bodenheimer, Disease Management, February 2003
Challenges to Providing Patient Access to Appropriate Medications

- Lack of health coverage
  - 40 million Americans with no health insurance

- Lack of, or limited, Medicare coverage for prescriptions
  - Medicare prescription drug bill

- Rising copayments for those with Rx coverage
Models of Drug Benefit Redesign


- Three-Tier: One payment for generic drugs, another for preferred drugs, and a third for non-preferred drugs
- Two-Tier: One payment for generic drugs and one for all brand name drugs
- Payment is the same regardless of type of drug
- Other/Don’t Know
Impact of 3-Tier Formulary on Patient Discontinuation of Therapeutic Class

Higher Copays May Take Toll on Health

- Raising copays is a fairly blunt instrument in controlling rising healthcare costs
- Some worry that copays could actually increase healthcare costs for certain patients, if cutting back on medicines leads to expensive complications
- A recent Rand study found that as copays doubled for diabetes, asthma, and gastric acid disease
  - Use of prescription drugs fell between 17% & 23%
  - Visits to emergency rooms rose 17%
  - Hospital stays increased 10%

When copayments were doubled, average prescription drug use declined among people with:

- Depression: 8%
- Hypertension: 10%
- Gastric Acid Disorder: 17%
- Asthma: 22%
- Diabetes: 23%
- Arthritis: 27%
- Allergic Rhinitis: 31%

The Effect of Medication Coverage on Health Outcomes

Older Americans with heart disease who decrease their medication because of cost factors were 50% more likely to suffer heart attack, stroke or angina

Heisler M, Langa K et al., Medical Care, July 2004
Challenges

- Reducing drug costs continues to be a priority among private and public payors.
- Benefit design and formulary decision-makers will continue using a multi-tiered approach with higher copays for the foreseeable future.
Opportunities

- Overcoming the “siloh” cost mentality
- Measuring and demonstrating positive outcomes and/or productivity gains that can be directly attributed to appropriate pharmaceutical usage
- Ensuring medication compliance, timely medical follow-up, and lifestyle changes to maximize the true value of the pharmaceutical benefit
Planning for the Future
Who will influence cost-effective application of drug technology?
The Medicare Prescription Drug Improvement and Modernization Act of 2003

- Mandates medication therapy management services to prevent, identify, and resolve medication problems (to insure value)
- Possibly placing profession of pharmacy in a key role
IOM Launches Two Year Study to Assess Quality and Safety of Medication Use Process

- Two-year comprehensive assessment of problem and solution
- Goal to provide a blueprint for system wide change
- Chronic Conditions will be a major focus
- Brings to the forefront nationwide implementation to curtail and minimize medication related problems
- Provide guidance to consumers and payers as to their role
- Process is inclusive from prescription to consumption

www.IOM.edu
The Strategy to Optimizing Pharmaceutical Value, Patient Health, and Productivity

- Encourage appropriate drug utilization while minimizing inappropriate utilization

- Balance the need to contain drug costs with the need to:
  - Increase patient access to valuable drug therapy
  - Optimize patient outcomes and overall cost management (i.e., total medical costs and worker productivity costs associated with non-medication use)
  - Ensure patient compliance to maximize therapy value
Prudent balance of generic and brand utilization optimizes value in drug benefit design and management

- Increases access to valuable drug therapy (i.e., if there were no generics, patients and payers could not afford newer, innovative drug therapies)
- Optimizes patient outcomes and cost management
Concluding Comments

- Pharmacoeconomics and outcomes data will be increasingly critical
- Post marketing surveillance will take on a new paradigm
- Electronic information system will be key
- Current system to manage chronic disease will undergo dramatic change