Prescription Drug Formularies: Friend or Foe?

An Honors Thesis (HONRS 499)

by

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I would like to thank Professor Gary Dean for serving as my thesis advisor. It has been a pleasure having him as a teacher for two classes and as an advisor for my thesis project this year. His enthusiasm for learning and the actuarial profession has been an inspiration on this project and in my other studies. Despite having never been a thesis advisor before since this is his first year at Ball State, he was able to point me in the right direction several times while working on this project.
Abstract

This examination of prescription drug expenditures and the usage of formularies in managing drug utilization is divided into two main sections. First, the prescription drug industry is studied for reasons why drug costs are increasing so dramatically in recent years. Statistics are given to explain why there should be a concern in our society about this trend, and the therapeutic classes are identified to show where the most money is being spent. The following possible reasons for increasing drug expenditures are discussed: increasing prices, product shift, higher utilization, patents, research costs, decreasing out of pocket expenses, our aging society, and direct-to-consumer advertising.

In the second section of this paper, a definition of what constitutes a formulary and the different types of formularies are explained. Incentives used in open formularies such as tiered copays are detailed. Ethical concerns about the usage of formularies are outlined, and the process of selecting drugs for a formulary is explained. Different pricing techniques for cash customers and third-party coverage (usually employer based) are demonstrated. The next part of this section addresses concerns about formulary usage, and different ways to respond to these concerns. At the end of this section, recent developments with Medicaid formularies are discussed.

In the final section, a summary of major points is given along with personal commentary and recommendations for the future.
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Introduction

National health-care expenditures increased by 6.9% in 2000, continuing a trend of quick-paced growth that occurred throughout the 1990’s. Spending on health-care as a percentage of our Gross Domestic Product has been steadily increasing, and reached 13.2% in 2000, totaling $1.3 billion. The Health Care Financing Administration predicts by 2010, national health expenditures will total $2.6 trillion and be 15.9% of the GDP. Even with the United States economy growing at a very healthy rate in 1999 and 2000, health-care expenditure increases still outpaced GDP growth. In terms of health-care spending per person there has also been dramatic increases. In 1980, the national health expenditure per capita was $1,067. In 2000, our country spent $4,681 per person on health-care.

Although spending in all areas of health-care has been steadily increasing, the HCFA notes prescription drug spending accounts for a large share of the increases. Since 1980, overall health-care expenditures have increased by 433%, whereas prescription drug expenditures have gained more than double, 874%. In a snapshot of national health-care spending in 2000, prescription drug expenditures accounted for 9% of costs, compared to 32% for hospital care, 22% for physician and clinical services, 7% for nursing, 6% for administration costs, and 24% for other spending. In 1980, prescription drugs accounted for only 4.9% of total spending, and in 1990 the statistic was 5.8%. By 2010, it is projected prescription drugs will account for 13.9% of health-care costs. As noted above, national health expenditures accelerated by 6.9% in 2000, but spending on prescription drugs increased by 17.4%. It is unquestionable prescription drugs have had and will continue to have a much larger role in our health-care system.
Utilization

The first step in understanding why prescription drug costs are rising is to identify how utilization is allocated between various illnesses and diseases. What diseases or ailments do Americans need a prescription drug for? The following table with data taken from the National Institute for Health Care Management lists the top therapeutic classes in terms of sales, the percent of total sales, the best-selling drugs in the category, the market share controlled by the top drugs, and % sale increase from 1999 to 2000. The information is taken from Table 2 and Table 5 in the NIHCM report.[16],[17]

**Best-Selling Therapeutic Classes**

<table>
<thead>
<tr>
<th>Therapeutic Class</th>
<th>1999 Sales in Millions of Dollars</th>
<th>% of Total Drug Sales</th>
<th>Top Drugs</th>
<th>% of Market Share for Top Drugs</th>
<th>% Sales Increase from 1999 to 2000</th>
</tr>
</thead>
<tbody>
<tr>
<td>Antidepressants</td>
<td>$8,630.4</td>
<td>7.9%</td>
<td>Prozac</td>
<td>68.2%</td>
<td>20.9% 7.6% IAP 12.4% UI</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Zoloft, Paxil, Wellbutin Sr</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Antiulcerants</td>
<td>$7,875.5</td>
<td>7.2%</td>
<td>Prilosec, Prevacid, Ranitidine HCl Pepcid</td>
<td>88.3%</td>
<td>20% 7.6% IAP 11.5% UI</td>
</tr>
<tr>
<td>Cholesterol Reducers</td>
<td>$6,470.2</td>
<td>6.2%</td>
<td>Lipitor, Zocor, Pravachol Lescol</td>
<td>89%</td>
<td>27.4% 5.3% IAP 21.0% UI</td>
</tr>
<tr>
<td>Broad Antibiotics</td>
<td>$7,331.8</td>
<td>5.9%</td>
<td>Cipro, Zithromax Z-Pak Levaquin Biaxin</td>
<td>41.8%</td>
<td>6.5% 7.3% IAP -0.8% UI</td>
</tr>
<tr>
<td>Antiarthritic</td>
<td>$4,444.8</td>
<td>4.7%</td>
<td>Celebrex, Vioxx, Enbrel, Relafen</td>
<td>52.3%</td>
<td>39.3% 21.3% IAP 14.3% UI</td>
</tr>
</tbody>
</table>

*IAP: Increase in Average Price  UI: Utilization Increase*
In addition to the best-selling therapeutic categories, it is also of importance to note, which drug classes are growing the most quickly in terms of price. In 2000, antiarthritic drugs led the way with an increase of 21.3%. They were followed by narcotic painkillers with 21.1%, antipsychotics at 16.4%, oral diabetes with 15.6%, and dermal acne therapy at 14.8%.[17]

Although the pharmaceutical industry has thousands of products on the market, it may come as a surprise that the top 50 selling drugs make up more than 40% of the market.[7] From the chart on the following page, the dramatic difference between the best selling drugs and the rest of the market in terms of sales, number of prescriptions, sales growth, and price can be seen. These differences will be discussed further in the next section.
# The Prescription Drug Market in 2000

<table>
<thead>
<tr>
<th>All Drugs</th>
<th>1999</th>
<th>2000</th>
<th>Percent Change</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total Sales (billions)</td>
<td>$111.1</td>
<td>$132.0</td>
<td>18.8%</td>
</tr>
<tr>
<td>Total Scripts (millions)</td>
<td>2,712.4</td>
<td>2,915.2</td>
<td>7.5%</td>
</tr>
<tr>
<td>Avg. Price Per Script</td>
<td>$40.96</td>
<td>$45.27</td>
<td>10.5%</td>
</tr>
<tr>
<td><strong>50 Best Selling Drugs (2000 sales)</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total Sales (billions)</td>
<td>$44.9</td>
<td>$58.2</td>
<td>29.7%</td>
</tr>
<tr>
<td>Total Scripts (millions)</td>
<td>730.6</td>
<td>866.6</td>
<td>18.6%</td>
</tr>
<tr>
<td>Avg. Price Per Script</td>
<td>$61.41</td>
<td>$67.15</td>
<td>9.4%</td>
</tr>
<tr>
<td><strong>Rest of Market (2000 sales)</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total Sales (billions)</td>
<td>$66.2</td>
<td>$73.8</td>
<td>11.4%</td>
</tr>
<tr>
<td>Total Scripts (millions)</td>
<td>1,981.9</td>
<td>2,048.6</td>
<td>3.4%</td>
</tr>
<tr>
<td>Avg. Price Per Script</td>
<td>$33.42</td>
<td>$36.01</td>
<td>7.7%</td>
</tr>
<tr>
<td><strong>50 Drugs Contributing Most to Sales Growth</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total Sales (billions)</td>
<td>$37.5</td>
<td>$52.6</td>
<td>40.2%</td>
</tr>
<tr>
<td>Total Scripts (millions)</td>
<td>533.5</td>
<td>693.1</td>
<td>29.9%</td>
</tr>
<tr>
<td>Avg. Price Per Script</td>
<td>$70.32</td>
<td>$75.88</td>
<td>7.9%</td>
</tr>
<tr>
<td><strong>Rest of Market</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total Sales (billions)</td>
<td>$73.6</td>
<td>$79.4</td>
<td>7.9%</td>
</tr>
<tr>
<td>Total Scripts (millions)</td>
<td>2,178.9</td>
<td>2,222.2</td>
<td>2.0%</td>
</tr>
<tr>
<td>Avg. Price Per Script</td>
<td>$33.77</td>
<td>$35.72</td>
<td>5.8%</td>
</tr>
</tbody>
</table>

* Script is abbreviation for prescription

Table taken from Prescription Drug Expenditures in 2000: The Upward Trend Continues.[7]
Causes of Expenditure Increases

There are numerous reasons why prescription drug expenditures are increasing rapidly in the United States. In the following section, a brief overview of these causes will be given.

Product Shift, Increasing Prices, & Rise in Utilization

In the case of prescription drugs, the use of new products is labeled “product shift.” Product shift is demonstrated when new brand drugs are used in place of older and less expensive drugs. The costs for these newer drugs are justified by increased health benefits to the consumer. Many recent drugs have provided therapies where none have existed before, greater-cost effectiveness, and have reduced costs of non-pharmaceutical expenditures.[5] For example, in many cases drug treatment is available for ailments that in the past would require more expensive surgical procedures. If a drug is noted for being more beneficial than others, its utilization will naturally increase.[6]

In a study done by Mullins et al, an attempt was made to distinguish rise in drug expenditures between product shift, price increase, and utilization increase. Basing their study on the American Druggist’s top 100 drugs in terms of prescription volume from the period 1995 to 1998, they ascertain one-third of expenditures increases were due to utilization increases in existing drugs, a little more than one-third because of product shift, and a less than one-third from price increases on existing drugs.[6]

The NIHCM conducted a similar study for factors contributing to retail prescription drug spending increases in 1999-2000. Of the $20.8 billion increase in spending, 36% was attributable to product shift. Price hikes and rises in the number of prescription accounted for 22% and 42% of the expenditure increase, respectively.[17]
**Average Price of Old Drugs Compared to New Drugs**

a) **Average Price of All Old Drugs (pre 1992 approval, 1998)**

b) **Average Price for all but Top Four Best-Selling Drugs (2000)**

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Antidepressants</td>
<td></td>
<td></td>
<td>Broad Antibiotics</td>
<td></td>
<td></td>
</tr>
<tr>
<td>a) $48.82</td>
<td>Celexa</td>
<td>$69.05</td>
<td>a) $25.99</td>
<td>Zithromax</td>
<td>$41.00</td>
</tr>
<tr>
<td>b) $45.11</td>
<td>Paxil</td>
<td>$78.62</td>
<td>b) $24.89</td>
<td>Levaquin</td>
<td>$77.77</td>
</tr>
<tr>
<td></td>
<td>Weilbutrin</td>
<td>$85.88</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Anti-Ulcer</td>
<td></td>
<td></td>
<td>Oral Antidiabetics</td>
<td></td>
<td></td>
</tr>
<tr>
<td>a) $86.99</td>
<td>Prevacid</td>
<td>$125.98</td>
<td>a) $27.27</td>
<td>Glucophage</td>
<td>$63.00</td>
</tr>
<tr>
<td>b) $78.52</td>
<td></td>
<td></td>
<td>b) $34.18</td>
<td>Avandia</td>
<td>$116.27</td>
</tr>
<tr>
<td>Cholesterol Reducers</td>
<td></td>
<td></td>
<td>Respiratory Steroids</td>
<td></td>
<td></td>
</tr>
<tr>
<td>a) $71.89</td>
<td>Lipitor</td>
<td>$82.58</td>
<td>a) $51.48</td>
<td>Flovent</td>
<td>$72.28</td>
</tr>
<tr>
<td>b) $52.01</td>
<td>Zocor</td>
<td>$112.36</td>
<td>b) $54.37</td>
<td>Flonase</td>
<td>$53.88</td>
</tr>
<tr>
<td>Arthritis/Osteoarthritis</td>
<td></td>
<td></td>
<td>Estrogen Replacement</td>
<td></td>
<td></td>
</tr>
<tr>
<td>a) not available</td>
<td>Celebrex</td>
<td>$88.93</td>
<td>a) $26.53</td>
<td>Prempro</td>
<td>$34.06</td>
</tr>
<tr>
<td>b) $30.42</td>
<td>Vioxx</td>
<td>$79.17</td>
<td>b) $36.35</td>
<td></td>
<td></td>
</tr>
<tr>
<td>HIV/AIDS</td>
<td></td>
<td></td>
<td>Narcotic Pain Killers</td>
<td></td>
<td></td>
</tr>
<tr>
<td>a) $318.68</td>
<td>Combivir</td>
<td>$551.58</td>
<td>a) not available</td>
<td>OxyContin</td>
<td>$189.01</td>
</tr>
<tr>
<td>b) $327.70</td>
<td>Viracept</td>
<td>$590.84</td>
<td>b) $24.77</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

From figure 7[17]

Newer drugs, which often are the best sellers, have increased in price and utilization must faster than older drugs. According to the NIHCM, in 2000, pharmacists dispensed 18.6% more prescriptions than in 1999 for the top 50 best selling-drugs. This compares to only an increase of 3.4% for all other drugs.[17] In terms of price increases, the top 50 selling drugs had an average price of $67.15, compared to only $36.01 for the average price of all other drugs.[17] From the table entitled “Average Price of Old Drugs
Compared to New Drugs”, the dramatic difference between the newer, top-selling drugs and older drugs in terms of prescription price can be seen.

Aging Population

As the baby-boomer generation creeps into old age, the more elderly United States population will demand prescription drugs that can treat chronic conditions and aid in the prevention of disease.[8] The growth of Americans in the over sixty-five age category slowed in the 1990’s due to the decrease of the birthrate during the Great Depression, but is expected to have its greatest increase between the years 2010 and 2030 as baby-boomers reach sixty-five.[9] In 2000, people over age 65 accounted for 13% of the population. This will increase to around 20% by 2030.[23]

The pharmaceutical industry has already geared their research towards medical advances that will correspond with the aging of our population.[20] The elderly population will have to deal with chronic and disabling diseases that will require new drugs.[20] Insurance companies covering older populations have already noted steadily increasing drug costs, and believe costs will continue to escalate.[20] The average patient over age 65 fills twenty prescriptions per year, compared to only three prescriptions for patients in their twenties.[23],[31] The average cost for a person age 65 to 70 is $700, nine times higher than a person in their twenties.[23],[31]

Research & Development Costs

Another factor causing prescription drug costs to rise is the enormous cost of developing and researching new drugs. The Tufts Center for the Study of Drug Development found a pharmaceutical company typically spends about $800 million over a period of ten to fifteen years to develop a new drug.[10] This cost is up from a similar study done by Tufts in 1987 which put the price at $231 million.[11] If adjusted for
inflation, the 1987 cost would be only $318 million.[11] In terms of overall revenue, in 2000, research and development spending was around 15% to 18% of drug manufacturers’ total revenue.[37] What makes drug development cost so much?

Prescription drug research and approval is a long and tedious process. The process begins by a new drug being developed by a sponsor, which could be an individual, partnership, corporation, government agency, or scientific institution.[10] The sponsor then must file an initial new drug application with the Food & Drug Administration if it intends to conduct clinical studies.[10] The chances of a new substance even reaching this step are extremely slim. The Pharmaceutical Manufacturers of America claim that of every 1,000 medicines tested, only one is tested in clinical trials.[10]

Once a prescription drug reaches the clinical trials stage, its approval for marketplace use is by no means assured. The clinical phases are the longest and most expensive part of drug development, and represent a significant investment on the part of the pharmaceutical manufacturer.[12] Clinical development usually has three phases of study.[10] Phase I involves studying volunteers to see how the drug affects the general processes of the body and what side effects may occur.[10] After the first phase, the company decides if the results favor starting Phase II. Phase II determines if the drug is effective in treating the disease or ailment it is intended for.[10] Phase III studies generally have hundreds to even thousands of patients in controlled and uncontrolled trials. The purpose of Phase III is to find data that will be eventually be put on physician labeling.[10]

From a drug’s synthesis, until it reaches the marketplace, the average time is around twelve years.[12] After making such a significant investment in research and time, the pharmaceutical company hopes to recoup its expenditures by having tremendous sales of
the product. Naturally, these companies do not want other companies benefiting from their difficult work, therefore, patents are used as a reward to compensate pharmaceutical companies for their costs in bringing a drug to the marketplace.[13]

*Patents*

Patents grant temporary legal monopoly power to the maker of a specific drug.[14] Currently in the United States, patents have a period of either twenty years from the date of filing or seventeen years from the date of grant, whichever is longer.[15] Without patents, drug manufacturers would not have the financial incentive to devote millions of dollars of research and development to the production of a new drug.[14]. At the same time, the use of patents is obviously going to limit competition which in turn will cause higher prescription drug prices.[14]

Pharmaceutical manufacturers have been increasing their research and development budgets with the expectation of patent protection for their new drugs.[14] Over the past decade private funding of biomedical research and development has surpassed government spending in the area despite the budget for the National Institute of Health being doubled at the same time.[13] Pharmaceutical manufacturers continually say they cannot cover their research investments without patent protection.[13]

*Direct-to-consumer Advertising*

In the last few years, most Americans have surely noticed an increase in prescription drug advertising, and data supports these findings. According to the National Institute of Health Care Management, after the FDA changed the rules on prescription drug advertising in 1997, spending on direct-to-consumer advertising has gone from $1.1 billion in 1997 to $2.5 billion in 2000.[18] Of the $2.5 billion of direct-to-consumer advertising in 2000, 57.2% was composed of television ads, 11% on the
radio and billboards, and 31.8% in magazines and newspapers.[18] For example, the antiarthritis drug Vioxx had $160 million in direct-to-consumer advertising (DTC), beating Pepsi, Budweiser, Nike shoes, and equaling Dell's expenditure on its best-selling computer line.[18]

Obviously, the drug companies must be having some success with their DTC, or it would not be worth the tremendous amount of money they have spent. In a study done by Scott-Levin, doctors noted an 11% increase in office visits by patients visiting for greatly advertised conditions from January to September 1998. During the same period, there was only a 2% increase in total office visits.[20] Also, in a recent study done by IMS Health, it was reported 42% of physicians reported an increase in requests for a specific brand name drug by patients.[43] Additionally, physicians found 86% of their patients first learned about a brand name drug through a manufacturer's ad.[43]

The focus of DTC advertising has been on conditions that are chronic, non-life threatening, widespread amongst the public, and the people affected often go untreated.[5] The statistics support this claim very well. Vioxx, the anti-arthritic medicine, ranked number one in DTC advertising with $160.8 million. It was followed, in order, by Prilosec (anti-ulcerant), Claritin (oral antihistamine), Paxil (antidepressant), Zocor (cholesterol reducer), Viagra (sex function disorder), Celebrex (anti-arthritis), Flonase (respiratory steroids), Allegra (oral antihistamine), and rounding out the top ten was Meridia (anti-obesity).[18]

A study done on ten popular magazines with a diverse reading population gives more information about what drugs are advertised most heavily. It was found that advertisements for drugs providing symptom relief accounted for 63% of all advertisement.[18] In this category, the most prominent advertisements were related to
allergies and menopause-related symptoms.[18] Medications designed for specific diseases were second with an advertising share of 26%.[18] The main diseases targeted were Alzheimer's, diabetes, HIV, depression, fungal infections, arthritis, and hypertension[18]. Only 11% of drug advertisements were for preventive medicines targeting smoking, osteoporosis, breast cancer, and cholesterol.[18]

Below Chart taken from Prescription Drugs and Mass Media Advertising, 2000. Figure 1[42]

![% Change in Sales($) & Number of Prescriptions, 1999-2000](chart)

Dark shaded bars represent 50 Drugs Most Heavily Advertised and light shade represents all other drugs.

What rules does the FDA have for prescription drug advertising? The drug advertisement may not claim it is superior to another drug without scientific data. Also, the advertisement should show a fair balance between the benefits and risk. If the
advertisement is in a print media, it must have a summary of the effectiveness, adverse
effects, and warnings about its use.

Why are some experts concerned about drug advertising? The main argument is
that DTC increases patients' demand for more specific and expensive drugs, which has a
negative effect on their relationship with their physicians and medical practice in
general.[19] If patients are making self-diagnosis, the physician may have to explain
why the medication advertised is not appropriate.[53] A 1998 survey done by IMS health
reported 53% of physicians reported an increase in brand name requests, a 30% increase
from mid 1997 (before the advertisement regulations were relaxed).[20] Doctors are also
likely to give the patient the drug they ask for. In a study done by Prevention and the
American Pharmaceutical Association, 73% of consumers claimed their doctors fulfilled
a specific drug request.[20]

One specific example of consumers being led by DTC advertising occurred in New
York. A health plan introduced a higher $50.00 prescription copayment on a non-
preferred, non-sedating antihistamine. Despite the higher payment the consumer had to
make, and the fact another drug on the market was more effective, the health plan saw no
decrease in patient use. The health plan presumed this was the effect of DTC
advertising.[23]

An argument could be made that heavily advertised drugs are utilized more because
they are newer and more effective. However, a study done by the National Center for
Health Statistics and Centers for Disease Control and Prevention from 1997 to 1999
found this theory to be somewhat flawed. The analysis found the drugs most often
prescribed were also the drugs with the most advertising spending.[18] 80% of drugs
reaching the market place in the last several years that had considerable consumer
advertising were in the top 20% in terms of utilization.\[18\] A striking difference is that only 10% of recently developed drugs not heavily advertised are in the top 20%.\[18\]

There are also people who argue that drug advertising educates consumers about conditions and treatment options.\[20\] If a person hears about a new drug or medical practice through an advertisement, this could stimulate dialogue with their doctors, and help improve their overall health.\[20\]

*Increased Third-Party Coverage*

With the rapidly increasing prescription drug costs in this country, how much of it are consumers spending out of their pocketbooks? In the beginning of this paper, it was noted prescription drug costs have increased 874% since 1980, but how much of the increase is covered by third-parties (employer based health plans) rather than by consumers themselves?

### Out of Pocket Prescription (OoP) Drug Expenditures as a % of Total Health and Prescription Drug Spending ($ Billions)\[21\]

<table>
<thead>
<tr>
<th>Year</th>
<th>Rx Expenditures</th>
<th>% of Health Expenditures</th>
<th>OoP Rx Expenditures</th>
<th>% of Rx Spending</th>
<th>Health Expenditures</th>
<th>OoP Rx as % of Health Expenditures</th>
</tr>
</thead>
<tbody>
<tr>
<td>1980</td>
<td>$12</td>
<td>4.9%</td>
<td>$8.4</td>
<td>70.0%</td>
<td>$245.8</td>
<td>3.42%</td>
</tr>
<tr>
<td>1990</td>
<td>$40.3</td>
<td>5.8%</td>
<td>$23.8</td>
<td>59.1%</td>
<td>$695.6</td>
<td>3.42%</td>
</tr>
<tr>
<td>2000</td>
<td>$116.9</td>
<td>8.9%</td>
<td>$40.2</td>
<td>34.4%</td>
<td>$1311.1</td>
<td>3.07%</td>
</tr>
</tbody>
</table>

From the above table, it is obvious consumers are paying a smaller portion of prescription drug spending. Although this data is not in the table, out-of-pocket spending...
for all health care expenditures has gone from 23.7% in 1980, to 19.8% in 1990, and had decreased even farther to 15.4% by 2000. What entities are picking up for the drop in consumers' share of prescription drug expenditures?

**Division of Prescription Drug Expenditures ($ Billions)**[21]

<table>
<thead>
<tr>
<th></th>
<th>Rx Expenditures</th>
<th>OoP Rx</th>
<th>Private Health Insurance</th>
<th>Federal</th>
<th>State and Local</th>
</tr>
</thead>
<tbody>
<tr>
<td>1980</td>
<td>12</td>
<td>8.4</td>
<td>2.0</td>
<td>0.9</td>
<td>0.8</td>
</tr>
<tr>
<td>1990</td>
<td>40.3</td>
<td>23.8</td>
<td>9.9</td>
<td>3.2</td>
<td>3.4</td>
</tr>
<tr>
<td>2000</td>
<td>116.9</td>
<td>40.2</td>
<td>51.3</td>
<td>5.1</td>
<td>4.4</td>
</tr>
</tbody>
</table>

**Division of Prescription Drug Expenditures (%)**[21]

<table>
<thead>
<tr>
<th></th>
<th>Rx Expenditures</th>
<th>OoP Rx</th>
<th>Private Health Insurance</th>
<th>Federal</th>
<th>State and Local</th>
</tr>
</thead>
<tbody>
<tr>
<td>1980</td>
<td>100.0%</td>
<td>70.0%</td>
<td>16.7%</td>
<td>7.5%</td>
<td>6.7%</td>
</tr>
<tr>
<td>1990</td>
<td>100.0%</td>
<td>59.1%</td>
<td>24.6%</td>
<td>7.9%</td>
<td>8.4%</td>
</tr>
<tr>
<td>2000</td>
<td>100.0%</td>
<td>34.4%</td>
<td>43.9%</td>
<td>4.4%</td>
<td>3.8%</td>
</tr>
</tbody>
</table>

From the above tables, you can see private health insurers are the main source of funding for prescription drugs. With the United States labor market being very tight throughout most of the 1990's, employers used more extensive prescription drug coverage to increase retention and productivity.[31] Typically, an insured will pay a copayment or coinsurance to the pharmacist upon receiving their prescription.[5] Even though private health insurers prescription drug expenditures increased annually over 15% in 1996, 1997, and 1998, recipients of the drugs had out-of-pocket payments increase by only about 5% each year.[5] Ernst Bendt notes in an insurance-protected environment, it is expected that employees' prescription drug use will increase.[5]

Because of the drop in out-of-pocket prescription drug expenses, some experts feel consumers are not concerned about price at time of purchase.[17] Without being
concerned about prices, many consumers want to buy the latest and most expensive drugs.[17]
Drug Formularies

Introduction

With any resource that is limited, it is necessary to manage and use the resource effectively in order for it not to be exhausted. For example, when a part of the United States experiences a prolonged drought, water usage does not continue on a normal basis, but must be reserved or contained for the most beneficial uses. If this did not occur, the water supply might be exhausted and the area could suffer severe consequences. In the same way, prescription drug usage must be managed and used effectively. Health plans and employers could not afford to provide a prescription drug benefit if the demand for drugs was left unconstrained. In a typical drug benefit plan, there are usually several methods of managing utilization. One such tool that is widely used is drug formularies.
Definition

What exactly is a drug formulary? The Managed Care Handbook defines a drug formulary by the following: a preferred list of medications developed by the health plan or pharmacy benefit manager to guide physician prescribing and pharmacy dispensing. The purpose of a drug formulary is to control inventory and encourage the use of the most cost-effective products.[24] A formulary will generally contain information about drugs eligible for coverage in each therapeutic class, whether a brand-name or generic is covered, coverage restrictions, cost index, and a copayment classification.[24] Further explanation of these characteristics will be done in the following sections of this paper.

Formularies are popular with managed care organizations (MCO’s) because they control both the supply and demand for prescription drug products by sharing the financial risk with employees, medical networks, and even physicians.[24] In the following section, it will be shown how formularies allow the financial risk of a drug plan to be shared with all three entities.
Types and Structures of Formularies:

There are two main types of prescription drug formularies: closed and open. With a closed drug formulary plan, a consumer will not be covered if a drug is not listed in the formulary unless special approval is granted by their health plan.[27] Normally, only a benefit is included for generic and preferred brand-name drugs.[31] About 10% of all health plans operate with closed formularies, but are found in 27% of all HMO's.[27]

An open drug formulary is much more prevalent than the closed version because consumers are not very enthusiastic about having their drug choices limited, and do not like the hassle of getting special approval for a particular drug.[27] Instead of forcing people to select certain drugs like a closed formulary, an open formulary instead gives the buyer and others incentives to select specific drugs in each class.[27]

One such incentive are copayment tiers. Approximately 80% of managed care plans are now offering a tiered prescription program with their drug benefit plan.[31] When a consumer purchases a drug, he or she will pay a fee at the time of purchase referred to as a “copay.” Copayments are used to make consumers share in the financial risk of drug costs.[24] A person is likely to think twice about paying for a particular drug if they have to pay for a share of the cost. Copays help eliminate frivolous prescription drug use.[24]

With tiered copayments, there are generally three different classes differing by amount and type of drugs, and occasionally a fourth tier for “lifestyle drugs”. [28] The table on the next page describes the characteristics of the various tiers, with the 3rd row describing a common copay for each tier.
<table>
<thead>
<tr>
<th>Tier I</th>
<th>Tier II</th>
<th>Tier III</th>
<th>Tier IV</th>
</tr>
</thead>
<tbody>
<tr>
<td>Generic Copayment</td>
<td>Preferred Brand</td>
<td>Non-Preferred Brand</td>
<td>Nonformulary products</td>
</tr>
<tr>
<td>&lt;$10</td>
<td>$10 to $25</td>
<td>$15 to $40</td>
<td>50% of cost up to a max</td>
</tr>
</tbody>
</table>

From the table above, Tier I has the lowest copayments because generic drugs are much cheaper than brand-name drugs, and the lower copayment is an incentive for the consumer to select a generic drug if possible.[24] Tier II drugs are generally shown to be more effective or less expensive than drugs from the same therapeutic class. The copayment is less for Tier II than Tier III to encourage Tier II selection. Tier IV is reserved for drugs referred to as “lifestyle drugs” (Viagra is one example).[24] The goal of tier usage is to provide the consumer with more selection, but to require the patient to accept the 3rd or 4th tier copayment if a more costly or unnecessary drug is selected.[24]

Another incentive used by open formularies that is very effective at cost-containment is a mandatory generic substitution program.[28] The health or drug plan agrees to pay the pharmacist only the Maximum Allowable Cost (based on the lowest estimated acquisition cost for any of the generic equivalents of a given drug), whether the drug is generic or brand-name. The patient will end up paying the difference between the brand-name cost and the MAC.[24]

Physicians and pharmacists can also be influenced to prescribe and dispense drugs on a formulary. Many drug plans have linked compensation for plan-affiliated physicians and pharmacists to their following of formulary guidelines.[33] For example, if a
physician’s prescribing practices were lower than the average physician linked to the health plan or if they switched patients from expensive brand-name drugs to generics, the physician could receive a bonus for his cost-saving efforts.
Ethical Concerns

Is it ethical to limit drug choices or to make consumers pay more for certain drugs? According to Burton et al, limits on coverage and use of drugs are an ethical requirement and economic necessity.[30] However, when constraints are in place, they must serve their intended purposes or become nothing more than a burden. If a drug formulary is not saving consumers or the health plan any money, there is no point for it to be in place.[30]

The main and primary goal of any medical practice is to help the sick. A health plan should therefore make sure all members have access to drugs that are necessary for survival.[30] A well designed formulary should help payers save money on life enhancing and life lengthening drugs, which also happen to be areas of greatest spending increases.[31] It is also important that low-income consumers have affordable access to the drugs they need.[30] For example, a drug that is used only to enhance one's lifestyle(such as Viagra), should be more expensive to consumers than a drug that could be the difference between life and death.

Another important ethical requirement between health plans and consumers is trust.[30] If a person thinks their formulary plan is created to put them at a disadvantage or cheat them out of certain drugs, he or she will likely be dissatisfied with the health plan.[30]

A drug formulary must also be trusted by physicians.[30] A physician has a medical responsibility and goal of giving patients the best treatment possible. If the physician feels the drug formulary inhibits how he or she practices medicine, there could be a conflict of interest between the health plan and physician.[30]

There is also an ethical concern about giving physicians financial incentive, as mentioned before, to select drugs on a formulary. The American Medical Association
believes such practices should be permissible only if they promote cost effectiveness, and not when patient welfare is compromised. The AMA recommends that financial rewards should be done on a group basis, and should not be done on a physician by physician basis.\[33\]

When a drug formulary is designed, the considerations of not just a few individuals, but all members must be incorporated. Burton et al believe foregoing formulary restrictions for one individual's needs can make all restrictions objectionable.\[30\] If very expensive medications are provided to certain patients, then this could drive up costs for all members, and leave very poor and sick patients with a lack of coverage.\[30\]
Formulary selection:

Pharmacy & Therapeutics Committee

How do certain drugs make a formulary, and what are the main factors influencing selection? The body that makes such decisions is called a “Pharmacy and Therapeutics” committee, and is composed of a committee of experts consisting mostly of physicians and pharmacists.[24] The P&T committee must determine a drug coverage policy and how it will be implemented, along with how to educate various people in the utilization process (manufacturers, physicians, pharmacists, consumers).[24] The committee will meet frequently to update their drug formulary selections.

There are several factors a drug must satisfy in order to be placed on a formulary. According to the Managed Care Handbook, the P&T committee considers the following criteria: source of supply, reliability of manufacturer and distributor, drug class, similarity to existing drugs, clinical advantages, dosage ranges, and cost comparisons.[24] The committee will consider peer reviewed material when making drug selections, along with information from manufacturers, albeit a degree of bias is always looked for when reading data directly from manufacturers.[24] The committee will also consider research done on a managed care organization with a similar member demographics.[24]

Pharmacoeconomics

One tool that is being used more frequently in formulary development is pharmacoeconomics. Pharmacoeconomics is defined as identifying, measuring, and comparing the costs and conquests of pharmaceutical products and services.[55] The goal of pharmacoeconomic studies is to enable health care experts make better decisions that will benefit the overall health of the public, and will allow us to measure value between differing treatment options.[55]
For formulary development, it is suggested that an effective pharmacoeconomic approach should emphasize pharmaceuticals that are expensive, have high utilization rates, and make a large impact on public health. Expensive drugs should be targeted for study because their higher costs should be justified by added health benefits. J.D. Kleinke refers to such drugs as "fast pays." Fast pays are characterized by lower-short term medical costs for patients compared to alternative therapies, such as surgery.

Pharmacoeconomics attempts to determine the cost per outcome of different treatment options. The measures of costs can be by a clinical, economic, or humanistic means. If a drug is found to lower blood pressure, prevent strokes, or reduce heart attacks, this would be a good measure of clinical outcome. The economic measure of a therapy would be completed by examining costs undertaken and costs avoided by a decision. Humanistic measures would include quality of life, increased life expectancy, and patient satisfaction. By using these three different measures, one could determine the cost per treated patient, clinical outcome achieved, life years gained, or event avoided.

To find the data necessary for such studies, it is suggested a formulary development committee looks at a number of data sources. First, the committee could look at data on the characteristics of its enrollee population. Is the population relatively old or young? Are there the same numbers of males as females? What health services are the enrollees more likely to utilize? Next, the committee might examine claims to determine which diseases are more prevalent, and how many of the enrollees are affected. The committee could determine what areas of health the formulary should be most concerned with.
Once the formulary is developed through a pharmacoeconomic approach, the rationale for the decisions should be explained to both patients and physicians. Because the formulary was researched and developed carefully, plans using pharmacoeconomic approaches generally deal with less non-formulary requests. In the near future, more health plans will likely using this very valuable technique when selecting drugs for their formularies.
Drug Manufacturers and Formularies

Example

What incentive does a drug manufacturer have to get their drug on a formulary, and how does this affect prescription drug pricing for people under different forms of coverage? Imagine you are trying to sell a product you have just invented. One person talks to you and says he would like to purchase your product for his own use. Another person then contacts you, and says he and 30,000 of his friends would like to buy your product, but only if they are given a discount from what the first person paid. Naturally, you agree to such a deal because with the amount of volume you will sell, a nice profit will be made. This is similar to how drug pricing works. When a managed care plan approaches a drug manufacturer, they have much more clout than a single person. In economic terms, this is referred to as price discrimination.[27]

Theory of Price Discrimination

Before the process of drug pricing is explained, the theory behind the process will be shown. For price discrimination to exist in a market, three criteria must be met. First, the product seller must have some form of monopoly power. If this were not the case, the seller would be unable to set different prices for various groups or individuals.[28] For drug manufacturers, patents give them temporary monopoly power over their products.[27]

Second, the seller must be able to judge approximately how much various buyers are willing to pay for their product. The seller has to be able to divide its buyers into various groups or segments and determine the elasticity of demand between different groups.[28] When drug classes have multiple products to choose from, large health plans become very responsive to price and have the ability to redirect the market share of the
drug class by changing what drug is on their formulary. Manufacturers, naturally not wanting to lose market share, will be very careful about not charging the health plan too much for their products.[27]

The third and final criteria for price discrimination is the ability to prevent resale or arbitrage of the product.[27] For example, if a large enough discount was given to a group of people to purchase GM cars, they might buy the cars, and then try to sell them to the general public for a profit. This generally does not happen with prescription drugs because of laws and regulations.[27] The Prescription Drug Marketing Act of 1987 sets rules for how and who can resell drugs. The PDMA forbids groups such as hospitals, nursing homes, and HMO’s from engaging in arbitrage.[28]
Process of Determining Prices

How does price discrimination influence how much you pay for a drug at your local pharmacy? The price you pay will be more if you are uninsured or have indemnity coverage, than if you were part of a managed care plan. According to the Department of Health & Human Services, a cash customer will generally pay 15% more than a customer in a third-party drug plan, and the gap in price differences has been increasing in recent years. To understand how this price difference is gained by third party administrators, an examination of drug pricing outside of a managed care plan will be first explained, and then the managed care pricing process will be shown.

Pricing for a Cash Customer:

The process of setting a price for your prescription begins naturally with the manufacturer. The manufacturer will set a price for their product depending on a number of market inputs. First, the form and strength of the product is analyzed. If a pill is only needed to be taken once a day, it will be more expensive compared to another pill serving the same purpose that must be taken ten times a day. The manufacturer also looks at how much competition their drug if facing. For example, if only one drug existed for a certain disease, the manufacturer would be able to command a high price without worrying about a drop in market share. Generic drugs are much cheaper than brand-name drugs because the market is flooded with manufacturers.

A manufacturer will often distribute their drugs to what is known as a “wholesaler.” Wholesalers will buy large volumes of a drug and then distribute them to pharmacies. The manufacturer’s price of a drug does not necessarily reflect development costs. A manufacturer who is trying to get their specific drug to gain market share will often offer
the drug at a discount to a wholesaler, hoping the wholesaler will be able to distribute the drug to pharmacies and increase demand for their product.[25]

"Average wholesale price" is the term for what pharmacies pay to wholesalers to acquire drugs they will distribute to consumers. AWP is not the average cost incurred by pharmacies, but is a price recommended by the manufacturer of the drug.[25] The pharmacy will pay the acquisition cost of the wholesaler, plus an additional fee added by the wholesaler. The wholesaler generally is able to purchase drugs twenty percent below the AWP, and then sells them to pharmacies at a two to four percent markup.[25]

The final cost paid by the consumer includes the transaction cost the pharmacy incurred for acquiring the drug from the wholesaler, plus a charge for the cost of filling the prescription.[25] A customer with indemnity coverage may pay the full price, and then be compensated by his or her insurer. Because of economies of scale, a large pharmacy chain will usually be able to fill prescriptions at a cheaper rate than a small-independent pharmacy.[25] Pharmacies generally charge the consumer a price twenty-five percent above their acquisition cost to pay for expenses, taxes, and of course profits.[25]

**Pricing for Third Party Coverage**

For third party coverage, a new entity comes into play for prescription drug pricing. Since appropriately used pharmaceuticals are one of the most cost efficient forms of therapy, it is only natural for a managed care organization devoted solely to pharmaceuticals to exist.[24] Pharmacy benefit managers (PBM's) are able to manage a drug benefit for a large group of people, and therefore have the leverage to negotiate with retail pharmacies and manufacturers for discounts.[25]
According to the Managed Care Handbook, a PBM will own or contract with community pharmacy providers to control both the drug ingredient cost and administrative costs. The PBM has three different types of pharmacies at its disposal to distribute drugs to members: owned, in-house pharmacies within health plan medical centers, independent and chain community retail pharmacies, and mail service or Internet pharmacies. PBM’s have several different stipulations for members and pharmacists in order to keep their costs down.

For the PBM and the pharmacy network to enter into a contract, it must be mutually advantageous for both of the entities. By entering into a contract with a PBM, the pharmacy must follow a number of rules. First, the pharmacy agrees to accept a defined reimbursement for each prescription filled for a member of the drug plan. This reimbursement is usually a 15% discount of the AWP for brand-name drugs and 50% off the AWP for generic drugs. Second, the pharmacy must agree to a set dispensing fee, on average about $2.50. When determining discounts, a PBM will generally take into account the pharmacy’s cost for acquiring the drugs from a wholesaler. Also, the PBM might offer a higher price to large retail pharmacies rather than small independent ones. For a small pharmacy network, members might complain if they have to travel long distances to fill their prescriptions. Third, the patient cannot pay more than their copayment (what the patient pays at the time of purchase), and the pharmacy must agree to accept the PBM reimbursement as the full payment. Finally, the pharmacy must agree to dispense drugs according to the drug formulary.

For a pharmacy network to enter into such an agreement, the benefits must be considerable. The PBM must agree to have all their members obtain prescriptions from
the contracted pharmacy only. When a pharmacy is contracting with the PBM, they are basically buying customers.

A PBM can also obtain discounts directly from a manufacturer. The PBM can get a negotiated rebate with a manufacturer if the PBM agrees to put the manufacturer’s drug on their formulary. These rebates average 10% to 12% of the original cost, and can rise as high as 15% to 17% if the drug shows rising market share.

Manufacturers of brand-name drugs for therapeutic classes where several alternative therapies are available have a strong incentive to offer the PBM discounts in order to be on a formulary, or else risk losing market share. Mary Kuhn, Vice President of North American Operation for Bayer’s pharmaceutical division, adds that drug manufactures will sometimes “bundle” fast-selling products and those that are having more trouble gaining market share. Another technique drug manufacturer’s use is offering deep discounts on a product when it first is introduced to the market.

There are three main tools the PBM has at its disposal to obtain price savings from the drug manufacturers: chargebacks, rebates, and discounts. A wholesaler usually buys a large volume of drugs at the wholesale acquisition cost (WAC), and then distributes them to various pharmacies at the WAC, plus the distribution fee. The PBM will negotiate for manufacturers discounts with certain pharmacy networks, so some drugs can be obtained for even less than the WAC. The wholesaler will then “chargeback” the manufacturer for any difference between what the pharmacy paid and what it paid originally. If chargebacks did not exist, wholesalers would be distributing drugs for less than their acquisition cost, which would be a very bad business practice.
For an example of a chargeback, the manufacturer and PBM agree on a price of $25 for each prescription of a certain drug. However, the wholesaler must pay the manufacturer $30 to buy the drug. The wholesaler would then get a chargeback of $5, the difference between what the wholesaler and PBM pay, from the manufacturer for each prescription.

 Rebates are used as an incentive for PBM’s to increase the market share of a manufacturer’s drug.[27] Rebates only involve the manufacturer and the PBM, and the savings to the PBM are retrospective.[27] Suppose a drug manufacturer approaches a PBM, and agrees to give a 10% discount if the PBM successfully introduces its drug to its enrollees. If the PBM is successful, the PBM will get a discount. If the PBM failed, no discount would be given.

 Only HMO’s and hospitals that have in-house pharmacies and the ability to buy drugs directly from the manufacturers use direct discounts. The manufacturer simply reduces the price for drugs the groups buy.[27] A wholesaler is not involved in this process.
The following table illustrates how the price differences between cash and third-party customers are obtained. Table taken from April 2000, “Report to the President Prescription Drug Report”, done by the Department of Health and Human Services.[44]

**Illustrative Example of Pricing for Brand Name Prescription Drugs**

<table>
<thead>
<tr>
<th></th>
<th>Cash Customers</th>
<th>Insurers and PBMs</th>
</tr>
</thead>
<tbody>
<tr>
<td>List Price (AWP)</td>
<td></td>
<td>$50</td>
</tr>
<tr>
<td>Manufacturer’s Price</td>
<td>$40</td>
<td>$40 (excludes any rebates)</td>
</tr>
<tr>
<td>(manufacturer to wholesaler or other entity)</td>
<td>20% off AWP</td>
<td>20% off AWP</td>
</tr>
<tr>
<td>Acquisition Price</td>
<td>$41</td>
<td>$41</td>
</tr>
<tr>
<td>(wholesaler to pharmacy)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Retail Price at Pharmacy</td>
<td>$52</td>
<td>$46 (excluding rebates)</td>
</tr>
<tr>
<td>(total of amounts paid by customer and reimbursed by 3rd party payer)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Retail Price, less typical manufacturer rebate</td>
<td>N/A</td>
<td>$30 to $44</td>
</tr>
<tr>
<td>(5% to 10% rebate)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ultimate (net) amount paid by final purchaser and/or customer</td>
<td>$52</td>
<td>$30 to $44</td>
</tr>
</tbody>
</table>
Addressing Concerns with Formularies

Agency Relationships

In the United States' pharmaceutical utilization system, the entities that carry out its various functions have very dependent relationships. For example when you go to a doctor, you depend on him or her to select the right drug for you.\(^{[26]}\) You also are hoping your insurance plan will be helping offset the cost of the drug, and drug manufacturers will be producing the drug you need.\(^{[26]}\) If any of these three groups did not perform the job you expected, trouble would likely be ahead.

Why do such dependent relationships exist? According to Mott et al, parties are interdependent because they either do not have the specialized knowledge and skills to perform an action or the acquisition of the knowledge and skills is too costly.\(^{[26]}\) Who would want to go to medical school just so they could select their own prescription drugs? Such relationships where one party (principal) depends on another party (agent) to perform an action for the principal’s benefit, an agency relationship develops.\(^{[26]}\)

Agency relationships work fine, unless the agent begins acting not in the best interest of the principal. Mott et al describes the agents' performance as an outcome that varies between perfect and imperfect.\(^{[26]}\) There are several examples of agency problems involving prescription drugs

Conflict of Interest for Physicians

In the case of formularies, there has been questioning about whether the relationship between physicians and drug manufacturers influences formulary selection and drug prescribing.\(^{[32]}\) Recalling many physicians serve on P&T committees to select formulary drugs, this is a grave concern. In a 1994 study done by Chren and Landefield, it was found physicians who received monetary support from drug companies for travel,
lodging, speaking, engagements, or research expenses, were more likely to request drugs to a formulary produced by the supporting manufacturers, even if little or no advantage existed over similar drugs already on the formulary.[32] The study concludes there may be a need for stricter guidelines to minimize physician relationships with drug manufacturers.[32] If physicians on P&T committees are not selecting the most cost-effective or best-value drugs, the goal of the formulary is being undermined.[31] An agency problem will develop if physicians are not carrying out the intentions of the PBM by selecting improper drugs for the formulary.

To combat agency problems arising from a physician on a P&T committee who has a relationship with drug manufacturers, the Academy of Managed Care Pharmacy makes a few suggestions. First, require P&T committee members to reveal any economic and other relationships with pharmaceutical entities that could influence formulary decisions by signing a conflict of interest statement.[36] Second, product sponsor representatives should not be allowed membership on a P&T committee nor admittance to any meeting.[36] Finally, committee members must follow policy concerning disclosure of any conflict of interest during discussion of formulary policy.[36] By following these three guidelines, the formulary should be able to be properly created and administered without any improper influence by pharmaceutical manufacturers.

When physicians are prescribing a drug, they are often unaware of the price, effectiveness, and risk of substitute products.[32] The physicians lack of knowledge about these attributes is caused by their lack of financial responsibility for drug selection.[32] It is typical for physicians to select a costly brand-name drug in place of a generic for two reasons: less liability in a malpractice suit and usually a brand-name drug has a simpler name than the chemical version of the generic drug.[32]
Web-based Prescribing Tools

A recent technological innovation has allowed physicians to prescribe drugs more efficiently, safely, and effectively. Physicians are using web-based tools that will help them select the right drug for a patient, look at any side-effects of the drug, check for formulary compliance, and electronically send the prescription to the pharmacy of the patient’s choice.[37]

How effective are these new tools with helping physicians comply with formularies and whom do they help? In a study done by Cap Gemni Ernst & Young, physicians using a personal digital assistant (PDA) prescribed drugs on a formulary 96% of the time.[39] Physicians normally succeed in prescribing a formulary drug 85% to 89% of the time.[39] By adhering to the formulary more often, physicians will not only save themselves trouble, but also pharmacists and the PBM. If the drug is already on the formulary, the pharmacist does not have to spend time calling the physician to make a switch to a formulary drug.[39] The study also found the devices generated a higher generic substitution rate.[39] This is good news for pharmacies because they generally make more money off generics than brand-name drugs.[39] The PDA’s also cut out illegible prescriptions that cause pharmacists further headaches.[37] The PBM will benefit from PDA’s because of better formulary compliance and increased use of generics. The study also importantly noted physicians using the PDA’s did not increase drug utilization.[39]

In addition to helping with formulary compliance, the web-based devices should also reduce prescription errors. The Institute for Safe Medication Practices estimates that approximately 7,000 people are killed annually due to medication errors, and prescribing
errors cost around $77 billion each year.[38] In a study done by Brigham and Women’s Hospital in Boston, by using computerized prescribing devices, serious medication errors decreased by 55%.[38]

Pharmacists’ Role with Formularies

A pharmacist is usually in the position to determine whether or not generic substitution can be carried out, and therefore play a key role in formulary compliance.[32] Pharmacists do have a financial incentive to dispense generic drugs because the profit margins are often higher on generics than on brand-name drugs.[32] Customers will also show greater loyalty to a pharmacist if it is shown to them that generics consistently save them money.[32] Possible reasons pharmacists might not dispense generics are concern about quality and added time spent communicating with the consumer about why the switch from brand-name drug to generic was made.[32]

From the previous discussion, it is evident that PBM’s are very dependent on physicians and pharmacists to make decisions consistent with the goals of a formulary. It appears that pharmacists have a more vested interest in complying with formularies, and the concern over agency problems mostly centers on physicians. In order for a formulary to be as effective as possible and not an administrative burden, all parties involved must be first concerned with patients receiving high-quality care.

Quality of Care & Formularies

One complaint often heard about formularies is that all patients do not respond the same to a certain drug, and often only one drug is the most effective in a therapeutic class.[33] Studies backup up this concern and show only 50% to 60% of all pharmaceuticals are easily interchanged with other drugs in the same therapeutic class.[37] It is argued if one patient suffers because of not receiving the best drug for him
or herself, then the increased number of office visits and hospitalizations will outweigh the savings from other patients. [33] Often a drug is selected to a formulary on the basis of average patient-outcome, and individual effectiveness is ignored. [33]

The more open a formulary, the more responsibility physicians are given to choose the best drug. [34] Additionally, the American Medical Association believes a physician is ethically required to ask for a formulary addition for an individual patient if the patient will respond better to treatment from a particular drug. [33]

In a recent study done by Schweitzer, a correlation between formulary generosity and health plan member satisfaction was analyzed. Two therapeutic classes, calcium channel blockers and antidepressants, and 19 different health plans were studied on how satisfied enrollees were with their drug coverage and overall treatment. [34] The health plans' drug coverage variation was divided into 5 categories: most generous, generous, medium, frugal, and most frugal. [34] Of the 19 plans, 4 were defined as being generous, 2 as most frugal, 2 frugal, and the other 11 plans were medium. [34] The study concluded the correlation between formulary generosity and health plan satisfaction was not statistically significant. [34] Schweitzer believes one possible reason for this result is the lack of enrollee education about the differing amount of drug coverage amongst various plans. [34]

Research has also shown managed care organizations will make sure consumers have access to expensive drugs if there is no substitute available in the therapeutic class. [40] If a brand-name drug has no generic substitute, the drug will usually not be placed on the highest tiered copay. [40] MCO's are well aware of the potential high health-care costs a patient might incur if access to a needed drug was poor.
It is difficult to conclude whether or not formularies compromise patient care, but if the proper formulary development guidelines are followed, it should not be an issue. It also seems likely that a physician would be ethically required to prescribe a different drug if the patient was not responding to a previous substance.

Health-Care Expenditures & Formularies

When a formulary is developed, one goal is naturally to cut down on medical costs, but is that really happening? The Institute for Clinical Outcomes Research recently conducted a study on closed formularies by looking at the care of almost 13,000 patients in 6 HMO's across the country.[35] The institute found the less drugs that were available to patients in different therapeutic classes, the higher the costs were for prescription drug costs, along with increased hospitalizations and office visits.[35] It is hypothesized this was the case because of a few patients who did not respond well to drugs on a formulary and therefore drove up costs.[35]

One specific example of the reduced number of prescriptions involved asthma treatment. Patients with the least severity of asthma averaged 8.4 prescriptions per year with no drug restrictions. However, in plans where 75% of asthma products were not available, patients averaged 26.3 prescriptions per year.[35] In the case of 50 patients with severe asthma, researchers found those whose formulary restricted the usage of inhaled steroids also had to deal with an increased number of emergency room and physicians visits, along with no long term relief of asthma symptoms.[35]

One flaw in this closed formulary study is the failure to taken into account the HMO's ability to have access to discounted drugs. The study set its cost data based on average wholesale price(AWP).[35] As mentioned earlier in this paper, the discount for managed care plans from AWP is 15% for brand name drugs and 50% for generics.
Health plan administrators often argue that if formularies did not save money, why would widespread use of them occur? It is agreed upon that a drug list which is very restrictive could increase costs, but a well-designed formulary where patient well-being is the first priority should save money. According to a pharmacy benefit manager at National Medical Health Card Systems, formularies typically save 5% to 10% on overall health care costs. More specifically, open formularies with a three-tier copay design have also proven to save money in most cases. Formulary Journal reports that in a Scott-Levin survey, 71% of HMO pharmacy executives said their three-tier plan has saved money, and 75% of PBM pharmacy executives report the same.

Rob Damler, a health actuary with Milliman USA in Indianapolis, presents another argument against the closed formulary study. One might assume that in a non-formulary situation, physicians would prescribe the most effective drug in every instance. However, this does not always happen. In Damler’s experience, he has come across many situations where drugs that have a higher switch rate (a patient switching from drug A to drug B) or noncompliance rate (a patient stops taking the drug) will have the greater market share. His explanation is that many physicians will simply prescribe the drug they are most comfortable with, and not the drug that will be most beneficial. Damler makes it clear that a non-formulary setting is by no means a perfect world, and should not necessarily be used as a comparison to a formulary environment.
political & government developments with formularies

medicaid plans

recently, a few states have turned to prescription drug formularies for their medicaid plan to help save money for their already tight budgets. collectively, the 50 states spend over $25 billion on prescription drugs through their medicaid plans, and these costs are expected to increase just as quickly as the overall expenditure on drugs.[48]

maine was the first state to develop a formulary for their medicaid plan. mainerx, the state’s drug plan for those who are uninsured, negotiated with drug manufacturers for discounts and threatened them with price controls if they did not give any price concessions.[46] florida then shortly followed in the same direction as maine. 1990 medicaid laws require drug manufacturers to sell their drugs to medicaid programs at a price that is equal to the lowest price they offer to any group.[48] florida took this one step further by demanding that drug manufacturers give the medicaid program an additional 6% discount. florida is expected to save an estimated $100 million in 2002 because of its new medicaid formulary.[48]

michigan, faced with a $42 million budget shortfall for 2002 and drug costs that had doubled in only two years, decided to take even more dramatic action.[48] the michigan medicaid plan took 40 therapeutic classes, and selected two “best in class” drugs based officially on “clinical effectiveness and safety”. [47] if a manufacturer wished to be on a preferred list, they had to offer discounts which would match the prices for the two drugs in each category.[47] a drug not on the preferred list could still be prescribed, but a physician would have to get special approval to prescribe the drug, and this is generally seen as a major deterrent of utilization.[47]
These recent formularies have had a dramatic influence on the Medicaid market share of certain drugs. For example in Florida, the market share of Prilosec (antiulcerants) went from 30% to 4% in the span of 3 months. Likewise, Prevacid (antiulcerants) saw its market share increase from 43% to 65%. [48] Guess which one made Florida’s preferred list?

In Maine, there is evidence formularies are influencing not only Medicaid market share, but even non-Medicaid customers, although to a lesser degree. Protonix saw its market share jump from 3% to 75% since it became the preferred heart-burn drug in Maine’s plan. Additionally, with non-Medicaid customers, there was a 10% increase in market share. [48] The belief of pharmaceutical manufacturers is that doctors will prescribe Medicaid drugs out of habit, even to non-Medicaid patients. [48]

The pharmaceutical industry has been outraged by the developments in Maine, Florida, and Michigan. Lawsuits in all three states have failed to put a stop to the Medicaid formularies. [49] In Europe, where countries have drug policies similar to Michigan’s, pharmaceutical profits have been hurt gravely. [48] If this is allowed to happen in the United States, it is argued by many that drug manufacturer’s will have less incentive to conduct research and bring new drugs to the market place. [48] However, one pharmaceutical industry source believes this would not be the case. Mary Kuhn believes that formularies certainly have decreased the profits of the industry and have changed the way drugs are marketed and sold, but does not believe it has discouraged research. [31]

The industry plans on beginning an intense campaign against drug restrictions in March 2002 by lining up physicians and consumer advocates against formularies. [49] Don Rounds of the Consumer Alliance based in Lansing, Michigan, believes state
Medicaid programs such as Michigan’s are trying to “balance their budgets on the poor and elderly” and believes drug restrictions are “medically and morally wrong”. [49]

However, from discussion with those having knowledge of the Michigan Medicaid plan, Rob Damler feels that safety and effectiveness were the primary concern when picking the best drugs in each therapeutic class. [54]

The drug industry believes programs such as Michigan’s are not distinguishing between old and new drugs. For example in Michigan, in the antiarthritic class, Celebrex and Vioxx were left off the list in favor of the generic naproxen, which costs $130 less. [48] It can be easily seen from this one example why states are very eager to implement formularies for their Medicaid programs, but drug manufacturers cringe at the thought of seeing them in all 50 states. If Medicaid formularies are allowed to stand in court, expect many other states to follow through with formularies of their own. [49]

A campaign promise in the 2000 presidential election by both candidates was a Medicare prescription drug benefit. Due to the events of September 11th and the budget shortfall, this has taken a backseat in 2002, but when the issue is brought up again, there is a good possibility formularies will be used to make a Medicare drug benefit affordable. [47]

From the recent developments with several states’ Medicaid plans, it is obvious that formularies will continue to make national news. Without question, these states feel formularies will save them money on their prescription drug costs. It may be argued by some the formularies will increase overall health expenditures because the cheaper drugs are not as effective and will lead to other medical expenses, but if these states follow the proper formulary development guidelines, this should not be a problem. To provide further evidence for the value of formularies, in a 1996 study, it was found elimination of
a restrictive Medicaid formulary did increase the number of prescriptions for the top 200 drugs, but there was very little therapeutic value gained by this development.[24]

Remembering Michigan’s plan resembles formularies in European nations, a study done by D.J. Gross found no evidence that formularies in Europe reduced the quality of drug coverage.[24] The pharmaceutical industry’s outrage over the recent Medicaid formularies are more likely related to profits than medical or safety concerns.
Summary & Commentary

From the first half of this paper, it is obvious usage and expenditures are increasing rapidly on prescription drugs in the United States. However, although this is certainly a concern for the future, it should not be looked as necessarily a bad situation. Many new drugs are being offered for diseases or ailments that would result in hospitalization or a decreased quality of life in the recent past.

The aging population is another unpreventable factor contributing to drug spending. As the American population grows older as a whole, health expenditures in all areas will be taxed heavier than ever before. Prescription drugs will help alleviate the heavy burden on other medical resources, and allow these resources to be utilized by the patients who truly need the services.

The increased amount of third party coverage for Americans, usually in the form of an employer health plan, has decreased the amount of money we spend on prescriptions as a percentage of overall drug expenditures. The robust U.S. economy in the last decade had undoubtedly made some health plans very lucrative in order to try and retain employees. A quality prescription drug benefit is an especially desirable workplace perk.

Patent laws are unquestionably necessary so that drug manufacturers have the incentive to make an investment in time and money when developing a new drug. Without patents, research and development would be stagnant, and the government would likely be the only means of furthering medical advances. Any reasonable person would agree our current economic system is a much better way of giving people the proper reward for their creativity and hard work.
At the same time, there should also be scrutiny on drug manufacturers who keep trying to delay the expiration of a patent on a popular drug. Currently, companies can extend patents by 30 months simply by telling the government a generic manufacturer would infringe on their patent.[51] One very good example is the drug Prilosec which had $4.7 billion in sales in the United States alone in 2000. The patent for the drug was supposed to expire in the fall of 2001, but the manufacturer was able to get an extension.[51] What is this costing providers? The chief pharmacist at General Motors reports it loses $1.3 million every month because it cannot buy the generic version of the drug for which 346,000 prescriptions are written each month.[51]

Direct-to-consumer advertising is one topic that should be studied further, and will become more controversial as time passes. In a study released in March 2002, it was found only 50 drugs out of 9,482 were responsible for almost a $14 billion increase in 2001 drug expenditures. Amazingly, the other drugs only contributed to a roughly $8.5 billion rise.[52] Also, the price difference between the top 50 drugs and the average for the rest of the market was a little over $31.[52] Not surprisingly, many of the top 50 drugs also had the most spending in advertising.[52]

When consumers see a famous baseball player, NASCAR driver, or even ex-presidential candidate pitching a new drug, many will have a much stronger interest in taking this specific drug themselves. The question is not whether or not direct-to-consumer advertising works, but whether or not it is an ethical practice. Should not a physician be the sole person determining whether or not a person should be on any prescription? Patients should be able to trust that their physicians will make a decision in their best interest.
When doing advertising to consumers, it seems much more ethical just to be advertising for a certain disease or ailment, and not a specific drug. If consumers see this kind of advertising, they will know drugs are available for these conditions, and then will be able to ask their doctor whether or not they need a prescription. If your car breaks down, does not the average person let the mechanic decide what needs to be fixed on the car, rather than telling the mechanic what to do and how to do it? A similar and hopefully much stronger relationship should exist between the physician and patient.

If one drug in a therapeutic class is clearly more effective than other substances, the best drug should naturally be the one prescribed most often. The pharmaceutical industry should concentrate their product-specific advertising at physicians who can then make informed decisions about the effectiveness of a particular product.

Ironically, drug manufacturers and insurers have completely opposite goals when it comes to pharmaceutical usage. Manufacturers would like to increase demand as much as possible, whereas insurers would like to see that same demand constrained.[50] It is foolish to believe that there are or should be no cost constraints in the United States’ health care system. In order for as many Americans as possible to receive proper health care, controls must be in place to prevent over-utilization of certain services, and prescription drugs are no exception. In the second half of this paper, it was seen that formularies are becoming a widespread means of managing drug usage.

Unfortunately, when many people hear the word “formulary,” they automatically think of not receiving the best prescription drugs, and believe their health is being compromised for cost savings. This could be the case when a formulary is not selected properly, but if the proper guidelines are followed, both the consumer and insurer should benefit. Safety, how well does the drug work, and is the drug needed for therapeutic
purposes should be the primary concerns of any Pharmacy & Therapeutics committee when selecting drug for a formulary.[53] After these areas have been properly addressed, the P&T committee can then look at how much the prescription will cost.

The open formulary gives more options than a closed formulary, and consumers usually like more options. A health plan with an open formulary is justified in setting up tiered copays. If there was no difference in copay between various drugs, what incentive would the consumer have to purchase a generic rather than a costly brand-name drug? Tiered copays are also a good way of separating drugs that are necessary for survival, rather than drugs that merely enhance your lifestyle. By making these lifestyle drugs more expensive, the PBM or insurer can save money on their overall plan and allow consumers to purchase the truly necessary drugs at a lower price.

The second half of the paper also examined the power formularies have over drug manufacturers and pharmacy networks. By yielding a large amount of enrollees and the ability to shift market share, a PBM can negotiate for discounts from manufacturers, pharmacies, or both. The consumer benefits from these discounts by paying less out of his or her pocket than a person not enrolled in a health plan.

Several states have also realized they can put considerable pressure on drug manufacturers to lower drug costs in Medicaid programs. The actions of Maine, Florida, and Michigan could establish a model for Medicaid formulary development that would be followed by other states. The largest opponent of these new Medicaid plans are the drug manufacturers, which view the formularies as an added obstacle considering law already requires drug manufacturers to give Medicaid plans the "best" price. With around 50 million Americans in the Medicaid program, the drug manufacturers will certainly have decreased profits if every state adopts similar programs to Michigan, Florida, and Maine.
Physicians often have trouble adhering to formularies, but fortunately web-based tools will make this easier and will also cut down on costly prescription errors. These tools are not widespread at the present time, but their implementation is likely to happen soon on a wider basis.[53] The web-based tools will also benefit pharmacists by reducing the number of times they have to call the physician about illegible prescriptions, formulary compliance, or switching to a generic. Consumers will be more informed about their choices through the web-based tools, and will instantly be able to see the cost of a prescription and then have it faxed to the pharmacy. When web-based tools become commonplace, physicians, pharmacists, insurers, and consumers will all benefit.

Conclusion
In conclusion, the pharmaceutical and managed care industry has and will continue to change drastically in future years. Regulations can be put in place, new drugs can be developed, health plans can be restructured, and new technology can allow old tasks to be done more efficiently. In these industries of change, it can be guaranteed drug manufacturers are going to make better and more specific drugs. Also, it is almost a sure bet formularies will be incorporated even more in designing the prescription drug benefit of a health plan. Americans will want the best drugs possible for their ailments, but at the same time, they do not want their medications to cost a fortune. With our added dependence on prescription drugs for our health needs, a well developed and managed formulary can help our society by serving two of our basic prescription drug wishes: access and affordability.
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