Economic Analysis of Price Determinants in Pharmaceutical Industry in United States

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Economic Analysis of Price Determinants in Pharmaceutical Industry in United States

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Executive Summary:

In recent years increase in spending for prescription drugs in US has outpaced spending in every other category of health expenditures. Expenditure on the prescription drugs in recent years has grown more rapidly then any other component of health care. National prescription drug spending rose by about 4 ½ (inflation adjusted rate of 14.5% since 1997) times from $40.3 billion in 1990 to $179.2 billion in 2003. Prescription drug expenditure growth galloping by about 17% per year is the fastest growing item in health care inflation. It accounted for 11% of total healthcare spending (which was only 5.8% a decade earlier), resulting in third highest category of healthcare expenditures after hospital care and physician services. Older Americans have to pay more and more on drugs, either at the pharmacy, in higher premiums or in cutback in benefits. All these factors have made US pharmaceutical industry a focus of considerable public attention and controversy.

Increase in this spending can be attributed to several factors like:

- Increased utilization
- Shifts in the type and mix of drugs used
- Price inflation
- Innovation or R&D
- Third party financing and public resistance to restrictions on coverage
- Advertisement and promotion

This paper analyzes the causes for increase in prescription drug expenditures, its economic evaluation and policy recommendations for the perceived inequity and inefficiency.
RESEARCH METHODS:

The methods used for the analysis of the above mentioned problem were: literature search for the relevant information, online web search, academic database search and statistical analysis of data obtained from Center for Medicare and Medicaid Services, Medical Expenditure and Utilization Panel Survey, Healthcare Utilization fact book, National Center for Policy Analysis, Kaiser Family Foundation and many more.

LITERATURE REVIEW:

Prescription drugs play a very important part in the life of most people daily lives and has led to substantial improvement in quality of life years, life expectancy, and lowering the burden of disease and disability from the society. In a survey conducted by Kaiser Family Foundation, “majorities say that prescription drugs have had a positive impact on the health and quality of life of Americans in general (78%) and have made a “big difference” in the lives of people with chronic conditions such as heart disease (72%) and cancer (63%)”.

![Perceived Value Of Prescription Drugs](image)

Source: Kaiser Family Foundation, Health Poll Report Survey, 2005
The graph below reflects the substitution of effects of drugs on total medical care input, as discussed earlier;

Source: Adapted from Folland et al., The economics of Health and Health Care

Despite this perception about benefits in general, whole pharmaceutical industry today is under intense public and government scrutiny and heightened criticism. Several factors are responsible for it:

- Pharmaceutical firms raking in huge profits (as per normal accounting methods, not taking into account many other factors like R&D) and being among the largest and most
profitable firms in US. Three pharmaceutical companies figured in top ten and seven in top 50 in the list compiled by Fortune 500 firms. In the same report pharmaceutical industry as a whole ranked first in terms of sales and rate of return on revenues and stakeholders equity (Fortune Magazine).

- Highly visible sales growth of 12-13% annually, over last 12-15 years (Pharmaceuticals in US Healthcare: Determinants of Price and Quantity, Ernst R. Brendt).
- More than 17.3 % growth in US prescription drug expenditure per year, the sixth consecutive year of double digit increase (The economics of health and health care, Folland et al.)

Source: Prescription Drug Trends, Kaiser Family Foundation
• Increasing burden on elderly to pay for their prescription costs coupled with dramatic rise in the total population cohort of people aged 65+ and emergence of chronic diseases.

• Increased burden on common people in the form of higher co-payments, insurance premiums and deductibles. Survey conducted by Kaiser Family Foundation reveals that around 70% of people agree that pharmaceutical companies put profits ahead of people and more than half say that they do a “bad job” (48%) of serving customers.

• Federal and state government are experiencing fund crunch and are exploring ways to cut down costs.

The chart below gives an excellent snapshot of the peoples view about pharmaceutical industry and rising health care costs.

**Views Of Pharmaceutical Companies**

*Please tell me if you have a favorable or unfavorable opinion of each of the following...*

<table>
<thead>
<tr>
<th></th>
<th>Very favorable</th>
<th>Somewhat favorable</th>
<th>Not too favorable</th>
<th>Not at all favorable</th>
</tr>
</thead>
<tbody>
<tr>
<td>Doctors</td>
<td>42%</td>
<td>40%</td>
<td>11%</td>
<td>4%</td>
</tr>
<tr>
<td>Hospitals</td>
<td>39%</td>
<td>39%</td>
<td>12%</td>
<td>6%</td>
</tr>
<tr>
<td>Banks</td>
<td>28%</td>
<td>47%</td>
<td>14%</td>
<td>4%</td>
</tr>
<tr>
<td>Health insurance companies</td>
<td>10%</td>
<td>34%</td>
<td>24%</td>
<td>18%</td>
</tr>
<tr>
<td>Airlines</td>
<td>18%</td>
<td>40%</td>
<td>15%</td>
<td>8%</td>
</tr>
<tr>
<td>HMOs / managed care plans</td>
<td>15%</td>
<td>30%</td>
<td>24%</td>
<td>20%</td>
</tr>
<tr>
<td>Pharmaceutical companies</td>
<td>14%</td>
<td>30%</td>
<td>25%</td>
<td>23%</td>
</tr>
<tr>
<td>Oil companies</td>
<td>10%</td>
<td>20%</td>
<td>27%</td>
<td>27%</td>
</tr>
<tr>
<td>Tobacco companies</td>
<td>7%</td>
<td>10%</td>
<td>19%</td>
<td>56%</td>
</tr>
</tbody>
</table>

*Don’t know responses not shown

Source: Kaiser Family Foundation Health Poll Report Survey (conducted Feb. 3-6, 2005)

Source: Kaiser Family Foundation Health Poll Report Survey, 2005
**Underlying Drivers of Drug Spending:**

One of the basic economic equation is:

\[ \text{Expenditure} = \text{Price} \times \text{Quantity} \]

Almost all the factors leading to increased expenditure can be grouped into these two categories.

**Increased Utilization (Quantity):**

Major portion of the increase in expenditure on prescription drugs can be explained by increased utilization in past decade. More and more people are using more medicines, often the new and more expensive kind. From 1994 to 2004, number of prescriptions purchased in US increased by 68% as compared to the total population increase of only 12%. This accounts for increase in ~1.4 billion dollars in expenditure during the same time period. The average number of prescriptions per person increased from 7.9 to 12 per person. However it increased more for people age 65+, among whom the percentage of people who had prescription drug expense is about 91% as compared to those below age 65, among whom the percentage is 61%. (KFF Trend book Report on Pharmaceutical Industry).

There are several factors that drive up the utilization:

- *Increased availability of the stream of new drugs*, especially drugs used frequently in prescription – antihistamines, antidepressants, hypolipaedimic drugs, anti-ulcerants, pain killers, to name a few. (Factors affecting the growth of prescription drug expenditure, NIHCM, July 1999).
Increase in the insurance coverage is also responsible for increase in spending as it shields both the consumers and physicians from the price effect – Moral Hazard. Employers are principal source of insurance coverage in US providing prescription drug coverage to almost 60% of Americans (KFF Fact book). Low out of pocket costs by patients in managed care ($5-$10 per prescription), improves their access to physicians and insulate them from cost of medication. This increased in expenditure is borne more by employers than by public insurers. Up till 1990, two third of the drug expenses were paid by the end consumers as out of pocket expenses. By 1999, end consumers paid only one third of it and most of the coverage is provided by employer based health insurance and private insurance (Reinhardt). The situation will further worsen or in other words, utilization is bound to increase by introduction of Medicare Prescription Drug Coverage, Part “D”, from January 2006. See the table below;
Moving just opposite to the other trends in pharmaceutical industry – consumers out of pocket spending decreased from 53% to 37% of total private spending (NIHCM). In 2000, out of pocket spending per person per year was $450, which increased to $565 in year 2002 (HCFA). However averages can be misleading (distribution is highly skewed) as most of the utilization is by elderly and sick people who may not be able to afford the medication cost or go through financial hardships to do the same.
The graph below illustrates the insurance effects on total prescription drug expenditure:

![Graph](image)

Where:
- \( P_0 \) is equilibrium price without insurance.
- \( P_i \) is total equilibrium price or expenditure after insurance.
- \( Q_0 \) is quantity consumed without insurance.
- \( Q_1 \) is quantity consumed after insurance.
- \( C_1 \) is demand or consumption curve with insurance.
- \( C_0 \) is demand or consumption curve without insurance.
- \( S \) is Supply.

Source: Folland et al, The Economics of Health and Healthcare

- **Direct to consumer advertising and promotion** also increases utilization very effectively.

Since 1994, total spending on direct promotion for prescription drugs increased by ten times (KFF 2000). In 2000 itself the industry spent close to $16 billions for drug promotion. Out of this 16% was spent on consumer advertising and rest on physician detailing and free samples (PhARMA).
In pharmaceutical industry there are two types of drug promotion activities: one aimed at providers, like physician detailing, citations in journals, sponsorship of medical education events, free samples, marketing aimed at health plans and hospitals; and others aimed at end consumers, which includes direct to consumer advertising (DTCA), TV, internet, newspaper and other media promotional campaigns. This change in marketing mix is a response by pharmaceutical companies to recent policy and environmental changes such as FDA regulations changes regarding print and electronic media advertising and growing backlash within physicians community over free samples, promotional lunches, increasing participation of consumers in their own healthcare, etc.

The economic basis of consumer advertising is that, for a profit maximizing monopolist firm facing downward sloping demand curve, the optimum advertising cost to sales ratio in dollars, equals the ratio of two elasticities, Eqa and Eqp.

\[
\frac{advertising}{sales} = \frac{Eqa}{Eqp}, \quad \text{Dorfman-Steiner equation}
\]

Where Eqa is elasticity of quantity demanded with respect to advertising efforts and Eqp is elasticity of quantity demanded with respect to absolute price. We have to add the “carryover
effect” to it as the above equation is for one-year period only but in real world the effect of advertising persists for several year.

**Provider Oriented Marketing:** Various economic studies on the physician oriented marketing claim that it was more “persuasive” than “informative” (Caves, Leffler, Vernon, Hurwitz, et al.). The overall effect, which might be very subtle, was to increase entry barriers for new entrants by increased entry costs, decreased price competition and increased perceived product differentiation and loyalty (Rosenthal et al., 2003). There are two types of marketing efforts for this sector -: “industry expanding” and “rivalrous”. A recent research by King (2000), shows that marketing strategies aimed at providers, decreases own brand demand price elasticity but the total marketing industry reduces the extent of product differentiation. This vests some degree of monopoly power to the existing firms and barriers to entry for new ones. Various econometric studies have suggested, “The coefficient estimates for the impact of detailing on sales imply elasticity estimates of between 0.017 and 0.034. All three estimates are quite precisely estimated with t-statistics ranging from 4.25 to about 10” (Rosenthal et al, 2003). Susan A Cole of American College of Physicians, Ethics and Human Rights Committee, goes as far as to say that "Physicians frequently do not recognize that their decisions have been affected by commercial gifts and services and in fact deny industry's influence even when such enticements as all-expenses-paid trips to luxury resorts are provided”. However there is no denying of the fact that, physicians who have been out of medical school for quite some time, forget a bit about the drugs not directly relevant to their specialty. Also with everyday increasing number of brands and new combinations, they become overwhelmed and a bit dependent on the reps. So we can safely conclude that provider directed marketing does exert some influence on the prescription behavior
of the physicians, however it may be a bit more complicated by the consumers expectations, DTCA, etc, which we will discuss in detail in the following section.

**Consumer Oriented Marketing:** Many types of marketing comes under this umbrella term which includes advertising through print or electronic media, aimed directly to influencing the prescription seeking behavior of consumers. However the industry people may say otherwise, like its for the consumers knowledge and information, which is true to a certain extent. Direct to consumer advertising was non-existent before 1980’s. It started catching up pace in early 1980’s and 90’s, and reached feverish pitch after clarified and relaxed FDA guidelines in 1997. In 2000, DTCA accounted for 15.7% of total promotional expenditure (Rosenthal et al., 2003). A recent study by KFF, 2000, reports that about 30% of Americans ask their doctor about a prescription they have seen or heard in media and 44% of them ultimately receive it. The study also shows, “1 in 3 people say their doctor had recommended lifestyle changes instead of or in addition to the drug; 1 in 4 had been prescribed a different drug and 1 in 5 received no drug”.

![Outcome Of Talking To Doctor As Result Of Ads](chart.png)

Source: Kaiser Family Foundation Health Poll Report Survey, 2005
On this background we will study how does marketing influences the volume or price of prescription drugs. The changing healthcare environment like less physician discretion in prescribing, increased participation form consumers, new guidelines, cost pressure, etc, as discussed earlier, makes DTCA a favored choice. Now the companies can promote both brand name and the generic class. DTCA increases so called “physician office foot traffic” by raising awareness among the previously untreated consumers of the potentially beneficial results of the medication and new treatment modalities. This results in growth in overall sales of the therapeutic class as well as brand name, however these studies are still in nascent stage and there is no documented evidence for that. A study by Wionska and colleagues reports that DTCA positively impacts the total therapeutic class sales and also impacts the brand name sales if it’s in the preferred status of third party formulary. Another study by Brendt et al (1995) showed that “for the entire H2 therapeutic class, advertising demand elasticities were 0.55 for detailing, 0.20 for medical journal advertising, and 0.01 for this type of DTCA; the sum of these elasticities is 0.76”. The effect of DTCA is even more prominent of on OTC drugs. Ling, Brendt and Kyle studies the effect of DTCA on prescription and OTC drugs and concluded that for prescription drugs, own brand oriented physician detailing and medical journal citations have positive and long lived impact, and a positive spillover on OTC shares, while DTCA has a limited impact on this segments market share. For the OTC segment, DTCA has significantly positive and long-lived effect. The effect of it can be appreciated by looking at the buying behavior of older Americans for common drugs like, celebrex, vioxx, prilosec, Claritin, zocor, paxil, etc, to name a few. Table on the next page shows amount of money spend in dollars on promotion and sales from 1996 to 2000.
Advertising effect of pharmaceutical firms can be justified if we take into account the structure of industry and effects of drugs. Pertinent structural variable here is that these firms have low variable cost and high fixed cost, so they indulge more in advertising to increase the quantity consumed and to establish brand loyalty, to protect against uncertainties in future. As far as effects of drugs are concerned, we have to take into account the fact that every human being is unique in genetic and psychological makeup and drugs have variable and ambiguous effects. This leads to two types of goods in DTCA sector – Search Goods and Experience Goods (Nelson, 1970), however there is no precise demarcation and a good can have both attributes. A good is said to have a search quality if the consumer can make its decision about it by just examining its attributes through visual, tactile and cerebral function, e.g.; electronics, credit cards, etc. A good is said to possess experience quality, if the consumer must consume it to predict its quality and impact, e.g.; cosmetics, food and even drugs. Pharmaceutical firms exploit the consumers through advertising for both of these qualities. In case of highly specialized drugs

### Table 1: Spending on Physician-Directed Promotion and Promotion to Sales Ratios, 1996–2000

<table>
<thead>
<tr>
<th></th>
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</thead>
<tbody>
<tr>
<td>Detailing</td>
<td>3,010</td>
<td>2,365</td>
<td>4,057</td>
<td>4,320</td>
<td>4,803</td>
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<tr>
<td>Journal Advertising</td>
<td>459</td>
<td>510</td>
<td>498</td>
<td>470</td>
<td>484</td>
</tr>
<tr>
<td>Retail Value of Samples</td>
<td>4,904</td>
<td>6,047</td>
<td>6,602</td>
<td>7,230</td>
<td>7,954</td>
</tr>
<tr>
<td>Total Physician Promotion</td>
<td>8,373</td>
<td>9,022</td>
<td>11,157</td>
<td>12,020</td>
<td>13,241</td>
</tr>
<tr>
<td>Direct-to-Consumer Promotion</td>
<td>791</td>
<td>1,069</td>
<td>1,317</td>
<td>1,848</td>
<td>2,467</td>
</tr>
<tr>
<td>Total Promotion</td>
<td>9,164</td>
<td>10,091</td>
<td>12,474</td>
<td>13,868</td>
<td>15,708</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
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<th></th>
<th></th>
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<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Detailing</td>
<td>0.046</td>
<td>0.047</td>
<td>0.050</td>
<td>0.043</td>
<td>0.043</td>
</tr>
<tr>
<td>Journal Advertising</td>
<td>0.007</td>
<td>0.007</td>
<td>0.006</td>
<td>0.005</td>
<td>0.004</td>
</tr>
<tr>
<td>Retail Value of Samples</td>
<td>0.076</td>
<td>0.084</td>
<td>0.081</td>
<td>0.071</td>
<td>0.071</td>
</tr>
<tr>
<td>Total Physician Promotion</td>
<td>0.129</td>
<td>0.138</td>
<td>0.137</td>
<td>0.118</td>
<td>0.118</td>
</tr>
<tr>
<td>Direct-to-Consumer Promotion</td>
<td>0.012</td>
<td>0.015</td>
<td>0.016</td>
<td>0.018</td>
<td>0.022</td>
</tr>
<tr>
<td>Total Promotion</td>
<td>0.141</td>
<td>0.153</td>
<td>0.153</td>
<td>0.136</td>
<td>0.140</td>
</tr>
</tbody>
</table>

Sources: Physician Promotion spending data are from IMS Health, Integrated Promotion Service, June 2001; Sales data are from Pharmaceutical Research and Manufacturers of America, Annual Survey, 2001; Direct-to-Consumer Promotion spending data are from IMS Health and Competitive Media Reporting, June 2001.

Source: Rosenthal et al., 2003
with predictable outcomes, they focus on search qualities to promote use. In case of everyday use or OTC drugs, for which many substitutes are available, they focus on experience qualities, like taste, effect, calories, etc.

So in nutshell, advertising does have a significant impact in increasing overall costs by exerting its influence through increase in utilization, price and entry barriers. We should also neglect the amount of money that drug companies spend on lobbying and courting legislature. The chart below drives down the fact about extent of money involved in lobbying.

![Wooing Washington with Big Bucks Chart](chart.png)

Source: Patricia Barry, drug Companies Spends Huge Sum Guarding Prices, May 2002

- **Public resistance to restrictions on coverage:** Despite the American people’s aversion to federal intervention in business matters and strong belief in competitive market theory, Americans are big proponents of the employer based or government sponsored insurance to cover the sick and elderly to prevent them against economic hardships. It has become a big election issue and can make or break the government. So policy makers and regulators are avers to cut down on benefits. It becomes a big issue, if we take into account the ageing population, increasing burden of chronic illness and disability, and
movement of large cohort of ~70 million baby boomers towards age 65, who exert big political influence.

Government Negotiating With Drug Companies

Source: Kaiser/Harvard Health Care Agenda for the new Congress, 2004

This has resulted in increasing coverage for prescription drugs and other benefits, most of which (~60%) is borne by employers. With the new Medicare Part D prescription drug benefit, and baby boomers, utilization and consequent expenditure will increase manifold. The dynamics of it has been discussed in previous sections.

- **High prevalence of treated conditions:** Within the last part of 19th century, there has been a shift from the infectious disease to chronic conditions, coupled with increase in life expectancy, and new technological advances, prolonging the end of life. This has increased the quantity and intensity of treatment with consequent rise in drug expenditure.

- **New applications of Drugs:** As discussed earlier, pharmaceutical industries have high fixed costs in manufacturing and R&D facilities and low variable cost to produce a unit of drug. To maximize profit and to promote efficient use of resources, they exploit their
expertise and knowledge base to find new use for drugs or existing technology. This good for society as a whole and is the basis for mankind’s progress, but it comes with a price. A classic example is Thalidomide, which was used in 1960’s for antiemesis or morning sickness in pregnant females but was called off the market due to sever adverse effects. However it reentered the market as anticancer drugs in late 1990’s and has been a big success. There are numerous other examples, all of which increase the number of drugs available in market, and availability has always been positively correlated with consumption and consumption involves expenditure.

**Price Inflation:**

\[ \text{Expenditure} = \text{Price} \times \text{Quantity} \]

We discussed the role of quantity in preceding section. If we break up expenditure in quantity and price, higher prices accounted for 64% increase and utilization – 36%, from 1993 – 1998. In 1997 US spent 1.4% of its GDP on prescription drugs (Reinhardt). From 1987 to 1994, price change was responsible for half (6.1% of total 11.9%) of the revenue growth, and from 1994 to 2000, it accounted for one fifth (2.5% of 12.9%) of revenue growth. There are several factors responsible for price inflation, of which the favorite of critics and policy makers is price of new and existing drugs. However a thorough discussion of pricing issues in pharmaceutical industry is not possible without considering some peculiarities of pharmaceutical industry like, R&D, reference pricing, patent production, etc, to name a few. They exert a direct influence on prices and are discussed in brief below.
• **New and existing drug prices:** As discussed earlier, since the last part of 19th century there has been explosive growth in technology, scientific knowledge and know how into the molecular basis of disease. This resulted in development of a vast array of new drugs as well as new uses for the existing one. For example, since the emergence of AIDS as a major epidemic in 1980’s, every year a new drug is added in our arsenal to fight this deadly disease, for which at one time there was no cure. With more drugs there’s more consumption. Department of Veterans affairs reported 434% aggregate rise in treatment cost for HIV from 1992 to 1998. However a study on a subset of patients in Florida, concluded that overall spending for a more aggressive therapy in this subset of HIV patients was much lower, than it would have been otherwise, as it led to significant savings in inpatient costs (J D Klienke, 2001). But that’s only half of the story. New drugs and technologies, have resulted in marked
in QALY, decrease in ALOS, preclude or delays surgeries and in the long run pay for themselves many times over. Similar is the case with drugs used for treatment of mental disorders. It represents a major structural shift from labor to capital and is one of our cheapest defenses against disease and disability related costs limitation.

So the culprit is not high cost, high end technology and markedly effective new drugs, but a subset of drugs used more often due to advertising/promotion, patients and physicians preferences and practice styles, non specific use, demographic shift to older population, mix of drugs used towards more costly alternatives, overall inflation, increase in intensity of treatment, etc. This issue is discussed with other relevant sections like R&D, patent protection, and price discrimination in the following sections. Following tables illustrate the effects of volume and price on prescription drug expenditure.

| Factors Responsible For Growth In Price And Volume For Various Pharmaceutical Categories |
|---------------------------------|-----------------|-----------------|-----------------|-----------------|
| Category                        | Price Inflation rate | Mix (established therapies) | New drug prices | Prevalence | Prescriptions per patient | Days per prescription |
| Asthma                          | -0.5%             | 17%              | -5%              | 25%         | -19% | 63% | 14% | -0.3% |
| Humoral replacement therapy     | 42                | 21               | 0.3              | 100         | 36   | 21  | -0.6 | -0.1 |
| Antidiabetics                   | 11                | -13              | 23               | 34          | -41  | 67  | 9    | 4    |
| Anti hypertensics               | -7                | 10               | -4               | 54          | -42  | 54  | 16   | -1   |
| Antidepressants                 | 7                 | 10               | 2                | 38          | 2    | 17  | 9    | 0    |
| Antihistamines                  | 6                 | 8                | 0.1              | 22          | -32  | 48  | 13   | 1    |
| Gastrointestinal                | 2                 | 3                | -2               | 23          | -17  | 24  | 10   | 0    |

SOURCE: Authors’ analysis.

Source: Robert W Dubois et al, Health Affairs, March/April 2000
Table B. Percentage Contribution of Changes in Price and Utilization to 1993-98 Increase in Prescription Drug Spending

<table>
<thead>
<tr>
<th></th>
<th>Price Effect</th>
<th>Utilization Effect</th>
</tr>
</thead>
<tbody>
<tr>
<td>New Drugs (1992 and later)</td>
<td>42%</td>
<td>23%</td>
</tr>
<tr>
<td>Older Drugs</td>
<td>22%</td>
<td>13%</td>
</tr>
<tr>
<td>TOTAL</td>
<td>64%</td>
<td>36%</td>
</tr>
</tbody>
</table>

Source: Parentis Group analysis of Scott-Levin Source Prescription Audit Data for 1993 and 1998. For older drugs, the price effect measures additional spending due to the increase in the average price per prescription between 1993 and 1998 for these drugs. For newer drugs, the price effect measures increased spending due to the fact that the average price per prescription for these drugs in 1998 is higher than the 1993 average price per prescription for older drugs. For both new and old drugs, the increased spending due to a greater number of prescriptions filled is calculated using the 1993 average price per prescription for older drugs.

Source: NIHCM study, 2001

**Peculiar Features of Pharmaceutical Industry:**

**Research and Development, Innovation and Patent Protection:**

For research based pharmaceutical firms, R&D cost rose from $428 million in 1980 to $31 billion in 2001 (PhRMA, 2001), and two-third of these cost is attributable to the preclinical phase. According to the data compiled by Brown Research report on eight largest pharmaceutical companies in 1998 figures, 27% of the revenue was absorbed by manufacturing costs, 35% by marketing and general administration, 13% for R&D, 7% for taxes, and 18% was the reported after tax profit (Reinhardt, 2001). From the above figures it seems like R&D expenditure in pharmaceutical industries is not too high, but if we compare it with other industries, it is one of the highest, and its growth ratio from 12% in 1980 to 19% in 2001 (PhARMA, 2001), is highest among all major industries.
Few of the factors to explain this huge outlay on R&D are:

- Approval process for new drugs by FDA is very long and costly, and in the meanwhile external environment may change a lot, making existing drugs irrelevant. So a pharmaceutical giant needs to have a portfolio of drugs under development to spread out the risk.
- Out of about 5,000 to 10,000 compounds screened, only one is approved as a drug, out of those reaching market stage only 3 of 10 products become profitable (PhRMA, 2001).
- Drug companies having high fixed cost, use R&D to make profit from it by finding new use to their old drugs or manipulation of the generic chemical compound.
- Only top 20% of the new drugs marketed earn any profit in terms of net present value, most other new drugs actually have negative NPV.

So to cover these costs and risks, pharmaceutical industry needs some kind of protection and incentives, particularly protection for the privileged use of the product of their huge investment. A “Patent System” is in place to provide some protection. It gives the patent holder the right “to exclude others from making, using, or selling the invention” and its usual life is about 20 years. There is also an Orphan Drug Act in place, which provides patent protection, extension and other benefits, for drugs, which are designed to treat rare conditions, which might otherwise would not have been profitable. Despite the relaxation of FDA guidelines to facilitate generic drugs entry into the market after patient expiration, brand name drugs face continuing price rigidity due to many factors, 1984 Drug Price Competition and Patent Term restoration Act being the major regulation responsible for it. According to Stephen Schondelmebr of PRIME institute, “a pill is sometimes protected by not one but anywhere from three to thirty patents”. Besides there has been allegations that in
many cases brand name drugs have paid millions of dollars to generic drug firms to hold off from entering the market. However, we will limit our discussion to more theoretical and relevant aspects and keep away from wild speculations.

The equation given below for the NPV of an investment decision in pharmaceuticals, taken from the textbook, “The economics of health and health care”, Folland et al., gives deep insight into dynamics of the industry;

\[
NPV = \sum_{k=1}^{m} \frac{(R_k - C_k)}{(1+r)^k} + \sum_{j=m+1}^{m+n} \frac{(R_j - C_j)(1+r)^{n+j-k}}{(1+r)^j} + \sum_{k=m+n+1}^{m+n+s} \frac{(R_k - C_k)}{(1+r)^k}
\]

Where:

a. The research, testing and review period (m years)

b. The effective period of patent protection (n years) after the product is launched

c. The period following patent expiration (s years, where m+n+s = T)

In the first period, a, NPV is negative and there are huge expenditure, so the firm expects to huge positive cash inflows in second period, b, to have a net positive NPV by using patent protection, marketing, creating a niche market and barriers to entry. In the third period or c, company may still make profits despite competition from generics, due to the established brand loyalty, marketing, new uses to the same product or expanding the uses or filing for a range of composite uses during patent filing itself.

The system of patent protection seems logical and an essential requirement to foster growth and development, but in economic terms it creates a barrier to entry. Small firms can not launch new compounds as they can’t afford huge R&D expenditure and they cant enter the market for
existing compounds because of patent protection. So the big keeps on getting bigger and rest have to be content being a small fish.

**Pharmaceutical Supply Chain:**

Pharmaceutical supply chain is very diverse, varying according to the type of drug, type of health system, commercial relationships, etc. For the sake of convenience, we will discuss about a prototype of the supply chain. In a prototype supply chain, drugs are manufactured in industries, transferred to wholesale distributors, stocked at retail, mail order and other type of pharmacies, goes though price negotiations and are subjected to utilization and quality management, screened by pharmacy benefit management companies (PBM’s), dispensed by pharmacies and ultimately consumed by patients (KFF, 005).

Source: Follow the pill understanding, KFF, March 2005
These arrangements lead to several key features in pharmaceutical industries like price discrimination and reference pricing to name a few, which are discussed in brief in the later sections.

Apart from these, physicians, large employers and health plans also play a vital role in the supply chain and exert substantial influence in price negotiations. A detailed discussion of the arrangements and its financial and economic implications, which can be manipulated for greater efficiency, are beyond the scope of this project. Enumerated below in the form of a table adapted from KFF report (Follow the pill understanding, KFF, March 2005), are some of the salient features of this supply chain and its key players.

### Key Players in Pharmaceutical Supply Chain & Their Characteristics

<table>
<thead>
<tr>
<th><strong>Pharmaceutical Manufacturers:</strong></th>
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<tr>
<td>• A relatively few large, multinational firms comprise the bulk of the brand pharmaceutical manufacturing industry today – the 10 largest pharmaceutical corporations, as measured by U.S. sales, accounted for almost 60 percent of total U.S. sales in 2004.</td>
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<tr>
<td>• Pharmaceutical manufacturers have the most influence over pharmaceutical prices, assessing expected demand, future competition, and projected marketing costs to establish the wholesale acquisition cost (WAC), which is the baseline price at which wholesale distributors purchase drug products. Discounts and rebates may be applied, based on market share, volume, and prompt payment.</td>
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<th><strong>Wholesale Distributors:</strong></th>
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<td>• The wholesale distribution industry has consolidated in the last 30 years, with the number of wholesale distributors in the U.S. declining from approximately 200 in 1975 to fewer than 50 in 2000. The top 3 wholesale distributors account for almost 90 percent of the wholesale market.</td>
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<tr>
<td>• Wholesale distributors typically sell drugs to pharmacies at WAC plus some negotiated percentage. They may facilitate discounts negotiated between manufacturers and other customers.</td>
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Pharmacies:
• Although comprising a small overall percentage of total prescriptions filled (approximately 6.1 percent in 2004), mail-order pharmacy sales were the fastest growing sector of the U.S. prescription drug retail market in 2004, increasing by 18 percent over the previous year.
• Pharmacies may negotiate with manufacturers or wholesalers for discounts and rebates based on volume sales or market share, and they may negotiate with PBMs for inclusion in their networks and for their reimbursement (drug cost plus dispensing fee).

Pharmacy Benefit Managers (PBMs):
• Approximately two-thirds of all prescriptions written in the U.S. are processed by a PBM.
• PBMs may achieve savings for their customers by negotiating discounts and through cost containment programs, including use of formularies and cost sharing.

Source: Follow the pill, KFF, prepared by The Health Strategies Consultancy, LLC, 2005

Price Discrimination:
Price discrimination means charging different prices to different segments, without any clear difference in the cost of production and distribution. In pharmaceutical industry, law of one price for all never holds. Price discrimination has been an established practice in this sector for last 40 years or more. The ugly side to it is that people who are less able to pay or are financially less stable are the ones who pay more like elderly, uninsured, low income individuals without insurance coverage and others. This fact is substantiated by a study conducted by Department of Health and Human services, which found out that people who pay cash for drugs, pay ~15% more than their insured counterparts having third party payers. CMS had similar findings for Medicare beneficiaries, among whom cash payers paid significantly higher for 19 of the 20 most frequently prescribed drugs in 1999. The table below shows the difference in price paid by different parties in health care sector for drugs.
On the other extreme are large employers and agencies like Department of Veteran Affairs and Defense Department, which pay significantly lower prices - ~58% of the cash/retail prices (Frank, 2001). A general rule is that institutional buyers pay far less than the retail outlets or end consumers.

The basic economic principles that lead to price discrimination are:

- Market power of sellers: exerted by patent protection, brand loyalty and familiarity by advertisements and promotion. So in most cases there are no effective substitutes to compete in the market (patented drugs).

- Market power of buyers: exerted by the sheer volume of patients they control and the estimation of profit loss in forgoing these markets. E.g.; VA, Defense Departments, large employers, hospitals, health plans, etc.

- Markets that are segmented according to price responsiveness: Pharmaceutical industry is highly segmented for price responsiveness, with uninsured lying on one extreme and affluent people and fully insured one on the other extreme. So the profit maximizing pharmaceutical firm charges price according to price elasticity of the buyer, i.e., highest to the segments whose demands are least price elastic or sensitive and vice versa.
• Potential for negotiations and arbitrage: The above price differentials will only hold if the buyer who gets the commodity at lower price cannot resell it at lower cost to other buyers. This is facilitated in pharmaceutical industry in US by several federal laws and regulations like Prescription Drug Marketing Act.

The graph below illustrates the effect of most of the factors discussed in the preceding sections on the effective drug prices and quantity supplied, and the exertion of monopoly power by pharmaceutical industries to varying extent;

![Monopoly Drug Pricing Graph]

MC = Marginal cost
AC = Avg. cost (includes R&D expenses)
Monopoly price & quantity = Pm, Qm, where MC = MR.
MP = Monopoly profit.
Qm & Pm = quantity & price required.
Qe & Pe = quantity & price expected.
Price & quantity offered are very different from the competitive market due to monopoly, entry barriers, patent protection, advertising, low substitution and many more factors.

Source: Adapted from Folland et al., The economics of Health and Health Care
The practice of differential pricing is closely correlated with the structure of healthcare system. In 1960s with FFS being predominant form of reimbursement, price discrimination was at the level of large employers and federal agencies only. With the advent of Medicare, Medicaid, Managed Care, HMO’s, increased insurance coverage, PBM’s and pressure for cost containment on institutions from late 1960’s through 80’s and to this period, the practice of price discrimination has become more rampant and has come into considerable public and legislative attention and is a form of cost shifting and profit maximizing behavior of manufacturers.

**Flow Of Funds From Pharmaceutical Manufacturers, As A Percentage Of Total Sales, 1998**

![Flow chart of funds from pharmaceutical manufacturers](image)

Source: Richard G Frank, Health Affairs, 2001

*So all these factors act in concordance to increase the price of the drugs as a whole, both for institutions and for individual buyers. In nutshell, the increase in total expenditure is due both to increased utilization of*
drugs and rise in prices, but more so with increased utilization, as discussed earlier.

Policy Recommendations:

It’s clear from the discussion above that prescription drug expenditure is a burning topic with allegations and counter allegations flying on. Journals and literature abound with critics advocating radical measures to clamp down on the pharmaceutical industry specifically. However the current situation is the cumulative result of radical changes going on in the US healthcare system and “ambivalent social ethics and inconsistent goals, distrust of government intervention, and incremental nature” of US health policy.

Drug industry as a whole is a set of investor owned, profit seeking companies, and at the same time being a creature of government, because it cannot survive without government protection of its economic turf (Reinhardt, 2001). Drug spending is not a macroeconomic burden as a whole, because its share in total national health spending has been on the decline from 2000, after a peak in 1999, which is expected to continue at least till 2010 (Heffler et al., 2001). Currently it is 1.4% of GDP and liberal estimates put it to 2.2% of GDP by 2010 (Heffler et al., 2001) It is infact a microeconomic burden with potential to disrupt economic stability of households or individuals. Individual spending is highly skewed so data interpretation becomes more difficult. Most of the spending is concentrated in less than 20% of individuals, particularly the elderly. Medicare Part d coverage has brought some relief to this segment, but it is too early to comment about that. So the spending has to be correlated with real benefits that accrue, current estimates of which are
vague to define. Spending or R&D is a necessary pre-requisite for the innovation and is the price that we pay for progress and betterment of quality of life. Patent production follows R&D spending. The real profits earned by pharmaceutical companies are also very difficult to estimate because of vast number of accounting practices used by individual firms.

This situation calls for a more holistic approach, a public-private participation, to limit waste and increase efficiency, which fall in their domain. Some of the strategies to achieve cost containment are discussed in brief below.

**Direct Limits:**

Direct utilization limit strategies focus on the end consumers – patients. The strategies to affect utilization are:

- **Exclusion of specific drug classes from the benefit plan.** Depending upon the type of consumers a health plan or an institution serves, it can exclude certain drugs that are not relevant to the population or are non-specific or have no evidence of benefit, using best clinical practice guidelines. For example, “Medicaid by statute allows states to exclude coverage for several classes of drugs: drugs for anorexia, weight loss, or weight gain; infertility treatments; drugs for cosmetic purposes or hair growth; drugs for symptomatic relief of cough and colds; smoking cessation products; vitamins and minerals; nonprescription drugs; barbiturates; and benzodiazepines” (CMS).

- **Exclusion of OTC drugs from coverage:** Most of the OTC drugs are for non-specific use and for intermittent and less severity discomfort or illness. Various studies show that it also accounts for a major portion of the market share as it is an experience good and has high lability and price elasticity. However OTC drugs for specific disease management
programs like beta-blockers should be allowed for the diagnosed people. In those cases their generic counterparts should substitute it.

- **Managed Drug Limitation & General Limits or Caps on spending:** Which limits the quantity of prescription per period or person. Most of the institutions and employers use it to certain extent, but are generally averse to it because of employees or enrollees backlash which is justified by its vague understanding and unique nature of the subjects. More studies are needed to make it efficient. In case of caps, the consumer has to pay out of pocket, once the spending limit as specified by the contract is reached, although he/she may still be entitled to the discounted prices through their PBM, or programs like Medicare+Choice, alternative insurance, etc.

- **Drug Utilization Review (prospective/concurrent):** In this case the plans or PBM’s review the utilization pattern of drug use and assess whether it is necessary or not. The reimbursement of prescription costs is subject to assessment report. It may be very helpful in cutting down utilization, as it puts pressure on both patients and the physicians for efficient use of resources and adhere to the guidelines and necessity.

**General Utilization Review:** Apart from the utilization review discussed earlier, there are several other utilization review strategies aimed at limiting quantity consumed, modification of the behavior of physicians, comprehensive case management to limit overall cost, etc. It includes prospective, retrospective and concurrent utilization of the prescription and its amount, profiling of the physicians according to their performance in cost saving endeavor and following of best practice guidelines, prior authorization for a particular medication, disease management, and review targeted specifically to high cost users. Most of the plans and providers including Medicaid, implement this strategy but the intensity of its application is not known.
**Step therapy or first fail requirements**: is a program where payment for a class or particular drug is restricted unless certain other less expensive and equally effective drug as attested by clinical guidelines and literature, have been tried.

**Better Pharmaco-economic Information**: Reinhardt puts this issue beautifully in words, “Whatever means employers and government ultimately adopt to shift more of the rising cost of prescription drugs onto patients, one can expect much rancor over the practice and possibly much litigation—unless the underlying formularies or therapeutic groupings can be explained to physicians, patients, and juries with appeal to scientifically sound cost-benefit analyses”. It implies dissemination of the knowledge about cost and benefits of drugs to physician’s (including detailing or counter detailing), patients, providers, and health plans by pharmaceutical industries, research institutes, medical community, not for profit organizations, etc to promote more efficient patterns of prescription and consumption. It will also force the pharmaceutical companies to correctly price drugs, be more efficient, be more conscientious in ads and promotions, etc. However, how it can be effected is very complex and beyond the scope of this paper.

**Cost Sharing**: There are many approaches to affect cost sharing, like co-payments, coinsurance and reference pricing. To be effective they are often used in conjunction with utilization management approaches. It brings down total expenditure by affecting the utilization by the consumer by making him/her more price sensitive and demand more price elastic and also by transferring some cost from payers to consumers. To be successful, it needs a competitive market or preponderance of generic drugs. In case of drugs under patent protection with no substitutability, it has no effect on utilization and may even adversely affect the health status of an individual and increase in overall costs as shown by a study by Reeder and Nelson, who found
that, utilization remained unchanged for sleeping pills or pain medications for which effects were obvious and instant, but it decreased for anti-hypertensives and hypolipidaemics, which were critical to them. A more comprehensive study by Goldman et al., suggests otherwise, but still the possibility is not zero.

However, it is quite successful in generic markets, in which providers employ several mechanisms to shift utilization towards less costly substitutes. There are tiered cost sharing in which co-payment depends on the type of drug being purchased. The intent is to shift the consumers from more expensive brand name drugs to less expensive generic counterparts by providing positive and negative incentives. It can be one tier, two tier, three tier or more complex four-tier mechanism, which cannot be discussed in detail over here. Kaiser/HERT study reports that only 10% of the enrollees in private sector face no tiered co-payments. Some researchers argue that it will provide disincentive for pharmaceutical companies for R&D and it surely increase consumers burden, but the question here is that does benefit outweighs cost and does not effect overall progress and innovation. Issue of freedom of choice to consumers and physicians is addressed by multi tiered plans with varying co-payments.

In contrast to co-payments flat rate, coinsurance requires the patients to pay a part of their expenses, which is usually a fixed percentage and not amount. It has mechanisms in place to prevent from catastrophic loss in which the plan takes over, once the limit has been reached. It increases price elasticity and sensitivity and makes the consumer make prudent choices and restrain from indiscriminate use, most of the times.

**Economic Impact:**

The above-mentioned techniques focus on the utilization aspect or the demand side with very limited effect on the supply side. By making consumers more price sensitive and price elastic it
limits the total expenditure on prescription drugs. One can also argue that it provides added benefit by preventing against the indiscriminate use of medicines with side effects. It also limits the problem of Moral Hazard. To promote equity and efficiency, the PBM’s in this case have to be ingenuous in devising the benefit plans, with a clause for appeals and catastrophic coverage, etc.

**Drug Formularies:**

Drug Formulary means a compendium of drugs on the approved list of a hospital or plan, available for dispensing. It limits the usage to drugs on the list, which usually has generic drugs or less expensive brand name drugs. A positive formulary restricts the choice of drugs to those on list and the negative formulary excludes drugs from the list.

Compiling a formulary is an elaborate process requiring review and approval by pharmaceutical and therapeutics committee (P&T), comprised of physicians, pharmacists and clinical experts, based on clinical effectiveness and cost benefit analysis. However as with other cost containment approaches in health care it faces enormous opposition from the involved parties. But faced with increased cost pressure, it is going to stay and become more prevalent, albeit in different format like open and closed formularies, with higher payments in the open one and out of pocket payment in closed one for excluded drugs.

Formularies are an effective tool for price negotiation and it also forces pharmaceutical firms to divulge more information about the benefits and cost effectiveness of their drugs, for it to be included in the list. It has a significant impact on the manufacturers as illustrated by a study, which assessed the impact of only VA’s closed formulary on prices, market share and drug spending. The study revealed, “Where a class of drugs was
closed, 85 percent to 97 percent of the market went to the on-formulary drug (up from 16 percent to 47 percent before the class was closed). By contrast, use of the preferred drug in another class, where the formulary was not closed, rose from 15 percent to only 23 percent” (Huskamp et al.).

**Generic Vs Brand Names:**

It’s a known fact that brand name drugs have significantly higher prices than their generic counterparts and FDA certifies their therapeutic equivalence. So it makes sense to use generics but still generics occupied only 47% of the market share in 2000. The reasons behind it are many like brand loyalty, marketing, preferences of consumers, experience rating of experience goods, patent line extension, kickbacks, etc.

However, the situation has become much better than in 1960’s and 1970’s with “DAW”, and antisubstitutions law in place. The shift towards generics is facilitated by Waxman-Hatch act of 1984, which allows the company to file for new drug application using pioneer companies research.

![Image](image.png)

Source: Patricia Barry, *Drug Companies Spends Huge Sum Guarding Prices*, May 2002
With use of strategies like multi-tier co-payment requirements, formularies, etc, the market for generic is bound to improve. It affords benefits, both to the consumers and the providers in monetary terms, the only losers being the pioneer companies. Pioneer companies realize this fact and are entering the generic market at an increasing rate, after their patent has expired.

**Pricing Strategies:**

These strategies aim at lowering the prices paid for the purchases. Large employers, health plans, hospitals, can make use of the sheer size of their consumer base to negotiate prices with the manufacturers or wholesalers. They can also use continuously evolving expertise like PBM’s and networks for negotiation and less transaction costs. The mechanisms employed for it are:

- **Purchase Pools and Higher Rebates Through Market Leverage:** large employers can band in together to gain more market power by virtue of their increased market share, to negotiate for lower prices. A good example is the tie up between department of defense and veteran affairs, which pay significantly, lower for the drugs (as low as 50% of retail prices, discussed previously). States followed suit and created a similar National Medicaid Pooling Initiative, started by Michigan, collaboration between participant states to negotiate a matrix or prices and rebates. Multi state health plans and health systems and employers in an area also employ this mechanism quite frequently, either by themselves or through their pharmacy benefit managers.

- **Transparency and Better Information:** One of the key economic principle is that a consumer makes rational decisions based on complete and freely available information. Unfortunately for pharmaceutical industry, this is not true. Buyers don’t have enough information to negotiate about the price. Schondelmeyer argues that, “price transparency
would improve economic efficiency in the prescription drug market, empower buyers to negotiate more effectively, give policymakers and researchers access to actual price information, and make pharmaceutical firms more accountable for the prices they charge”.

- **Pharmacy Networks:** Contracting with a select group of pharmacies (restricted pharmacy network) by hospitals or plans can reduce total prescription costs significantly. The benefit accruing to the pharmacy would be increased traffic and volume of sales, maximizing profit, despite low profit per transaction. Plans are charged less by pharmacies for the drugs, in return. Consumers who use pharmacies in network get reimbursed but those who go out of the network share prices or pay out of pocket, depending on the plan.

- **Discount Cards and Rebates:** this is a relatively recent approach, aimed at individuals who do not have prescription coverage or are uninsured or willing to pay an enrollment fee. The individuals sign up with the sponsoring agency which may be state government, PBM, pharmaceutical firms, insurers, providers, etc, get a discount card to buy the covered drugs at a discount within the network. It is still evolving and the benefits that accrue from it is still not clear, but it does perform a social function.

- **Mail Order Pharmacies:** Benefits accrue from mail order pharmacies in several ways; lower cost of the drug, lower administrative overheads, more generic substitution choices, ability to purchase drug in bulk and repackage them in larger orders, flexibility to improve other techniques like prior authorization, utilization review, formulary compliance, etc.
• **Expanded access to federal Medicaid rebates:** Under omnibus budget reconciliation act, it is mandatory for manufacturers to offer rebate to states for drugs purchased under Medicaid, which at present is about 15% of the difference between average manufacturers price and best market price. It is estimated that states on an average save around 20% each year due to rebate (CBO). This saving can be passed on to the public in many forms, like Maine Rx, which will be instrumental in lowering overall price of the drugs consumed.

• **Direct Price Regulation:** This is one of the most controversial techniques. American public in general is a big proponent of free market conditions and businesses in general are averse to government interference. At present government does exercise this power to a limited extent for certain sections of Medicare drug purchases and for VA. However how successful will the more comprehensive price regulation be, is a matter of conjecture? If it does happen to certain extent, it will reduce the prices for consumers, decrease profit margins of manufacturers, and decrease total spending. Price regulation is also negatively correlated with innovation.

• **Importing Drugs:** Over the last 10 years there has been a huge debate going on about importation of drugs from countries having price regulations in place and thus lower cost, and about it safety concerns, but till date no law has been passed which permits unrestricted import of drugs. In 2000, Medicine Equity and Drug Safety Act was passed, which permitted it, but required department of health and human services to certify that there would be no safety concern and violations, which is utterly difficult to do and was never done. From economic viewpoint, it does seems prudent to import drugs from other countries at low prices, particularly when the drugs are manufactured in US and then the
benefits are passed on to other countries like Canada and Mexico, with American people having to pay higher prices. However the scenario is too complex with lots of stakeholders and issues involved. At this moment we can only wait and watch.

The above discussion reflects on the key issues of pharmaceutical industry, its key features, its price determinants, and strategies for cost containment. The basis of all these strategies is to affect demand and supply through utilization and price controls and ultimately bring down total cost expended by the society on prescription drugs.
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