

# ISSUE BRIEF

The Massachusetts Health Policy Forum

## THE COST AND AVAILABILITY OF PRESCRIPTION DRUGS—WHAT CAN WE DO IN MASSACHUSETTS?

Wednesday, May 12, 1999

8:30 to 9:00 – Breakfast

9:00 to 11:00 – Discussion

**Omni Parker House Hotel**

**School and Tremont Streets**

**Boston**

**Registration: Please call Sue Thomson at 617-338-2726 as soon as possible**

NO. 4

*Issue Brief prepared by Nancy Weiland Carpenter, an independent health care consultant in Cambridge, Massachusetts and Simon Kedikoglou, a physician from Greece and degree candidate at the Harvard School of Public Health.*

## Introduction

Retail spending for prescription drugs has been growing at double-digit rates over the past several years. In 1998, it was estimated that prescription drug sales increased by 16.6% from the previous year, reaching \$91.9 billion. This increase in drug spending is more than 4 times the increase in health care spending overall.<sup>1</sup>

The elderly and disabled are among those who are most vulnerable to the rising cost of drugs. While those over 65 represent about 13% of the population, they consume nearly one-third of all medications prescribed in the United States.<sup>2</sup> Of those who are over 65, nearly all are covered by Medicare, yet it is estimated that 35%<sup>3</sup> to 45%<sup>4</sup> of Medicare beneficiaries do not have supplemental coverage for outpatient drug benefits. Though debate in Washington to expand Medicare to include pharmaceuticals continues, many in Massachusetts and elsewhere are reluctant to wait for a national solution, fearing that in the end drug coverage will not be included.

The uninsured are also at risk as drug costs rise. While many who are uninsured are able to get some medical attention through the patchwork of services and systems that are put in place community by community, the struggle to assist those who are uninsured to obtain medications is a difficult and time consuming one. Efforts by physicians and others to help include: 1) provision of pharmaceutical samples when available; 2) submission of applications to pharmaceutical company patient assistance programs for free medications; and, 3) community philanthropic initiatives. Many who are uninsured and chronically ill manage their medications according to their financial means, rather than their medical needs. It is not clear what impact this has on their health or on health care costs, as their conditions may worsen requiring emergency treatment or hospitalizations that might otherwise have been prevented.

Not only is the increasing cost of pharmaceuticals reaching crisis proportions for some elderly citizens and the uninsured, but also it has been cited as a contributing factor to the increased cost of health insurance premiums, particularly for managed care. The cost of prescription drugs is rising faster than any other component of HMO health care costs and is also being blamed for HMOs' diminishing profits.<sup>5</sup> As the cost of health insurance premiums increases, employers are asking employees to absorb a larger percent of the cost of their health insurance. A greater number of employees are declining coverage because of the increasing cost of their share of the premium, thus increasing the number of uninsured in the country.<sup>6</sup>

Against this backdrop, the pharmaceutical industry continues to be among the most profitable in the country. And, prescription drugs are cited as the most cost-effective technology, averting massive costs of illness, improving the quality of life, and saving lives.<sup>7</sup>

The following discussion is intended to provide background from a number of perspectives on the impact that increased pharmaceutical costs are having on access and affordability of drugs, with a particular focus on the Medicare beneficiary population.

Several options for state level action in Massachusetts are presented. These include:

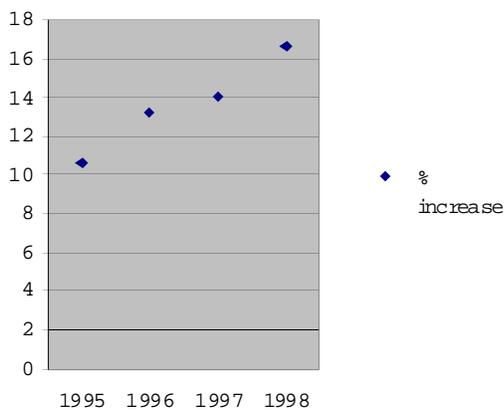
- three initiatives to improve access to pharmaceuticals for the most vulnerable (Options I – III)
- an initiative to obtain better prices for drugs (Option IV)
- strategies to improve the pharmacological knowledge-base of physicians (Option V)
- one possible area for state leverage in negotiating with the pharmaceutical companies (Option VI).

## Section I: Growth in Pharmaceutical Spending

Between 1990 and 1997 prescription drug spending in the U.S. more than doubled from \$37.7 billion in 1990 to \$78.9 billion in 1997. In comparison, spending on hospital care grew only 2.9% in 1997, and spending for physician services grew by 4.4% that year. Overall, national health expenditures grew by 4.8% in 1997.<sup>8</sup>

In 1998 it was estimated that prescription drug sales would increase by another 16.6% from the previous year, to \$91.9 billion, more than 4 times the increase in health care spending overall.<sup>9</sup> Projections indicate that there will be considerably higher drug costs in 1999.<sup>10</sup> Figure 1 shows the double-digit growth in prescription drug spending from 1995 through 1998.

**Figure 1: Growth in Drug Expenditures, 1995-1998**



Sources: Health Affairs Vol. 17/6, p. 99; Wall Street Journal, 11/16/98

### *Why is Spending on Prescription Drugs Rising So Quickly?*

The growth in spending associated with pharmaceuticals has been attributed to increased utilization of drugs, changes in intensity (changes in size and mix of prescriptions), and changes in the sources of payment for prescription drugs.<sup>11</sup> The aging of the population, the number of new drugs introduced in recent years, direct-to-consumer marketing strategies by the manufacturers, and the decrease in time for Food and Drug Administration (FDA) approval of new drugs are also being cited as the basis for escalating spending. The increased coverage by third party payers, as a managed care benefit, has been further implicated as a factor contributing to increased prescription drug spending and diminished HMO profits.<sup>12</sup>

*Increased utilization of prescription drugs:* The increased utilization of pharmaceuticals is evidenced by the growth in retail spending for prescription drugs, which has grown at double-digit rates over the past several years. In 1990, nearly 1.7 billion prescriptions

were reported dispensed in the United States, which is almost seven for every man, woman and child in the country.<sup>13</sup> By 1997, the National Association of Chain Drug Stores claimed the number of prescriptions filled nationwide had reached 2.6 billion.<sup>14</sup>

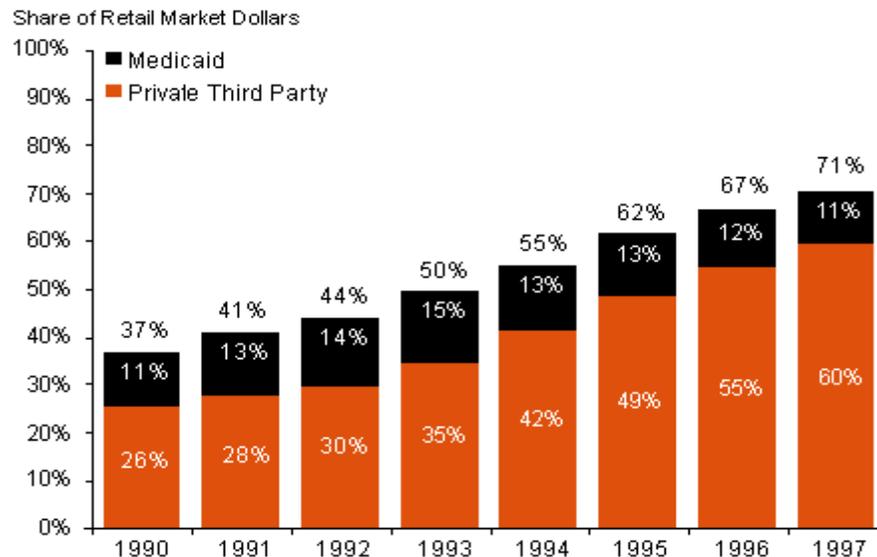
*The elderly use more prescription drugs, and are a growing proportion of the population:* Those over age 65 are 13% of the U.S. population, however, they consume nearly one-third of all medications. Seniors are a growing proportion of the population, and it is projected that the number of people over 65 will double by the year 2030, growing to 20% of the population.<sup>15</sup>

Compared to the average person's use of 2 to 3 prescriptions annually, people over 65 consume 9 to 12 prescriptions annually.<sup>16</sup> Eighty percent of those who are retired are reported to take a prescribed drug every day. Eighty-six percent of Medicare beneficiaries living in the community reported using at least one prescription drug during 1995, with the average beneficiary using 18.5 prescriptions that year.<sup>17</sup> The American Association of Retired Persons (AARP) has noted that older Americans spend, on average, nearly 4 times as much on prescription medications annually as persons under 65.<sup>18</sup>

*Changes in sources of payment for prescription drugs:* Before the mid-'70s pharmacy was not a significant part of the benefit dollar. In 1970, only 18% of outpatient prescription drugs expenditures were covered by third party payers.<sup>19</sup> By 1990, third party reimbursement for pharmaceuticals had grown to 37% of the retail market dollars, and by 1997 covered 71% of these expenditures (Figure 2).<sup>20</sup>

For those who are insured, out-of-pocket expenses for drugs have been low since 1993, and the low expense has been suggested as a factor contributing to both the increased utilization and increased price as consumers with coverage do not directly experience the impact of rising pharmaceutical costs or expenditures.<sup>21</sup>

It has been suggested that managed care organizations (MCOs) have helped to shield the consumer from the impact of rising prescription costs. The percentage of premium attributed by MCOs to pharmaceuticals has ranged from 6% in 1988 to 8.6% in 1994. In the meantime, however, pharmaceuticals have accounted for approximately 10% of the MCOs operating expenses over the same period, as MCOs have found it beneficial to absorb some portion of the cost of the pharmacy benefit.<sup>22</sup>

**Figure 2: Coverage of Drug Benefit by Source**

Source: PhRMA 1998 Industry Profile

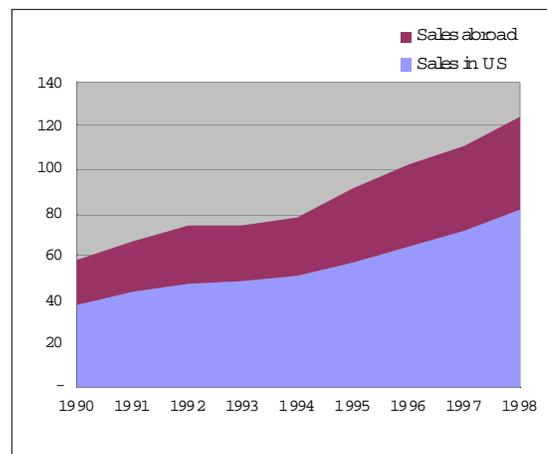
*High introductory costs of new drugs:* Of the 16.6% increase in pharmaceutical spending in 1998, 3.2% is estimated to result from higher prices for existing drugs. The remainder of the increase is being attributed to the prices at which new drugs are introduced, and the large number of prescriptions being filled. Between 1995 and 1997, 120 new drugs were introduced, with an additional 30 new drugs expected in 1998.<sup>23</sup>

*Direct-to-consumer marketing by the pharmaceutical industry:* Pharmaceutical firms are estimated to have spent \$1.3 billion on consumer advertising in the United States in 1998, targeted primarily to older consumers and baby boomers, with a heavy emphasis on quality of life improvements achievable with prescription drugs.<sup>24</sup> For example, Merck & Co. is reported to have spent \$91 million in 1998 promoting Propecia, a prescription drug that prevents baldness, directly to consumers in the U.S.<sup>25</sup>

## Section II: The Pharmaceutical Industry – Focus on New Products\*

There are more than a hundred research pharmaceutical companies in the US, with total sales, both US and abroad, of approximately \$120 billion in 1998.

\* Appendix A provides more detailed information on facets of the pharmaceutical industry in the U.S., including the role of the FDA in approving new drugs. Appendix B presents a description of the regulatory climate governing the pharmaceutical industry in several European countries.

**Figure 3: Sales of US Research Companies**

Source: PhRMA, Industry profile, 1998

Sales in the US account for around \$80 billion, and have constantly increased during the '90's (Figure 3).<sup>26</sup>

The Pharmaceutical Research Manufacturers Association (PhRMA) is the trade association for approximately 100 pharmaceutical companies. Information on the pharmaceutical industry is closely guarded by the individual companies. Thus, most of the following discussion reflects information and data com-

piled and made available from PhRMA and other industry sources.

The combined work force of these companies totals more than 200,000 employees. Three key functions define the pharmaceutical industry: Research and Development, with 25% of the industry's employees, Production and Quality Control, employing 27% of the workforce, and Marketing, which represents 31% of the workforce.<sup>27</sup>

### *Research*

The intensity of the research and development (R&D) function distinguishes the pharmaceutical industry from other industries. In 1996, research-based pharmaceutical companies reported research costs as 19.8% of their sales, compared, for example, to 4.3% in the automotive industry, 3.9% in aerospace and defense, and 3.9% in telecommunications.<sup>28</sup>

With the introduction of the first antibiotics, the industry discovered that it could generate high consumer demand by developing more effective drugs. This recognition that new and improved products could be highly profitable has resulted in the large and increasing investment in R&D.<sup>29</sup> By 1998, expenditures for research and development had increased to \$20 billion, or 20 percent, of the sales in the U.S.<sup>30</sup> A driving force behind the profitability of the industry is the principle that when new drugs are introduced that replace older ones, demand will be high for the more effective product.<sup>31</sup>

### *Federal Support*

The federal government both indirectly and directly contributes to pharmaceutical R&D. It contributes indirectly through methods such as tax breaks (see Appendix A). The government also supports clinical research directly. For example, a 1993 Office of Technology Assessment report estimated that when the support of the National Institutes of Health, Alcohol, Drug Abuse, and Mental Health Administration, were combined in 1988, 11% of the Pharmaceutical Manufacturers Association's funding for clinical research was from federal sources.<sup>32</sup>

### *Brand-name Versus Generic Drugs*

Drugs are usually divided into two big families: brand-name or generic drugs. Brand-name drugs are further divided into "innovator" or "breakthrough" drugs, and "me-too" products. Because of their patent

protection during their initial years in the market, brand-name drugs command a higher price than generics, which only become available after the patent protection has lapsed.

*Brand-name drugs:* The price-commanding status of a single-source brand-name drug results from its original invention as a chemical compound that can influence the molecular pathway of a certain disease. Once invented, these compounds undergo rigorous testing for biologic activity, safety, and effectiveness (first in animals and then in humans). Trial results are submitted to the FDA and, if approved, the drug is ready to enter the market.

Brand-name drugs are granted a patent, which prohibits copies and offers market exclusivity for a certain period. As a result, the company can charge higher prices and earn substantial revenue as compensation for the research costs it already has incurred. After the patent expires, other companies are free to launch generic drugs (i.e., identical chemical copies) under a different commercial name.

*"Me-too" drugs:* Although generic substitutions may not be sold for patent-protected brand name drugs, there are "therapeutic" substitutions that may be sold. A therapeutic substitution is a drug that targets the same molecular pathway of a certain disease as that of another brand-name drug. Unlike a generic substitution, however, the chemical compound of a therapeutic substitution is not identical, but rather only similar. The first brand name drug that enters the market is the "innovator" drug; the similar brand-name drug(s) that enters soon after is called a "me-too" drug. "Me-too" drugs are usually therapeutically indistinguishable from the "innovator," (i.e., they are equally safe and effective). Sometimes, there may be differences, however. For instance, a "me-too" drug may have fewer side effects, or slightly higher biologic activity.

Usual market behavior is affected by the pricing of "me-toos." In one case, when a new anti-ulcer drug entered the market, the old one held steady, and then the prices of both drugs were raised. When the next two anti-ulcer drugs entered the market, unlike normal conditions in which there may be an attempt to undersell current standards, their prices were somewhat higher than those of the first.<sup>33</sup> Because an innovator drug commands a higher price than a "me-too" drug does as it enters the market, manufacturers are interested in being able to claim a potential difference in their product than the previously available innovator, or even from

other "me-too" products. In order to claim such a difference and to claim superiority of the product, a company has to organize additional clinical trials and gain FDA approval. This procedure is both very expensive and uncertain, as FDA closely scrutinizes claims for superiority and unless overwhelming evidence exists, rejects them.

"Me-too" drugs have two important economic effects. First, they limit the monopoly power of the first drug; with the entrance of the "me-too" product providers have more than one option, and competition reduces the earnings of all companies. As companies focus on the same prevalent diseases and extensive research reveals their molecular pathways, "me-too" drugs are emerging more frequently and more rapidly after the "innovator" has entered the market.<sup>34</sup>

Secondly, "me-too" products tend to increase the risk for a competitive pharmaceutical company with an innovator or other "me-too" product. As more "me-too" drugs with fewer side effects or easier ways for administration come into the market at a faster pace, they will drive the innovator out of market dominance sooner, risking the company's ability to recoup its R&D expenditures.

*Generic drugs:* As explained above, a generic is chemical copy of a brand name drug whose patent has expired. Usually research pharmaceutical companies do not copy products of one another; rather, generics come from specialized generic companies. Typically, these companies do not spend much on advertisement, as physicians are usually well aware of the activity and the side effects of the original compound. Instead, generic drugs rely on their low price to find a position in the market, and their market share has increased substantially since 1984. State laws may encourage generic usage. For example, Massachusetts law requires pharmacists to substitute a generic for the brand name if available, unless the physician states otherwise.<sup>35</sup>

*The process of discovery:* Ten to 15 years generally elapse from the day a compound is synthesized in the laboratory to its appearance in the market. At the conclusion of the pre-clinical phase, the company files an Investigational New Drug (IND) application, and a second separate application for the patent. The date on which the patent application is submitted begins the countdown for the 20 years of patent protection that the law allows. Companies work under considerable pressure to complete the clinical trials, submit the results for

FDA evaluation, and have enough time left to market the drug before the patent expires.

*Patents:* Clinical trials typically last approximately 7 to 8 years. A company then submits an application for market approval to the FDA, a procedure that usually takes approximately one year. The company has the remaining years of patent protection, usually 11 to 12 years, to recoup the expenditures undertaken in the R&D period before there is competition from generic drugs. The company has a strong interest in shortening the time necessary for the clinical trials and speeding the FDA approval phase in order to be able to market the drug as soon as possible.

*Is research under- or over-compensated?* There is no easy way to estimate research costs. The 1993 study of the Office of Technology Assessment is the best known effort to estimate research costs. The OTA study estimated that each drug that entered the market had a 4.3% higher return than that necessary to finance its R&D expenditures. It further described that "[d]ollar returns are very volatile over time" and that "the cost of bringing a new drug in the market is very sensitive to changes in science and technology, shifts in the kinds of drugs under development and changes in the regulatory environment."<sup>36</sup>

*Today's research focus:* Today's research is concentrated on the following clinical conditions: heart disease and stroke (96 drugs tested), cancer (316 drugs tested), Alzheimer's and Parkinson's diseases (118 drugs tested), infectious diseases (125 drugs tested), as well as AIDS (124 drugs tested). In 1998, R&D costs were close to \$20 billion, and are expected to increase further in 1999, possibly reaching \$24 billion.

*Cost implications of new products for pharmaceutical spending:* Between 1995 and 1997, 120 new drugs were introduced, with an additional 30 new drugs expected in 1998.<sup>37</sup> Of the 16.6% increase in pharmaceutical spending in 1998, it was estimated that higher prices for existing drugs was responsible for only 3.2% of the increase, with the rest of the increase "due to the high introductory prices of new drugs and to large number of prescriptions being filled."<sup>38</sup>

The greater number of prescriptions written in the last few years is related partly to the introduction of new drugs, many of which offer dramatic improvements for various conditions that were not previously treated or were treatable with side effects.<sup>39</sup> Though prices are expected to come down once a brand-name product

comes off patent and generics are available, by that time "brand-name drug makers have often cranked out a new generation of higher-priced replacements."<sup>40</sup>

The *Wall Street Journal* cites the competition over arthritis medications as an example of how new products increase pharmaceutical spending. Merck and Monsanto have been competing over a new class of arthritis painkillers called "Cox-2" inhibitors that promise relief without the severe indigestion that current medications cause in about 2 – 4% of those using the medication. Even though only this small percentage of users (2 –4%) experience the side effects, Michigan's Blue Cross Blue Shield plan is cited in the *Wall Street Journal* article as expecting fully half of its arthritis patients to switch to the new drugs. At an anticipated cost of \$2 to \$5 per pill, they will cost up to 17 times as much as current generic arthritis medications.<sup>41</sup>

#### *Industry Marketing Strategies*

*Marketing Force:* Pharmaceutical marketing occurs in several forms. These are: sales representatives, through the presence of detail men and women who call on physicians individually to present the products offered by their firms (detailers); direct mail; samples provided to physicians (sampling); medical journal advertising; sponsorship of continuing medical education; and public media advertising.<sup>42</sup>

Because pharmaceuticals are only prescribed by health professionals, and predominantly by physicians, the industry has historically targeted its products specifically at medical personnel. In 1991, nearly \$8000 was spent for every physician in the country on marketing and advertising (and nearly \$1 billion more was spent on these activities than on research).<sup>43</sup>

In 1994, the top 40 pharmaceutical companies employed 35,000 full-time sales representatives. By 1998, that number had increased to 56,000, with an additional 6,000 employed by independent marketing agencies. It is estimated that pharmaceutical companies in the United States spent \$5.3 billion in the first 11 months of 1998 sending representatives into doctors offices and hospitals, and another \$1 billion more holding marketing events for doctors.<sup>44</sup>

When the FDA restrictions that prohibited direct consumer advertising through television were eased recently, manufacturers responded accordingly. In 1998, drug companies were projected to spend an estimated \$1.3 billion on ads aimed at consumers, seven times greater than the amount they spent 5 years ago.<sup>45</sup>

In total, the industry was expected to spend about \$11 billion marketing its newest drugs to doctors and consumers in 1998.<sup>46</sup>

### **III. Complexities of Pharmaceutical Pricing and Purchasing**

#### *Controlling Prices*

Most industrialized nations make an effort to control prescription drug prices for their citizens. Examples include setting limits on what their country's insurance companies will pay for prescription drugs (e.g., Germany and Japan), determining what their government is willing to pay for prescription drugs and including only those for which the company agrees to pay the set price on the national formulary (e.g., France, Sweden and Australia), and limiting the pharmaceutical manufacturers' profits (e.g., Great Britain). The United States does not use any of these methods on behalf of the average citizen. Not surprisingly, studies repeatedly demonstrate U.S. pharmaceutical prices to be higher than other nations.<sup>47,48,49</sup>

Other countries use their large purchasing power to get better prices. For example, Australia has a federal formulary called the Pharmaceutical Benefits Scheme. Pharmaceuticals included on the formulary are subsidized for Australian residents. After approval from Australia's counterpart to the FDA, any drug can be sold there. But, if it is not on the formulary, it won't be subsidized. Pharmaceutical manufacturers offer lower prices so they can be included on the formulary and, therefore, gain access to 18 million potential purchasers. One study of 29 pharmaceuticals showed that in the median case the U.S. price was 216% higher than Australia's.<sup>50</sup>

Many of these pharmaceuticals are from U.S. manufacturers. Government intervention may be necessary to prevent U.S. prices from continuing to be higher than prices for the same drugs in other countries.

#### *Prices of Drugs in the U.S.*

The prices of drugs are particularly unpredictable; after three years of near stability (1994-1997), they rose dramatically in 1998.<sup>51</sup> Several factors are cited as explanations for this increase. These include the introduction of many new drugs, the significant acceleration of the FDA rate of approval beginning in 1997, the lack of competition for new drugs, which allows companies

to charge high prices, and the substantial increase in research costs.

Drugs have some pricing particularities that are important in understanding the wide variations in costs of drug products. These include the fact that manufacturing costs *per se* are relatively low, research costs are high, and that marketing costs are high as well. Research costs are a fixed or sunk cost, (i.e., the company has already undertaken the research before the first pill is sold). On the other side, the manufacturing costs are low; the compound itself is just a chemical entity relatively easy to synthesize.

The relatively low cost of manufacturing gives the pharmaceutical companies larger discretion to grant discounts. For example, if manufacturing costs are 30% of the final price of a product (a frequent percentage) then it pays for the company to grant a discount of up to 60%, rather than to forego the transaction altogether, because it will still be able to profit from the sale. Of course deep discounts are not routinely given; rather, their level depends primarily on the existence of competitors in the market (i.e., "me-too" or generic drugs), and the bargaining clout of the buyer. Discounts are usually higher for larger entities that manage to achieve larger market share, and smaller for independent pharmacies.

In light of the information above, comparing growth in pharmaceutical costs from one sector to another, or even from one payer to the next, is confounded by the complexities of pharmaceutical pricing and purchasing.

#### *Lack of a Standard Price*

As has been described for other countries, pharmaceutical manufacturers often charge different purchasers different prices for the same product. The Congressional Budget Office (CBO) cites the pharmaceutical industry's degree of market power and the existence of groups of purchasers with a varying sensitivity to price as the bases for the price discrimination that exists. The CBO states that, "varying price sensitivity, when combined with patent protection and low production costs, can lead to a wide spectrum of prices for a single pharmaceutical product."<sup>52</sup>

One of the more confounding aspects of pharmaceutical pricing is that there is no single price for an individual product even at a specific time. Although manufacturers establish a list price for each drug, sales often are at a discounted price, and these discounts can

be substantial. The amount of the discount is volume driven, and those purchasers in the best position to deliver on the volume receive the best discount. Therefore, an HMO with a large membership and an effective formulary strategy can win deep discounts from a manufacturer because the physicians prescribing will produce the demand anticipated by the manufacturer in accordance with the formulary stipulations.

Thus, many MCOs are able to negotiate discounts due to the volume they command, and obtain rebates because of the market share they can deliver. HMOs and other managed care organizations are also able to negotiate the deep discounts from manufacturer price lists in part because they are able to influence prescribing decisions by their participating physicians.

Rebates offered by the manufacturer in turn serve to reinforce the HMOs' willingness to enforce physician prescribing behavior in accordance with formulary stipulations. A rebate agreement specifies some monetary amount, usually a percentage of dollar purchases, to be returned to the purchaser (payer) by the product's manufacturer. Manufacturers are generally willing to extend rebates to plans or providers with a large number of members in order to gain access to a particular group of patients, have their product included on the plan's formulary, or to increase sales and market share for their products. The rebate is typically paid quarterly, based on product sales in the previous quarter.<sup>53</sup>

*Benefits of large volume purchasing:* Large volume purchasers, such as hospital groups, Medicaid, retail pharmacy chains, and others, are able to negotiate substantial discounts and rebates from manufacturers as noted above. Manufacturers offer discounts on brand-name drugs based not only on the volume purchases but also on the buyer's ability to affect the drug's market share, generally through using a formulary to systematically favor one brand-name drug over another for a large number of patients by influencing provider prescribing habits. Discounts on brand-name drugs tend to be higher when more generic and "me-too" drugs (a patented drug therapeutically similar to another patented product) are available. The CBO found that the best price discount for a brand-name drug was 10 – 14% greater when a generic version was available from 4 or more manufacturers. As the number of brand-name manufacturers in a therapeutic class increases from 1 to 5, the best price discount grows by 10%.<sup>54</sup>

*Medicaid best price discount:* In 1990, concerned that Medicaid was not receiving the benefit of these

advantages as a large volume purchaser (the Medicaid pharmaceutical market represents about 11% of pharmaceutical retail sales nationwide), Congress mandated rebates and best price discounts for all Medicaid programs. The General Accounting Office (GAO) studied the impact of this mandate for best price discounting and found that as an unintended result it appears that HMOs and hospitals experienced overall price increases for outpatient drugs. The GAO reviewed prices from 8 Group Purchasing Organizations and 4 HMOs on a total of 1,600 unique price observations. In reporting their findings the GAO stated:

"We found that after [the Omnibus Budget Reconciliation Act] OBRA of 1990 the prices for the HMOs' drugs rose, on average, more than twice as fast as the year before. These drugs, which are almost exclusively outpatient drugs, had more large price increases the year after OBRA than the year before. In contrast, prices increased for the GPOs' inpatient drugs, on average, at a lower rate the year after OBRA than the year before. Price increases for the GPOs' outpatient drugs were slightly higher, on average, the year after OBRA."<sup>55</sup>

Currently, government pays for about 25% of prescription drug expenditures. If Medicare expands to include prescription drug benefits government's share of prescription drug expenditures in the country would increase dramatically.

*Differences in discounts:* As already noted, although manufacturers establish a list price for each drug many sales are made by discounting that price, and these discounts can be substantial. The CBO has estimated that based on average invoice prices for top selling drugs sold primarily to retail pharmacies, hospitals and clinics pay 9% less than retail pharmacies, and HMOs pay 18% less. Veterans Administration hospitals get an even more substantial discount – over 40% on average compared to the retail pharmacy. These comparisons are based only on invoice prices, so they do not account for rebates and other types of discounts that do not appear on the invoice. In another survey of prices in Los Angeles, the average price charged for a selection of well-known products sold to hospitals was only 19 percent of that charged to a local pharmacy."<sup>56</sup>

### *Pricing of Brand-Name Versus Generic Drugs*

The demand for brand-name drugs versus generics is an important factor in efforts to control drug spending. The Congressional Budget Office estimates that in 1994 purchasers saved a total of \$8 billion to \$10 billion on prescriptions at retail pharmacies by substituting generic drugs for brand name counterparts.<sup>57</sup> PhRMA has reported that generic drugs are accounting for an increasing percentage of prescriptions, taking business away from brand-name pharmaceutical companies. It estimates that 44% of prescriptions were filled with generic drugs in 1997, up from 27% in 1996.<sup>58</sup>

In the Medicaid program, regulations encourage States to promote lower-cost generic drugs through reimbursement limits on 100 – 200 drugs that have generic substitutions. These regulations limit the state expenses that are eligible for federal reimbursement to 150 percent of the lowest published generic price plus a reasonable dispensing fee. However, the lower federal reimbursement rate does not apply if the physician stipulates that the brand-named drug is needed for medically necessary reasons. CBO estimates that 52% of Medicaid prescriptions dispensed nationally in 1993 were for a generic drug. However those drugs only accounted for 22% of the dollar value of reimbursements for outpatient drugs that year, because of the significant difference between generic drug prices and those of brand-name products.<sup>59</sup>

Most states have legislation authorizing pharmacists to substitute a generic compound for a brand-name drug. State laws differ in the amount of discretion granted to the pharmacist. In Massachusetts a pharmacist must substitute a therapeutically equivalent generic product unless the physician specifically indicates that only the brand-name product is to be issued.

### *Uninsured Pay More*

Managed care organizations often pass on the price advantage they are able to obtain through large volume purchasing to enrollees in terms of smaller out-of-pocket expenses or by not fully reflecting pharmaceutical costs in premium charges. The uninsured and the underinsured (those with coverage that does not include pharmaceuticals or entails high deductibles and co-payments for them) do not realize the same advantages of discounts and rebates in the price they pay at the retail pharmacy. These individuals often pay the highest price for their medications because the discounts that retail pharmacies are able to

negotiate as a result of volume purchasers may not be as substantial as those negotiated by MCOs for members of their groups. The prices are also highest because the retail pharmacist cannot control prescribing patterns for physicians treating these patients through formularies, and therefore cannot negotiate the same price advantages as the MCO by affecting market share.

Notwithstanding the retail pharmacists' ability to substitute a therapeutically equivalent generic drug for a brand-name product in most states, retail pharmacists have not been able to negotiate discounts that are as favorable as those achieved in other sectors (9% less in hospitals and clinics, and 18% less in HMOs). In addition, depending on the competition they face, retail pharmacies may have differing incentives to return rebates they receive to customers through lower prices.

The difference in discounts, coupled with the percentage of rebates returned to the customer through lower prices, often result in the most vulnerable individuals paying the highest prices.

*Loss of pharmacy access in the community:* In addition to questions of higher prices paid by the uninsured for medications, their access may also be affected by other changes occurring as a result of competition for pharmaceutical market share. Managed care strategies to contain pharmaceutical costs are impacting access to pharmacies in the community. Network development of pharmacy services by MCOs as well as their increased utilization of mail order pharmacy services has shifted consumer pharmaceutical purchasing patterns and the loss of pharmacy access in some communities is a concern.

#### Section IV: Implications of Increase in Drug Costs and Spending

The double-digit increases in spending for pharmaceuticals are challenging the efforts in the health care industry over the past decade to bring costs under control. As the costs for prescription drugs continue to rise unchecked, efforts are escalating within HMOs, other MCO entities, and other purchasers to find ways to curb the increase in spending for prescription drugs. At the same time, as costs continue to increase, access to pharmaceuticals becomes more difficult for those who are poor, uninsured or whose coverage does not include a prescription drug benefit.

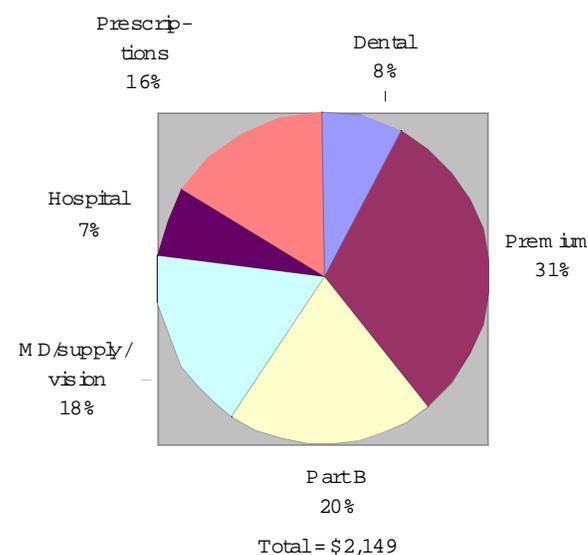
*The impact on the elderly:* The elderly are disproportionately affected by increasing costs of outpatient

prescription drugs, as are other Medicare beneficiaries, i.e., the disabled and patients with end-stage renal disease.

Nationally, estimates range that from thirty-five to forty-five percent of Medicare beneficiaries do not have supplemental coverage for outpatient drug benefits.

Overall, Medicare beneficiaries 65 and over living in the community were projected to spend \$2,149, or on average 19% of their income, on out-of-pocket health care costs in 1997 (based on the Medicare Current Beneficiary Survey, 1995). Of this out-of-pocket spending, almost half was projected to be spent on direct payment for health services, including 16% that was projected to be spent on prescription drugs (Figure 4).<sup>60</sup>

**Figure 4: Average Out-of-Pocket Health Care Costs for Medicare Beneficiaries, 1997**

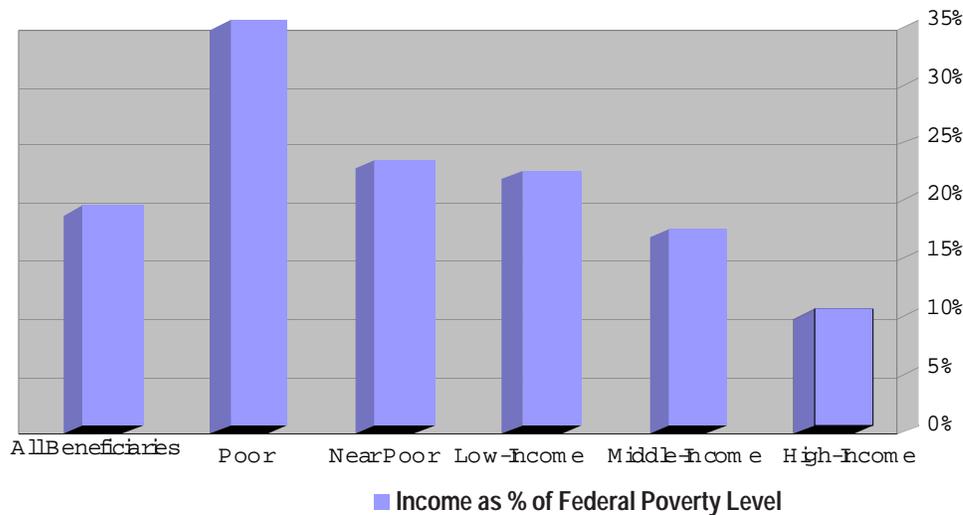


Source: Adapted from AARP Public Policy Institute/The Lewin Group

Out-of-pocket health care spending constitutes a substantial percentage of income for the poorest beneficiaries (35% for those below poverty, and 50% for those below poverty and not receiving Medicaid), while it represents a lower percentage of income for middle- and high-income beneficiaries (10% for those above 400% of poverty).<sup>61</sup>

In 1992, the average annual expenditure for prescription drugs was \$549 per Medicare beneficiary (for

**Figure 5: Average Out-of-Pocket Health Care Costs for Medicare Beneficiaries As Percent of Income, by Income Status, 1997**



Source: Adapted from AARP Public Policy Institute/The Lewin Group

non-institutionalized enrollees), over half of which was paid out of pocket.<sup>62</sup>

An estimate of the percent of Medicare beneficiaries using prescription drugs and the average prescriptions per person shows 86% of Medicare beneficiaries living in the community used at least one prescription drug during 1995. The survey showed that the average beneficiary used 18.5 prescriptions in 1995. Beneficiaries with drug coverage averaged 20.3 prescriptions per year, while those with no drug coverage averaged 15.3 prescriptions per year.<sup>63</sup>

*Impact on the number of uninsured:* The increase in pharmaceutical costs is also being implicated in the increase in the number of uninsured. A portion of the increase in the uninsured is being attributed to the number of workers who decline employer-sponsored insurance coverage. Employers who offer insurance are asking workers to pay an increasingly greater percentage of the premium costs, up to 22% in 1996 from 13% in 1988. As a result, one in four workers offered employer-subsidized insurance in 1997 declined coverage, while only 1 in 10 declined in 1987. Here too evidence is pointing to the impact that rising pharmaceutical costs, along with the rising cost of hospital stays and visits to the doctor, is having on this decline in coverage, as these cost increases push up premiums.<sup>64</sup>

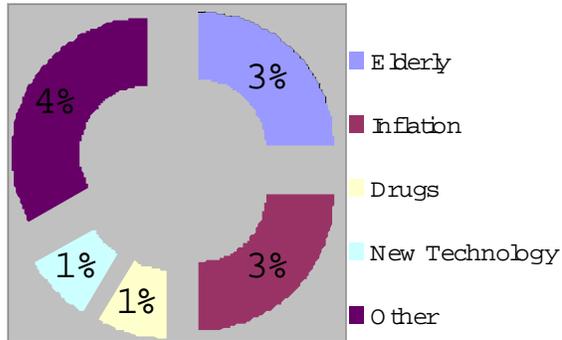
*Impact on HMOs:* HMOs are feeling pharmaceutical cost increase pressures too. In 1993 HMO spending

on pharmaceuticals in Massachusetts represented 7% of total medical care spending while hospital expenses were 24%. Between 1992 and 1993 HMO spending on pharmacy services in Massachusetts grew by 7.7% (compared to an increase of 6.5% in overall medical spending).<sup>65</sup> A year ago, Harvard Pilgrim Health Care projected that by 2002 drugs will make up 22% of an average patient's total medical costs while hospital expenses will be 20.8%.<sup>66</sup> These percentages are also affected by shortening average lengths of hospital stays. Tufts Health Plan reported a \$12.8 million net loss for 1998 and attributed a portion of the loss to higher-than-expected prescription drug costs.<sup>67</sup>

Managed care premiums are expected to reflect pharmaceutical cost increases beginning in 1999. While premium increases were held to single digits between 1994 and 1998, increases of 10 – 12% are projected for managed care coverage in 1999. Allocation of the increases have been attributed to a 3% increase in inflation, a 3% increase in the cost of medical care for the elderly, and a 1% increase each for drugs and new technology.<sup>68</sup>

*Impact on Massachusetts Medicaid:* Massachusetts Medicaid's pharmacy budget has been growing 15 to 20% a year for the past three years. At that rate of growth the Division predicts that by 2003 the drug budget would overtake acute hospital service expenditures.<sup>69</sup>

**Figure 6: Allocation of Basis for Project Premium Increases**



Source: Adapted from B. Mehl and J.P.Santell, 1999

*Impact on hospitals:* Group purchasing organizations predict price increases in 1999 of 3% for contracted drugs, 5% for non-contracted drugs, and 8% for current and newly marketed drug products.<sup>70</sup>

#### *Does Decreased Access to Pharmaceuticals Result in Greater Costs Elsewhere in the Health System?*

While drug expenditures increased by around 12% annually between 1994 and 1997, annual increases in drug prices were only 1 to 2%. Thus, it appears that the increase in expenditures is due to an increased utilization of drugs as well as the high cost of new drugs entering the market. Substitution of drugs for other health services has been cited as a cost-shifting phenomenon that needs to be considered when assessing the impact of increased expenditures for pharmaceuticals.

As noted by the editor of *Inquiry*, "many pharmaceuticals permit people to avoid expensive modes of treatment, including surgery, inpatient hospital care, and prolonged inpatient psychiatric stays."<sup>71</sup>

While most Medicaid programs have data to show the effectiveness of medications, much of it is contained in paid claims data. Because of the sophistication needed to conclusively show the effectiveness of pharmaceuticals, particularly as a substitution for other services, the information is not readily available to address the full range of questions about this cost-shift. More research and evaluation on this issue is needed.<sup>72</sup>

In a recent article in the *New England Journal of Medicine*, Soumerai and Ross-Degnan cite multiple examples of cost savings through the use of drugs. One such example is the detrimental effect of the Medicaid

drug payment cap in New Hampshire, where chronically ill patients were twice as likely to be admitted to a much more expensive nursing home as a result of the decrease in their access to pharmaceuticals. The increased cost for the state continued even after drug access was restored. Also, there was a 17-fold increase in New Hampshire state-costs for emergency mental health care after the state implemented a policy reducing use of psychotropic drugs among patients with schizophrenia. A similar effect from the reduction in coverage in the Georgia Medicaid program has also been cited.<sup>73</sup>

As noted by Swartz in *Inquiry*,<sup>74</sup> a large proportion of new pharmaceuticals improve the quality of life rather than substitute for more expensive treatment. In these instances, the pharmaceuticals may relieve symptoms and prevent large future medical expenditures or enable people to work without debilitating illness. Examples include:

- Cholesterol-lowering drugs that reduce cardiac disease
- Anti-inflammatories to aid people with arthritis and eczema
- Hormone-replacement therapies
- Pain relievers for back ailments
- Antidepressants

These drugs are contrasted with a third type — "life-style" drugs — that, apart from substituting for other services, treat medical conditions that are not life-threatening (e.g., impotence or baldness). Often, these drugs are very expensive and raise the question of who should pay — the individual consumer or the health insurance plan.

## **Section V: MCO Strategies to Manage Pharmaceutical Spending**

MCOs are the largest source of reimbursement for prescription drugs in the nation, accounting for \$24.8 billion of the \$48 billion reimbursed from all sources in 1997 and the rising cost of pharmaceuticals has been cited as a cause of their diminishing profits.<sup>75</sup>

To improve their ability to manage pharmaceutical utilization and control costs, MCOs have instituted several actions, as shown in the examples outlined below.

### *Influencing Physician Prescribing Behaviors*

Strategies to influence physician prescribing behavior have been instituted. These strategies include the following.

*Formularies:* Formularies are frequently used by managed care plans to reduce pharmaceutical costs by restricting drug utilization to products that are viewed as cost-effective. Most MCOs use formularies, and 39.1% are reported to use a closed formulary.<sup>76</sup>

*Delay in listing new drugs on formularies:* An important factor incorporated into industry marketing strategies for product promotion is timing. Physicians and other health professionals generally decide to use a new product soon after it has been introduced. Accordingly pharmaceutical companies have a strong incentive to promote their products heavily at that time. As managed care companies seek ways to challenge the primacy of the drug industry in influencing the prescribing patterns of physicians, some managed care companies are considering a time delay in listing new drugs on their formulary. Under this scenario, the MCO would institute a policy that would delay the listing of a new drug on its formulary for a period of 4 to 6 months after the drug's initial release. This delay is intended to interrupt the pattern of prescribing that is established as the new drug is promoted heavily during its initial launch by the drug companies, because it is more difficult to break a prescribing pattern than it is to establish one.

*Physician drug budgets:* Some MCOs are providing physicians with budgets for drug expenses and rewarding those who stay within their budgets. Even though this strategy has raised criticism among consumer advocates who suggest that this has the effect of limiting the prescription of needed medications, it is being increasingly looked to by MCOs. The number of physicians in drug risk pools is reported to have increased from 22% in 1995 to an estimated 46% in 1998.<sup>77</sup>

*Prior approval:* Another technique used by MCOs to influence provider prescribing is to require prior approval for certain drugs. Prior approval techniques are frequently used for drugs that are very expensive if there is a less costly therapeutic equivalent drug available, though there may also be other reasons why justification of a drug as medically necessary is required.<sup>78</sup> Several state Medicaid agencies are also

utilizing prior approval strategies to manage their pharmacy budgets.<sup>79</sup>

*Counter detailing:* Courting physician prescribing patterns has long been a key focus of the pharmaceutical industry's marketing strategy. In the late 1960's, questions were raised that are still relevant about the adequacy of physician training in the clinical application of drugs, as well as the skills needed to differentiate between large numbers of competitive and duplicative products. At that time, it was noted that physicians face certain challenges in dealing with advice, both biased and unbiased, on pharmaceuticals from industry detail men and women, advertisements, and other forms of promotional information. Other concerns include the lack of adequate sources of objective, up-to-date information in useful form on both drug properties and drug costs.

Many pharmaceutical products are introduced after most physicians in practice complete their training and they must learn about advances and new products outside of their formal educational experience. Given this need, the medical care system by default has relegated responsibility for physician post-graduate pharmaceutical education to promotional activities and materials developed and distributed by drug manufacturers.<sup>80</sup> While the FDA regulates the content of printed drug promotional materials, the content of face-to-face detailer to physician interactions are not monitored and have been termed an almost unregulated activity.<sup>81</sup>

With the advent of managed care, other forces are interceding to advance competitive sources of information and education. Innovative efforts are being developed by MCOs and other organized provider groups to counter the drug industry's intensive detailing and advertising activities. Among these is a "counter-detailing" strategy, as employed by Tufts Health Plan. Under this initiative, Tufts sent out pharmacists to visit Tufts Health Plan physicians and administer "anti-dotes" to the marketing messages of drug companies. Anti-dotes may include information that encourages doctors to use generics, for example.<sup>82</sup>

*Future approaches:* The question remains open as to whether a more structured, efficient approach to communicating information on new pharmaceuticals is possible. As pharmaceuticals now in the Research and Development pipeline are launched, the issue will become of even greater concern. As biotechnology advances its sophistication in genetically targeting specific sites, the need for increased physician knowledge

and discretion about competing drug therapies will be essential.

*Massachusetts Medical Society and the Health Plan Common Formulary:* Five health plans (Blue Cross/Blue Shield, Harvard/Pilgrim, Tufts, Neighborhood Health Plan, Fallon) participated in a collaborative effort to develop a pocket-size formulary of commonly prescribed outpatient drugs.

The guide is intended to assist physicians by compiling a list of the participating health plans' commonly prescribed outpatient formulary drugs in a readily accessible pocket size format. While it does not reflect the comprehensive formularies of the participating health plans, it does provide a convenient listing of the outpatient formulary drugs commonly prescribed. Because formulary information changes frequently, the common formulary will be up-dated on a periodic basis. In describing their effort, a Massachusetts Medical Society staff member stressed that the information in the guide has been provided by and at the sole discretion of each individual health plan.<sup>83</sup>

#### *Strategies to Influence Consumer Awareness of Drug Costs*

Other strategies being used by MCOs to manage pharmaceuticals focus on influencing consumer awareness of drug costs. Strategies include increasing co-payments, co-pay differentials for brand-name or generics, and directing patients to specific pharmacies and mail-order discount programs.

*Generic versus brand-names:* In 1991, 70% of HMOs mandated use of generics.<sup>84</sup> Approximately 40% of prescriptions filled by MCO enrollees were filled with generic compounds. With the average cost of a generic drug estimated from 40 to 70% less than the equivalent branded product, there is a large incentive for the MCO to encourage use of generics.<sup>85</sup> The complexity of assuring that the generic drug is prescribed by the physician and then filled by the pharmacist is the subject of considerable attention by the more aggressively managed health plans. Policies that require members to pay the difference between generic drugs and brand-name products when the brand-name is requested by either the physician or member over a generic equivalent are important components to managing the pharmaceutical benefit.

*Partial payment strategies for managing pharmaceuticals costs:* Prescription benefits with a requirement that the beneficiary pay a portion of the cost of the med-

ication are becoming more popular. Variations in the amount are a significant factor in enabling the payer to manage the drug cost. Co-payments and deductibles are the primary partial payment mechanisms in use.

- **Co-payment:** The beneficiary pays a co-payment at the point of service, with the cost typically varying from \$3 to \$20 per prescription. The amount of the co-payment may be differentiated by whether a brand-name or a generic product is prescribed. Charging a higher amount of co-payment for a brand-name product, which is more expensive, when a therapeutically equivalent generic is available, is intended to encourage the beneficiary to request a generic or agree to the pharmacist's suggestion that a generic be substituted for the prescribed brand-name product. Differentials in co-payment may also be used to encourage beneficiary utilization of a formulary versus a non-formulary product.<sup>86</sup>

A recent report in *Health Affairs* on drug spending looked at the use of co-pays on drug use and found that higher patient drug co-payments were associated with significantly lower drug spending in IPA plans but had no effect in network plans.<sup>87</sup>

The *Boston Globe* recently reported that Tufts Health Plan "will double its co-payments to \$25 to \$35 for certain top-shelf, brand-name drugs. Other leading health maintenance organizations in Massachusetts are expected to follow suit."<sup>88</sup>

- **Deductibles:** Primarily used by indemnity and self-insured employer groups, deductibles are also gaining popularity with HMOs as on-line point of service claims processing makes calculation and notification of up-to-date deductible amounts possible. Under the deductible scheme, beneficiaries are responsible for the first dollar amount of the pharmaceutical benefit, after which the insurer pays the rest. Typically, deductibles are supposed to be approximately 25 to 35% of the annual drug cost. However, because the percentages are calculated prospectively they usually are under-estimated, especially when drug costs increase dramatically.<sup>89</sup>

## Section VI: Initiatives for the Uninsured

Obtaining medications if one is uninsured or underinsured can be financially prohibitive, depending on the individual's income and other related factors. Throughout the country there are numerous efforts underway in local communities and by providers serving the uninsured and underinsured to help them access medications. The following is a brief outline of some of the ways that the uninsured and underinsured access or manage their medications.

*Drug Samples:* As noted earlier, a large part of the marketing strategies employed by pharmaceutical companies involve detailers visiting physicians. There is a beneficial by-product of the detailing activity for the uninsured. Often detailers provide samples of medications to physicians as part of the detailing visit. Detailers frequently will stock and replenish medication supply cabinets maintained by physicians in their offices, or in hospital and free-standing clinics. The sample strategy is intended to influence physician prescribing patterns through easy access to products (generally those newly released). These samples are often important sources of medications for the uninsured. Samples are often dispensed directly by a prescribing physician to an uninsured patient, when the physician is aware of a patient's lack of coverage. As well, organized efforts have been initiated within communities throughout the country to gather samples and utilize them as part of an initiative to provide medical services to the uninsured.

However, there may be an unfortunate down-side to the use of samples for the uninsured. The samples that are provided are usually for newly introduced products. Therefore, if the physician provides samples in conjunction with a prescription for the same product, the patient may have to pay high costs at the pharmacy when filling the prescription. This is because samples are usually available for a newly introduced brand-name product that the manufacturer is trying to get the physician to use, and are likely to be more costly than others already on the market.

*Pharmaceutical Patient Assistance Programs:* Approximately 70 pharmaceutical companies offer patient assistance programs. Under these initiatives a physician may request free medications for a specific patient who qualifies under a pharmaceutical company's eligibility criteria for specific medications.

The process to apply for medication assistance is generally cumbersome and labor intensive. In most

cases, physicians are required to fill out an application and submit it to the manufacturer. Each company has a specific list of medications available under their patient assistance programming (not all of the company's products are available). In addition, each company has their own application form, eligibility criteria and processing requirements. Review of an application can take several weeks, and if the application is approved the medication will be sent to the physician's office. Generally a three-month's supply of the medication is made available. If the medication is to be continued, the physician must reapply on the patient's behalf. Physicians and clinics that serve large numbers of uninsured have devised sophisticated systems to maintain a pipeline of medication supply through patient assistance programs for their uninsured patients.

*Medication Cost Management Strategies:* Patients who are uninsured or underinsured for their medications utilize a range of techniques to manage their medication costs. The other costs to the health care system that may result from treatment requirements and hospitalizations due to non-compliance with medication regimens present another serious challenge. A recent survey by the Kaiser Family Foundation and the Commonwealth Fund found that 24 percent of the uninsured declined to fill a prescription that had been given to them by a doctor in a given year, compared to 6% of those who had insurance.<sup>90</sup>

*City of Boston to Assist Elderly and Disabled with Prescription Drug Costs and Access:* Boston Mayor Thomas Menino has instituted an initiative entitled the "Mayor's Drug Care" to be issued to city residents below 400% of poverty. The initiative will enable the city to partner with 40 independent pharmacies that will honor the cards. Cardholders will be able to obtain discounts for their prescriptions, as well as assistance with transportation to participating pharmacies.

*Worcester Health Outreach:* Worcester Health Outreach assists uninsured patients obtain primary and specialty care. As part of that effort, free prescription drugs are provided to low income uninsured patients through a formulary arrangement and through a medication fund.

## Section VII: Senior Pharmacy Programs

Fourteen states, including Massachusetts, provide some drug benefits for poor elderly and disabled persons who do not qualify for Medicaid. Eligibility for these programs and their scope of coverage vary widely.

Co-payments range from \$3 per prescription to 40% of drug costs. Pennsylvania and New York both have two-tiered programs, which are described below.

*Massachusetts Senior Pharmacy Program*

Individuals are eligible for the Massachusetts Senior Pharmacy Program if they are residents, age 65 or older, and have lived in the state for 6 months. To be eligible they must not have any other prescription drug insurance coverage, must not be eligible for MassHealth, and must have a gross annual income of 150% or less of the federal poverty level (FPL). Participants are eligible for \$750 in benefits, \$15 of which is deducted upon enrollment as an enrollment fee. There are co-payments for prescriptions and certain medical supplies: \$3 for generic drugs and \$10 for brand name drugs.

As of mid-February, 1998 over 20,000 seniors were enrolled. The Senior Pharmacy Program has an operating budget of \$30 million, funded by revenues derived from the Children’s and Seniors’ Health Care Assistance Fund and the 25-cent tobacco tax increase enacted in 1996.

Several bills are now pending in the state legislature to restructure the Massachusetts Senior Pharmacy Program. Most of the bills raise income eligibility for the Senior Pharmacy Program to 200% of FPL (\$16,500). As well, some of the bills remove provisions currently in place that disqualify participation in the Senior Pharmacy Program for those with other insurance coverage that provides some pharmacy benefit. Removal of this restriction is intended to make the Senior Pharmacy Program the payer of last resort, available to those who are income eligible after they have exhausted their other pharmacy benefits. Other provisions of pending bills include raising the cap from \$750 to \$1,500. A catastrophic coverage program has also been proposed that would raise eligibility to 400% of FPL for individuals after they have spent over \$8,000 on medications. Further, there is a proposal to include the disabled by expanding eligibility for the Senior Pharmacy Program to all otherwise eligible Medicare enrollees.

The following are highlights from two other states’ pharmaceutical assistance programs, Pennsylvania’s PACE and PACENET program, and New York’s EPIC program, both of which are structured differently than the Massachusetts program.

*Pennsylvania’s PACE and PACENET Programs<sup>91</sup>*

Pennsylvania’s Pharmaceutical Assistance Contract for the Elderly (PACE) program is a two tiered initiative, with different income eligibility requirements for each tier. Both tiers receive the same level of benefits. The first tier, the PACE program, is for lower income individuals and requires co-payments and does not have a deductible. The second tier – PACENET -- is for a higher income bracket, and requires a deductible of \$500 and higher co-payments.

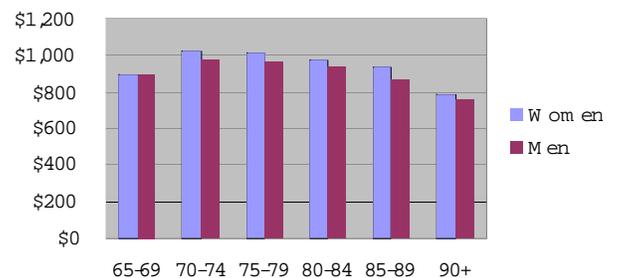
To be eligible for PACE, as of November 21, 1996, the combined income for married applicants must not exceed \$17,200, and the annual income for single applicants must not exceed \$14,000 during the calendar year prior to application. Income eligibility for PACENET ranges from \$17,200 to \$19,200 for married couples and \$14,000 to \$16,000 for single individuals. Co-payments for PACE are \$6 per prescription. Co-payments for PACENET are \$8 for generics and \$15 for brand name medications.

At the end of 1997, the fourteenth year of the PACE program, there were 250,671 PACE cardholders enrolled in the program. This number is significantly less than the number of enrollments at the height of enrollment in 1988, the fourth year of the program, when enrollments totaled 477,772.

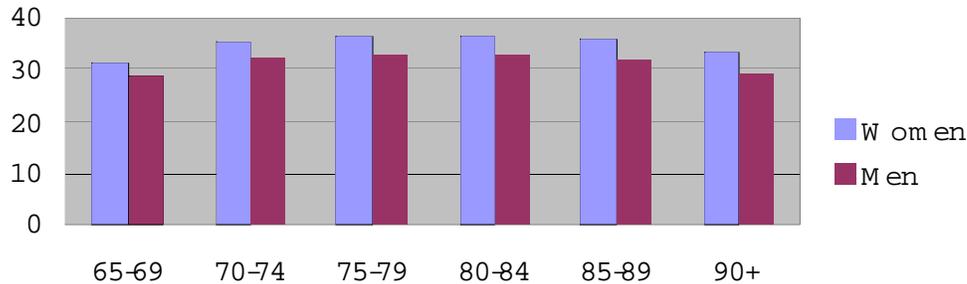
As an indication of how increasing pharmaceutical costs are effecting the PACE program, an analysis of PACE expenditures for 1991 through 1997 shows that *despite declining enrollments* (a 31% decrease during this time) and a 17% *decrease in claims*, total expenditures *increased* about 6%, to \$123,482,056.

The following is a summary of PACE expenditures in 1997 by age and sex.

**Figure 7: Expenditures Per Participating PACE Cardholder by Sex and Age, 1997**



**Figure 8: Number of Claims Per Participating PACE Cardholder by Age and Sex, 1997**



PACE expenditures per participating PACE cardholder in 1997 ranged from \$903 to \$1,023 by age group for women 65 – 89 years of age, and from \$864 to \$973 by age group for men 65 – 89 years. For those over 90, the expenditures decrease, with expenditures for women at \$791 and men at \$761. The number of claims for participating PACE cardholders during that time ranged from 33.1 to 36.2 by age group for women, and from 28.4 to 32.8 by age group for men.

#### *New York's EPIC Initiative*

New York enacted its Elderly Pharmaceutical Insurance Coverage (EPIC) in 1987 to help low and moderate income senior citizens purchase prescription drugs. New York residents are eligible if they are over 65 and have incomes below \$18,000 if they are single, and \$23,700 if they are married. EPIC is the payer of last resort for seniors with other prescription coverage, a modification enacted in 1996.

The EPIC program provides two different types of coverage – comprehensive coverage for those with lower incomes, and catastrophic coverage for seniors with more moderate incomes who have higher medication costs.

For comprehensive coverage, eligible seniors pay a small annual fee (ranging from \$20 to \$76). Enrollees then pay a co-payment (ranging from \$3 to \$23) at the pharmacy for each prescription they purchase. Once participants spend a specified amount on co-payments, all medications they purchase for the remainder of their coverage year are provided at no charge.

For catastrophic coverage, seniors who join pay either a substantially higher premium or meet a deductible.

- Seniors enrolled in the Premium Plan, receive the same benefits as those who have Comprehensive coverage. However, the annual fee ranges from \$302 to \$414.
- Seniors in the Deductible Plan join without paying an annual fee. Instead, they are required to meet an annual deductible ranging from \$468 to \$638. Once the deductible is met, these enrollees pay only the co-payment amount (\$3 to \$23) for the remainder of the coverage year.

In response to declining enrollment, New York State passed legislation in April 1998 to improve EPIC, reducing the fees some seniors pay for coverage, and eliminating the large differential in premiums between comprehensive and catastrophic.

During FY97, 107,767 seniors used EPIC to purchase 3.4 million prescriptions, costing almost \$142.2 million.

Enrollment in the EPIC program has also been declining, with enrollment decreasing by more than 5% from the previous year. Despite a 3% cost-of-living increase to income limits in January 1996 and enhanced outreach efforts, fewer seniors joined and more cancelled their coverage.

During FY97 the average EPIC participant purchased 37 prescriptions, costing \$1,572. EPIC's enrollees are reported to be older and frailer than other groups of seniors. They are also characterized as using more prescriptions, with most participants using more than four medications simultaneously.

While EPIC participants all have drug utilization rates well above the general elderly population, there is a subgroup of enrollees with especially high drug costs.

For FY97, slightly more than 20 per cent of the 107,767 seniors who used the program had annual drug costs of more than \$2,000. These 22,370 seniors purchased 1.4 million prescriptions, accounting for 41 percent of the prescriptions purchased and 56 percent of program pay-

ments. These seniors suffer from catastrophic illnesses such as kidney disease and cardiac failure.

The following is a summary of the characteristics of some of the state-sponsored pharmacy programs.

**Table 1: Characteristics of State Pharmacy-Assistance Programs for Elderly and Disabled Persons** <sup>93</sup>

Characteristic	Pennsylvania 1984	Pennsylvania 1986	New York 1987	Massachusetts 1995
Year	1984	1986	1987	1995
Eligibility				
Age				
Elderly	>65	>65	>65	>65**
Disabled	NA	NA	NA	
Income				
Single	<\$14,000	<\$16,000	<\$18,500	<\$12,804
Married	<\$17,200	<\$19,200	<\$24,000	NA
Discount	Other	Other	Medicaid	Medicaid
Co-pay	\$6	\$8 generic \$15 brand	\$3 to \$23 Percost	\$3 generic \$10 brand
Deductible	None	500	None	\$15/fee
Cap	None	None	None	\$750
Drugs Covered	Most Drugs	Most Drugs	Most Drugs	Most MA Formulary
Source of Funding	Lottery	Lottery	General Fund	Tobacco Tax; Health Care Assistance Fund
Enrollment	260,000	12,889	94,800	24,000
Program Cost				
Per Participant	\$855.35	NA	\$582.00	
Per Year	\$222.39mil	NA	\$55.17mil	\$30mil*

\*\$30 million is available annually, but spending is less, projected at \$15,537,094 for FY99 <sup>94</sup>

## Section VIII: Role for the State

Government intervention in the pharmaceutical industry in the United States is primarily focused on assuring the safety and efficacy of medications through the authority of the FDA. Congress, through legislating patent protections and tax credits, has created incentives for the industry to aggressively invest in research and development activities that are resulting in a host of new drugs being introduced each year, while doing nothing to limit prices.

As concern with the impact of increasing drug costs is being felt nationwide, and particularly by the elderly, states are seeking to determine what if any efforts they can take to control cost increases.

The following is a summary of some possible options for Massachusetts.

### Option I: Restructure the Senior Pharmacy Program

The Massachusetts Senior Pharmacy Program (SPP), as described above, provides pharmaceutical assistance to eligible residents over age 65.

Interest in restructuring the SPP has been heightened with the preemption by the Balanced Budget Act of 1997 of the Massachusetts law mandating pharmaceutical coverage as a provision of Massachusetts HMO Medicare coverage. The following components of a restructured program are currently under review in several bills now pending in the Massachusetts Legislature.

#### *Restructuring Options*

*Expand eligibility:* Income eligibility for the Massachusetts SPP is <150% of the Federal Poverty Level (FPL), or \$12,084. This is low in comparison to other states. (See Table 1 for other state income limits.) Most proposals for restructuring the Massachusetts program recommend increasing eligibility to 200% of poverty. There is also at least one proposal to include the disabled by expanding the SPP to include all Medicare enrollees.

*Raise the cap:* In 1992 the average annual expenditure for prescription drugs nationally was \$549 per non-institutionalized Medicare beneficiary. While expenditure experience information is not yet available for the Massachusetts SPP, similar programs in other states have generated data that may help inform policymakers considering the current \$750 cap in the

Massachusetts SPP. One legislative proposal would raise the current cap to \$1500. (See previous section for information on the Pennsylvania and New York experience.)

Neither New York nor Pennsylvania cap their senior pharmacy programs.

*Eliminate the restriction for those with other drug coverage benefits:* Under current legislation, individuals who would otherwise meet the eligibility requirements for the Massachusetts Senior Pharmacy Program are precluded from enrolling in the SSP if they have coverage for drug benefits, such as those seniors enrolled in HMOs. This past year, after the elimination of the mandate for an unlimited prescription drug benefit by HMOs, the HMOs changed their policies so that all plans would include some drug coverage. All plans have caps on benefits, which, with one exception, are equal to or lower than the SPP. The SPP was created in an era of uncapped benefits; since HMO drug coverage is no longer full, having access to some portion of a benefit is not enough. It is expected that the HMOs will curtail the quarterly drug benefit and increase co-payments over time, and seniors will be faced with increasingly greater out of pocket expenditures for their medications. Eliminating the restriction on other coverage for eligibility would permit the Massachusetts program to become a payer of last resort for seniors, after they have exhausted their other pharmaceutical benefits.

*Create a two-tiered program:* Several states, including Pennsylvania and New York have created a two-tiered program for senior pharmaceutical benefits. In addition to providing coverage to the lowest income, a second tier was developed that provided coverage for a higher income group, with a deductible and higher co-payments.

In Pennsylvania the PACENET program serves a higher income range than the PACE program, and requires a \$500 deductible, as well as higher co-payments.

In New York, EPIC's Catastrophic program, offers either a premium or deductible for moderate-income eligible participants, as well as co-payments that are higher than those for low-income enrollees in the Comprehensive program.

Other approaches to creating a second tier for those at higher income could include gradually lowering the cap as income increases. Under this scenario,

there would be a cap of \$1,200 for those with income below \$12,000. The cap would decrease by \$100 for each additional \$1,000 of income, ending at \$700 for those with income between \$16,000 and \$17,000. This approach assumes that an individual can pay \$100 out of pocket, or 10%, of each additional \$1,000 for income for drugs.

*Mandate participation in SPP of all pharmaceutical companies participating in Massachusetts Medicaid:* When the SPP was established, the DMA asked pharmaceutical companies to extend their rebate policies to SPP. Many companies agreed, but some refused to participate and consequently there are some medications that are not covered under the program. A state mandate requiring pharmaceutical companies participating in Medicaid to extend the same rebates to the SPP program would eliminate this obstacle to their medications for eligible seniors.

## Option II: Create a Pharmaceutical Insurance Program for all Massachusetts Medicare Enrollees

The changes in HMO drug coverage policies are escalating the crisis in the affordability of pharmaceuticals for seniors. Leading authorities on health insurance in the state indicate serious doubt that HMOs will continue to provide prescription drug coverage for seniors in the long term.

As HMO coverage disappears, and premiums for supplemental insurance with drug coverage become unaffordable for most seniors, there will be an increas-

ing demand on the Senior Pharmacy Program for those within income guidelines. Those above the income guidelines are vulnerable too, as medication costs continue to rise and certain conditions require exceedingly costly medications, jeopardizing the stability of middle class senior citizens living on fixed resources.

To address this concern, Massachusetts should consider developing a Pharmacy Insurance Program for seniors and Medicare beneficiaries. The fact that the private sector has proved unwilling to provide such insurance schemes indicates the need for some state subsidies; their exact magnitude and the overall sustainability of the program will vary considerably, depending on the way the program is structured.

The National Academy of Social Insurance reports that adding a drug benefit to Medicare would add between 7% and 13% per year to Medicare costs. The construction of the design, and cost and administration of such a benefit raise difficult public policy questions. Among these is who should bear the costs of a drug benefit and whether subsidies should be provided to help lower income beneficiaries pay costs borne by participants. Also to be considered is the question of how to address the issue of adverse selection and how to encourage lower-cost individuals to enter the risk pool, thus lowering the costs for all beneficiaries. The National Academy's *Medicare Brief* includes a presentation of findings from a commissioned report by the Actuarial Research Corporation showing the costs of five illustrative drug benefit options. Presented below is the summary table from that report.<sup>95</sup>

**Table 2: Estimated Cost of Five Illustrative Medicare Drug Benefits, 1999**

Benefit	Cost Per Beneficiary	Percent Increase in Medicare Costs
\$200 deductible, 20% coinsurance, \$2000 maximum benefit	\$610	10.0%
\$200 deductible, 50% coinsurance, \$2000 stop loss	\$463	7.6%
\$200 deductible, 50% coinsurance, \$3000 stop loss	\$443	7.2%
\$500 deductible, 20% coinsurance, \$2000 stop loss	\$530	8.7%
\$200 deductible, 50% coinsurance, \$1000 stop loss	\$552	9.0%

Source: National Academy of Social Insurance, 1999. Estimates by Actuarial Research Corporation, based on data from 1995 Medicare Current Beneficiary Survey

Following are some possible approaches for a state Pharmacy Insurance Program for seniors and Medicare enrollees:

#### *Annually Renewable Coverage*

Under this approach enrollees would pay a premium, plus a deductible, with the insurance carrier picking up their pharmaceutical costs after they have met a deductible. The policy would be renewable each year.

The key consideration to the viability of this type of program is whether it is offered to the state's senior citizens on a voluntary or mandatory basis.

A voluntary program raises considerable concern with its long-term viability, a factor that has precluded private insurance companies from offering such policies. Drug expenditures are highly predictable in the short run. Thus, the main concern with a voluntary annually renewable program is that an elderly individual, once diagnosed with a chronic condition such as diabetes, arthritis, heart disease etc., and prescribed medications to manage it, can generally be expected to take the medications continuously during the remainder of their lifetime. At such a point participation in the program would be appealing.

Therefore, an annually renewable policy runs the significant risk of being appealing only to those seniors who spend more than the sum of the premium and the deductible each year. These are money-losers for the underwriter; very few elderly who have low expenditures for their prescription drugs would join voluntarily, and even fewer would stay in the long run. The insurance product then faces strong adverse risk selection and the carrier will end up subsidizing the high premiums to render them affordable, and underwriting the predictable losses.

One way to address this adverse risk selection is to render the program mandatory. Under this scenario, all elderly in the state will be required to join; including people with low expenditures, thus, sharing the costs of the neediest ones. This increase in the risk pool will drive premium costs down. While state subsidies may still be necessary, depending on where the premium and deductibles are set, a mandatory program would minimize the amount of state subsidy required.

The main caveat of this approach lies in its enforceability; people with low expenditures may choose to establish residency in a neighboring state or

any other way to circumvent the requirement. A second caveat are the difficult politics involved with any form of mandatory purchased insurance policy (e.g., While this state does require mandatory automobile insurance, no one is required to purchase an automobile.). In a voluntary insurance program, incentives must be included to discourage risk selection. These incentives could include significantly higher deductibles or separate risk pools for late enrollees or re-enrollees.

#### *Lifetime Coverage*

Under this approach, upon eligibility for Medicare, all Massachusetts residents will be offered the option to join an insurance program that covers his/her drug expenditures once a certain annual deductible is met. An individual who elects not to enter the program at age 65 will either be administratively prohibited or financially discouraged from entering the program at a later age. (The latter approach, i.e., the requirement that members who join late pay a significant premium penalty, has as its precedent Medicare Part B policies.)

This approach is based on the unpredictability of drug expenditures in the long run. A relatively healthy individual at age 65, who has low drug expenditures, is completely uncertain about the drug expenditures he or she might incur at age 75, and even less so at age 85.

Therefore, in order to insure him or herself from future potentially exorbitant costs, the program will be structured so that an individual has an incentive to join as soon as he or she becomes Medicare eligible (by otherwise facing stiff financial and administrative penalties). At this point, individuals with low expenditures will be net contributors to the program, thus ensuring inflows to the system. At a later age, these same individuals would expect to be cross-covered by those younger and healthier individuals who are continuously entering the system after them.

At the program's inception, the elderly who currently have very high costs would be expected to join the program, with their medication costs cross subsidized by the younger and healthier ones who face a financial and administrative penalty if they don't join at the start of the program. If the program turns out to be successful, private management through an annual or biannual bid could ensure its administrative robustness.

The program would feature three components: a deductible, premium and co-payments. There are two approaches to be considered: a comprehensive program and a catastrophic program.

*Comprehensive program:* The lower the deductible, the more comprehensive the program, with individuals receiving the benefit of smaller out-of-pocket expenditures. At the same time, the program must be structured to be financially viable, and the level of deductible will be an important consideration. As has been noted previously in this report, the average drug expenditure of a Medicare enrollee was \$549 in 1995. The National Academy of Social Insurance report projected that in 1999 the average drug expenditure was \$949. Monthly premium payments and co-payments would also be included, in which case the deductible would be adjusted accordingly. As a point of reference, the Medicare part B premium is about \$50 per month.

*Catastrophic program:* Another approach would be to develop a catastrophic program, with a significantly higher deductible, which would drive program costs down, and also enable a lower premium. Such a catastrophic program would be attractive for healthy seniors of age 65-70. At the same time a high deductible may be prohibitive to those at lower incomes. However, under this scenario the Mass Senior Pharmacy Program could be restructured to help low income seniors partly pay costs of their deductible, with the percent covered income-dependent.

The deductibles could also be structured so that enrollment in an HMO could be appealing in that the amount of the deductible could be met by the HMO's benefit. Thus, for example, if an HMO offered a \$500 pharmaceutical benefit, a senior would enroll, as well as purchase the pharmacy insurance product with a \$600 deductible. If the senior maximized the HMO benefit, he or she would then only have an out-of-pocket deductible expense of \$100 plus co-payments, the differential between the HMO benefit and the insurance product benefit.

An additional policy that could complement the program is the adoption of a formulary, in an effort to drive costs down. With the potential number of enrollees, the program would have access to substantial discounts and rebates from the pharmaceuticals in order to grant access to their drugs in the formulary which could be utilized to reduce subsidize and deductible costs.

### *Considerations*

Implementing a Massachusetts Senior Pharmacy Insurance Program has several caveats that must be considered. The first is that Massachusetts would be

engaged in an uncertain domain of the health insurance market, with all private players having withdrawn. The extent to which a lifetime approach could solve the problems of the risk selection remains to be seen. However, by entering the market, the state will assume responsibility towards individuals that join at age 65-70, promising to cover their pharmaceutical expenses for the rest of their lives. If for any reason the program becomes insolvent, individuals that have participated and contributed money into the program will fail to receive the support that they expected when they need it, severely undermine the credibility of the state.

The second caveat is that the state would become engaged in an area of health insurance where costs increases are generally beyond the control of any administrator (aging population, cost shifting etc). As stated in Section I, drug expenditures are expected to surpass hospitalization costs in the next three to four years. Regardless of how well the program is administered, premiums will go up, simply because drug expenditures increase faster than any other component of the health care sector. Inevitably the rate of premium growth will be compared with the MCOs Medicare packages, whose premiums will increase at a lower rate as they are inclusive of other areas where costs increase at a lower rate (inpatient care etc) as well.

The program would require a significant deductible, again graduated by income, with those below 200% of poverty exempt, and those above required to pay an increasingly larger, income-dependent deductible. Monthly premium payments would also be included. Co-payments would also be required, with those below 200% of poverty paying under \$3 a prescription, and those over paying a gradually increasing share, capped at a specific per prescription amount, as well as total annual amount.

Another concern is the impact of a state program on the status of retiree drug benefits.

The advantage of a state program is that a larger number of seniors would be expected to be included in the risk pool, thus spreading the costs of the sickest and most vulnerable across all of the elderly. With seniors at all income levels participating, and a state subsidy for the program, the costs for prescription medications for seniors will then be shared by all residents of the state.

### **Option III: Pharmaceutical Companies Establish Uniform Eligibility, Single Application Form, and a Standard Process for Accessing Patient Assistance Programs in Massachusetts for the Uninsured and Underinsured**

#### *Overview of Patient Assistance Programs*

While more extensive reforms are needed, the industry itself can play a role by making its patient assistance programs more accessible. Currently most pharmaceutical companies provide access to a limited number of drug products through indigent patient assistance programs. There are over 70 companies offering patient assistance programs. Each company has devised their own application process, eligibility criteria, and access information. These programs are almost universally administratively cumbersome, time consuming and labor intensive on the part of those helping an uninsured or underinsured patient access medications. The medications available through these programs change frequently, as do phone numbers to access them, the application forms to apply for assistance, and the criteria for eligibility. Efforts in the past by advocacy groups to get the pharmaceutical companies to streamline their indigent patient assistance programs by developing a single entry point, uniform criteria for eligibility, and a standard application form, have not been successful. In the past, efforts to get the companies to work together to devise a uniform system have stalled as the companies raised their concerns with being accused of anti-trust violations if they act collaboratively.

#### *Role for the State*

Massachusetts may be able to convince the pharmaceutical companies through legislation, advocacy and professional appeal that the current inefficient, labor-intensive and time-consuming process that the companies have established to help the uninsured obtain pharmaceutical assistance must and can be changed. Massachusetts could provide national leadership by getting the pharmaceutical industry to improve its performance in managing these programs. Pharmaceutical company participation in efforts in the state to improve these programs could be a requirement for inclusion of products on the state's Medicaid formulary.

*Option A:* The pharmaceutical companies could take the lead in establishing a Massachusetts patient assistance program that provides access to the patient assistance programs for all pharmaceutical companies.

Using a toll-free telephone access point, the pharmaceutical companies could enable physicians in Massachusetts to apply for patient assistance through a single phone number, regardless of the drug being sought or the company offering it. New communication technologies could be used to enhance the efficiency with which these programs operate, reducing the time currently being spent by physicians and staff on trying to navigate them. A uniform application form agreed to by all companies may relieve the administrative burden currently facing health providers who must try to keep with up at least 70 individual companies' forms. Making the application easily available through a phone call and over the Internet, with submission via the Internet, would also be an improvement in current operations. The companies could develop and use standard eligibility criteria for all programs participating through PhRMA.

*Option B:* If anti-trust concerns are again raised by the companies as barriers to their collective efforts to develop a streamlined uniform system, the state could convene an authority to manage patient assistance access to medications. Under this scenario, the authority would define uniform eligibility criteria, a single access point, a standard application form, and maintain a list of participating companies and the drugs they are providing. In this way, the drug companies would not be engaged in collective action, but rather would be dealing solely with a single state-sanctioned authority that would work with each company as a separate entity and develop the uniform program. The authority would also be charged with approving applications in accordance with established eligibility. The pharmaceutical companies would be looked to for funding for either option.

### **Option IV: Develop a State-wide Purchasing Cooperative to Deepen Discounts and Utilize Rebates to Provide Prescription for the Uninsured**

Legislation entitled "An Act to Reduce Outpatient Prescription Drug Costs and Expand Coverage" (H.2886) has been filed in Massachusetts to establish an outpatient prescription drug cost reduction and coverage expansion program within the Division of Health Care Finance and Policy.

The program is intended to "seek to obtain the best prices and widest coverage for all Massachusetts patients requiring covered outpatient prescription

drugs." To this end, the legislation would authorize the Commissioner of the Division to negotiate with pharmaceutical manufacturers to secure the largest possible discount and rebate for outpatient prescription drugs.

Under the proposed legislation, in order for a covered prescription drug to be dispensed in the Commonwealth, the manufacturer must have entered into and have in effect an agreement with the Commissioner on behalf of patients requiring covered outpatient prescriptions. There are provisions limiting the legislation, including a preexisting discount or rebate agreement between a manufacturer and an entity that would preclude the Commissioner from negotiating a discount or rebate agreement.

However, notwithstanding such existing discounts or rebates, the Commissioner could still enter into such agreements for drugs when existing discounts and rebates do not cover specific drugs, groups or circumstances. The legislation also provides for equal access to the discounts and rebates for each wholesaler or retailer (or other purchaser representing a group of wholesalers or retailers).

The rebates negotiated would be deposited into a trust dedicated as an outpatient prescription drug trust fund administered by the Commissioner. The funds are to be used for the benefit of patients purchasing covered outpatient prescription drugs who have incomes up to and including 400% of the state level of poverty or who spend more than 3% of their gross income on covered outpatient prescription drugs.

There are currently several large buyers of drugs and they achieve an equally wide variety of discounts:

- Large HMOs, or the even larger prescription benefit managers (PBMs) that buy on their behalf, often achieve significant discounts and rebates. Pharmacy benefit managers operate nationally and may actually have even higher bargaining clout than the state. (For example, PCS manages drug benefits for around 17 million enrollees). The impact of this initiative on HMOs is uncertain. Initially they might receive lower discounts than the current ones, if the manufacturers try to discourage this initiative. Further, HMOs would face higher administrative costs, as one entity (the state bulk purchaser) buys drugs and another entity (the PBMs) distributes them. However, if the initiative turned out to be sustainable, HMOs would actually benefit if the price achieved by the

state were sufficiently lower than the current price the HMO currently achieves (and high enough to cover the increased administrative costs).

- The status of Medicaid as one of the state's largest purchasers in this initiative would be important, as well as complex. The Division of Medical Assistance, as the purchaser for the Medicaid population, currently receives the best national price, in accordance with the provisions of the 1990 federal Omnibus Budget Reconciliation Act. Whether Medicaid would be precluded from participating because of existing federal requirements, and the impact of their loss of participation would need to be assessed. If Medicaid were not included, and the purchasing initiative succeeded in obtaining deeper discounts than Medicaid currently obtains under the best price provision, then Medicaid would likely benefit from the initiative, by gaining even deeper discounts. However, if the effect of the purchasing initiative were to lessen discounts because of fragmentation in the existing purchasing groups, then Medicaid could lose, as the current level of discount was lost. However, because it is highly unlikely that such an initiative will achieve the best national price, and assuming Medicaid did not participate, it would be unaffected.
- Retail pharmacists, are either independently owned or are part of a chain. Since some of the chains are national, the degree to which they would participate in a state purchasing group to achieve better discounts than they currently receive would vary, depending on the strength of their current group.
- Individual consumers, either completely uninsured or lacking drug benefit coverage, pay the highest prices. Any opportunity for those individuals to obtain the advantages of deeper discounts and rebates would clearly be beneficial.

## **Option V: Improve Physician Prescribing Competency**

Whatever arrangements are made for purchasing and reimbursement of pharmaceuticals, a single final common pathway will still have to be addressed — the need for the physician and, to a lesser extent, other prescribers, to make a prescribing decision that is clinically appropriate as well as cost-effective. If this goal is

achieved, it will create the necessary pre-condition for any drug program that is to be affordable and improve the public health. If this goal is not achieved, no combination of purchasing, payment or formulary policies will be workable.

One central issue is responsible for the sharp escalation of prescription drug expenditures as well as the often-reported quality problems of drug over-use, under-use, and mis-use.<sup>96</sup> That is, the fact that there is presently no mechanism in place to ensure that doctors in the Commonwealth have current and comprehensive information about ideal prescribing practices. Continuing education concerning medication use is not required, nor must competency be demonstrated in this vital area. The pharmaceutical industry has been very effective in moving into this void and providing physicians with their point of view concerning what drugs should be prescribed, generally in the interest of promoting the use of the costliest products. Ample data exists to document that considerable improvement is possible in physicians' clinical decision-making in this area, especially concerning drug use in the elderly.

It is entirely within the capacity of the Commonwealth to ensure that every physician practicing in Massachusetts must possess the knowledge necessary to make accurate and cost-effective prescribing decisions, and demonstrate such competency at regular intervals. A variety of means exist to reach this goal, alone or in combination:

- a) Require that a physician (or other prescriber) demonstrate a basic level of knowledge about current pharmacologic therapy and cost-effective prescribing in order to renew licensure and/or to receive reimbursement from the state Medicaid program;
- b) Create a category of required CME (Continuing Medical Education) courses, analogous to the current requirement for risk-management education, required for re-licensure. (Note that most observers believe that the demonstration of competency, as in (a) above, is far preferable to the mere certification of attendance at a series of lectures.)
- c) Develop a state-wide program of educational outreach ("academic detailing") in which the most current information on appropriate prescribing is offered to physicians on a voluntary basis through a program sponsored by a medical

school or other not-for-profit entity, similar to the way in which drug manufacturers successfully influence prescribing through such brief one-on-one interactions, on an ongoing basis. This approach has been shown to significantly improve prescribing in several large-scale studies (e.g., Avorn et al. *New England Journal of Medicine* 1983 and 1992) and is currently in widespread use in many parts of the world; it has been shown to save considerably more than it costs.

Whatever other approaches are put into place to improve access to medications in the Commonwealth, they will all require the concurrent development of programs to ensure that the prescribing decisions that underlie all medication use are improved as well.

## Option VI: Pharmaceutical Liability

One of the difficulties in developing effective state strategies to influence the pharmaceutical industry, such as improving performance of their patient assistance programs, is finding the leverage points that the state has with the pharmaceutical companies to bring about an improvement.

Unlike so many other components of the health care system, the state does not have regulatory authority over the pharmaceutical companies. With regard to purchasing power, under the current circumstances, Medicaid is the state's largest pharmaceutical purchaser, but its clout as a purchaser has been defined at the federal level, under provisions of the 1990 OBRA legislation.

It has been noted, however, that the pharmaceutical companies are concerned with the variation in liability systems in place in each state. As PhRMA reports, state health-care liability systems have had an impact on research and development.<sup>97</sup> Under the current liability system, in which each state has different laws and there are separate rules in federal courts, damage awards can vary widely. Particularly troubling to PhRMA are punitive damages and joint and several liability.

In further discussing their concerns with punitive damages, PhRMA notes that

"In most states, a pharmaceutical company can be held liable for huge punitive damage awards even though all drugs must meet FDA's stringent approval standards....Four

states do not allow claims for punitive damages – Massachusetts, Nebraska, New Hampshire and Washington."<sup>98</sup>

An effort to cost out the benefit that this protection affords the pharmaceutical industry in Massachusetts may be helpful as issues arise that require state negotiation with PhRMA and the individual companies.

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## APPENDIX A

### The Development of a New Drug

The following overview highlights key phases in the development and introduction of a new drug.

#### OVERVIEW OF THE DEVELOPMENT PROCESS

Ten to fifteen years can elapse before a compound that is synthesized in a laboratory can enter the market as a new drug. The following stages represent critical pathways in the process of development:

- **Pre-clinical testing:** This phase includes the synthesis of a chemical compound and the subsequent laboratory and animal studies to indicate (1) the biological activity of the compound against a specific disease, and (2) the safety of the compound. No test on humans takes place at this phase. This phase lasts about 7-8 years, and only one in one thousand compounds make it to the next phase.

- **Investigational New Drug (IND) Application:** Having decided during the pre-clinical testing which compounds seem to have the best biologic activity against a disease, as well as the least side-effects, the pharmaceutical company files an IND application with the U.S. Food and Drug Administration (FDA) to begin to test the drug on humans. Between the filing of the IND application and the patent application, the drug is covered by an annual provisional patent, however, the filing of the IND application starts the "patent term clock." The patent term is 20 years.

- **Clinical Trials, Phase I:** These are the first tests on humans. They involve a small number (20 to 80) of healthy human volunteers. The data retrieved is used to study both the drug's safety as well as its pharmacokinetic profile (its absorption, distribution, metabolization, duration of action and excretion). Usually this phase lasts one to two years. Only if a drug is safe enough to be tolerated by healthy volunteers will it make it to the next phase.

- **Clinical Trials, Phase II:** This phase aims to assess the effectiveness of the drug, i.e. the extent to which it targets the specific disease. Phase II trials involve about 100 to 300 volunteer patients with the specific disease and last about two years.

- **Clinical Trials, Phase III:** This is the most expensive phase: it usually involves 1,000 to 3,000 patients in clinics and hospitals. The target is the exact

assessment of the drug's efficacy and the side effects. The need for statistically significant results as well as the need for identification of relatively rare adverse events explains the large number of patients.

- **New Drug Application (NDA):** If after the clinical trials the company is confident about the value of the drug, it fills a New Drug Application (NDA). The NDA contains all of the scientific information that the company has gathered.

- **Approval:** If the FDA approves a NDA, the new medicine becomes available for physicians to prescribe. However, the company must continue to submit periodic reports to the FDA, including any reported cases of adverse reactions, and appropriate quality-control records.

- **Clinical Trials, Phase IV:** For some compounds, the FDA requires additional trials, which are conducted after the drug has already entered the market. The purpose of these trials is to evaluate long-term effects of the drug.

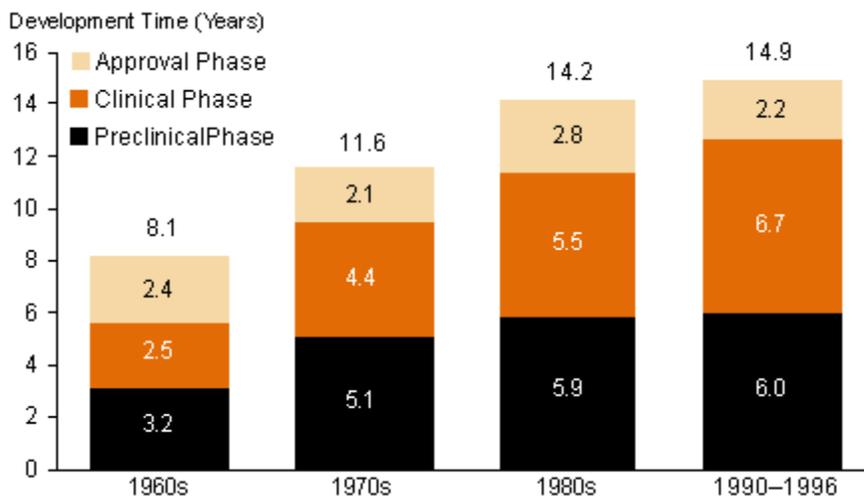
Since 1995, the FDA has managed to shorten the approval process. However, companies have to conduct additional trials during the pre-clinical and clinical research stages, which lengthened the development time. See Figure 1 below.

#### CURRENT RESEARCH FOCUS

The two-year total of new therapeutic agents approved by the Food and Drug Administration in 1996 and 1997 surpasses the number of approvals for any previous two-year period, although the number has dropped somewhat in 1998. Of the New Molecular Entities (NMEs) approved, "eight were targeted for heart disease and stroke, and seven for the treatment of patients with cancer; the others were osteoporosis drugs, anti-infective agents, and antihyperglycemic products. The NMEs approved are for treatment or prevention of 39 diseases affecting 160 million people."<sup>a</sup>

Today's research is concentrated on the following clinical conditions: heart disease and stroke (96 drugs tested); cancer (316 drugs tested); Alzheimer's and Parkinson's Disease (118 drugs tested); infectious diseases (125 drugs tested); and AIDS (124 drugs tested). In 1998, research and development (R&D) costs were close to \$20 billion. These costs are expected to increase further in 1999, possibly reaching \$24 billion. Table 1 illustrates the focus of the research by sector and the amounts in billions of dollars spent on each sector.

**Figure 1: Development and Approval Phases Intervals, 1960-1996**



Source: Tufts Center for the Study of Drug Development.

**Table 1: Main Research Sectors and R&D Expenditures in Billions of Dollars**

Central nervous system	\$4.8
Neoplasms/endocrine system	\$4.4
Cardiovascular system	\$3.1
Infectious diseases	\$3.0
Respiratory system	\$1.5
Biologics	\$0.9
Digestive & genitourinary sys.	\$0.7
Skin	\$0.3
Diagnostic agents	\$0.1
Vitamins and nutrients	\$0.1
Other human-use	\$1.6
<b>Total R &amp; D</b>	<b>\$20.5</b>

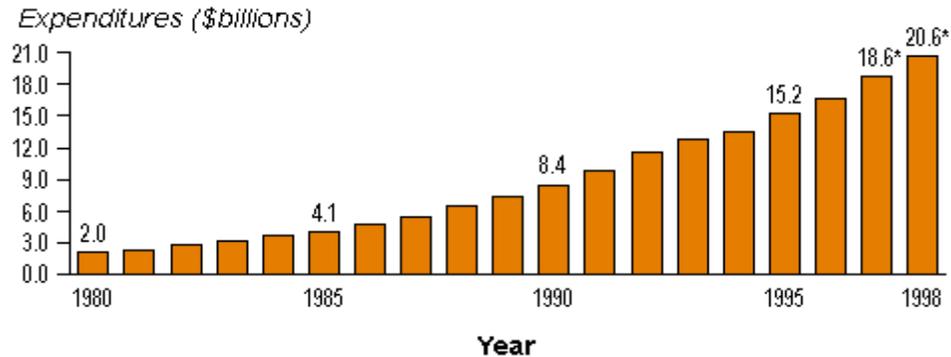
Source: Pharmaceutical Research and Manufacturers of America (PhRMA), Industry Profile 1998.

*ECONOMIC ASPECTS OF RESEARCH*

Size of investment

Companies spend an increasing portion of their revenues on research. In the last twenty years R&D costs have increased not only as absolute amounts but also as a percentage of sales. These trends are depicted in the following graphs:

**Figure 2: R&D expenditures in billion of dollars, 1980-1998**



Source: PhRMA: Annual Survey, 1998

**Figure 3: R&D Expenditures as a Percentage of Sales, 1980-1998 (selected years)**

Source: PhRMA, annual survey

### Cost of Developing a New Drug

It is very difficult to estimate the exact cost of developing a new drug. Among the difficulties are the ten to fifteen years it takes to bring a drug to market, as well as the multiple steps involved in the different phases of development. For those groups or individuals working outside of the pharmaceutical companies the most significant difficulty is the fact that much of the data on which a cost estimate would be based is never fully released by the companies, at least in the United States where it is not even made available to Congress, although this information is made available in the UK.<sup>b</sup>

Due to the length and the complexity of the overall development and marketing procedure, it is difficult to give one numerical figure as the cost of a drug. Factors that have a significant impact in the development costs are:

- **Taxation:** Even though R&D costs are exempted from taxation, the cost of taxation on pharmaceutical companies affects R&D expenditures. Due to their size and the amount of their annual sales, the taxable income of most pharmaceutical companies falls into the highest tax bracket. This means that under the current tax structure, pursuant to changes made by the 1986 Tax Reform

Act, the level of taxation for pharmaceuticals companies is 34%. In accordance with economic theory, the current opportunity cost of a dollar invested in R&D becomes 66 cents, i.e., if the company does not invest a dollar on R&D this dollar is subject to taxation that leaves the company with only 66 cents. The R&D tax credit is renewable by Congress for limited periods. Since 1981, there has only been a one and a-half year period in which the R&D credit was not in effect.

Apart from the general federal tax credit, there are other forms of tax credits, such as state tax credits and tax credits for specific purposes that need to be factored into drug development costs. These include:

Tax credit (20%) for *increases* in specific qualifying R&D expenses (currently 20% of total); and,

Tax credit (50%) for qualifying *clinical* R&D for orphan drugs (i.e. drugs for rare medical conditions).<sup>c</sup>

- **Capitalized Cost:** This economic notion tries to capture the time sequence of the investment, and reflect the reality that research occurs for ten years before the product developed begins generating revenues. Given the length of the research process, consideration must also be given to the foregone interest the invested monies could have earned during this time. As the process involves ten to fifteen years, with significant dollars invested, foregone interest on that money can be substantial, with the actual dollar amounts fluctuating based on the interest rates in effect during the period of time in question. This lost interest can have a significant impact on the final cost calculation.

However, in the absence of precise estimates available regarding future interest rates, when attempting to estimate the cost of developing a new drug assumptions are necessary, some of which can be quite arbitrary. This explains in part the striking differences in the various estimates that can be found in the literature. Two 1993 reports, one by a pharmaceutical industry consulting group and the other by the former Office of Technology Assessment (OTA) of the U.S. Congress, varied widely in the estimated costs of new drug development. The OTA report did note the many difficulties it encountered in trying to come up with an estimate, including the various assumptions that were necessary to calculate the estimate and the government's inability to access exact economic data from the companies. Nonetheless, the OTA was able to calculate an estimate based on a study that was both scientifically rigorous and unique.<sup>d</sup>

The 1993 OTA study is the best known effort to estimate research costs. The OTA study estimated that each drug that entered the market had a 4.3% higher return than that minimum necessary to finance its R&D expenditures.<sup>e</sup> It further described that "[d]ollar returns are very volatile over time," and "the cost of bringing a new drug in the market is very sensitive to changes in science and technology, shifts in the kinds of drugs under development and changes in the regulatory environment."<sup>f</sup>

Average returns on R&D investment can be misleading. Aggregate figures cannot accurately reflect the fact that drug development projects do not have uniform returns. Out of ten drugs, one will be a so-called "blockbuster" drug, returning nearly five times its research costs.<sup>g</sup> Two more of the ten will return sufficient earnings to recoup the company's R&D expenses. Among the remaining seven some will be marginally financially successful, and some will be substantial money losers for the company. In order to increase their opportunity to discover the highly profitable blockbuster drug, pharmaceutical companies continuously increase their research budget. Those companies that succeed can more than recoup expenditures undertaken. Those that fail are the usual objects of mergers and acquisition, which are spreading throughout the industry.

#### Risks of Developing a New Drug

The amount of risk one is willing to take is in direct relation to one's anticipated compensation. Obviously, any investor would prefer a risk-free investment to an uncertain one, and, as such, a risky investment has to give higher returns to be appealing. That is why, for example, US Treasury Bills, a risk-free investment, have a lower rate of return on investment than do stocks. As drug R&D is a risky and uncertain investment, pharmaceutical companies seek to be compensated accordingly.

An estimate of the magnitude of the uncertainty involved is the fact that out of 5,000 initial compounds, only 5 will make it to the clinical trials. However, the bulk of these 5,000 compounds will be discarded quite early in the development and testing process, thus avoiding any substantial expense to the company, as the most expensive aspects of the development of a new drug are the clinical trials. By the time a compound goes into clinical trials, a significant amount of the risk has been eliminated since one out of five compounds tested in clinical trials will enter the market as a drug.

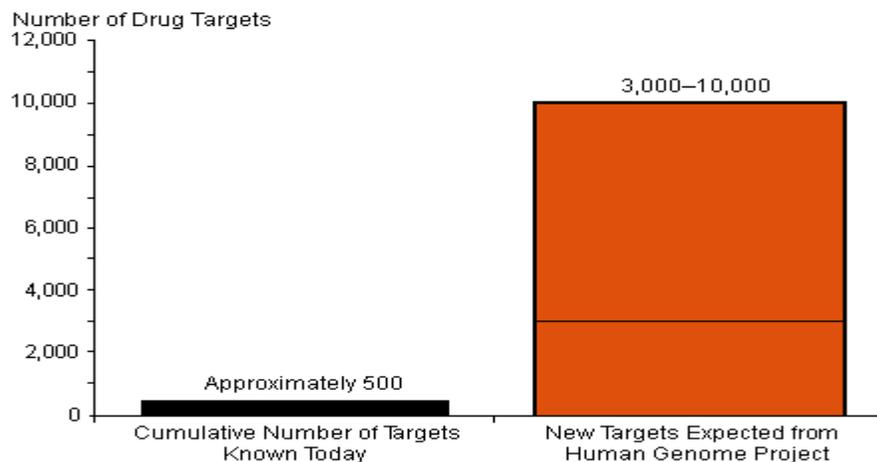
Pharmaceutical companies take into account the above concepts when planning which projects they will fund. Modern investment theory encourages companies to successfully *diversify* the risk they undertake.<sup>h</sup> Pharmaceutical companies invest in more than one family of drugs, and in more than one clinical condition (heart problems, diabetes, etc). Moreover, the companies have increased the number of drugs tested in order to cover any unexpected statistical failure. More simply stated, they "put their eggs in more than one basket."

The above does not mean that there is no risk left. Indeed, companies still have to face the so-called "undiversified" risk, which reflects the post-development

uncertainties of how physicians and clinicians will assess the drug, whether a competitor (a "me-too" drug, or another medical treatment) will appear, or even the future state of the general economic environment. Of course, pharmaceutical companies are not alone in facing these uncertainties of R&D investments.

Finally, the pharmaceutical industry may face major changes in the way research is conducted with the development of biotechnology, which offers a deeper understanding of the disease process and increases the number of target sites for drugs. See Figure 4 regarding estimated increases in target sites due to genetic research and other scientific advances.

**Figure 4: Estimated Increases in Target Sites Due to Scientific Advances**



Source: PhRMA, Industry Profile

### PATENTS

Several Congressional actions have affected patent provisions for pharmaceuticals in the last 15 years. Two of the most critical are the Uruguay Round Agreements Act (URAA) of 1994<sup>i</sup> and the Drug Price Competition and Patent Term Restoration Act of 1984, also referred to as the Hatch-Waxman Act. Under the general copyright provision of the former, a company granted a patent has 20 years of market exclusivity in the production of a certain compound. Patent applications must be filed within one year of the date that the application for clinical trials is submitted.

As discussed previously, clinical trials usually last about 7 to 8 years. Then, a company submits an appli-

cation for market approval to the FDA, a procedure that usually takes another year. The company has the remaining 11 to 12 years of patent protection to recoup the expenditures undertaken in the R&D period before there is competition from generic drugs. As such, the company has a strong interest in shortening the time necessary for the clinical trials and the FDA approval phase of the process in order to be able to market the drug as soon as possible. Although it is difficult to predict the exact time intervals for each drug, the Congressional Budget Office estimates that a drug now has an average marketing period of 11.5 years under patent protection, versus only 9 years before 1984.

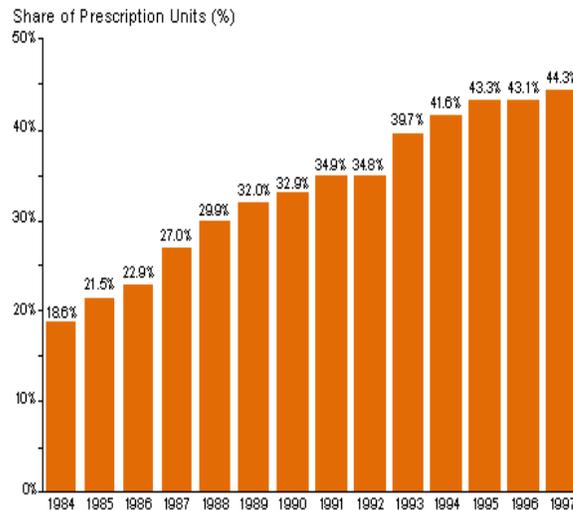
The Hatch-Waxman Act provided pharmaceutical companies with some additional patent protection.

Under the Act, a company receives an extension of its patent protection when new forms of an existing drug are created. The new form may be a higher dosage or an extended release formula of a drug already on the market, or even a switch from prescription to over the counter status. Historically, the FDA required additional clinical investigations for these types of changes. Under the provisions of Hatch-Waxman, however, the drug is granted three additional years of market exclusivity based on the changes and improvements. Usually manufacturers introduce these alterations just before the patent of a drug expires, so as to benefit fully from the

extended exclusivity period. Some examples are the over the counter versions of Zantac® and Tagamet®, as well as the extended release form of ProcardiaXL®.

The Hatch-Waxman Act also encouraged the use of generic forms of drugs and eliminated barriers for their introduction to the market. Since 1984 generics have increased their market share, and currently account for almost half of the prescriptions filled. See Figure 5 for a comparison of the market share of generic drugs from 1984 to 1997.

**Figure 5: Market Share of Generic Drugs, 1980-1998 (by prescriptions)**



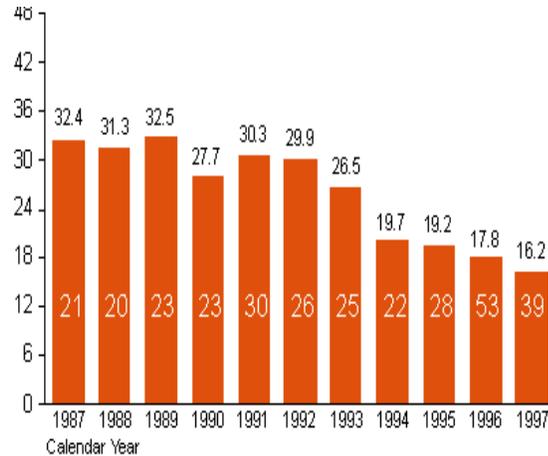
Source: IMS Health, 1998

#### *FDA AND REGULATORY AUTHORITY*

The pharmaceutical industry operates under the close surveillance and regulation of the FDA. The FDA has undergone significant changes during the '90s, as a result of the Prescription Drug User Fee Act of 1992 and the FDA Modernization Act of 1997. The first established and the second renewed pharmaceutical company "user fees," that is, fees paid by pharmaceutical companies when they submit applications for drug approval. From 1993 to 1997 user fees totaled \$327 million and enabled the FDA to hire additional reviewers (around 600) and improve the approval process. The new approval process is often mentioned as "fast track" and has placed the FDA ahead of other national agencies in the approval of new drugs.<sup>j</sup>

Pharmaceutical companies have willingly agreed to pay these high fees because the longer the approval phase the shorter the marketing time under patent protection. While it is estimated that a one year extension of a drug patent will garner an additional \$12 million of revenue for the patent holder,<sup>k</sup> shortening the approval process by one year generates \$22 million in additional revenue for each drug marketed. Since 1992, the average time required for approval has dropped by 13.5 months. Figure 6 shows the striking impact of the user fees on the mean time required for FDA approval.

**Figure 6: Mean FDA Approval Time(months) 1987-1997**



Source: US FDA, 1998

The FDA Modernization Act had other important provisions as well. In the discretion of the FDA, a drug can now be approved with only one clinical trial instead of the previous minimum requirement of two. This allows for fast track approvals of drugs targeting unmet needs relating to serious or life-threatening diseases. The Act also allowed promotion of pharmacoeconomic information to managed care organizations, as long as it is based on reliable evidence.

The most visible change however, is the modification of the rules regarding direct advertising to consumers. Now, commercials can mention the name of the drug in conjunction with the name of the disease. Also, the commercial must include only the most important warnings and side effects and a source of information, for example, a toll-free telephone number, instead of the full text of contraindications and side effects. As a result the use of media for direct-to-consumer advertising has increased.

## APPENDIX B

### *Prescriptions Drugs in Major European Countries*

Similar to the US, major European countries are both consumers and producers of pharmaceuticals. Table 2 compares the per capita health expenditures as

well as the cost share of pharmaceuticals in major industrialized countries with domestic pharmaceutical manufacturers:

**Table 2: Total Health Expenditures and Drug Costs, Countries with Domestic Pharmaceutical Industry<sup>1</sup>**

Country	Pharmaceutical Expenditures	Total Per Capita Health Expenditures	Pharmaceutical's Share of Total
France	\$351	\$2,102	16.7 %
Japan	\$348	\$1,740	20%
USA	\$319	\$4,090	7.8 %
Germany	\$294	\$2,333	12.6 %
Canada	\$264	\$2,095	12.6 %
UK	\$233	\$1,347	17.3 %
Sweden	\$219	\$1,724	12.7 %
Switzerland	\$190	\$2,500	7.6 %

Source: OECD data, 1997, conversions based on purchase power parity.

As the above table shows, the US spends one of the lowest percentages (7.8%) of total health expenditures for pharmaceuticals. However, this reflects mostly the increased denominator of the ratio, namely the high overall US expenditures for health care: as an absolute number, the US figure is third only to France and Japan.

There are two important implications that stem from the extremes of the above table:

- **France:** Although France has the strictest price controls among all major countries of the European Union, it also has the highest per capita expenditure for drugs globally (\$328, in comparison to \$307 for the US). This inconsistency is mainly attributed to the lack of incentives for the final consumer to reduce utilization. The example of France highlights the inability of price regulation alone to control expenditures, even if it keeps prices low. (See discussion of France in below section on Pharmaceutical Manufacturers.)

- **Switzerland:** Switzerland is a country with major pharmaceutical industry. In the last 20 years, 9% of the 152 major global drugs have been developed by Swiss

industries. However, the country manages to benefit from the lowest per capita expenditure among all major developed countries as an absolute number, and one of the lowest percentages. This provides an example of the sustainability of research in a lower cost environment

Major European countries, namely the UK, France, and Germany have faced a dilemma known to the US: they have sought to support their domestic pharmaceutical industries, while keeping the overall health budget in control.<sup>m</sup> Despite the lower prices, total pharmaceutical expenditures have increased during the last few years, in part as a result of demographic and scientific changes common to the US (aging population, changing role of pharmaceuticals, etc). In view of the escalating costs, national pharmaceutical policies that aim to reduce overall expenditures have been initiated.<sup>n</sup>

These policies have focused to the demand side of the market. They have sought to provide incentives to physicians to adopt more conservative prescription patterns, and required consumers to face a higher cost for drugs, especially when cheaper substitutes are available. A major tool available for achieving these goals is

the existence of universal health coverage that provides prescription drugs. There is mandatory insurance, either national or social, which is coordinated by governmental agencies. The system can ensure substantial compliance of the physicians, as their reimbursement is directly or indirectly controlled by the coordinating agency. Further, pharmaceutical companies have been willing to accept regulatory measures in order to ensure access to the national formulary, which covers more than 90% of the market.

The following describes the new pharmaceutical policies that have emerged and some new trends are highlighted.

#### Distribution Network

Contrary to the US, the European system is characterized by the absence of competitive pressures in the distribution network. Although substantial cost savings should be anticipated in case competition were introduced, most countries have been unwilling to go along this path:

- **Pharmacy Stores:** With the exception of the UK, most European countries have no pharmacy chains. The law allows only independent pharmacists. Further, pharmacy fees are a standard percentage of the drug price, which gradually decreases as the price increases. This percentage is often close to 25-30% of the wholesaler price.<sup>o</sup> In the UK pharmacists receive an additional dispensing fee for each prescription filled, but are subject to reimbursement reduction in case of high volumes, in order to reflect the discounts granted by the companies to the chains.

- **Wholesalers:** Wholesaler fees are heavily regulated. Some countries set a flat percentage of the manufacturer price, for example around 11% in France. In Germany the wholesaler can negotiate fees within a range, although there is a maximum allowed ceiling, expressed as a percentage of the manufacturer price.<sup>p</sup> In general, the market is dominated by small and medium size companies, in a picture similar to the US experience of the '70s and early '80s.

#### Pharmaceutical Manufacturers

Most countries have adopted policies to lower the ex-factory price of drugs, that is, the prices a manufacturer sells its products. Most of the countries use a combination of regulatory policies and central bargaining through the use of the enormous bargaining clout of the central insurance. These initiatives cannot be sepa-

rated, but rather form an overall pharmaceutical policy. Specific examples are provided below.

- **France:** France has the strictest policy imposing product-by-product price controls. The company has to apply to the AMM (an agency similar to the US FDA), which reviews scientific data.<sup>q</sup> Then, the drug is reviewed by a "Transparency committee," composed of representatives from the government, academia, the industry and the social insurance funds, who review the cost-effectiveness of the drug and propose a "technical price." This is usually in comparison to the prices of similar drugs, allowing a higher price for a drug with fewer side effects. In the absence of competitors, the cost for treating the disease is taken as a benchmark. Finally, the economic committee, composed of government officials, proposes a price to the manufacturer. Interestingly, this may be higher than the "technical price," if the drug offers benefit to the national economy.

The manufacturer can further negotiate the price with the economic committee, and the outcome of the negotiations is the price of the drug. These negotiations may last up to 6 months. A manufacturer is theoretically not required to accept the price; in this case however the drug is not reimbursed by the social insurance and its sales are drastically reduced. If a manufacturer does not seek reimbursement from the social security scheme its price can be set freely.

The French government has adopted an additional strategy aimed at controlling spending at the level of the individual consumer. Drugs are divided into three categories. The first includes "vital" drugs, and drugs for chronic conditions; these are fully reimbursed. Around two-thirds of the drugs (that account for 50% of total expenditures) fall in the category of partial reimbursement, which requires a 30% co-payment from the consumer.<sup>r</sup> In addition, some drugs, a relative few, are not covered and the consumer has to pay the full cost. As in most European countries, many segments of the population, including the poor, and pregnant women, are excluded from the co-payment. However, the French government, in view of the very high per capita expenditures has expressed increased interest in introducing changes in the system that would increase the cost sharing that consumers pay.

- **Germany:** In Germany things are done differently.<sup>s,t</sup> Germany does not impose prices. Rather, the country has adopted a system of reference prices. Drugs are divided into similar categories and a refer-

ence price is determined for each category through a complicated procedure that accounts for actual prices of drugs within the category.<sup>u</sup> This is a "statistical" price for the category; then a sophisticated statistical formula is applied, that takes into account pharmaceutical data (each drug's strength and package size) and reimbursement aspects (namely proposals of price levels by the social insurance plans).

Usually the final outcome is a reference price for the whole category in the middle between the lowest and highest of the category. This is the price at which the sickness funds reimburse a category of a drug. If the consumer wishes to buy a more expensive drug within the category, for example, a brand name versus a generic, the consumer bears the added cost. Reference prices are adjusted at least annually. Categories that have many generics available have low reference prices, close to the price of generics. On the other hand, single-source products do not have reference prices, as there are no competitors to calculate it and manufactures can then set their prices freely.

In contrast to the French system that aims to reduce prices as much as possible, the German system tries to keep all prices within a short range from an average. Indeed, pharmaceutical manufacturers usually lower the prices of products whose price is higher than the reference, so as to reduce consumer out-of-pocket expenditure; cheaper drugs simply increase their prices towards the "statistical" price.<sup>v</sup>

In 1993 the government, concerned with the rising costs of pharmaceuticals in an era of tight budget controls due to the reunification expenditures, implemented further mandates. It adopted an additional system of price controls, a "global budget" for pharmaceuticals. This means that physicians at the regional level are responsible for keeping overall drug expenditures under a certain level. Excess costs reduce physician fees and pharmaceutical manufacturer reimbursement. Further, the government required pharmaceuticals to reduce their non-reference prices by 5% and ordered a price-freeze for two years.<sup>x,y</sup>

- **United Kingdom:** The system in the United Kingdom is different still.<sup>z</sup> The UK has a single payer system. The National Health System (NHS) buys more than 90% of all prescription drugs. Consumers pay a flat co-payment, which has increased substantially since 1991. It is currently around \$8 per prescription, regardless of number of drugs. However, major segments of

the population (poor, elderly, pregnant women) are exempted.

Price controls have mainly focused on brand-name drug manufacturers. The UK has a unique system of profit regulation,<sup>aa</sup> the Pharmaceutical Profit Regulation Scheme (PPRS). This is a form of a flexible independent agreement between the government and the individual manufacturer. Manufacturers are initially free to set the price of new drug. This price should lead the company to a target profit level; manufacturers are allowed a profit margin of 17% to 21% per drug, plus an allowance for innovative products. If a manufacturer exceeds the target level, it must repay the government the excess profits. In order to calculate the profit margin, the government has access to confidential data on total sales investment, capital investments, R&D expenditures and marketing costs of each firm; companies are required to submit all these data 6 months after the end of their financial year.

Further, the government regulates price increases; manufacturers that fall short of the target profit level submit an application to the government requesting a price increase. These are usually below the rate of inflation, and their target is to bring the profits from a drug back to the initial level set. During the early '90s, drug price increases have been close to 2%. In 1993, government regulation strengthened: a 2.5% reduction of prices was mandated and a three years price freeze was adopted.

Finally, the government has adopted strategies to modify physicians' prescription patterns. These include the Selected List Scheme, which is essentially a NHS formulary; the PACT system, which is a form of utilization review of the prescription patterns of individual physicians; and an educational initiative, aimed at informing physicians about the cost effectiveness of drugs. However, the most powerful tool has been the financial incentives. Primary care physicians with large practices face a form of capitation, and their fee is reduced if drug expenditures exceed a certain limit.

**The European Union:** During the last three years, the European Union (EU) has assumed an increased responsibility in the pharmaceutical sector.<sup>bb</sup> A major policy forum introduced by the EU, the Round Table on Pharmaceuticals has been examining possible reforms of the policies of individual member states, with an eye towards at least a partial reversal of the above strict regulatory schemes. Its last available report called for increased deregulation of the over-the-counter drug sec-

tor. The report stated that "...even in the prescription sector, higher levels of price competition could be developed, so as to allow some relaxation of direct price controls on products, particularly in the patent-expired sector."<sup>cc</sup>

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