Ensuring Cost-Effective Access to Innovative Pharmaceuticals

Do Market Interventions Work?

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THE BOSTON CONSULTING GROUP
Ensuring Cost-Effective Access to Innovative Pharmaceuticals
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This paper summarizes the findings from a study of the effects of government interventions in the global pharmaceutical marketplace. The study was conducted by The Boston Consulting Group (BCG) and sponsored by Warner-Lambert Company. BCG is solely responsible for the content of and analysis in this report. Although the report draws on data provided by a variety of sources, including IMS Health and Parke-Davis, all analysis was conducted by BCG.
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Executive Summary

- Market interventions such as price, volume, and spending controls are widely used in both the public and private sectors to manage pharmaceutical and other health care spending
- Pharmaceutical spending can also be managed by encouraging free market competition in the form of free pricing for, and competition between, patented products allied with competition from generics once patents expire
- Although introduced to contain overall spending while retaining wide access to new medicines, market interventions such as price controls have often been counterproductive
- In particular, government interventions in the pharmaceutical market have often failed to achieve desired long-term outcomes
  - Some forms of intervention, particularly those aimed at curbing demand, have contained, or reduced, drug spending in the short term
  - Market interventions have not reduced longer-term pharmaceutical spending growth: pharmaceutical spending growth rates in the 1990s in many markets with widespread interventions have been no different from those in markets with few interventions, such as the U.S.
  - Irrespective of their impact on spending levels, market interventions often have unanticipated second-order consequences, such as spending increases in other parts of the health care budget
- Market interventions can also worsen health outcomes
  - Negotiations on reimbursement, volume limits, formulary access, or other interventions can delay widespread access to new therapies
  - Market interventions are correlated with a slower rate of diffusion of innovative therapies – in countries with market interventions some new classes of therapy have been adopted more slowly than in markets with few interventions, such as the U.S.
  - Market interventions can reduce the economic incentives for pharmaceutical manufacturers to conduct clinical trials and promote their innovations, thereby
reducing awareness among physicians and patients regarding appropriate use and benefits of new drugs

- Market interventions can also affect the incentives for pharmaceutical manufacturers to compete with one another and to invest in innovations
  - Many forms of market intervention limit the incentives for market participants to engage in price competition, particularly after patent expiration. As a result, prices may not fall as they would in markets where this competition occurs
  - Certain forms of market intervention encourage companies to direct R&D toward developing local market products with limited therapeutic advantage, rather than towards developing products for the global marketplace

- An agenda for governments seeking to reform their pharmaceutical markets should contain the following four elements:
  - A continued commitment to maintaining a strong system of intellectual property protection
  - An emphasis on reducing barriers to competition, for both patented and off-patent (generic) products
  - A move toward market pricing across the product life cycle, allowing the market to reward innovation early while rewarding low costs later
  - Consideration of ways to encourage active decision-making by both physicians and patients that is scientifically and economically informed

- A shift in the direction of a free market model, that encourages innovation and competition, is possible— and need not lead to a rise in overall drug or health care spending
  - Increased use of, and competition between, low-priced generic products could, in many markets, lead to savings that could fund relaxation of price controls on on-patent products
1. Introduction

Most economists and government officials agree that protecting intellectual property (IP) is a prerequisite for an innovative and dynamic pharmaceutical industry. The WTO agreement on the Trade-Related Aspects of Intellectual Property (TRIPs) has put in place a common standard of intellectual property protection in most of the world. Yet at the same time, policies and interventions that discourage pharmaceutical innovation have proliferated.

Market interventions*, such as price controls and volume limits, are an integral part of the health care financing system in many countries. These interventions seek to limit pharmaceutical and other health care costs while ensuring widespread access to appropriate therapies.

To what extent have these interventions achieved their goals? This paper addresses the impact of market interventions on pharmaceutical spending and consumption at a country level, on the diffusion of new drugs in particular markets, and on competition and innovation in the pharmaceutical industry. Using data from various sources, we address the effectiveness of market interventions from both an economic and a health outcomes perspective. Do the interventions meet the economic goal of containing pharmaceutical and other health care spending? Do they help countries achieve desired health outcomes? Finally, we assess the impact of various potential reforms in the current pattern of market interventions.

The value of pharmaceuticals

Pharmaceuticals can deliver value within the health care system in three ways. First, pharmaceuticals can improve health outcomes, reducing morbidity and helping control and manage the symptoms and effects of disease. Second, pharmaceuticals can extend

* Although there are many ways in which governments can intervene in the pharmaceutical market (e.g., by granting patents) this paper focuses on interventions that affect the price level of, supply of, and demand for pharmaceuticals.
life by helping make a disease that was previously life-threatening one that can be controlled or even cured. Third, pharmaceuticals can reduce costs by simplifying treatment for a condition, reducing the need for complex and expensive medical intervention and hospitalization.

Since the discovery of penicillin, these three effects have been observed in many disease classes. For acute illnesses, often ending in death, pharmaceuticals have initially played a role alongside other medical interventions in controlling and extending life, often at a high direct cost. HIV is a good example of a disease at this stage of scientific understanding. In some cases, such as stomach ulcers, pharmaceuticals have helped bring the disease under control to an extent that other medical interventions are no longer needed. For chronic illnesses, such as asthma, hypertension, and schizophrenia, pharmaceuticals can contribute to improved functioning and avoidance of hospitalization.

Data on the impact of pharmaceuticals on mortality are provided in Figure 1. For example, between 1965 and 1996, pharmaceutical treatments helped cut U.S. death rates from atherosclerosis by 74 percent and from stomach ulcers by 72 percent.
Pharmaceuticals can not only reduce mortality rates, they can also help extend productive life spans, reducing years of life lost in the working population. This can be demonstrated for many potentially deadly diseases, as shown in Figure 2. For instance, between 1980 and 1990, pharmaceuticals played a role in reducing the number of years of productive life lost to cerebrovascular disease by about a third. By adding years of productive life, pharmaceuticals can bolster the productivity of individuals and consequently of society as a whole.

Although these examples are generally accepted, a recent academic economic analysis has gone further, suggesting that after adjustments are made for wealth, lifestyle, and overall health care spending, the more a society invests in pharmaceuticals, the greater the life expectancy.¹

Apart from being efficacious, treatment with pharmaceuticals can be cost-effective. In relation to the total cost to society of a disease, including all the health-system costs and the loss of productivity associated with morbidity, direct pharmaceutical costs can be very small. This pattern played out in the 1950s with the introduction of vaccines for polio. Similarly, the use of antibiotics transformed the cost of treating tuberculosis, a

disease that used to require three to four of years treatment in a sanitarium, with a 30 percent to 50 percent chance of death. In recent years AIDS hospitalization and death rates have been sharply reduced following the introduction of a new generation of drugs.\(^2\)

In many disease categories, a treatment regimen in which pharmaceuticals play a central role can be very cost-effective. In Japan, for example, treatment of angina with TTS nitroglycerines has reduced annual treatment costs from more than ¥900 billion to ¥500 billion. Similarly, beta blockers have lowered the costs of treating ischemic heart disease by more than 60 percent, and a vaccine for hepatitis B led to an 85 percent reduction in spending.\(^3\) In the U.S., as in other countries, introduction of H2 antagonist drug therapy in the 1970s transformed the treatment of stomach ulcers. In 1977, 97,000 operations were performed for ulcers. By 1987 this number had dropped to less than 19,000. In 1990, the annual cost of drug therapy was about $900, compared with $28,000 per surgical intervention.\(^4\) Introduction of therapies that combine H2 antagonists with antibiotics to eradicate the H pylori bacterium, which is the principal cause of ulcers, has brought annual treatment costs down even further, to about $140 per patient.

In addition to affecting direct medical costs, pharmaceuticals can create indirect economic value for society by reducing the impact of disease on productivity. A study of the impact of a new drug for migraine showed a benefit of $435 per month to the employers of those using the drug due to reduction in productivity losses. This compares with the $44 per month cost of the drug treatment.\(^5\)

Though drugs are often cost-effective, their inappropriate use can raise overall health spending. Pharmaceutical spending can rise if there is inordinate prescribing, and/or drugs are prescribed for conditions other than those for which they have been proven to be efficacious. Unfortunately, studies show that physicians do not always prescribe the most appropriate medicines in the correct doses.\(^6\) Spending goes up not only because of the costs of the drugs themselves, but also because inappropriate prescribing of a drug may drive up other health care costs. For example, there is evidence that antibiotics have been overprescribed or prescribed inappropriately for a variety of conditions.\(^7\) Such
inappropriate prescribing has negative consequences for health (bacteria building up resistance to the drugs) as well as pharmaceutical budgets.

**Government interventions in the pharmaceutical market**

The *appropriate* use of pharmaceuticals is therefore a critical component of any health system. Where the state funds universal health coverage, governments often seek to reduce the costs of pharmaceuticals to maintain broad access without exceeding spending limitations. To this end, governments have instituted a variety of price controls, volume limits, and spending limits.

The pharmaceutical market in such a state-funded system differs substantially from markets in which multiple payers (e.g. insurers) compete, such as the U.S. First, the government is a monopsony buyer and may seek a price below that needed to recoup R&D investment and provide incentives to fund future innovation. Second, there is only a weak link between price and the supply and demand for pharmaceuticals. In most single-payer systems, neither providers nor patients have incentives to consider price in their decisions. Demand is driven by patients and providers, while price levels are set by negotiation between the government and drug companies. Without a competitive market in which price levels equalize supply and demand, governments manage the pharmaceutical market through price controls, spending limits, and other forms of market intervention.

Yet how successful are these interventions? This paper assesses their impact on pharmaceutical prices, health care costs, and access to medicines. The analysis suggests that such attempts have been somewhat successful in curbing pharmaceutical costs in the short term, but have had little effect on longer-term spending trends. It is also often the case that the very effort of controlling expenditures on pharmaceuticals, which are simply one component of health care, results in increases in other cost components and increased overall spending.
Apart from their failure to meet the direct financial goals, interventions in pharmaceutical markets can have a host of negative effects, including reducing competition among pharmaceutical companies (which can lead to higher, not lower, prices for medicines); increasing the time it takes to make new medicines widely available; and making short-term budget targets, rather than longer-term health benefits, the main consideration in the provision of drugs.

Furthermore, intervening in the pharmaceutical market undermines the social benefits derived from intellectual property protection. One of the oft-cited rationales for market interventions is the need to counterbalance the monopoly granted to a drug manufacturer in the form of a patent. Yet while the value of intellectual property protection is widely recognized and accepted, many governments are eroding that value by limiting the pharmaceutical industry’s ability to freely price and market its innovations (see page 7, “Intellectual Property Protection and Market Interventions.”)

By contrast, enabling a freer market and competition in pharmaceutical markets can result in many positive effects for health care. A free market for pharmaceuticals provides incentives for pharmaceutical companies to invest in innovation, and encourages appropriate use of the new drugs resulting from that investment. The analysis suggests that a government wanting to provide innovative medicines to its citizens in an efficient and equitable way does best by not intervening, directly or indirectly, in the pharmaceutical market.
The 1995 World Trade Organization Agreement on the Trade-Related Aspects of Intellectual Property (TRIPs) has done much to harmonize intellectual property (IP) protection in most developed countries. IP protection is in itself a form of market intervention, but it is a form that is widely recognized as necessary to encourage investment in innovation, which in turn leads to new products.9 The pharmaceutical industry relies heavily upon patent protection to drive innovation. In a survey of several industries, drug companies indicated that 65 percent of their drugs would not have been introduced in the absence of patent protection—more than twice the ratio applicable in any other industry.10 The widespread use of market interventions in pharmaceuticals can erode the value of IP protection. This paper discusses many of the ways market interventions slow the diffusion of, and reduce the returns from, innovation, undermining not only the intrinsic value of IP protection, but also the social benefits derived from it.

Some governments in developing countries are still debating the merits of such protection. The debate is based on the belief that granting such protection raises drug prices. This claim is refuted by a 1998 analysis of data from nine developing countries on pharmaceutical prices and sales at the manufacturer’s level for six therapeutic categories over a period of eleven years (1985-1996).11 The data showed that improving intellectual property protection does not have any measurable impact on either the prices of existing drugs or price changes for drugs introduced after IP protection was implemented. The major factors influencing price changes were found to be competition, direct regulation of pharmaceutical prices, and the power of governments as large purchasers. Lack of IP protection may also discourage multinational companies from investing in local R&D and manufacturing facilities. Such investments are important for technology transfer, which leads to increases in local capability, putting downward pressure on prices.
2. Methods of intervention in pharmaceutical markets

Goals of market interventions

Governments that provide health care to all or parts of their populations intervene in pharmaceutical markets for a variety of reasons. Among the most important are:

1. **Concern over monopolistic pricing.** As patented products, individual pharmaceuticals (chemical entities) are not subject to direct competition. Many governments are concerned that this apparent monopoly will be exploited, with the government, as the single payer in most instances, having to pick up the bill.

2. **Concern over excess demand.** Governments believe that the demand for medicines may not be price-sensitive: although doctors prescribe medicines and patients consume them, the government pays. Intervening in the pharmaceutical market on the demand or supply side can help manage this separation of demand from payment.

3. **Concern over equity and access.** Various diseases that are cured by pharmaceuticals have a significant impact on the well-being of society. Governments may intervene in the pharmaceutical market in an effort to ensure that drugs are made as widely available as possible, on a socially equitable basis.

Most economists argue that government intervention is the worst way to achieve these goals because it invariably leads to unexpected second and third order consequences. Instead they argue that free-market competition is a better impetus toward lower prices and access to innovation.

Our analysis confirmed this hypothesis. Market interventions have been only partially effective in limiting pharmaceutical spending. Most governments that have regulated pharmaceutical prices have experienced the same rate of long-run pharmaceutical spending growth as those that have not. Furthermore, these interventions have had negative consequences for health outcomes and for incentives to innovate.

* Although there is almost always competition between many different chemical entities in a therapeutic class, and between drug based and other forms of treatment
In thinking about the effect of interventions in the pharmaceutical market it is important to remember that pharmaceuticals are only one, often relatively small, component of overall health care spending. There are marked differences between countries’ health care spending (Figure 3), and the amount of spending that goes for pharmaceuticals (Figures 3 and 4). Even within Western Europe, for example, pharmaceutical spending ranges from a high of 1.6 percent of GDP in France to 0.7 percent of GDP in Denmark and Norway. As a share of total health care spending, it ranges from 20 percent in Spain to 9 percent in Norway.

Different levels of spending on pharmaceuticals also reflect marked differences in consumption volume and price level. Although it is very difficult to make cross-country comparisons of consumption and price levels, an indicative analysis (Figure 5) suggests that higher consumption is associated with lower prices. Any proposed system of market intervention must therefore address the dynamic of price and volume that drives overall pharmaceutical spending. For example, reducing prices in response to rising consumption may help contain overall drug spending but does nothing to address the drivers of rising consumption, such as inappropriate prescribing.
FIGURE 4: WIDE VARIATION IN PHARMACEUTICAL SPENDING BETWEEN COUNTRIES

Comparative pharmaceutical spending in OECD countries, 1996


FIGURE 5: LOWER PRICE LEVELS ROUGHLY CORRELATED WITH INCREASED CONSUMPTION

Indicative relative consumption and price level in OECD countries

(1) Derived from 1996 and 1997 spending data; 1990-1997 volume data (using most recent available). Prices are converted at $ exchange rate.
(2) Index is based on consumption per capita per year.
Note: U.S. data are 'scrips per capita, average script is between 21- and 30-day supply comparable with definition of container in OECD data, Japanese consumption is an estimate based on analysis of 11 therapeutic categories relative to the U.S.
Governments regulate pharmaceutical markets in several ways. These interventions can be directed at either the supply of medicines (the manufacturers) or the demand (wholesalers, retailers, doctors, and patients). They fall into three general categories: price controls, volume controls, and spending controls. Figure 6 provides a simple framework for considering the range of ways in which governments have intervened in the pharmaceutical market. Many of the same techniques are used by private-sector health insurers, such as HMOs in the U.S. But in those instances no player has a monopoly. If a pharmaceutical price is too high, an HMO can adopt policies to discourage its use (e.g. taking it off the formulary, or passing on its cost to physicians). In turn, if an HMO’s policies are too restrictive, patients and providers can move to another health insurance plan. However, in countries with national health care systems, such freedom to switch between providers does not exist.

* Appendix 1 provides brief profiles of ten major OECD markets and describes some of the market interventions employed
Direct price controls

Many governments have historically imposed direct controls on drug prices. Such controls can be imposed on a per-drug basis (e.g., direct price-setting systems in France and Japan) or they can be designed to affect the prices of entire classes of drugs (e.g., the German reference price approach). Some countries also base their prices on the prices in other countries (e.g., cross-country reference pricing in Italy and the Netherlands).

Supply-side price controls are one of the oldest forms of market intervention but suffer from a number of limitations. First, they fail to address the volume of pharmaceuticals consumed, and, as already observed, lower prices may in fact encourage greater (though not necessarily appropriate) consumption. Second, some forms of price control, particularly reference pricing, assume different drugs are in fact comparable, with the result that comparative price levels, prescriber behavior, and the returns for innovators are distorted.\(^\text{14}\)

Sometimes countries intervene on the demand side, requiring patients to pay a part of the cost of their medicines, or mandating the substitution of generic (off-patent) counterparts for certain prescription medicines. Carefully designed policies can encourage appropriate use of off-patent medicines and dissuade patients from demanding unnecessary prescriptions. But, as with any intervention in the complex health care decision-making process, a badly designed policy can lead to inappropriate substitution and rationing.\(^\text{15}\)

Volume controls

In lieu of or in addition to directly mandating prices or copayments, governments occasionally seek to moderate the amounts of drugs flowing into the marketplace. In fact, a trend through the 1990s has been for governments to overlay volume limits on existing price controls. Figure 7 illustrates the range of policies instituted in France through the 1990s.
As in the case of direct price controls, governments can intervene at the level of producers, for example, by directly limiting the volume of particular products they allow to enter the market, or at the physician level, by issuing strict guidelines for prescribing. Such guidelines can take the form of lists of drugs that can be prescribed (formularies or positive lists) or lists of those that cannot be prescribed or will not be reimbursed (negative lists). Governments may also issue more detailed guidelines setting out how and when certain drugs should be prescribed.

Supply-side volume limits, while effectively capping total spending, require that those setting the limits know what the “appropriate” level of prescribing is. Our analysis suggests that these kinds of measures can limit the diffusion of treatments for underserved conditions, with deleterious consequences for overall health care spending. Demand-side volume limits, such as prescribing guidelines and formularies, take prescribing decisions out of the hands of physicians. Many studies have examined the impact of these restrictions, which in most cases simply displace volume from a nonreimbursed product onto another, potentially less effective, product, or cause an increase in another form of health care spending.16
Spending controls

In addition to attempting to control consumption and price levels directly or indirectly, governments are increasingly intervening at the level of overall spending. The U.K. Pharmaceutical Price Regulation Scheme (PPRS) is a longstanding system that attempts to control the pharmaceutical market by regulating the profit pharmaceutical companies can make. While allowing substantial freedom for companies to price across a portfolio of products, the PPRS attempts to limit overall spending to a given proportion of the capital invested by pharmaceutical companies in the U.K. The French government has taken a different approach: negotiating revenue limits on a bilateral basis with each pharmaceutical company. These kinds of approaches offer some freedom to market participants, but they can be counterproductive because of new-product development in the market. A single breakthrough drug can double a company’s sales in a few years.

With supply-side spending controls, a company’s sales in future years are constrained by historical company performance or investment. These approaches therefore discriminate against the companies that have the most demanded drugs. They effectively reward companies with a less dynamic portfolio.\(^\text{17}\)

Finally, an increasing number of governments are turning to demand-side spending controls such as budgets for physicians or broader region-level budgets for drugs or total health care spending. Our analysis suggests efforts to manage pharmaceuticals in isolation as one component of health care spending (e.g., German drug budgets instituted in 1993) often lead to cost displacement onto other parts of the health care budget.\(^\text{18}\) Capitation approaches that give physicians financial responsibility for all health care spending are less prone to this sort of problem, but have proven difficult to institute in most single-payer health care systems.\(^\text{19}\)

Unintended consequences of market interventions

A brief examination of the different ways in which governments have intervened in the pharmaceutical market begins to highlight the unintended second- and third-order consequences of such interventions. The health care system in any country is complex, with many interlinkages. Interventions targeted at one area can cause costs to increase, or
behaviors to change, in other areas. Consequently, the results of any policy of interventions are often far from those intended.

In the remainder of this paper we examine the impact of market interventions from both an economic and a health care perspective. First, do the interventions meet the economic goal of containing pharmaceutical and other health care spending? And second, do they distort health system behaviors, with negative consequences for health outcomes?
3. The economic consequences of market interventions

Market interventions and pharmaceutical spending

Market interventions do not have the expected or desired long-term economic impact. Change in policy can have a short-run impact on pharmaceutical spending, but over the longer run, there is no difference between spending levels or spending growth in countries with many market interventions and in countries with few or none.\(^{20}\)

![FIGURE 8: U.S. PHARMACEUTICAL SPENDING AND SPENDING GROWTH COMPARABLE TO THAT IN CONTROLLED MARKETS](image)

Throughout the 1980s and 1990s, many countries imposed new market interventions to control their spending on pharmaceuticals. One way to gauge the success of such efforts is to see whether countries that intervened more achieved lower pharmaceutical spending growth than those that intervened less. As Figure 8 shows, countries employing more market interventions (such as France, Spain, and Japan) did not have lower spending levels than countries with fewer interventions (such as Switzerland, the U.K., and, most particularly the U.S.). For example, from 1990 to 1997, the compound annual growth rate (CAGR) in Rx spending per capita in the U.S. was 3.9 percent, compared with 6.4 percent in the U.K., 4.7 percent in Spain, and 4.3 percent in the Netherlands.
Over shorter periods, market interventions can have a substantial impact on pharmaceutical spending. The real annual rate of growth in Italian drug spending, for example, fell from 6.8 percent in the 1980s to 0.7 percent between 1990 and 1997. This change is largely attributable to reforms enacted since 1994, when many inefficacious drugs were removed from the reimbursement list. Since 1996, however, Italian spending has begun to revert to its long-term trend. Differences between short- and longer-term effects are also borne out by recent study of the impact of reference pricing and physician budgets on public pharmaceutical expenditures in Germany. From a detailed regression analysis the study found that reference pricing (initially introduced in 1989) was not successful in reducing pharmaceutical spending in the short or long term (Figure 9). Physicians’ budgets, on the other hand, reduced spending during the year in which the measures were imposed (1993); but in the 1994-1996 period, spending went back up, following the trend that existed before the imposition of the budgets.

Simple trend data on drug spending mask the actual causes of these increases. Consider, for example, recent spending trends in the U.S. The most recent data on pharmaceutical spending show an increase of 11 percent from 1996 to 1997, and continued double-digit
increases into 1998. A detailed examination of the drivers underlying this spending suggests that increases were caused mainly by greater use of some important new drugs rather than by price increases for existing drugs. Data on price levels and consumption collected by a major U.S. pharmacy benefit manager show that of the 11 percent increase in 1997, 2.4 percent was attributable to price increases, 4.5 percent was attributable to increased use of existing products, and the remaining 4 percent increase was caused by the introduction of new products. In other words, almost three-quarters of the increase resulted from greater use of newer, more innovative products, while about 20 percent (2.4 points) came from price increases.

As Figure 10 shows, more than half (53 percent) of the 1996 to 1997 spending increase was due to the sales of 23 pharmaceuticals, many of which are part of a new generation of treatments for chronic diseases. Any assessment of the costs incurred in providing these drugs must be balanced with an analysis of their benefits. As our analysis suggests in two categories—statins for treating cholesterol and SSRIs for treating depression—treatment with these newer drugs may lower overall health care costs, although it does increase drug spending. Thus the question to ask of any increase in drug spending is whether it has been offset by a reduction in spending elsewhere. Similarly,
where government intervention leads to a drop in drug spending, has this been offset by increases elsewhere in the health budget?

**Market interventions and cost displacement**

When a government intervenes in the pharmaceutical market, unintended cost increases sometimes result. The effect can be likened to squeezing a balloon—the tighter the squeeze in one area, the greater the bulge in another.\(^{22}\) In the case of Japan, despite a price control system that drove pharmaceutical prices down by more than 60 percent between 1980 and 1993, overall drug spending rose 59 percent, driven upward by increased prescribing volumes and the introduction of new drugs at higher price levels.\(^{23}\) Tight control of one aspect of drug spending fails to address the other drivers of spending and may even encourage inappropriate prescribing, as many observers have suggested of the Japanese system (in which physicians also dispense drugs).\(^{24}\)

More specific examples of this cost displacement include the case of a U.S. state Medicaid program that limited recipients to three prescriptions per month. Although this policy reduced drug use by 35 percent, it resulted in a doubling of nursing home admissions; after the drug limitations were lifted, both drug prescribing and nursing home admissions returned to the base line.\(^{25}\) A series of studies of U.S. HMOs offers some of the most comprehensive evidence of the balloon effect. In a study of 13,000 patients from six HMOs, it was found that greater formulary limitations on drug availability resulted in more emergency visits and hospital admissions, higher drug costs, and more office visits. The increase in resource use as a result of restrictive formularies was even more pronounced for elderly patients, who in general require more specialized care. Further, increasing copayment levels for prescription drugs had the unexpected result of raising hospital admission rates.\(^{26}\)
The introduction of physicians’ drug budgets in Germany in 1993 also led to cost displacement onto other parts of the health care system. As Figure 11 illustrates, restrictions placed on physicians’ Rx budgets did indeed result in lower pharmaceutical spending, but this decrease was offset by a 10 percent increase in both specialist referrals and hospital admissions. Basically, to stay under budget, physicians were passing on the costs to other parts of the health care system. Direct savings in drug budgets therefore often translate into direct effects elsewhere in the health system, and indirect costs to society from lost productivity.

**Market interventions and competition**

Government interventions such as direct price controls can also have unanticipated and counterproductive effects on competition among pharmaceuticals. Sometimes these interventions actually raise prices rather than lower them. But short of that, sometimes prices in controlled markets simply remain high. For example, the patented ulcer drugs known as H2 antagonists remained big sellers in France, at “patented” prices, after they went off-patent (see Figure 12). With government-mandated prices, few new generic manufacturers entered the market, so prices remained little changed. Other countries
encourage generic competition to drive down prices. For example, in Germany between 1986 and 1997, the entry of several generic manufacturers drove the average price for an H2 antagonist down by 75 percent in real terms, in contrast to a decline of only 22 percent in France.

Multiple market entrants, in and of themselves, may not be enough to encourage vigorous competition. Consider H2 antagonists in the U.S. and Spanish markets (Figure 13). Spain actually has more suppliers of H2 antagonists than the U.S., but most of them are branded local licensees or copy products introduced before the adoption of patent protection in 1992. With little active competition from generics, the prices of these branded drugs have not fallen. In the U.S., on the other hand, there is a sharp contrast between the period up to 1994, when there were only patented products in the market, and the subsequent period, after generics entered. As a direct result of generic competition, the average real price for a day’s therapy with an H2 antagonist fell by 35 percent in real terms between 1994 and 1996.∗

∗ This may actually understate the impact of patent expiration, as the pricing data exclude rebates granted by manufacturers, particularly on patented products sold to major purchasers. Some of the manufacturers

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(1) Average price is in 1997 DM and FFr, converted to real terms using GDP deflator
Source: IMS sales and volume data; Warner-Lambert ADD estimates; BCG analysis
Some forms of market intervention can also distort the incentives for drug manufacturers to compete on price. For example, the introduction of reference prices often leads to price convergence. An analysis of the impact of reference pricing in the German market showed examples of prices converging on reference levels. Most manufacturers pricing above the reference point reduced their prices. However, some manufacturers pricing below the reference point increased prices. While overall price levels fell 11 percent in the reference pricing segment between 1989 and 1990, prices have subsequently stabilized. There is also evidence that manufacturers subject to reference pricing in one segment of the market were able to recoup lost revenues by increasing prices in other areas.28 The impact of reference pricing on overall drug spending was minimal, while distorting manufacturers incentives to compete on price, and creating a substantial administrative burden for both regulators and manufacturers.29

with products that remained patented may well have increased their rebate levels in response to generic competition, again lowering prices for consumers.
These examples illustrate why countries have had such difficulty using market interventions to limit increases in pharmaceutical and other health care costs: market interventions often reduce competition in the pharmaceutical marketplace and hold prices up; as a result, spending is higher than it would have been otherwise.

Pharmaceutical spending, however, is only one of the areas in which there may be differences between a market with many interventions intended to keep prices low, such as Spain, and markets in which competitors are able to price and market freely, such as the U.S. The second major goal of market interventions is to ensure widespread appropriate access to quality innovative products. Our analysis examined the extent to which countries had been able to use market interventions to ensure that access.
4. The health care consequences of market interventions

In addition to the social goal of limiting pharmaceutical and other health care spending, countries may use market interventions to balance two other clear social goals: ensuring widespread appropriate access to innovative drugs, and setting incentives to encourage pharmaceutical companies to invest in developing and marketing those drugs.

In seeking to ensure widespread access, governments want to ensure that medicines are available to everyone, that they are made available as quickly as possible, and that doctors use the products appropriately. At the same time, governments want to set incentives that reward continued innovation. The reason for intellectual property protection and its recent expansion was to ensure that companies would invest in research and development because they would receive an economic return on their investment.

The analysis suggests that market interventions can substantially influence both the way in which new drugs are adopted and the incentives for pharmaceutical companies to invest in research and development. The interventions can reduce access by inducing delays in market introduction and often limiting the number of patients who receive treatment, and, as a result, may decrease the quality of health care delivered and increase the cost. The interventions can also discourage research into innovative therapies and reduce the industry’s economic incentives to develop and introduce new drugs.

Impact of market interventions on the availability of innovative medicines

In countries where governments impose a wide variety of market interventions, it may take longer for pharmaceutical companies to market new drugs. Apart from the time it takes for a product to be approved in a market (ensuring it meets the local government’s requirements for safety and efficacy), our research shows that markets with more market interventions tend to get broad (reimbursed) access to new medicines relatively later than those with fewer market interventions. Hence, as Figure 14 shows, Greece, Belgium, and France, markets with considerable market intervention, have the longest delays between product approval and marketing, whereas Germany, Norway, the U.S., and the U.K., countries with relatively less intervention, have the fewest delays.
The delays illustrated in Figure 14 are not associated with registration, i.e., with the scientific evaluation of a drug’s efficacy. Although registration delays remain a substantial factor in some markets, such as Japan, the past decade has seen substantial progress in harmonizing product registration procedures around the world and reducing the differences between markets in how quickly registration is achieved. Still, in Europe, a region in which there are now two efficient routes to product registration (central registration via the EMEA or mutual recognition), there is a marked pattern of delays between regulatory approval and marketing.

One of the causes of such delays can be negotiation over price. Interviews with industry leaders confirmed that the time it takes to negotiate pricing was increasingly the bottleneck in launching new medicines. While governments try to achieve the lowest possible price, and companies hold out for a price they will accept, large segments of the population that may benefit substantially from the new treatments are left waiting. The problem is particularly acute in Europe, where parallel trade and cross-country reference pricing can cause uneconomically low prices to spread between countries.
Price negotiations, however, are not the only source of delays. Delays are also caused by
the bureaucracy of approval and reimbursement (notwithstanding an EU target to have all
reimbursement issues addressed in 180 days), and the wait for new drugs to be listed on
the official reimbursement list, which in some countries may be issued only once every
six months. All of these policies and hurdles form a “back door” delay mechanism.
During this interregnum there is effectively a two tier-system of access to drugs. In
countries where products are approved, but not reimbursed, those who can pay out of
their own pocket obtain new medicines, while those reliant on government
reimbursement are denied access.

**Impact of market interventions on the diffusion of innovative medicines**

Apart from slowing the widespread availability of innovative therapies, market
interventions may limit the number of patients who get access to these therapies. Some
interventions, such as formularies, directly restrict access to selected newer medicines
with substantial adverse consequences for health outcomes and health spending. The
Californian Medicaid program, for example, used to insist that those suffering from
schizophrenia try at least two older, less effective, but cheaper, medications before any of
a class of newer treatments was prescribed. A study by a patient advocacy group showed
that $4,842 could be saved per year if patients were given a new-generation antipsychotic
(risperidone) as a first-line treatment. The study found that only 10 percent of
individuals with schizophrenia were able to return to work following treatment with older
medications; usage of newer medications results in a doubling in the number of patients
returning to work. Overall it was calculated that unrestricted access to newer medications
could save the state $17 million annually and, moreover, relieve unnecessary suffering.
Given these benefits, Medi-Cal’s restrictions on the prescribing of atypical schizophrenia
drugs were lifted in 1997.

Despite many states’ and HMOs’ experiences with formularies, the U.S. Department of
Veterans’ Affairs (DVA) and the Department of Defense (DoD) have started to
implement a restrictive cost-based national formulary through a bidding process in which
the low bidder almost always wins. This formulary is being introduced despite the
DVA’s already being able to purchase pharmaceuticals at discounted prices through the federal ceiling-price program. The DVA has already awarded national contracts for 7 of 22 therapeutic classes that were selected for prescription drugs. As with reference categories under reference pricing systems, drugs are put in a therapeutic class according to their therapeutic equivalence, and within a class only one or two innovator drugs and one generic drug are chosen as the preferred treatment. This restrictive formulary continues to be enforced even in the face of mounting evidence that the basic premise—that drugs in a class are truly therapeutically equivalent—is flawed, and leads to worse health outcomes.  

Market interventions can have a more indirect impact on diffusion by affecting the incentives for pharmaceutical companies to promote and ensure the fastest adoption of some innovations. This negative impact can be particularly apparent in patients suffering from classically undertreated conditions. These sorts of diseases, such as hypertension, high cholesterol, and depression, are not immediately life-threatening and are often asymptomatic, but have very substantial cost implications for society. Estimates of the annual economic cost to the U.S. of chronic conditions range from $274 billion for cardiovascular disease, to $98 billion for diabetes and $14 billion for osteoporosis. According to one study, the cost to the U.S. of depression in 1990 exceeded $43 billion, of which pharmaceuticals accounted for only 2.7 percent. A similar pattern is seen for heart disease associated with hypercholesterolemia. Coronary heart disease results in about 500,000 deaths annually in the U.S. With the relation between elevated LDL cholesterol levels and increased morbidity and mortality from coronary heart disease well

* Although the creators of a reference group may regard its members as therapeutically interchangeable, there may be substantial differences in effectiveness, even for different formulations of the same molecule. An analysis of hypertension treatments in a Canadian reference price system highlighted the superior effectiveness (improved compliance, improved outcomes) of a once-per-day formulation of the compound diltiazem in comparison with the immediate-release formulation around which a reference group had been created. These differences are exacerbated if the reference concept is extended across whole classes of drugs (e.g., all SSRIs, or all H2 antagonists), as it has been in Germany and New Zealand.
established, a recent study estimated that nearly 12 percent of the adult U.S. population would benefit from drug therapy that lowers cholesterol levels.\textsuperscript{35}

Recently introduced classes of pharmaceuticals can play a central and cost-effective role in treating these conditions. In the case of depression, for example, treatment with selective serotonin reuptake inhibitors (SSRIs) is often more cost-effective than treatment with older and cheaper drugs like the tricyclics; one study found that the total direct health care costs for six months are $1,970 for fluoxetine (an SSRI), and $2,100 and $2,400 for imipramine and desipramine respectively (tricyclics).\textsuperscript{36} With fewer side effects and a greater likelihood that patients will stick with the course of treatment, the higher direct cost of SSRI treatment is offset by lower comorbidity, lower rates of hospitalization, and simplified followup outpatient care.

Similarly in the case of hypercholesterolemia, new methods of treatment (both by pharmaceuticals and by other protocols) can extend life expectancy. With advice and diet alone, the cost of adding one year of life expectancy among males at risk for heart disease due to high cholesterol levels is more than $200,000. But if the new class of pharmaceuticals (statins) is used, the cost is approximately $40,000-$45,000 per additional year of life expectancy.\textsuperscript{37}

Increasing treatment rates for these kinds of diseases crucially depends on building awareness among physicians and in the population at large. Such awareness-building either requires governments to make a substantial investment in doctor and patient education and communication, or requires pharmaceutical companies to launch efforts to communicate with and educate physicians and patients. Pharmaceutical companies play a major role in this awareness-building in the countries studied. They do so for rational economic reasons: to get a return on their investment in R&D. They do it by using physician seminars, sponsoring journal articles, sending sales people to visit individual physicians, and using other forms of marketing. In return, physicians learn about new methods of therapy and new treatments, and patients who need new therapy receive it.
In countries with less market intervention, companies have a clear economic incentive to support the appropriate use of their products. Market regulations reduce the attractiveness of providing substantial education and other marketing support by reducing the marginal returns so generated. In many countries there are also direct restrictions on the extent to which companies can make physicians and the public aware of new drugs. For example, in France, as in most European countries, phase IV studies, educational symposia for physicians, advertising to physicians, and sampling are all strictly controlled. Outside the U.S., direct-to-consumer (DTC) advertising for prescription drugs is not allowed.

Our hypothesis was that, as a result of the restrictions placed on marketing in many countries, both direct (e.g., bans on DTC advertising) and indirect (e.g., price controls), new innovative classes of drugs would penetrate further and faster in markets with fewer interventions than in markets with many interventions. This would be particularly true in disease categories with patients with asymptomatic conditions, where primary care physicians (as opposed to specialists) must be extensively educated about the new therapy.

Depression, hypercholesterolemia, and ulcers are all diseases that have benefited considerably from new, innovative therapies. Comparing treatment rates across countries is very difficult. There are wide variations in patterns of medical practice and in the comparability of data. However, as a first approximation, a comparison of rates of use of SSRIs and other antidepressants, statins and other cholesterol-lowering compounds, and proton pump inhibitors and H2 antagonists is instructive. Figures 15-17 present these data for a sample of countries.
In two cases, the market with the least intervention, i.e., the U.S., has one of the highest rates of usage of the newly introduced therapies—SSRIs for depression, and statins for hypercholesterolemia. Although these initial data do not establish whether all prescribing that drives these dispensing levels is appropriate (i.e., that every person prescribed a statin should have been, or for that matter that every statin dispensed was taken as prescribed), they are suggestive of some major differences in the rate of adoption of newer classes of therapies. However, in the third case, that of the antiulcerants, the newer class of treatments (proton pump inhibitors) has been adopted faster in many European markets than in the U.S.
How might these observed differences be explained? A first factor is the relative cost-effectiveness of the newer and older classes of drugs. Although the data on the relative pharmacoeconomic cost-effectiveness of SSRIs versus tricyclics are equivocal, the
consensus is increasingly that SSRIs should be prescribed as first-line therapy, because they have lower discontinuation rates and are more likely to be prescribed at appropriate doses.\textsuperscript{38} The picture for the statins is more clear-cut, with a number of studies indicating that they are able to lower LDL cholesterol levels two to three times as much as alternative therapies such as bile acid sequestrants.\textsuperscript{39} In the case of antiulcerants, proton pump inhibitors in many markets have a clear cost-effectiveness advantage in the treatment of gastroesophageal reflux disease but a less clear advantage in the treatment of peptic ulcers.\textsuperscript{40} In U.S. practice, on-patent proton pump inhibitors are relatively much more expensive than off-patent H2 antagonists or older antiulcerants such as bismuth. As a result, the cost-effectiveness argument for proton pump inhibitors as first-line therapy is generally weaker, and the new drugs have not penetrated as fast.\textsuperscript{41}

Clearly, intercountry differences in medical practice play some part in the pattern of treatment. As previously noted, France has one of the world's highest rates of pharmaceutical consumption, and it is therefore not surprising that we see higher consumption levels in France for SSRIs and statins. In the U.K., physician conservatism is often posited as an explanation for slower penetration of new therapies. (Note that in the case of depression, social differences regarding the acceptability of a diagnosis of depression are reflected in drug treatment patterns. For example, as of mid–1998, there had been no SSRIs launched in Japan.)

Finally, the source of a given innovation may be a factor. As a rule local manufacturers win a greater share of their home markets than of global markets. In the case of the statins and the SSRIs, U.S.-based manufacturers were the developers of the leading drugs in each category. Neither of the leading proton pump inhibitors was developed by a U.S. company, and lack of marketing presence in the U.S. may have been a factor in their slower growth in that market.

A closer examination of the drivers of differences in drug adoption rates can cast some light on the potential effects of market interventions. Figure 18 examines the absolute growth in use of statins across countries. Two factors can drive increased use of a given
class of drugs. First, patients already being treated with another drug can be switched to a newer drug. In many cases it may be inappropriate to switch a patient already doing well on one drug, so switching may or may not be of benefit. Second, new patients may be treated with the newer drug. The cross-country comparison indicates that the U.S. has experienced the fastest growth in usage; most of the growth represents growth of the entire drug category, and only a small part is driven by switching. This is in contrast to the growth in statin treatment in Japan, where one third of the growth in statin dispensing has been at the expense of older drugs.

![Figure 18: The U.S. Has Experienced Rapid Growth in Use of Statins](image)

We believe that these analyses support the hypothesis that in countries with limited market intervention, there are greater incentives for pharmaceutical companies to educate physicians and patients. The country benefits because more of its citizens receive appropriate treatment for their conditions. In countries with greater market intervention, either there are fewer incentives or there are restrictions on pharmaceutical companies educating physicians and patients about appropriate use of their new therapies. As a result, the country pays for the market intervention in the form of reduced use of the innovative therapy. Obviously there are exceptions, such as France and Japan, which have a tendency to adopt some new drugs very quickly and in large quantities. Although
those countries suffer because of delays in market entry, they are not as affected as other countries once the products are on the market.

**Awareness-building drives diffusion**

Awareness-building, whether among physicians or patients, is critical to ensuring that patients who otherwise would not be treated get treatment. This awareness-building is a critical part of the marketing carried out by pharmaceutical companies in categories where it is relevant. As the framework presented in Figure 19 suggests, market interventions can have the most impact where a disease is treated by primary care physicians and patient awareness of the condition, or the existence of treatments for it, is low. In this awareness-building segment, investment in educating physicians and patients is needed to increase rates of treatment with the most effective innovative therapies. In other words, the more resources companies commit to building awareness, the greater the growth in the numbers of patients benefiting from new therapies.

![FIGURE 19: IMPACT OF MARKET INTERVENTIONS BY THERAPEUTIC AREA](image)

By using methods such as DTC, physician detailing, articles in journals, and distribution of samples, pharmaceutical companies in the U.S. have invested in building awareness of hypercholesterolemia among physicians and patients. This marketing effort has helped
increase treatment rates: the number of days of therapy with five major statins increased from 774 million in 1993 to 1,959 million in 1997.\textsuperscript{42} It is worth noting that marketing spending in and of itself is not enough to drive consumption of a drug that offers little, if any, benefit. An analysis of marketing spending and growth rates in the SSRI category (Figure 20) clearly shows differences in marketing effectiveness between drugs in a class.

![FIGURE 20: LATER ENTRANTS IN THE SSRI MARKET HAVE EXPERIENCED DIMINISHED RETURNS FROM MARKETING](image)

For some diseases, market interventions have less impact on rates of drug diffusion. In diseases treated by specialists, rapid dissemination of scientific data, aided by patient lobbying groups, helps ensure that the latest drugs become available rapidly in most markets. Finally, in a growing class of so-called life-style drugs, government reimbursement is becoming less of an issue, as patients are increasingly prepared to pay for the treatments themselves. These disease categories--life-style drugs and diseases treated by specialists--represent a very small portion of pharmaceutical treatment. The vast bulk of pharmaceutical treatment is for conditions that can be treated by primary care physicians provided they have the most up-to-date information. These are the types of diseases that benefit most from pharmaceutical companies going out and educating physicians.
Our analysis of the diffusion of innovation seems to bear out a simple economic truth: where pharmaceutical companies have an economic incentive to ensure that more people get treated, and are given the freedom to price and market accordingly in response to market competition, more people will get appropriately treated. Where these incentives and freedoms are reduced, treatment levels reflect the policies put in place by the government officials who define pharmaceutical industrial policy.
5. **Benefits to patients and society of limiting market intervention**

*The value of competition*

Our analysis assessed the impact of market freedom (relatively fewer direct interventions in the market) on prices, access, and incentives to introduce new products. We found that greater freedom provides incentives to introduce new products and improves health outcomes while encouraging competition, which leads to lower prices. In markets where companies are free to launch products at prices the market will bear, the ensuing competition actually puts downward pressure on prices. This is most clearly seen in the U.S., as shown in Figure 21. In a competitive market new entrants are economically advantaged by entering at a discount to the market leader—on average the prices for new entrants are 14 percent lower. Interestingly, for the most active chronic disease categories, the prices of new entrants are on average 36 percent lower. Hence market interventions that attempt to control prices for particular drugs or drug categories may reduce price competition and lead to prices that on average are higher than they would have been had such price competition occurred.

![FIGURE 21: MOST NEW ENTRANTS IN U.S. MARKET DISCOUNT HEAVILY AGAINST THE MARKET LEADER](source)

A similar pattern is seen in other markets in which new entrants are free to select their price. Across a variety of markets as diverse as the U.K., South Africa, and Denmark, a 1996 study established a clear correlation between the number of competitive entrants and the trend in prices; where there were more entrants, prices fell faster. Similarly, a 1998 study of pricing in the U.K. since the 1970s illustrates a clear trend toward increasing price competition. In the 1970s two-thirds of follower drugs (second or later entrants into a therapeutic category) came in at prices one and a half times or more above that of the initial entrant. By the 1990s, no followers were pricing more than one and a half times above the initial entrant and 70 percent were pricing at or below that initial entrant’s price level. Accompanying this increase in price competition was a reduction in the period of exclusivity for the first entrant, down from two and a half years in the 1970s to an average of two years for drugs launched in the 1990s. The time between second and third entrants fell even more precipitously, from 5.3 years in the 1970s to 1.2 years in the 1990s.

The downward pressure on prices due to new entrants in a competitive market can also be shown by data on new depression therapies in the U.K. (Figure 22). In response to a new entrant (drug B), the market leader (drug A) reduced prices. That drop in price
allowed the market leader to lift its falling share. Such competitive dynamics would not be allowed to play out in markets where, for example, the government mandates the prices of individual drugs, or sets a reference price for an entire class of drugs.

The impact of price competition from generic products following patent expiration has already been discussed (Figures 12 and 13). In the antiulcerant category, for example, competition from generics drove the average real cost of a day’s H2 antagonist therapy down by 35 percent in the U.S. and by 50 percent in Germany between 1994 and 1996.

**Encouraging innovation**

So far, our assessment of the effects of market interventions has addressed questions of access to and cost of innovative medicines. Another objective of market interventions is to encourage a healthy and productive pharmaceutical sector within the country in question. The French price control system, for example, made explicit allowances for investments in R&D and manufacturing facilities in France. The PPRS is often cited as a contributor to the global competitiveness of the U.K. pharmaceutical industry. In addition to directly influencing investment and innovation, particular market interventions may encourage certain patterns of industry behavior. For example, the Japanese R-zone approach gives an incentive for manufacturers to release a multiplicity of “me-too” drugs that occupy new price points.

A country’s local pharmaceutical industry is directly and indirectly responsive to changes in government regulation of pharmaceutical markets. In Germany, for example, investments in R&D by pharmaceutical companies fell after the introduction of physician budgets for pharmaceuticals and rose again after reference pricing for patented products was abandoned (Figure 23). In Canada, the adoption of IP protection was accompanied by a sharp acceleration in local R&D spending.* Thus, although pharmaceuticals are

*It should be noted that the Canadian pharmaceutical industry made a commitment to the Canadian government to increase R&D investment in response to adoption of improved IP protection. The industry agreed to invest 10 percent of sales in R&D by 1996. It achieved this level by 1993.
developed for a global marketplace, the evidence suggests that the local market can play a major role in influencing local R&D investment.

In addition to reducing the overall R&D investment in a country, greater market intervention also seems to shape the innovative output of a country’s pharmaceutical industry. The results of a comprehensive study of the output of several countries’ pharmaceutical industries are shown in Figure 24. This analysis suggests that products developed in countries with more market intervention reach fewer other markets (i.e., are more likely to be “local” products). Another analysis by the same author has established a clear correlation between the level of globalization of a drug and its innovativeness as measured by molecular structure and scientifically proven improvement in efficacy. In other words, in countries with substantial market intervention, local companies focus their product development on products that can succeed within the local regulations rather than produce medicines for the global marketplace. The production of drugs for international and global markets is concentrated in companies based in relatively freer markets. Between 1990 and 1994, for example, the U.S., the U.K., and Switzerland accounted for 75 percent of drugs launched in four or more of the G7 markets.
So far we have shown that companies’ investments in R&D may be affected by market interventions. Investing in R&D is very risky, with very long payback periods. Only about a third of the total number of medicines developed and launched actually manage to recover the average fully allocated cost of R&D. The remaining two thirds, while probably covering their marginal costs of development, do not contribute to the sunk costs of basic research. In addition, they will not contribute to the costs of the many thousands of products that fail in early development and clinical trials. If companies expect lower returns on their R&D investments across the board as a result of market interventions, these marginal products are at risk. A 1994 GAO analysis demonstrated how drug-company R&D might be expected to decline in response to a reduction in drug prices. Hence, at the margin, patients may lose out on drugs that might offer significant therapeutic benefits for less prevalent conditions, or for groups of patients less well served by existing drugs.

If, as our assessment suggests, market intervention is counterproductive from both an economic and a health outcomes standpoint, how can countries reduce their level of intervention without exposing themselves to a sharp rise in pharmaceutical spending or
an unacceptable disruption of existing funding and prescribing mechanisms? Although
the answer will be different in every country, a number of key elements should be
common on any road toward lowering market interventions. The following section
describes those elements and proposes routes for the relaxation of market intervention.
6. Pathways to fewer market interventions

Four key elements

What are the characteristics of an open and competitive market for pharmaceuticals? Analysis of different health care systems around the world suggests four key characteristics of such a market (Figure 25).

<table>
<thead>
<tr>
<th>FIGURE 25: ELEMENTS OF AN OPEN AND COMPETITIVE MARKET</th>
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<tbody>
<tr>
<td>1. Respect for intellectual property rights</td>
</tr>
<tr>
<td>• 20-year patent life</td>
</tr>
<tr>
<td>• Patent restoration</td>
</tr>
<tr>
<td>• Data protection</td>
</tr>
<tr>
<td>2. No barriers to competition</td>
</tr>
<tr>
<td>• Speedy, equitable registration</td>
</tr>
<tr>
<td>• Transparency</td>
</tr>
<tr>
<td>• Marketing and reimbursement independent</td>
</tr>
<tr>
<td>3. Market pricing across the product life cycle</td>
</tr>
<tr>
<td>• Competition encouraged across product life cycle</td>
</tr>
<tr>
<td>• Market-based premium for innovation</td>
</tr>
<tr>
<td>• Market dynamics determine pricing</td>
</tr>
<tr>
<td>4. Informed and active decision-makers</td>
</tr>
<tr>
<td>• MD and patient informed about Rx benefits/science</td>
</tr>
<tr>
<td>• No limits on access to MDs or patients</td>
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<td>• Cost-sharing</td>
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The basis for any market for innovative pharmaceuticals begins with intellectual property protection. As already noted, linking of IP protection to the WTO/TRIPs process has enabled tremendous progress in establishing a common level of protection around the globe. Best-in-class IP protection is currently exemplified by the system in place in Europe. The EU regime combines a 20-year patent term with allowances for patent-term restoration to make up for time spent in meeting product regulatory requirements. Finally, under EU law, patented medicines are given a ten-year period of data exclusivity during which generic manufacturers may not make use of an innovator’s safety and effectiveness data in support of their own product applications. This compares with a five-year period in the U.S. IP protection underpins the incentives for pharmaceutical companies to innovate and to launch new products, but it does not protect them from free
and vigorous competition at any time. There are two elements to such competition: freedom to enter the market and freedom to price following entry.

Although many of the barriers to entry of new products and competitors into local markets have been reduced as part of the WTO/TRIPs process, there are still substantial differences among countries in how readily new products can gain access to the market. Registration is one area where substantial barriers remain. As noted above, requirements for local clinical trials are still a major driver of the so-called drug lag in the Japanese market. Our main focus in this study, however, is on barriers relating to reimbursement and marketing approval rather than registration.

Our analysis of market incentives suggests that any system of marketing approval should be transparent and fast. The system needs to be fair to any company or product, with predictable behavior based on past experience and defined policies. This will enable companies to plan better and increase their incentives to innovate. Many market interventions, particularly those that rely on loosely defined comparisons with “comparable products” for price-setting, have been criticized on the grounds that they lack transparency. Volume and price regulation policies, which rely heavily on confidential company information, can also suffer from a lack of transparency. The system should be fast, in that products approved as safe and efficacious should be able to be marketed, i.e., marketing approval should be independent of reimbursement approval. This will help to compensate for delays in establishing reimbursement, though there may be a period during which the drug is available only to those who are able to pay out of pocket.

A third characteristic of a free and open pharmaceutical market is that competition is encouraged across the product life cycle. As the analysis showed, vigorous competition from multiple entrants in a class and from generics after patent expiration is an effective way to hold down prices, while at the same time giving patients and providers more options. Key to encouraging competition is to allow different products to earn different returns by allowing the market to dictate pricing.
While ensuring market pricing is important, pricing dynamics are a complex subject. Even in markets free of interventions, different product classes show very different pricing behavior. The important characteristic, however, is that it is the market that dictates the appropriate price-volume relationship for a given product. Thus products with superior characteristics (e.g., greater efficacy, fewer side effects) can command premiums if, and only if, the market values those characteristics. Similarly, a me-too product may compete on price. Market interventions tend to distort these signals and behaviors and as a result artificially limit price competition.

Consider one element of market pricing: price at the point of entry. Many controlled markets seek to regulate entry price on the basis of the product’s worth in terms of scientific improvement or economic advantage. Unfortunately, there is no simple way to establish ex ante what a given drug is worth in a given market. Efforts to do so are just as likely to result in a price that is too high as in one that is too low. Where a product is a second entrant, the rule often devolves to pricing at the same level as, or at some agreed discount to, the existing player. Once again, opportunities for price differentiation, either higher or lower, are diminished.

Over the life of a product, market pricing is further distorted if the system drives down prices year after year according to a formula. This approach can lead to counterproductive and wasteful launches of imitative products simply to establish new price points, as in the Japanese R-zone system. In addition, continuing reductions in price diminish a player’s incentive to invest in further studies that might establish new indications for the product or better demonstrate efficacy, studies that in other markets could be rewarded by a relative price premium.

For the market to play its role in setting prices, however, there has to be a market for pharmaceuticals in which providers (physicians), consumers (patients), and payers (private insurers or governments) have appropriately aligned incentives. Many governments are realizing that, irrespective of price controls or other market interventions, pharmaceutical spending is rising, driven up by an aging population and
the introduction of new medicines. The beneficiaries of this increased spending are patients who are living longer and healthier lives than before. Having patients share part of the cost of pharmaceutical consumption directly through copayments, rather than indirectly through taxes, has therefore become part of almost every system. Without some economic incentive to consider the benefit delivered by drugs in relation to their costs, patients are liable to consume inappropriately.

Just as importantly, prescribers should be given an incentive to consider the cost-effectiveness of their decisions. Studies have shown that when physicians are informed about the prices of drugs they prescribe, they become conscious of the cost-effectiveness of their prescribing, and, in general, prescribe lower-cost drugs. This is critically important, as there remain substantial information asymmetries between patients and providers. Creating informed patients and providers necessitates some freedom for pharmaceutical companies to communicate the benefits, including the scientific value, and costs of their products. As we have noted, governments are increasingly allowing consumers to evaluate for themselves the cost-benefit tradeoff of life-style and over-the-counter drugs.

But can governments afford to adopt these four elements? In many cases implementing these types of policies could lead to a rise in the average price level of patented products, which, without anything else changing, would only raise overall pharmaceutical spending.

Simply looking at patented products in isolation, however, obscures the opportunities for economies that exist elsewhere in the pharmaceutical budget.

**Headroom for innovation**

The concept of there being “headroom” for innovation in a country’s or region’s drug budget has been proposed as part of the EU’s Bangemann Round Table discussions on “Completing the Single Pharmaceutical Market.” The concept of headroom is that drug spending in a given country is a function not only of the price level and volume of
Across the market as a whole, off-patent products win a larger share when they are relatively cheaper. Encouraging greater competition from off-patent products should therefore lead to lower prices and a higher share for this class of drugs. If Italy, for example, matched the EU average for off-patent share and price level, spending on off-patent drugs would rise by 24 percent. This rise would be at the expense of substitution for on-patent products. Although the volume of on-patent sales could fall by 30 percent, the price level for the remaining products could rise by 64 percent without changing overall drug spending.

Eliminating the distortions created by market interventions would lead to greater competition in the generic (multisource, off-patent) market, lowering off-patent prices and shifting consumption from on-patent products to effective off-patent generic substitutes. By taking advantage of the headroom in the current drug budget, governments might then in turn be able to relax controls on the prices of innovative
pharmaceuticals. The net effect of reducing the degree of market intervention would be to encourage competition later in the product life cycle, and reward and encourage innovation in the early years.

**Conclusion - delivering cost-effective health care**

Many governments are looking closely at how they might introduce market elements into the healthcare sector. A recent WHO study described some of the ways in which European countries are reforming their health care systems to introduce a greater degree of market-driven efficiency, while retaining equity in coverage. Other countries, particularly the U.S., face a different challenge: increasing access for those currently excluded from the private health care system. A recent *Wall Street Journal* article reported that about 19 million elderly people in the U.S. have little or no drug coverage, nor do an estimated 43 million younger Americans.

Pharmaceuticals can play a central role in the cost-effective delivery of health care, whether in government-funded single-payer or privately funded health care systems. This paper has suggested some ways in which the debate about pharmaceutical spending can be reframed. Key to this process should be acknowledgement of the following prerequisites:

- Any health care policy, of which pharmaceutical pricing and market interventions are a part, should have as its goal delivering cost-effective health care, rather than short-term budget savings or financial targets
- Cost-effective health care is delivered by the health care system, of which pharmaceuticals are a key element, but not an element that can be managed in isolation
- Over the long run, approaches that increase market freedom and reduce external interventions are likely to better optimize the cost-effective delivery of health care than more restrictive approaches

Approaches that leverage the economic incentives of all the players—Including pharmaceutical companies and other suppliers—are essential to ensure the successful
outcome of a government policy. Moving the pharmaceutical pricing and market intervention debate away from “how much” to “what benefit” is crucial, all the more so in systems where patients have no alternative avenues for the delivery of health care services. For, as this paper has demonstrated, it is ultimately the patient who suffers from a poorly designed and ineffective intervention regime.
Appendix I – Country Profiles*

CANADA

Health Care System
Canada has a publicly financed, privately delivered health care system known to Canadians as Medicare. The management and delivery of services is the responsibility of the provinces and territories. The federal government’s responsibility is limited to providing services to specific groups such as veterans, setting national standards, and assisting provincial health care services through fiscal transfers. The system is financed through taxes and employee/employer insurance premiums. The provinces must provide comprehensive coverage to everyone. Health services are delivered by the private sector: most physicians are private practitioners and over 95 percent of hospitals are operated as private nonprofit entities.

Pharmaceutical Pricing
Maximum prices for patented drugs are set by the Patented Medicines Prices Review Board. The guiding principle of price control at launch is that the price should not be more than the average of the price in seven other developed countries (France, Germany, Italy, Sweden, Switzerland, the U.K., and the U.S.). Prices are allowed to rise with the consumer price index. The maximum prices are voluntary in principle, but companies may be asked to lower prices, pay fines, or return excess revenues if product prices are deemed to be excessive. Patented product prices are monitored for the entire length of the patent term. In general, price differentials do not exist between provinces, since the lowest price in one province applies to all others.

Reimbursement
All health care services provided by physicians, most medical laboratory tests, and all in hospital procedures are covered. The reimbursement of non-hospital-prescribed drugs is based on the different provincial plans with eight provinces providing universal coverage with varying levels of copay and two provinces covering only the elderly and welfare cases.

Other Cost Control Measures
The main mechanism is control of patented drug prices, as described above. Some provinces, such as Ontario and British Columbia, have instituted other measures, such as generic substitution, price freezes, and reference pricing.

FRANCE

Health Care System
The French health care system covers the entire population. It is funded by employee/employer contributions (74 percent) and patient copayments (26 percent). Patient copayments are paid either by private insurance companies or by nonprofit insurance plans.

Pharmaceutical Pricing
Companies are free to price prescription drugs and generics, but there are strict controls on admission to the reimbursement list. OTC prices can be freely set. For reimbursed drugs, wholesaler margins are controlled (approximately 11 percent). Pharmacy margins are also controlled. For reimbursed products mark-ups fall into one of six bands, depending on the price of the drug. VAT is 2.1 percent for reimbursed drugs, and 5.5 percent for nonreimbursed.

Reimbursement
Using a number of criteria, the Transparency Commission decides whether the drug is eligible for reimbursement. Once it is accepted, the Economic Committee on Medicines decides the actual reimbursement price. Companies have to provide detailed data on costs, sales, and investments. The drug is then placed in one of three classes that
determine the level of reimbursement (35 percent, 65 percent, 100 percent).
Reimbursement prices for generics are typically set 25 percent - 30 percent below those of the original products. Reimbursement status and prices are reviewed every three years.

**Other Cost Control Measures**
The patient has to pay the amount that is not reimbursed, although many segments of the population are exempt from this copayment requirement. Primary care physicians are given prescribing guidelines and asked to limit the growth in total reimbursement. There is a tax on promotional spending by pharmaceutical companies. The tax varies between 9 percent and 20 percent, depending on the proportion of sales revenue spent on promotion (the higher the proportion, the higher the tax). The government enters into contractual agreements with the pharmaceutical industry to make sure that the government health insurance funds do not exceed an annual ceiling on health expenditure, including spending on pharmaceuticals. If the budgets are exceeded, pharmaceutical companies are asked to make a collective contribution toward the health care budget deficit (1996). Such payments take the form of taxes on advertising, taxes on sales, and taxes on extraordinary sales increases.

**GERMANY**

**Health Care System**
The health care system is decentralized, with ~700 self-governing nonprofit insurance funds (called sick funds) financed by employee/employer contributions. Sick funds must accept everyone for coverage. A part of the population (about 8 percent) whose income exceeds a certain level is allowed to buy private insurance.

**Pharmaceutical Pricing**
Companies are free to price prescription drugs and generics, but reimbursement is controlled. Companies can change their prices freely. Wholesaler and pharmacy margins are fixed by law, and depend on the ex factory price of the drug. VAT is 16 percent.
Reimbursement
Once a drug is approved, it automatically qualifies for reimbursement, unless it has been specifically excluded. Prices for reimbursed drugs are controlled by reference pricing. Drugs are put into a reference class on the basis of therapeutic considerations; all drugs in a class are reimbursed at the same level. Patients pay the difference between the reference price and the market price. Since 1996, all on-patent drugs have been exempt from reference pricing. Reference prices are reviewed every year.

Other Cost Control Measures
Patients have to pay a fee per prescription which is dependent upon pack size, although some groups are exempt from this requirement. In 1993, global budgets for prescription drugs were imposed on doctors. Since 1996, global budgets have been replaced by indicative budgets for individual practices although global budgets were reintroduced in late 1998. Generic substitution is legal if permitted by the prescriber. Because of the historically high consumption of branded drugs compared with generics, the government has also made a conscious effort to encourage generic use. This allied with budget constraints on physicians has led to a market in which in 1998 more than 40% of prescriptions were for generics.

ITALY

Health Care System
A comprehensive national health service covers the entire population. The system is funded mainly by general taxes and copayments.

Pharmaceutical Pricing
Companies are free to set prices for prescription drugs that do not seek reimbursement; prices of reimbursed drugs are controlled. Reimbursed generics have to be priced 20 percent below the original. OTC prices are not controlled. For reimbursed products, the wholesaler margin is set at 10 percent of the manufacturer’s price. For products approved through the centralized EU procedure, the wholesaler margins depend on the price of the products. Pharmacy margins for reimbursed products are set at 40 percent of the manufacturer’s price. VAT is 10 percent.
**Reimbursement**
The reimbursement price of prescription drugs can be no higher than the "European average," which was historically calculated on the basis of the average price in France, Germany, Spain, and the U.K. A new system of average prices based on a 12-country comparison has recently been adopted. Drugs are placed in one of three classes that determine the level of reimbursement (0 percent, 50 percent, 100 percent), depending on their efficacy and need. Products are removed from the reimbursement list if their prices are raised above the European average level. Prices of products that are not reimbursed can be raised once a year.

**Other Cost Control Measures**
Depending on the drug category, patients may have to pay 50 percent of the price. They also pay a flat copayment for every prescription. Some groups are exempt from copayment requirements. There is an annual global budget for pharmaceutical reimbursement. Primary care physicians have some prescribing guidelines. Generic substitution (substituting one generic for another) is permitted under certain conditions.

**JAPAN**

**Health Care System**
Universal medical coverage is part of the social security system. Most of the revenue for the system (approximately 90 percent) comes from general taxes and employer/employee health insurance funds, and the rest is paid directly by patients. The health care system is characterized by universal coverage, free choice of health care providers by patients, and fee-for-service payment to service providers. Hospital and clinic physicians may sell drugs directly to patients.

**Pharmaceutical Pricing**
The manufacturer’s prices are not directly controlled, but reimbursement prices are set, effectively acting as price controls. Companies have to sell to wholesalers who supply the national health system at a set discount; the wholesaler has a markup of approximately 4 percent.
Reimbursement
Almost all prescription drugs are on the reimbursement list. The reimbursement price of a new product is determined by comparing it with similar products on the list. The price allowed depends on the product’s relative efficacy, safety, or usefulness. If the drug is innovative, a premium of up to 30 percent is allowed: if it is “useful,” a premium of up to 4.5 percent is allowed; if it is a generic, it has to be priced at least 10 percent lower than the originator drug. If there is no similar drug on the market, the price of the product in other developed countries and the cost of manufacturing may be taken into account. Price are revised every two years (although annual revisions have been made recently). Price revisions are based on the “reasonable zone” (R-zone) method: prices are revised by the amount by which the reimbursement price deviates from the actual discounted market price (the R-zone is currently 5 percent). Price cuts may be mandated if the sales of the drug exceed expected sales targets. Since doctors receive the reimbursement price, they can profit from whatever discount they get from wholesalers.

Other Cost Control Measures
The government is considering additional measures such as cross-country comparisons and reference pricing.

THE NETHERLANDS

Health Care System
There is a national system of health care, but different parts of the system are financed in different ways. Serious illnesses and disabilities are fully funded by the government through general taxes and income-related payments. Acute care is funded by semipublic sick funds; people with incomes exceeding a certain amount can opt for private insurance.

Pharmaceutical Pricing
For prescription drugs and generics, the maximum manufacturer’s price is the average of the prices in Belgium, France, Germany, and the U.K., taking into account the impact of parallel imports into these markets. OTC prices are not controlled. Prices are revised biannually as the prices in the reference countries change. Wholesalers' margins are not
fixed. Pharmacies are paid a fixed dispensing fee per item. VAT is 6 percent for prescription drugs and 17.5 percent for OTCs.

**Reimbursement**
Listing for reimbursement is based on therapeutic and clinical grounds. Drugs that are classified as being unique therapies for hitherto untreatable diseases can be priced by the manufacturer, though few such drugs have been recently admitted to the reimbursement list, and then only after a delay of several years. Reimbursement limits for other drugs on the reimbursement list are based on a reference pricing system based on the WHO Defined Daily Dosage. The maximum reimbursement limit for a class of drugs is based on the price of the product priced just below the average price. Generic prices are taken into account in this calculation. Reimbursement status and limits are not reviewed in a periodic or systematic way.

**Other Cost Control Measures**
Most patients have to pay 20 percent of the cost of all outpatient care, including prescription drugs, up to a maximum level. There are indicative budgets and prescribing guidelines for general practitioners. Generic substitution is permitted with the consent of the physician and the patient.

**SPAIN**

**Health Care System**
The national health care service provides universal coverage. It is funded by general taxation (50 percent), social security contributions (22 percent), copayments, and other out-of-pocket expenses.

**Pharmaceutical Pricing**
Launch prices of prescription drugs are controlled. Prices are set using a host of factors, including cost of production, profit allowance, and anticipated volume of sales. The profit allowance is set by company. A reference-price system is being worked on for multisource drugs with the same ingredient, strength, and dosage forms. Generics are priced 25 percent - 30 percent below the originals. OTCs are not controlled.
Wholesalers’ margins are set at 12.4 percent, and pharmacy margins are set at 43.5 percent of the manufacturer’s retail price. VAT is 4 percent.

**Reimbursement**
Reimbursement is controlled and is based on a number of factors related to therapeutic value. Prices of all drugs on the reimbursement list are set. Reimbursement may be refused if other, cheaper drugs are already on the market. Reimbursement prices may be changed if the change is justified by the manufacturer. In the past, the government has mandated across-the-board price cuts and price freezes for all drugs on the reimbursement list.

**Other Cost Control Measures**
Companies can be asked to return a part of their reimbursement sales to the government. For reimbursed drugs most patients pay 40 percent of the cost. Health care centers have global budgets covering all forms of treatment. Autonomous regions may have additional cost control policies. Doctors’ prescribing behavior is monitored, and high prescribers may be warned. Pharmacists may substitute one generic for another. Promotional expenditure for a product is set at 12-14 percent of the manufacturer’s selling price.

**SWITZERLAND**

**Health Care System**
The different cantons (states) largely decide health policy, though insurance and the supply of drugs are federal responsibilities. Health care is financed by sick funds and private insurance firms (67 percent), general taxation (5 percent), and copayment (28 percent). An increasing proportion of the population is insured by private insurance companies and managed care organizations.

**Pharmaceutical Pricing**
Manufacturers are free to set prices for prescription drugs except for those on the reimbursement list. Generic prices must be below 25 percent of the original if they are to be reimbursed. OTC prices are not controlled. Prices of nonreimbursed products can be
changed freely. Wholesalers’ margins range from 11.1 percent to 17 percent, depending on the price of the product. Pharmacy margins range from 70.6 percent to 26.1 percent. The margins of OTCs are not controlled. VAT is 2 percent.

Reimbursement
Admission to the reimbursement list is based on a number of factors related to efficacy, need, and cost-effectiveness. Reimbursement prices are set by factoring in considerations such as prices in the country of origin, prices in other European countries (Denmark, Germany, The Netherlands), and innovativeness of the drug. Foreign imports are allowed an additional premium of 25 percent to compensate for transaction costs. Reimbursement status and prices are guaranteed for 15 years.

Other Cost Control Measures
Most patients have to pay out of pocket up to an annual deductible amount. After that, they have to pay 10 percent of all medical costs, including those for pharmaceuticals, up to a limit. Some cantons monitor physicians’ prescribing patterns. Generic substitution is illegal.

UNITED KINGDOM

Health Care System
The National Health Service (NHS) provides universal health coverage. It is funded by general taxation (96 percent) and patient copayments (4 percent). Patients have to register with general practitioners (GPs), who control access to specialists. GPs are organized in groups and paid by capitation. There is a move toward primary care groups, which consist of 50 or so GPs providing most health care services.

Pharmaceutical Pricing
The prices of branded prescription drugs are not controlled at launch. Generic prices are controlled – the price is set at the level of the weighted average price of the main suppliers. OTC pricing is not controlled. Prices may be lowered at will, but price increases are restricted to the products of companies whose profits fall more than 25 percent of allowed profits. For sales to the NHS, wholesalers get a mandated 12.5
percent discount from the manufacturer’s price. Pharmacies get a flat dispensing fee per prescription, and are reimbursed at the wholesalers’ list price (hence it is in their interest to negotiate the lowest price from the wholesalers). VAT is 0 percent for NHS prescriptions but 17.5 percent for OTCs and private prescriptions.

**Reimbursement**
All drugs are reimbursed, unless they are on the negative list, which consists of products in eight therapeutic categories. Prices of drugs are not directly controlled, though price increases are.

**Other Cost Control Measures**
The major form of market intervention is the pharmaceutical price regulation scheme (PPRS), which regulates companies’ profits on sales to the NHS. Maximum profits are negotiated on a company-by-company basis and are based on the rate of return on capital in the U.K., investments in the U.K., and level of long-term risks. Companies whose sales exceed their capital employed by a factor of 3.75 are granted a maximum return on sales. Companies that exceed their maximum return on capital or return on sales have to reduce their profits by repaying the excess in cash or lowering existing and future prices. GPs who belong to fund-holding or primary care groups have global budgets to provide all services. Spending is tracked monthly by the prescription analysis and cost (PACT) system. Most patients are charged a flat fee per prescription, or they may pay a certain amount per year for an unlimited number of prescriptions. Generic substitution is illegal, but the use of generics is on the rise. Promotional spending is limited to a percentage of sales to the NHS.

**UNITED STATES**

**Health Care System**
The health care system in the U.S. is mainly private, in terms of both funding and service provision, though there are publicly funded programs that provide health care to certain segments of the population. Care for the elderly is covered by Medicare, entitlement program that reimburses many medical benefits but currently does not include a comprehensive outpatient benefit. Care for the poor is provided via Medicaid which
includes comprehensive drug coverage. Additional publicly funded schemes cover defense personnel and war veterans (Veterans’ Administration). The private health care system consists mainly of health maintenance organizations (HMOs) and other forms of managed care organizations, which are financed primarily through employer/employee and individual contributions. Currently ~30% of pharmaceutical costs are borne directly by cash paying patients, this share is declining as third party payors expand, particularly in the government sector.

**Pharmaceutical Pricing**
Pharmaceutical companies are free to price their products, except that any sales to the government (Medicaid, VA) must at a specified discount to the market price. The last ten years have seen rising pressure on prices with increasing competition among managed care organizations and the rise of pharmacy benefit managers who manage drug spending for more than half of all insured lives.

**Reimbursement**
Co-payments are almost universal with increasing use of tiered co-payments to steer demand towards generic or on-formulary drugs (for which the managed care organization has usually negotiated a manufacturers discount).

**Other Cost Control Measures**
Most government programs that cover prescription drugs mandate some form of price control such as a mandatory rebate, discount, price cap or limit on price increases. In particular the Medicaid Drug Rebate Program requires that companies that sell to Medicaid provide rebates equal to the greater of 15.1 percent of the average manufacturers price (AMP) or the difference between the AMP and the manufacturers “best price” to any other purchaser (e.g. an MCO). Additional rebates are required for any products where price increases exceed the CPI. In addition to requiring rebates the federal and state governments make use of many other forms of market intervention including formularies, prescribing guidelines and other forms of demand side control.
Endnotes


Ikegami, N. et al. 1998. op. cit.

29 Maassen, B. 1994, op. cit.


33 1998 estimates drawn from U.S. patient groups including the American Heart Association, American Diabetes Association, and National Osteoporosis Foundation.


Based on data from Scott-Levin.


Thomas, L.G. 1998. op. cit.

