

APPENDIX A

ISSUES IN PRESCRIPTION DRUG COVERAGE, PRICING, UTILIZATION, AND SPENDING: WHAT WE KNOW AND NEED TO KNOW

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ISSUES IN PRESCRIPTION DRUG COVERAGE, PRICING, UTILIZATION, AND SPENDING: WHAT WE KNOW AND NEED TO KNOW

1. Introduction

This report summarizes the findings from an intensive review of the literature addressing important policy issues in prescription drug coverage, pricing, utilization, and spending. The review had three primary aims:

- To assess the current literature concerning prescription drug costs and trends for Medicare beneficiaries with and without prescription coverage,
- To assess the recent literature on international prices and spending for prescription drugs, and
- To summarize the findings of these reviews from the perspective of what is known and what needs to be known in order to inform the policy debate regarding a Medicare drug benefit.

The study employed a detailed literature search strategy designed to assure that all important research findings relating to the study aims were captured. This strategy involved: (1) traditional index searches of literature in the medical sciences, social and behavioral sciences, economics, health services research, and public policy arenas, (2) searches for relevant statistical data in domestic and international documents, (3) identification and review of relevant ongoing research efforts funded by government agencies and private foundations, (4) identification of relevant working papers and presentations at professional associations based on ongoing and recently completed studies, and (5) a detailed web search with search terms keyed to the study aims. The search was restricted to materials published in the English language since 1995 except for seminal studies published prior to 1995, which are also included.

The report is divided into six sections. Following this introduction is a section that addresses key issues relating to drug costs for Medicare beneficiaries. Seven topic areas are covered in depth:

- Drug cost trends
- Drug prices faced by the elderly
- Sources and determinants of prescription coverage
- Dynamic patterns in prescription coverage
- Impact of prescription coverage on drug use and cost
- Out-of-pocket prescription drug spending by Medicare beneficiaries
- What we know and need to know

The next two sections provide background and context for the Medicare drug benefit debate. Section 3 provides an overview of the market for prescription drugs in the United States including a description of the drug distribution chain and methods for measuring drug prices. Section 4 describes international drug prices and spending. The primary focus of this section is on what can be learned from the international experience particularly in the area of drug price controls. Section 5 is a bibliography of all studies examined in the course of the literature review. Section 6 contains of abstracts of studies considered to be of particular value.

2. Prescription Drug Costs for Medicare Beneficiaries

Spending on outpatient prescription drugs by non-institutionalized Medicare beneficiaries reached \$25.1 billion in 1996¹, the latest year for which accurate statistics are available (Poisal, et al, forthcoming). Four years earlier in 1992, beneficiaries spent \$16.2 billion (Laschober and Olin, 1996). Not only does this represent a substantial growth in spending (55 percent), but the rate of increase is also rising, from approximately 9 percent annually between 1992 and 1994 to over 14 percent annually between 1994 and 1996 (Laschober, 1997; Olin and Liu, 1998; Poisal, et al., forthcoming). In per capita terms, the growth rate over this period (44 percent) was somewhat lower (rising from \$468 to \$674), reflecting the fact that the size of the Medicare population has also continued to grow.

More current data are available on prescription drug costs for beneficiaries enrolled in Medicare HMOs. According to industry surveys, the average per member per month (PMPM) expenditure on prescription drugs rose from \$37.53 in 1995 to \$52.50 in 1998, a 40 percent increase in just three years (CibaGeneva, 1996; Novartis, 1999). The increase would have been even steeper had HMOs not raised patient copays by more than 25 percent over the same period (CibaGeneva, 1996; Novartis, 1999).

The issue of rising drug costs is at the core of the national debate over whether a prescription drug benefit should be added to Medicare coverage. On the one hand, rising costs are cited as a main reason why Medicare should cover drugs. Despite the fact that drug coverage of Medicare beneficiaries expanded during the first half of the 1990s (see section 2.3); the burden of out-of-pocket drug spending has also grown (see section 2.5). On the other hand, the growth in drug spending will make any meaningful Medicare drug benefit expensive to finance. From either perspective, there is a clear need to answer the question: **What factors explain drug spending by Medicare beneficiaries?**

The answers lie at both the individual level and the market level. The literature on individual determinants of drug spending by Medicare beneficiaries identifies seven factors: (1) health status, (2) functional impairment, (3) age, (4) gender, (5) race, (6) income, and (7) insurance coverage. Health status is an obvious factor. Beneficiaries reporting excellent health spent an average of \$363 on prescription medicines in 1996 compared to \$1,107 for persons reporting poor health (Poisal, et al., forthcoming). For beneficiaries with no functional impairment, drug spending per person was \$582 versus \$1,000 for persons with one or more

¹ The true expenditure levels may be higher than this figure considering the possibility of under-reporting of prescription drug use in consumer surveys.

functional impairments (Poisal, et al., forthcoming). Other highlights from the latest report of Medicare beneficiary drug spending (Poisal, et al., forthcoming) include the following:

- **Gender:** drug spending by females is higher than for males
- **Race:** whites spend more than blacks
- **Disability:** disabled beneficiaries under age 65 spend almost double the amount of aged beneficiaries
- **Income :** Beneficiaries with annual incomes below the poverty line have the highest per capita spending on prescription drugs, closely followed by those with incomes between 150 and 200 percent of the poverty line.
- **Insurance Status:** More than three-quarters (79%) of total 1996 prescription drug expenditures by Medicare beneficiaries were spent by persons with drug coverage. The average per capita drug spending by beneficiaries with coverage was \$769 and without coverage was \$463.

The finding that spending levels differ by socio-demographic status and insurance coverage are not unexpected, but simple descriptive comparisons may mask the true determinants of drug spending behavior. In one of the very few multivariate studies of prescription spending by aged Medicare beneficiaries, Lillard, et al. (1999) find that private health insurance, urban residence, and ill health are positive predictors of drug spending, while age and education level are negative predictors, when other factors are equal. Some factors that appear to be strong correlates of drug spending in descriptive comparisons lack predictive power in a multivariate framework, including gender, income, wealth, and Medicaid coverage.

2.1 Drug Prices Faced by the Elderly

The determinants of drug spending described above operate primarily through the drug selection decisions made by Medicare beneficiaries and their physicians. However, drug prices can be an important factor, particularly for those beneficiaries without stable drug coverage. The question most frequently asked in this regard is: ***Do Medicare beneficiaries pay more for their prescriptions than other Americans ?*** The underlying issue is whether the prices for drugs commonly used to treat age-related chronic conditions are either higher or increasing at a faster rate than drugs used for other diseases. Research on this question is difficult because drug prices vary greatly depending on the payor, and private payors rarely disclose their pricing practices. For this reason, most attempts to compare prices across age and disease groups are based on standardized price listings such as the Average Wholesale Prices (AWP), the Producer Price Index (PPI), or the average retail price (ARP). Highlights from three recent studies show that:

- Of the five best-selling drugs used by older Americans in 1997, the average retail pharmacy price (undiscounted) ranged from 78 percent to 299 percent higher than the

“best price” negotiated by the Department of Veterans Affairs. (US House of Representatives, 1999).

- The AWP for the 50 prescription drugs most frequently used by the elderly rose more than four times the rate of inflation during calendar year 1998. Over the past five years (1994-1999), the AWP prices of these same drugs rose at twice the level of inflation. During the same period, 22 of the 50 most commonly used drugs by seniors had generic or co-marketed versions available for some portion of the time (Families USA, 1999).
- Between 1990 and 1996, changes in the Producer Price Index (PPI) for drugs in therapeutic classes most frequently prescribed to elders were 51 percent for anticonvulsants, 39 percent for cancer products, 42 percent for cardiovascular agents, 38 percent for diabetes products, 45 percent for diuretics, and 53 percent for nutrients and supplements (Berndt, et al., 1998). Despite these high inflation rates, the authors found no evidence of age-related price inflation differentials at the producer level.

These studies do not resolve the issue of whether age-related price discrimination exists in the market for drug products because of what happens to prices at different points in the chain of distribution. For example, Berndt et al., (1998) found no systematic age-related difference in price increases at the juncture between manufacturer and wholesaler for three classes of drugs (antibiotics, antidepressants, and calcium channel blockers), but from the wholesaler to the pharmacy one of the three classes (antibiotics) showed more rapid growth for the elderly than the young. Furthermore, at the point where the patient makes the purchase in the pharmacy, relative age-related prices for antidepressants favored the young rather than the aged (Berndt, et al., 1998).

2.2 Sources and Determinants of Prescription Coverage

Medicare pays for prescription drugs only if they are administered in institutional settings (e.g., hospital or nursing home) or belong to several special drug categories such as immunosuppressives, erythropoietin, oral anti-cancer drugs, hemophilia clotting factors, and some vaccines. The vast majority of outpatient prescription drugs are not reimbursable under the standard package of Medicare benefits. Supplemental insurance thus plays an important role in understanding how much Medicare beneficiaries spend on prescription medications. ***What are the characteristics of Medicare beneficiaries with and without drug coverage?***

More than 90 percent of Medicare beneficiaries have some form of supplemental health insurance coverage, either by qualifying for public assistance programs or by enrolling in private insurance policies through employee benefits, retiree plans or individually purchased plans. There is no centralized database that records the characteristics of these supplemental policies or of the beneficiaries who obtain them. Instead, our information on coverage rates depends almost entirely on survey data. The best nationally representative survey (and the one used by most researchers in this area) is the Medicare Current Beneficiary Survey (MCBS). Since 1992, longitudinal samples of approximately 12,000 aged and disabled beneficiaries have been queried three times a year about their supplemental insurance (including prescription drug

coverage), health status, access to care, and use and cost of all health services. The scientifically rigorous methods used in selecting the respondents and soliciting accurate information make MCBS data the most reliable single source for estimating prescription drug coverage for the Medicare population.

According to 1995 MCBS data, 65.2 percent of community dwelling Medicare beneficiaries had some prescription drug coverage for at least part of the year (Poisal, et al., 1999). Over 70 percent of the disabled Medicare population had drug coverage in that year. Rates were lower among elderly beneficiaries, ranging from 66 percent of those aged 65-69 to just 60 percent of those over age 85 (Poisal, et al., 1999). Males and females have similar coverage rates (70 and 68 percent, respectively in 1995). White beneficiaries were less likely to have coverage (64 percent) than blacks (69 percent) or persons of other races (75 percent). Coverage rates rise with income from 65 percent among beneficiaries with annual incomes below \$10,000 to 72 percent among beneficiaries with incomes above \$30,000 per year (Poisal, et al., 1999). Beneficiaries who reside in metropolitan areas are much more likely to have prescription coverage (69 percent) compared to those who do not (54 percent) (Poisal et al., 1999). In 1995, 64 percent of beneficiaries reporting excellent health had drug coverage compared to 69 percent of those in poor health (Poisal, et al., 1999). The differences are much greater when health status is measured by counts of chronic conditions. In 1996, 65 percent of Medicare beneficiaries reporting having none of ten common chronic conditions had some prescription coverage compared to 77 percent of beneficiaries with five or more of these conditions (Stuart, et al., 2000).

The reasons for these differences are varied and complex. For beneficiaries above the poverty line, coverage rates rise with income. This could be due to higher purchasing power and the fact that retirees with higher incomes are more likely to qualify for employer-sponsored health insurance. The reason that prescription coverage is higher among nonwhites is probably not because of race per se, but rather because nonwhite retirees have *lower incomes* and therefore higher Medicaid eligibility rates. The negative correlation of coverage rates and self-reported health status *might* mean that those who need coverage the most are the most likely to seek it out, but it could also capture the impact of income and Medicaid eligibility status.

To date there has been just a single study of the determinants of prescription drug coverage for Medicare beneficiaries (Lillard, et al., 1997). It showed no evidence of adverse selection into prescription coverage, but the data for this study are quite old (1968-1990). There is a substantial body of research on selection into Medicare supplemental policies independent of benefit coverage. Recent studies of Medicare HMO enrollment (Hellinger, 1995; PPRC, 1996; Riley, 1996; Hamilton, 1999; Call, et al) find strong evidence of favorable rather than adverse selection. Indications of adverse selection in the Medigap market have been found by Ettner, (1997), Wolfe and Goddeeris (1991), and Atherly (1999). Other researchers (Cartwright, Hu, and Huang, 1992; Hurd and McGarry, 1997; Lillard, et al., 1999) find none. Most researchers assume that there is no selection into retiree plans given the nature of plan sponsorship, but Atherly (1999) finds evidence of adverse selection in this market. These thoroughly mixed findings do little to clarify the issue of possible adverse selection into prescription coverage.

2.3 Dynamic Patterns in Prescription Coverage

Although the determinants of who has prescription benefits remain unclear, there is no question that drug coverage rates among Medicare beneficiaries have been rising. In 1992, 57 percent of beneficiaries had prescription coverage (Poisal, et al., 1999). By 1996 the rate was 68.8 percent (Poisal, et al., forthcoming). The movement of Medicare beneficiaries into HMO plans is one reason for the trend. Enrollment into Medicare risk plans increased 30 percent between 1995 and 1996 and HMO enrollees are more likely to have prescription coverage (94.6 percent) than those in any other private supplemental insurance plan. However, these prescription benefits are often inadequate.

From a policy standpoint the critical unanswered question is: *Will the trends in prescription coverage of Medicare beneficiaries witnessed in the early and mid 1990s continue?* There are no reliable data on prescription coverage rates since 1996. However, it appears unlikely that the trend maintained its steep upward course in the late 1990s. Recent reports show that large employers are scaling back retiree benefits (Hewitt Associates, 1999) that HMOs are not renewing Medicare risk contracts (Barents Group, 1999), and that some Medicare risk plans are dropping drug benefits, lowering payment caps, or imposing stiff premium surcharges for such coverage (Gold, 1999). This is such a volatile mix of factors, that any forecast of beneficiary drug coverage rates is fraught with uncertainty in both short-term and long-term projections.

This uncertainty has its roots in dynamic patterns of coverage that became evident in the mid 1990s. Profiles of typical Medicare supplemental insurance portfolios present a dynamic picture of beneficiaries gaining and losing prescription coverage, holding multiple plans, and changing plans during the year. Poisal et al., (forthcoming) found that nearly nine percent (over 3 million people) of the total non-institutionalized Medicare population switched plans at least once during 1996. This figure is slightly higher than the previous year's estimate of eight percent (Davis, et al., 1999). However, both of these estimates understate the true degree of change. A month-to-month examination of supplemental insurance in 1996 by Stuart et al. (2000) shows that prescription coverage is often fragmented and non-continuous. They found that 18.9 percent (about 6.3 million people) of beneficiaries with full-year Medicare enrollment had drug benefits for only part of the year, averaging around six months of coverage. Having coverage at some point in the year may be a valuable benefit, but the continuity of that coverage is equally important.

2.4 Impact of Prescription Coverage on Drug Use and Cost

Surely the most compelling issue for policy makers regarding a possible Medicare drug benefit is the question of cost. For any given proposal, actuaries can readily determine that part of the program cost which represents a shift in financial responsibility from beneficiaries or other third party payors. It is much more difficult to predict the impact that coverage will have on the utilization patterns of previously uninsured beneficiaries. This issue has two important components: *Does drug coverage encourage Medicare beneficiaries to use*

more outpatient prescription medications? Does drug coverage influence the type and cost of the medications prescribed and used? The available literature on these topics is primarily descriptive, representing cross-tabulations of utilization and expenditure by presence and source of coverage. Taken at face value, the reported differences suggest that insurance plays a very significant role in the drug utilization decisions of Medicare beneficiaries and their prescribers. A sampling of these findings tells the story:

- Beneficiaries with drug coverage filled an average of 20.3 prescriptions in 1995 compared to 15.3 for beneficiaries without coverage (Davis et al, 1999).
- Beneficiaries enrolled throughout 1996 with full-year prescription coverage filled an average of 22.4 prescriptions compared to 20.7 for those with part year coverage and 16.7 for those with no coverage (Stuart, et al., 2000).
- Average spending on outpatient prescriptions by covered individuals was 66 percent higher in 1996 compared to non-covered beneficiaries (Poisal, et al., forthcoming).

The differences in utilization and annual drug spending by insurance status extend to all major population subgroups categorized by age, income, and health status:

- In 1996, disabled Medicare beneficiaries under age 44 who had drug coverage spent 300 percent more on prescriptions than their counterparts without coverage, \$1,077 to \$268. (Poisal, et al., forthcoming).
- Among the oldest of the elderly (aged 85 plus), those with drug coverage spent 60 percent more on prescriptions than those without coverage (Poisal, et al., forthcoming).
- Beneficiaries with annual incomes in 1996 below the poverty line and no drug coverage filled only 13.8 prescriptions compared to 25.4 prescriptions if they had coverage (Poisal, forthcoming).
- Beneficiaries reporting their health as fair or poor filled 36.7 prescriptions in 1996 if they had full-year drug coverage, but only 27.2 prescriptions if they had no coverage. Those with part-year drug benefits filled 34.3 prescriptions for the year (Stuart, et al., 2000).

The source of coverage also appears to matter:

- In 1995, Medicare beneficiaries with Medicaid drug coverage filled an average of 27 prescriptions compared to 16.2 for Medicare risk HMO enrollees and 18.6 for those with employer-sponsored coverage (Poisal, et al., forthcoming).

There have been no systematic studies of the relationship between drug coverage and the composition of drug utilization, i.e., the selection of specific therapeutic products for a given disease. However, there is a widely held belief that insurance affords better access to

newer, more expensive therapeutic agents. One recent finding consistent with this view shows that Medicare beneficiaries in 1996 who reported good to excellent health utilized drug products with an average cost of \$40.70 if insured, but only \$28.74 if they were not covered for prescription drugs (Stuart, et al., 2000).

All of these reported findings are subject to a major caveat. Although the differences in drug cost and use associated with insurance coverage appear both large and consistent, they are purely descriptive and do not necessarily mean that drug coverage *causes* or *induces* beneficiaries to use more. Indeed, some analysts argue that the differences are primarily due to the fact that sicker individuals who are heavy users of prescription medication are more likely to purchase drug coverage or enroll in public plans that provide it. While it is true that beneficiaries in poorer health are more likely to have prescription coverage (as noted in section 2.3 above), that does not rule out an independent insurance effect on demand.

There is a small but growing analytical literature that attempts to disentangle the various influences on the demand for prescription drugs by the elderly. Early studies by Long and Gordon (1989) and Long (1989) support the view that observed differences in drug use for persons with drug coverage under Medigap plans are the result of adverse selection rather than an insurance effect. These authors find no insurance effect among Medicare beneficiaries with employer coverage (where there is presumably little adverse selection).

More recent work supports the opposite view that drug coverage does induce additional usage. Based on data from a survey of Pennsylvania elderly, Coulson and Stuart (1995) and Coulson et al. (1995) found that prescription coverage increased drug use by approximately 3 percent for every 10 percent reduction in out-of-pocket cost to beneficiaries, all else being equal. These authors also found that the primary effect of drug coverage is to induce additional persons to use prescription medicine as opposed to increasing prescription use among users. This “hurdle” phenomenon associated with patient cost-sharing was first observed in the famous Rand Health Insurance Experiment of the late 1970’s and early 1980’s (Manning et al., 1989). It has since been observed in a number of recent studies of the insurance effect of drug coverage on elderly Medicare beneficiaries (Stuart and Grana, 1998; Stuart and Zacker, 1999; Ya-chen, 1999; Lillard, Rogowski, and Kingston, 1999). These studies all reach the same basic conclusion—drug coverage increases the probability of drug use but has minimal effect on the number of prescriptions filled by users. This conclusion is strengthened by the fact that the studies focused on different groups of elderly using a variety of databases. Stuart and Zacker (1999) used MCBS data to assess the impact of drug copayments on elderly Medicaid/Medicare dual eligibles. Stuart and Grana (1998) analyzed survey data on medicine use for 23 common health problems reported by a large sample of Pennsylvania elderly. Ya-chen (1999) used pharmacy records from the Dialysis and Morbidity and Mortality Study to study non-Medicare covered drug use by ESRD patients. Lillard, Rogowski and Kingston (1999) analyzed survey data on prescription use in the RAND Elderly Health Supplement to the 1990 Panel Study of Income Dynamics.

The empirical estimates of insurance effects produced by these studies vary within a relatively narrow range. The addition of drug coverage is estimated to increase the probability of any prescription being filled by between 4 and 16 percent depending on population subgroup

and generosity of drug coverage. The effect of adding a comprehensive drug benefit to Medicare is estimated to increase overall drug spending among elderly beneficiaries by between 20 percent (Lillard, Regowski and Kingston, 1999) to 34 percent (Coulson and Stuart, 1995).

2.5 Out-of-Pocket Prescription Drug Spending by Medicare Beneficiaries

Medicare beneficiaries who have no prescription coverage must, by definition, bear the entire cost of their drug purchases out of pocket. However, the obverse does not follow; no prescription plan currently available to Medicare beneficiaries covers the entire cost of outpatient prescription drugs. Were Medicare to adopt a drug benefit, it would presumably provide the greatest benefit to those who are presently most vulnerable to high out-of-pocket spending for drugs. The obvious question for policy makers is: *What factors make Medicare beneficiaries most vulnerable to high out-of-pocket drug costs?*

The literature on this issue identifies five principle factors: (1) total spending on prescription drugs, (2) insurance coverage, (3) income, (4) health, and (5) functional status. According to the Health Care Financing Administration, half of all drug spending by Medicare beneficiaries in 1995 was paid for out of pocket (Poisal, et al, 1999). The single greatest predictor of high out-of-pocket spending, is high total spending. The National Academy of Social Insurance estimates that 14 percent of Medicare beneficiaries had drug spending exceeding \$2,000 from all payment sources in 1999 (Gluck, 1999). Almost a third of these individuals also had out-of-pocket drug spending greater than \$2,000 for the year (Gluck, 1999).

The presence of prescription coverage mitigates against high out-of-pocket drug costs, but does not preclude them. A recent study published by AARP, estimates that Medicare beneficiaries with some drug coverage in 1999 spent just 3 percent of income on out-of-pocket drug purchases compared to 6 percent for beneficiaries without coverage (Gibson, et al, 1999). The income of Medicare beneficiaries is often lower in proportion to other populations, thus the out of pocket expenses are relatively burdensome. However, 42 percent of those with out-of-pocket drug spending exceeding \$1,000 also maintained some prescription coverage. The principal reason for this is the limited scope of benefits offered by health plans that supplement Medicare, particularly individual Medigap policies (Gibson, et al, 1999). The three Medigap policies with drug coverage all have a \$250 deductible followed by a 50 percent coinsurance up to maximum payment caps of \$1,250 or \$3,000. Stuart et al. (2000) found that Medicare beneficiaries with continuous coverage spent about half as much out-of-pocket in 1996 on prescription drugs (\$219) as persons with part year coverage (\$424) or no coverage at all (\$468).

There is surprisingly little variation in total or out-of-pocket drug spending by income level (Poisal, et al., 1999; Gibson, et al, 1999; Poisal, et al., 1999 forthcoming). In 1995, for example, beneficiaries with annual incomes below \$10,000 spent an average of \$707 for prescription drugs of which \$206 represented out-of-pocket payments. Those with annual incomes over \$30,000 spent an average of \$642 of which \$226 was out of pocket (Poisal, et al.,

1999). However, this similarity in dollar spending means that low-income beneficiaries spend proportionately more of their income on prescription drugs. Gibson, et al., (1999) estimate that beneficiaries below the poverty level in 1999 (\$8,760 for individuals and \$11,334 for couples) spent nine percent of their incomes on drugs compared to just 2 percent for those with income above 400 percent of the poverty line.

Twenty-seven percent of Medicare beneficiaries report being in fair or poor health. These individuals are the heaviest consumers of prescription medicines of any group and bear the highest average burden of out-of-pocket costs. Gibson, et al. (1999) estimate that they paid \$590 per-person in out-of-pocket prescription drug payments in 1999, representing seven percent of annual income. Being uninsured and in poor health magnifies the burden. Stuart, et al. (2000) show that beneficiaries self-reporting poor health and no drug coverage spent \$732 out of pocket in 1996 compared to just \$318 for those with continuous drug coverage for the year.

As this last statistic demonstrates, the burden of out-of-pocket drug expenses varies widely depending on the constellation of attributes that beneficiaries manifest. Because these attributes tend to be inter-correlated, to understand the independent effect of each predictor requires multivariate analysis. To date there are no published papers in this area. A study by Crystal et al. (in press) examines predictors of aggregate out-of-pocket spending by Medicare beneficiaries for all types of health care combined using standard multivariate techniques. They find that self-reported health status, number of medical conditions reported, privately purchased Medicare supplemental health insurance, and functional impairment all increase the level of predicted out-of-pocket payments, while only HMO participation predicts lower payments (Crystal, et al., in press). Given that outpatient prescription drugs comprise approximately a third of all out-of-pocket health spending by beneficiaries (Crystal, et al., in press), one would expect these multivariate findings to hold true for prescription drug spending by itself.

2.6 What We Know and Need to Know

This section reviews what is known as well as that which remains unanswered in the context of the bolded questions presented throughout the discussion above. There are some common themes. The first crosscutting theme is that the literature focuses on drug use and spending almost as if “prescription drugs” were a single homogeneous product. A few studies have analyzed utilization at the level of the therapeutic class, but there has been virtually no research on the nexus between insurance coverage and appropriate or inappropriate drug use. The presumption is that lack of drug coverage is a barrier to appropriate drug therapy and impacts access to medications. It is also possible that lack of coverage reduces exposure to inappropriate drug use and thereby reduces the incidence of adverse drug events. More research is needed to clarify this issue as adverse drug events contribute to additional health expenditures through hospitalizations to treat these events as well as the costly cycle of prescribing additional drugs to treat the side effects of many previously prescribed drugs.

Further research is also warranted to identify the relevant elements in insurance contracts that demonstrate empirical evidence of assuring quality and safety in drug use.

A second common theme in the literature is the focus on aged Medicare beneficiaries to the near exclusion of the disabled and beneficiaries with ESRD. Nearly all of the studies reviewed here focus strictly on the elderly or simply subsume the disabled in with the aged. Twelve percent of Medicare beneficiaries or approximately 5 million individuals receive their program entitlement from disability insurance. These beneficiaries are (by definition) all under age 65 and have very different characteristics and prescription drug needs than their aged peers. For example, there is a much higher prevalence of mental illness among the disabled compared to the elderly, making behavioral medicine a critical issue for this population group. Also, the disabled do not have the same access to private Medigap supplements as those over 65 years of age.

Another common characteristic of the literature on drug use and spending by Medicare beneficiaries is that it is largely descriptive rather than analytical. Making public policy on the basis of means, frequency distributions, and cross-tabulations can be perilous given the interdependence of factors relating to drug coverage, use, and spending in this population. There is a need for additional multivariate research in each of the areas addressed in this review as identified below.

What factors explain drug spending by Medicare beneficiaries? This issue is paid considerable attention in the literature, but the studies are predominantly descriptive. We know that beneficiaries in poor health are high spenders, but we have little knowledge of the drugs they use or the illnesses they treat with them. We know that white beneficiaries spend more in total for prescription medicine than blacks, but we do not know whether the explanation is racial or is due to some other co-varying factors such as income or education.

Do Medicare beneficiaries pay more for their prescriptions than other Americans do? There is scant research on this topic and even fewer answers. The question is important, as limitations in prescription drug policies place many beneficiaries with private insurance at risk of significant out-of-pocket purchases. The “best price” practices reserved for large purchasers of prescription drugs means that Medicare beneficiaries who buy prescriptions without the benefit of group volume discounts will tend to pay higher prices. It would be useful to know whether Medicare beneficiaries with supplemental prescription coverage are reaching maximum expenditure caps earlier in the year because of drug price increases. Research is also needed to examine the extent of generic drug use by age and how this is influenced by rising drug prices and drug benefit design.

What are the characteristics of Medicare beneficiaries with and without drug coverage? We know who has drug coverage but not why. Here is another instance where lack of analytic studies hinders interpretation of the descriptive statistics about which beneficiaries maintain coverage and which do not. A particularly important question yet to be answered is whether beneficiaries with the greatest need for coverage find it easy or difficult to obtain it. An equally important question is how stable the prescription coverage is for those who have it.

Will the trends in prescription coverage of Medicare beneficiaries witnessed in the early and mid 1990s continue? Most commentators think not, but the evidence to date is strictly anecdotal. Reliance on the Medicare Current Beneficiary Survey as the primary data source on Medicare drug coverage, means that the most up to date information is almost four years old before it is published.

Does drug coverage encourage Medicare beneficiaries to use more outpatient prescription medications? The answer is yes, but additional studies are critical to improve the precision of the estimated size of the “insurance effect.” Also needed is research that examines the characteristics of beneficiaries most strongly influenced by prescription coverage as well as drug regimens they use (or would use if given the opportunity). We need to know whether the observed difference in utilization rates between the insured and the uninsured arises because the uninsured fail to fill prescriptions or because the insured are simply prescribed more medications.

Does drug coverage influence the type and cost of the medications used? There is little known about this important issue. Research is needed on the potential influence that drug coverage plays on the patient-physician relationship. For example, do Medicare beneficiaries without drug coverage visit the doctor less often (and thereby avoid the problem of getting prescriptions that they would not fill anyway)? Are doctors less likely to prescribe medications to those without coverage? Are they more likely to prescribe less expensive generic drugs to these clients?

What factors make Medicare beneficiaries most vulnerable to high out-of-pocket drug costs? This is perhaps the best understood of all the major issues raised in this review. Although the research to date is descriptive, the range of comparisons is large enough to give a clear profile of which groups of beneficiaries are at greatest economic peril from out-of-pocket drug costs.

3.1 National Trends in Drug Spending

While prescription drugs represent only about seven percent of total national health expenditures, in absolute dollars the market is formidable (Copeland, 1999). In 1998, the prescription drug market represented over \$91 billion for approximately 2.5 billion prescriptions at the retail level. The average prescription cost increased 11.9 percent over the prior year (Glaser, 1999). Projections of U.S. retail spending on prescription drugs forecast expenditure levels of \$103 billion in 1999 and \$143 billion by 2002 (Sager, 1999). Increases in total drug spending are concentrated in a relatively small number of therapeutic categories. Four drug categories account for 30.8 percent of the total \$42.7 billion increase in drug spending between 1993 and 1998: antihistamines, antidepressants, cholesterol lowering agents, and anti-ulcerant drugs. (Barents, 1999).

Growth in drug spending is generally associated with two primary factors: (1) higher drug prices; and (2) increased demand for drugs (Smith, 1999). High drug prices account for about 64 percent of the total 1993-98 increase in drug spending (Barents, 1999). This is largely due to the recent flood of new and more costly drugs into the market following revisions in the Food and Drug Administration (FDA) procedures to accelerate the drug approval process. In 1998, the average price per prescription for a new drug was \$71.49, which is twice the average (\$30.47) for previously available drugs. Forecasters expect a slowdown in these introductions as the industry's drug development pipeline stabilizes to the new regulatory timelines (Smith 1999).

Increases in the number of drugs that patients use are largely attributed to the drop in out-of-pocket costs, resulting from greater prescription coverage through managed care plans and, until recently, a deceleration in drug price inflation (Smith 1999). Another influence is the change in FDA policy in 1997 (and finalized in 1999) to allow pharmaceutical manufacturers a freer hand in advertising directly to consumers through mass media. In 1998, pharmaceutical manufacturers spent \$8.3 billion promoting their products, of which \$1.3 billion was in direct-to-consumer advertising (Barents, 1999).

3.2 Drug Distribution Chain

Providing prescription drugs to patients involves an intricate, multifaceted system of drug distribution that includes a number of players such as pharmaceutical manufacturers, wholesalers, retailers, third-party administrators, pharmacy benefit management companies, managed care organizations, and providers. Each of these players participates in the pricing of drugs as either purchasers (who try to reduce their outlays) or providers (who try to maximize profits). The following section summarizes these roles.

While every facet of the drug distribution system attracts attention, pharmaceutical manufacturers tend to attract an inordinate amount because perception holds them as the most profitable link in the distribution chain. At the manufacturer level, there are two major distinctions in product lines: 1) brand name drugs and,

2) generic drugs. Typically, innovator companies who carry the burden of research and development costs that are factored into the prices of marketable products develop brand name drugs. Estimates of the cost of bringing a new drug to market range from \$125 million to \$500 million. In 1998, pharmaceutical companies spent over \$17 billion in research and development (PhRMA, 1998). The costs are, as a rule, borne during the drug development process and recouped after market approval during the time when the patent is still in place. In 1998, the median approval time for a new drug application was 12 months for a New Drug Application and 12 months for a new molecular entity (NME) (CDER, 1998). Research-intensive manufacturers generally try to price their products so that the bulk of research and development costs are recovered before competitors enter the market.

When a patent expires on a brand name prescription product, other manufacturers may enter the market and produce generic equivalents of that particular product. A generic equivalent is essentially a drug that is chemically identical to the brand name drug and is also bioequivalent. Generic pharmaceutical companies invest far less research and development monies to gain FDA approval for marketing their products. A generic manufacturer conducts only one or two bioequivalency studies before entering the market. These studies must demonstrate within certain statistical parameters that the generic version of the drug is absorbed into a patient's blood stream at approximately the same rate and duration of time as the brand name drug (CDER, 1998).

Unlike the pricing practices of the brand name manufacturer industry, the generic industry prices its products as another commodity trying to gain market share through lower prices. Generics offer one of the earliest and most frequently used methods of containing costs. Since generic drugs are usually more price sensitive to the market than brand name drugs, generic drugs are often required by third-party programs. It is important to note the program does not necessarily care whether patients receive a brand name drug as long as the price is no greater than that of the generic drug.

Nearly all of major research-intensive brand name manufacturers, numbering approximately 100, are members of the trade association, Pharmaceutical Research and Manufacturers of America, known as PhRMA. PhRMA reported that the domestic U.S. sales of its members were \$81 billion in 1998 (PhRMA 1998). In contrast, the generic industry reported sales of \$8 billion in 1998 (GPIA, 1998).

Not surprisingly, the marketing techniques of brand name and generic manufacturers differ considerably. Brand name manufacturers tend to focus their marketing strategies primarily on physicians, who will potentially prescribe their products, while the generic manufacturers focus on the purchasers, e.g. pharmacies and hospitals. Since generic drugs tend to be less expensive than brand name drugs, they are as a rule preferred by insurance programs and other third-party payers and even required when available for reimbursement. There are exceptions to this rule, however, such as when a large purchaser may negotiate a brand name price that is competitive if not less expensive than the generic alternative.

Drug wholesalers operate as the middlemen between the drug manufacturers and the retail pharmacy. The wholesaler provides a very useful function to both independent and chain pharmacies because it buys in very large amounts and then distributes in small allotments. This relieves the pharmacy from the burden of dealing with each individual manufacture for every purchase (Smith, 1975). In most cases, wholesalers also provide products within 24 hours, which helps the pharmacy maintain a less costly inventory.

Over the past few years, the wholesale drug industry has become quite concentrated. While there are still a number of wholesalers in operation, the top five wholesalers account for 90 percent of the entire wholesale drug market. (NWDA, 1999) In 1998, the net sales of prescription drugs by wholesalers were 57 billion dollars. Such concentrated purchasing allows these few pivotal entities much influence over drug pricing at this juncture in the distribution chain.

The retail level of the distribution chain includes independent and chain pharmacies, supermarket pharmacies, mail order houses and Internet web-based pharmacies. There are approximately 50,000 independent and chain pharmacies in the United States. In the current market, the number of chain pharmacies is increasing as independents are being purchased by multi-store pharmacies. Chain pharmacies have recently undergone a period of consolidation and now the market power of the surviving chains is considerable. The ability to move large market shares of drug products allows chain pharmacies to command volume discounts from manufacturers and to contract directly with managed care organizations for exclusive distribution rights. The chains are also in a position to negotiate favorable rates with managed care organizations that need the chains in order to serve a geographically dispersed member population.

To reinforce the concept that prescription drugs at the retail level are commodities, it is important to note the eroding gross margins of pharmacies. Gross margins have dropped from a high point of approximately 40 percent to a low point of about 16 percent between 1996 and 1998 (NCP, 1998; Carroll, 1996). Many pharmacies, especially the smaller ones, cannot stay in business within the narrow gross margins permitted by third-party reimbursement programs. One study documented a gross margin decrease of 26.9 percent following the change in one insurance company's reimbursement formula which caused the pharmacy a net loss on every prescription dispensed for members of that plan (Ganther, 1999).

Retail pharmacies use a variety of methods to control costs and maximize gross margin. One mechanism is to participate in a network of pharmacies to provide services to members of contracted health plans. The pharmacies in a network sign contracts agreeing to comply with the health plans' rules and regulations and to accept the reimbursement levels offered by the plan (Hejna, 1995). Membership in a network allows a pharmacy to participate in third-party reimbursement programs but this does not guarantee a reasonable reimbursement rate. Thus, pharmacies use other mechanisms to control their costs in obtaining prescription drugs. These include joining a buying group where the pharmacies consolidate market power to buy products with volume discounts. Some buying groups maintain warehouses of drug products and distribute them to the pharmacy members of the group as a way to reduce costs.

Internet pharmacies are a new phenomenon so their influence on drug prices is still largely unknown. It is interesting to note that they use mail order to distribute their products and thus are members of the mail order pharmacies' professional organization, the Pharmaceutical Care Management Association (PCMA). Mail order pharmacy accounts for about 12 percent of the total retail prescription market. Between 1997 and 1998 mail service pharmacy grew by 19 percent (Anon., American Druggist, 1999). This compares to the total prescription market, which grew by 18.5 percent (Glaser, 1999). The proportion of the market accounted for by mail order pharmacy continues to grow at a small annual rate. Internet pharmacies, in addition to providing prescription drugs, provide a wide array of other drug related products such as over the counter medications, some cosmetic products, etc. Both mail order and Internet pharmacies must be licensed and comply with the same level of regulation as any traditional pharmacy establishment. In addition, the mail order pharmacies must also generally register with the states where they mail medications.

Mail order pharmacy is commonly included in prescription drug programs because mail order pharmacies can offer prescription drugs at a discounted price. This is because of the volume of their drug purchases and economies of scale. Patients in plans with mail order options are often provided financial incentives for using this type of pharmacy. These incentives may include discounted or forgiven copayments.

Third party programs in pharmacy cover a variety of players. The third-party is an entity other than the patient or pharmacist who is paying for all or part of the prescriptions. These include insurance companies, third party administrators (TPAs), state Medicaid programs, large employers, and managed care organizations. Third party drug programs provide a wide range of activities. These include claims processing, drug use review, formulary administration (which may include rebates) and disease management programs. TPAs are responsible for processing claims and conducting drug utilization review to ensure the quality of the program. However, TPAs are not financially at risk for any of the payments as are insurance companies or other programs (Gardner, 1986). To capture the growth in third-party programs, it is instructive to note that in 1968, perhaps five percent of prescriptions were paid for by some third-party, whereas in 1999 that figure is closer to 70 percent (Lyles, 1999). This growth includes all types of third-party programs, including insurance programs where an insurance company or other payer for the prescription drugs they would purchase may merely indemnify a patient.

The widespread use of computers in pharmacy practice has made it extremely easy for a plethora of third-party programs to exist and operate seamlessly within a particular practice setting. Typically, the pharmacist enters information into the computer on each patient and dispensed drug. The information is routed through a computerized network as a claim for the product cost and dispensing fee to the patient's third-party plan. Each third-party plan's system has algorithms or reimbursement rules for coverage, eligibility, deductibles, pricing of the prescription, patient cost-sharing such as copayments, and therapeutic issues such as drug duplication or drug-drug interactions. The third-party plan's system responds back within minutes with information on potential drug interaction alerts, copayments amounts required from the patient and reimbursement approvals. The plan's computer system may be maintained

by the plan themselves, by insurance companies, by third-party administrators or by pharmacy benefit management companies (PBMs).

Pharmacy benefit managers (PBMs) are relatively new to the prescription drug arena and yet they now control a substantial part of the prescription drug market. PBMs act as intermediaries between pharmacists, patients, employers, managed care organizations, and third-party payers. According to Copeland, there are approximately 40 PBMs in the United States with the top five accounting for more than 75 percent of the market (Copeland, 1999). The U.S. General Accounting Office has issued at least two critical reports focusing on PBMs. The first GAO study addresses alliances between PBMs and pharmaceutical manufacturers. Several manufacturers own or legally participate in business alliances with PBMs, which has caused concern over whether this constitutes unfair competition. The theory behind this concern is that if a manufacturer owns a PBM then that manufacturer's products might appear on the PBM's formulary in an unfair manner and to the exclusion of other manufacturers' products. The results of this particular report were not definitive enough to conclude that there was unfair competition (GAO, 1995). The second GAO study examined whether the Federal Employees Health Benefits Program (FEHBP) was satisfied with savings and services related to pharmacy benefit managers. The three FEHBP plans that they studied had contracted with PBMs to manage pharmacy benefit payments. The PBMs did save the plans a substantial amount of money, however the study notes that the plans' decision to use PBMs can shift business away from retail pharmacies to mail-order pharmacies (GAO, 1997). In addition to bias issues, HMO concerns about PBMs include confidentiality of data, disclosure of information to patients, and the HMO's own oversight of the performance of PBMs (Office of Inspector General, 1997). Despite concerns, PBMs continue to be a dominant force in the prescription drug arena: PBMs currently serve over 150 million patients annually (PCMA, 1999).

As alluded to in one of the GAO reports, the PBMs have substantial relationships with the retail pharmacy sector. While the PBMs negotiate with drug manufacturers on the one hand, on the other hand they must assure adequate sites for patients enrolled in the various plans to obtain their prescription drugs. Therefore, they contract with retail pharmacies to provide this service as well as process claims and provide payment to the pharmacies. Obviously, the PBM will optimize its position by obtaining the widest geographic pharmacy coverage while keeping costs at their lowest. Chain pharmacies, with their considerable market power are able to negotiate more profitably (for them) arrangements with PBMs than are independent pharmacies that do not have the market share or geographic coverage of the chains. Because of this, relationships between independent pharmacies and PBMs are often quite strained (Ganther, 1999; Carroll, 1996).

One important way that PMBs control costs is through formularies. A formulary is a list that the plan uses to make reimbursement decisions about individual drugs. The formulary may be open or closed. An open formulary usually means that the plan will cover all drugs except those listed as exclusions to the drug reimbursement policy. A closed formulary details the specific drugs that meet the plan's reimbursement policy. Preferred formularies impose lower copayment amounts for formulary drugs versus non-formulary drugs. Ideally, formularies are constructed with two primary considerations, first clinical and then cost

(Grabowski, 1997). Restrictive formularies have been the subject of few peer reviewed research articles and the results are mixed. Horn (Horn, et al., 1996) suggested that restrictive formularies may result in increased costs and lower quality care while Walser et al. (1996) concluded that restrictive formularies might be more beneficial. Ideally, the list of covered drugs should first be based on sound clinical considerations after which cost should be taken into account. However, as Schulman (1996) has demonstrated, some PBMs report that the primary consideration is cost followed by clinical.

3.3 Drug Pricing

The pricing for prescription drugs is complex and varies greatly depending on who is the payer and who is the seller. The following is a summary of three major measures of prescription prices: the Producer Price Index, the Average Wholesale Price and the retail pharmacy charge.

The Producer Price Index (PPI) for pharmaceutical drugs measures inflation at the earlier stage of the production and marketing process. It is based on the prices of almost 50 therapeutic classes and indicates the prices paid at the wholesale level. The PPI is often used to determine whether the annual growth rate in drug prices exceeds those of other goods and services. The pharmaceutical manufacturer industry has long criticized the PPI as not properly assessing the impact of new medicines and thus overstating true drug inflation. (PhRMA, 1995)

The average wholesale price of a prescription drug (AWP) is undoubtedly the best known of the pricing terms. It is comparable to a sticker price on an automobile where the manufacturer suggests a certain price but almost everyone pays something different from that price. It tends to be a reliable price reference for brand name drugs but can be misleading with generic drugs since each manufacturer establishes its own AWP for the same product (Cohen, 1995). It is very important to have some reference point for pricing, negotiations, reimbursement, etc., and AWP serves effectively in this role. Unfortunately, the AWP does not really capture actual transaction prices including discounts and rebates (Schweitzer, 1997). The average wholesale price is referenced to some extent in most Medicaid and other third-party programs, but it is virtually unheard of for a plan of any size to pay AWP without extracting some discount from the retailer. Historically, pharmacists used AWP as their basis for pricing. However, they would usually purchase the drugs from wholesalers or manufacturers at some percentage discount from AWP and could thus retain the difference between what they paid for the drug and the cost basis for reimbursement as additional profit. As drugs became more of a commodity at the retail level, third-party payers including Medicaid programs and others, sought to share if not completely capture this "additional" profit. In effect, this substantially eroded the gross margins of pharmacies and thereby created friction between pharmacies and PBMs or other third-party payers. Using state Medicaid programs as an example, some states would reimburse pharmacists at AWP minus 10 percent plus a dispensing fee that varies depending upon the state. The AWP compares to the average manufacturer price (AMP) which is defined as the average price paid by wholesalers for products distributed to retailers (Cohen, 1995). This is obviously one step removed from the retail sector. This term gained widespread public notice with the passage of OBRA 90 where it was used as the reference

point for calculating the rebates that drug manufacturers would have to provide to state Medicaid programs (NPC, 1998). Today, it is still used as the primary reference point for determining drug rebates in a variety of prescription drug plans.

The most common method of pricing in a retail pharmacy is to start with a cost basis for the drug and then add a pharmacy-dispensing fee to arrive at a selling price. For mechanical purposes, let us assume that an AWP for a particular prescription is \$100 and the dispensing fee is \$3. If there were no discounts from AWP included in this particular example, the prescription would be priced at \$103. If the pharmacist paid AWP for this product then the pharmacist would gross \$3 on that particular prescription. Now let us assume that the pharmacist is being reimbursed at AWP minus ten percent plus the \$3 dispensing fee. In this case, the drug cost would be \$100 dollars minus \$10 (ten percent) or \$90. Adding the dispensing fee of \$3, the reimbursement price for this particular prescription would be \$93. In this case, the pharmacist would need to be able to purchase the product for at least AWP minus 10 percent.

Retail prescription charges are frequently quoted in the lay press but they are difficult to interpret across different types of pharmacies. *Drug Topics* reports the average value per prescription-drugstore acquisition cost for 1998 at \$36.79 per prescription (Glaser, 1999). For 1997, this cost is reported as \$32.87 (Gebhart, 1998). However, the average prescription charge for 1997 for independent pharmacies ranged from \$24.97 to \$34.44 depending on overall sales volume, and was actually higher for pharmacies with high third party activity (NCPA, 1998). A *Consumer Reports* survey examined retail prices for five commonly prescribed drugs at 26 pharmacies, including chains, independents, supermarkets, mass merchandisers and online/mail order. In general, online pharmacies provided the best prices and independent the highest, although the authors note that the extra service provided by independent pharmacies may be worth it (Consumer Reports, 1999). In general, individual consumers pay more out-of-pocket for prescription drugs than do other more favored purchasers such as HMOs or the federal government (Bettehheim, 1999). The marketplace, as it currently exists, has created a wide range of prices for the exact same product.

One of the thorniest issues surrounding prescription drug prices is rebates. When a PBM is considering adding to or deleting drugs from the formulary, it will negotiate with individual drug manufacturers about providing incentives since the inclusion or exclusion will ultimately mean large dollars to the manufacturer. Generally, these incentives constitute a manufacturer's rebate calculated as a percentage of the product that flows through the PBM to the plan. The rebate is often set in advance and based on the market share that a manufacturer expects to see for its product within a plan. As an example, assume that a manufacturer and PBM agree that sales of drug X for one year, at average manufacturer price (AMP), will be \$5 million. Based on this, the manufacturer agrees to "rebate" back to the PBM 10 percent of the AMP for products dispensed though the particular plan represented by the PBM. The PBM would ultimately receive \$500,000 from the manufacturer. The PBM, which is acting on behalf of a client such as a large employer, would receive some of this as a fee for services and the remainder remitted back to the client. The concept of a drug rebate was first widely applied when Congress passed the Omnibus Budget Reconciliation Act of 1990 (OBRA 1990) requiring drug manufacturers to provide rebates back to State Medicaid programs (NPC, 1998).

Rebates have revolutionized the prescription drug marketplace. In 1994, rebates to all Medicaid programs totaled \$1.8 billion out of total Medicaid outpatient drug payments of \$9.5 billion (Lyles, 1999).

Rebates do not directly affect the retail sector, per se. While rebates have a substantial effect on the overall cost of drugs to a particular program, they are negotiated between the manufacturer and PBM or other third-party payer. Thus, when pharmacists dispense a prescription drug to a patient, they are essentially ignorant of any rebate arrangements made for that particular product. This is not to say that the retail sector is totally unaffected. For example, if a plan were not able to obtain the percentage rebates necessary to operate profitably, it may attempt to extract additional from the retail sector.

4. International Drug Prices and Spending

“Why are American drug prices higher when compared to other countries?” Over the years, this has been a topic of much debate and study. Numerous studies have made drug price comparisons between the United States and other countries. Many of these are simply anecdotal reports appearing in the lay media. However, other more sophisticated analyses have also been published in the past decade. They all show that, to varying degrees, Americans do appear to pay higher drug prices than elsewhere in the world. How strong is this evidence? If it is indeed true, what factors are responsible? If the United States were to adopt regulatory policies implemented in other countries would drug prices fall here?

This chapter addresses each of these questions. The next section describes the factors that must be considered in making sound international price comparisons. A review and evaluation of four recent cross-national studies of drug prices follow this. Next is a section comparing prescription drug expenditures among European countries, the United States, and Canada. This section describes some of the reasons for differences in expenditure rates. The fourth section presents an overview of governmental price regulations adopted in other countries with detailed descriptions of the policies in place in Canada, France, Germany, and the United Kingdom. A concluding section summarizes what the United States can learn from these international experiences.

4.1 Making Sound International Price Comparisons

Although the literature appears to support the hypothesis that American drug prices are higher than prices in other countries, special care must be taken when making cross-national price comparisons. A recent article by Danzon and Kim (1998) found that cross-national study results are highly sensitive to methodological choices. These choices include sample selection, unit of measurement for price and volume, relative weight given to consumption patterns in the countries being compared, and exchange rates or purchasing power parities (PPP's) for currency conversions. This section describes each of these issues.

The first challenge in international price comparisons is finding a list of drugs that is comparable across the study countries. Most comparative studies use small samples of leading, branded, on-patent prescription drugs. This can create selection bias given the fact that some products available in the US are not available in other countries and vice versa. A similar problem arises when products that have been approved and marketed in both the US and a foreign country become accepted therapy in one country but not in the comparator country. This phenomenon can result in large differences in market share, and hence prices, for identical products.

In addition, the life-cycle price profile of products varies among countries. Japan, for instance, has relatively high introductory prices but post-launch prices decline at a faster rate than in other countries. This creates a product age bias that can affect conclusions about average price levels. While this bias can be upward or downward, it is very dependent upon the country being examined. Another source of product selection bias arises when a study

excludes lower-priced generic products. In some countries generics account for a third or more of all prescription sales, while in others they are less commonly prescribed. Generic products are sometimes available in foreign markets before or after introduction in the American market. This tends to increase the price of the foreign brand name drug. Excluding generic products will bias the price upward in countries that have a sizable generic market share and/or low generic prices, such as the United States (Danzon and Kim 1998; Schweitzer 1997).

The second challenge is matching units for a given drug. As specification of products become more precise (same compound, same manufacturer, same dosage form, pack size and strength) exact comparator products become more difficult to find. This is because the dosage form, strength or pack size may differ across countries. Researchers often impute prices for missing product strengths or dosage forms based on per unit prices, but this can lead to bias. For instance, in one study of Canadian versus American prices, the Canadian prices were calculated based on the largest package size available in Canada (GAO 1992). When converting prices to U.S. package sizes, the Canadian unit price was multiplied by the number of units in the U.S. package regardless whether the package sizes in the two countries were equivalent. Since unit prices are generally lower for large package sizes, the price comparisons are biased.

A third difficulty in cross-national comparisons is obtaining accurate transaction price data in the U.S. market. Many studies utilize US wholesale list prices when performing price comparisons. The wholesale list price does not incorporate any discounts or rebates afforded to large purchasers, such as Medicaid or large pharmacy chains. Some countries permit bulk packages, which are split by the pharmacist and dispensed to individuals, while many European countries forbid pack split, which leads to an underestimation of the European prices. The combination of an overestimated US price and an underestimated European price will inflate any existing price differentials (Danzon and Kim 1998, Schweitzer 1997).

A fourth challenge is accounting for differences in drug consumption patterns. Most cross-national studies use the drug consumption patterns in the United States as the base rate. Yet, medical norms in treating the same condition differ throughout the world. Differences in the mix of drugs and the significance of domestic products can also alter pharmaceutical consumption patterns. Failure to consider differences in utilization rates creates bias in price comparisons because price levels vary with volume. Less frequently prescribed drugs tend to be priced higher, other things being equal. This means that the popular American drug may appear more expensive in foreign countries, which in turn will bias foreign drug prices upwards. The opposite result occurs if the product requires a prescription in the US but not in the comparator country. In most cases, prescription-only products are more expensive. For instance, Claritin[®] is available in US as prescription-only but can be obtained in Canada over the counter. A comparison of Claritin[®] prices between the two countries would show lower prices in Canada, but the comparison would be misleading. Even comparing top selling products across the comparator countries will not alleviate the problem, since the drugs will be different in each country. One possible methodological approach to resolving this problem is to weight the price of the drugs based on level of consumption (Danzon 1997; Danzon and Kim 1998; Schweitzer 1997).

Currency conversions are inherently problematic in cross-national pricing studies. The use of exchange rates versus purchasing power parities (PPP) will yield different results. Using only exchange rates to calculate conversion prices does not directly address price differentials across countries for the same products. The PPP is created from a “basket” of similar drugs in the country used as the study base. Not all these drugs may be available in each country under comparison. Therefore, a PPP calculated for each country would be different, since the basket of drugs is different in each country. In addition, the PPP does not accurately compare purchasing power in different countries. For example, the official exchange rate may be two US dollars to the British pound. Yet, a product that sells for one dollar in the US may be priced at one pound in England. Using only an exchange rate will produce a conversion price for the product sold in Britain as approximately two US dollars. When a PPP is used, the conversion price may appear closer to one US dollar. The key is to employ both exchange rate and purchasing power parity conversions. If a study fails to report both conversions, it may be that the study results would change were the other conversion method employed. (Danzon 1997; Danzon and Kim 1998; Schweitzer 1997).

4.2 Studies of International Differences in Drug Prices

The US General Accounting Office (GAO) conducted one of the first widely cited studies of international price differences in prescription drugs in 1992 (GAO 1992). The study compared 200 frequently prescribed drugs in the US and Canada sold by the same manufacturer in both countries. These drugs represented 54 percent of all prescriptions dispensed in US pharmacies in 1990. Since the drugs were supplied in a variety of sizes, strengths and dosage forms, the GAO selected a single commonly used US product for comparison. In Canada, 121 of the 200 were found to be identical to US dosage form, strength, and pack size. The remaining 79 products were not available for comparison. The GAO used the wholesale acquisition cost (WAC) to represent the American manufacturers' prices and the best available price (BAP) from the February 1991 Ontario Drug Benefit (ODB) formulary to represent Canadian prices. The study found that the 121 products cost an average of 32 percent more in the United States than in Canada.

This study represented an important first step in examining the issue of international drug price differentials. However, it also highlights a number of methodological issues discussed earlier (Schweitzer 1997, Danzon 1997). The inability to match more than 60 percent of the drugs originally selected for comparison raises the issue of product selection bias. How does the exclusion of certain products affect the measured price differentials? Those products matched were leading branded patented products in the United States, while the generic equivalents of these products were excluded from the study. If the price differentials for the generics were less than for the brand products, then the GAO procedures would overstate the true differences between the two countries. For those products matched on product strength and dosage form but not pack size, prices were imputed based on the unit price from the ODB formulary. In doing so Canadian prices appear lower, since the ODB unit price is based on the largest pack size available, not the most common pack size used in the US. The wholesale price list used to price US products did not include the discounts and rebates available to large purchasers. This too, tends to overstate the real differences in drug prices

between the two countries. The GAO study also assumed that American drug consumption patterns for the products examined were the same as Canadian patterns when they are not (Katz et al, 1998, Pilote et al, 1994, Rouleau et al, 1993). Finally, the GAO used currency exchange rates and did not include a comparison based on the PPP. For all of these reasons, the main study conclusion that drug prices are lower in Canada must be treated with caution (Schweitzer 1997, Danzon 1997). Since 1992, other studies have been published that address some of the methodological concerns present here.

In 1994, the GAO followed up its earlier report with a comparative study of drug prices in the United Kingdom and the United States (GAO 1994a). Of the original 200 US drugs, only 77 were directly matched with products in Britain. In this study, the US price was based on the non-federal average manufacturer price (non-FAMP) from the Department of Veterans Affairs. The non-FAMP is a weighted average of the WAC, the list prices charged to wholesalers, and the lower prices charged to large purchasers such as HMOs. British prices were based on the national wholesale listing. These prices were then adjusted by a standard 12.5 percent discount rate provided to UK wholesalers. The exchange rate was taken as £ 0.5598 per dollar and the purchasing power parity (PPP) was £ 0.652 per dollar. Significant differences in prices were found between the United States and Britain. The GAO estimated that the 77 frequently dispensed drugs cost wholesalers 60 percent more in the US than in the UK.

This study advanced the field in measuring international drug price differences. The most important methodological advances were the use of a US price list that incorporated large purchaser discounts and comparisons based on both currency exchange rates and the PPP. Nonetheless, the study still has methodological shortcomings. By matching on brand name, pack size, manufacturer, strength, and form almost two-thirds of the original products selected for review were dropped from the study sample. As in its earlier Canadian analysis, the GAO imputed pack size price differences based on a single unit price, excluded generic equivalents of the branded products under study, and failed to consider differences in drug consumption patterns between the two countries (Schweitzer 1997, Danzon 1997).

In 1998, Danzon and Kim undertook a study designed specifically to assess the sensitivity of international drug price comparisons to the methodological issues described here. The study examined single ingredient cardiovascular products available between October 1991 and September 1992 in the US and eight OECD countries. The drugs included generic, over-the-counter, and brand name products. All pricing information was obtained from IMS sales data in the various countries. Two methods of product matching were employed; one based on the international product name (IPN), the other by anatomical therapeutic class. The researchers addressed the issue of dosage forms and strengths by converting all products to grams of active ingredient and the number of standard units, thereby permitting aggregation over all dosage forms, strengths and pack sizes. The authors address the issue of international differences in drug consumption patterns by using price indices weighted to reflect utilization rates in the US (a Laspeyres index) and each of the comparator countries (Paasche indices).

Danzon and Kim found that prices for cardiovascular drugs were generally lower in OECD countries than in the US regardless of the specific price index employed the matching

criteria used, or the unit measure selected. The robustness of the results to alternative measurement approaches lends particular credibility to the study findings. However, it is worth noting that Danzon and Kim found much closer parity in international drug pricing than in previous studies, and in some cases the direction of the price advantages depended on the choice of methodology. For example, the reported price differentials for cardiovascular drugs in Canada compared to the US ranged from 16.6 percent *higher* to 6.9 lower depending on which price index was used. Consistently greater price differentials were found when using a Laspeyres index weighted to quantities of drugs used in the US compared to Paashe indices with foreign quantity weights. A similar range of positive and negative price differentials was reported between the US and Japan. Prices in the UK were all lower than in the US, ranging from 28 percent to 54 percent less depending on the index and matching algorithm. The price differentials between the US and Germany, France, Italy, Switzerland, and Sweden were comparable to the US and UK.

The real value of the Danzon and Kim study lies not in its specific findings relating to cardiovascular drug prices, but rather in its approach to making international drug price comparisons. The finding that measured price differences are sensitive to the methods selected is scarcely a surprise. However, the fact that certain methodological choices tend to produce consistently higher (or lower) measured price differentials than other choices should help inform future work in this area.

In 1999, the advocacy group Public Citizen conducted a survey of international prices for five newer antidepressants and three antipsychotic drugs in 17 North American and European countries (Sasich et al. 1999). Not all of the drugs were marketed in every country. All eight were available in the US, Canada, and Sweden, but only five were marketed in Portugal. The researchers contacted one English-speaking pharmacist in each country to obtain the pharmacy acquisition cost for an average 30-day supply for each available drug. Drug costs were converted to US dollars at the exchange rate for that day. Although this study determined that US drug prices were double those in the 17 other countries on average, this finding lacks credibility because of the small sample sizes (one pharmacist per country), poor product matching, failure to consider price discounts or rebates, failure to include generics (in Canada, for example, a generic version of one of the study drugs, Prozac (fluoxetine) has been available since the mid-1990's), and finally, the failure to consider the impact of different drug consumption patterns on domestic prices.

Although the tools for making credible cross-national comparisons in drug prices have not been perfected, they have reached a level of sophistication that demands the attention of researchers and critics alike. Of the studies reviewed here, the Danzon and Kim analysis of cardiovascular drug prices sets a clear standard for others to follow. Their results confirm the widely held belief that Americans pay more for their prescription drugs than do Europeans, but the differences are lower than reported elsewhere. Moreover, depending on how prices are measured, cardiovascular drugs may actually cost more in Canada and Japan than here. Whether similar patterns hold for other drug groups has yet to be determined. Until further studies are done, the issue of who pays more is still an open question.

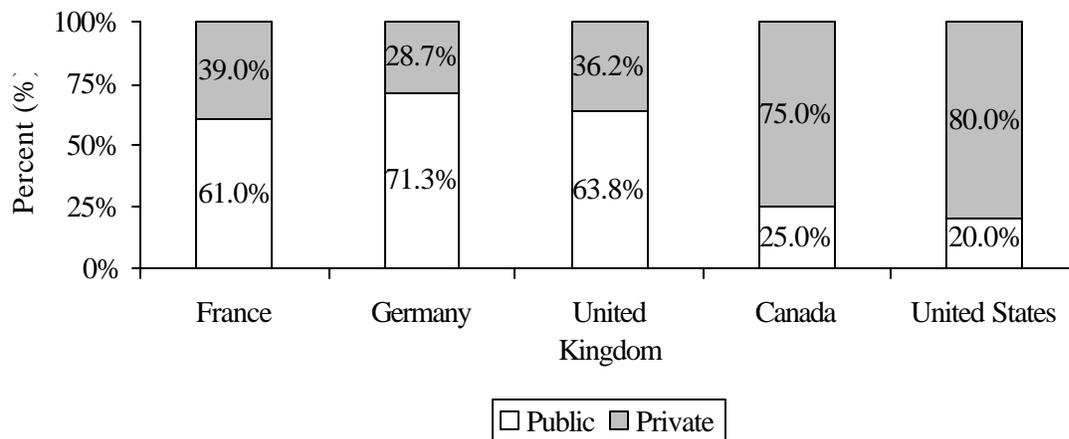
4.3 Cross-national Pharmaceutical Expenditures

From the perspective of public policy, the fact that drug prices vary across international boundaries is not as important as the cause of the differences. There are many other factors that can potentially contribute to cross-national price differences. These include national wealth, health insurance coverage of prescription medicine, the demographic makeup of the population, culture and its effect on medical practice patterns, and regulatory policies applied to prescription pricing.

It is essential that cross-national pricing studies be limited to countries with roughly similar levels of national wealth. By this standard, Mexico would not be considered an appropriate comparator country for the US as Mexico is at a less advanced stage of economic development. This means that real wages are lower, per capita incomes are lower, and prices for many goods and services, including pharmaceuticals are lower (Danzon, 1999). Comparisons of US drug prices to those in Canada and Europe are less affected by differences in national wealth given the similarities in level of economic development. However, some OECD countries like Portugal, Greece, and Ireland have substantially lower per capita GDP than their neighbors, and comparisons between the US and these nations should be conducted with caution.

A second important factor is the level of insurance coverage available to the residents of the countries under study. All of the OECD countries, except the United States, have some form of universal health insurance coverage. The level of coverage for pharmaceuticals varies from country to country. Chart 1 shows that France, Germany and the UK have high levels of public funding for pharmaceuticals compared to the US and Canada. The Access and Affordability Monitoring Project (AAMP) found that approximately 70 million or one in four Americans have no prescription drug coverage (Sager and Socolar, 1999). The presence of insurance coverage significantly increases utilization and expenditures for drug products (Lillard et al., 1999). It also provides a mechanism and an incentive for governments to control drug expenditures.

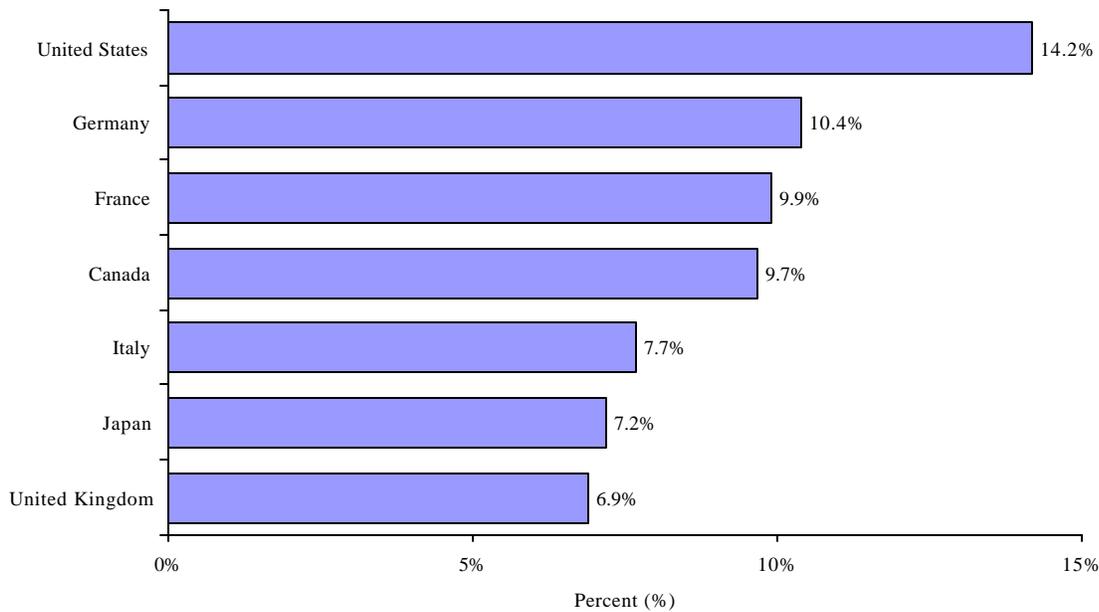
Chart 1: Public Funding as a Percentage of Total Pharmaceutical Spending



Data for France, Germany and United Kingdom are for 1995 (Lecomte and Paris 1998); Canadian data are for 1993 (Angus and Karpetz 1998); United States data are for 1994 (Kane 1997)

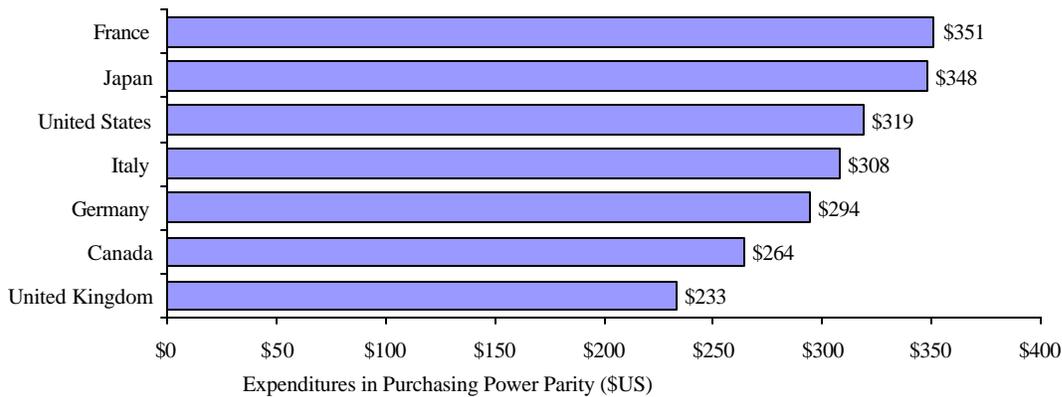
Demographics play a significant role in explaining international differences in level of health and pharmaceutical expenditures. However, these differences are generally not evident in simple cross-national comparisons. It is well known that seniors use more prescription drugs per year than other age categories. The expectation would be that countries that have a greater proportion of seniors would have greater health care and prescription costs. This does not hold true when comparing the US and Canada with European countries. France, Germany and the UK all have higher proportions of aged persons than either Canada or the US. Yet, chart 2 clearly shows that the US spends the highest percentage of GDP on health care (GAO 1994b, OECD 1998). In terms of pharmaceutical expenditures per capita, chart 3 shows that only France and Japan surpass the US (PhRMA 1999). Of course, the reason there is no direct correlation between age distributions and drug expenditures is that other factors associated with high health care spending also vary between these countries.

Chart 2: Health care expenditures as a share of GDP, 1995



Source: OECD 1998

Chart 3: Pharmaceutical Expenditures per Capita in G7 Countries, 1997



Source: PhRMA 1999

One methodological flaw present in almost all of the studies reviewed above is the failure to consider difference in drug consumption patterns among the comparator nations. Drug utilization is a function of the underlying norms of medical and health care practice in every country. Norms are part cultural and part imposed. For example, France has mandatory guidelines for physicians that outline “accepted” treatment options for given conditions (Bloor et al 1996). These leave little room for discretionary practice. Germany and the UK have capped prescription expenditure budgets for office-based physicians (Lecomte and Paris 1998). As discussed later, these give physicians a powerful incentive to prescribe generics and over-the-counter products. In the US, physician prescribing is influenced by drug formularies and financial incentives promulgated by managed care organizations. Basic cultural factors play a powerful role in the use of medicines to treat disease. In European countries, the use of alternative medicine, including herbals and homeopathy is an accepted standard of medical care and may be paid for under the insurance system. In the US, alternative medicine is not widely accepted by the medical profession although it is growing in popularity among patients. Still, the notion that no physician visit is complete without a prescription is a strongly ingrained attitude here (Barden et al 1998).

This review of factors that influence pharmaceutical utilization and expenditures is scarcely complete, but it does serve to set the stage for consideration of the importance of pharmaceutical price regulation. The next section describes the basic approaches used in controlling pharmaceutical prices and expenditures in OECD countries. The approaches used by four countries (Canada, Germany, France and the United Kingdom) are examined in detail.

4.4 Pharmaceutical Price Regulation

The OECD countries use a variety of pharmaceutical cost control approaches. The most common tactic in Germany is reference pricing, while France and Canada utilize product price controls and the UK uses profit regulation (Bloom and van Reenen, OECD, 1999; Dickson 1992). The most direct method of controlling drug costs is product price control whereby the

government negotiates directly with each manufacturer to determine the reimbursement level for individual products. In a typical system the price is established after the drug product obtains marketing approval but prior to market introduction. The government or a government-sanctioned body reviews the manufacturer's price application and determines whether the requested price is "fair." If the price is not acceptable, the government can set a lower price. If the government-determined price is lower than the manufacturer requested, the company can appeal the decision. The price setting process usually takes one of two forms: internal, which primarily focuses on the manufacturer's price justification, or external, which examines the prices charged for the same or similar product in other countries (Dickson 1992; Earl-Slater 1997). When conducting an internal evaluation of a manufacturer's price justification, governments take into account a myriad of factors such as the anticipated therapeutic benefit of the new product, anticipated sales volumes, and the company's contribution to the economy (Le Pen 1996; Earl-Slater 1997). In setting a low price for a particular product, the government may take advantage of the fact that research and development expenses were incurred in another country (like the US) where the selling price is higher. This, in turn, creates an incentive for "parallel trade" in drug products, where drugs from a "low price" country are imported and resold in other countries where they command a higher price (GAO 1994b, Bloor 1996).

Regulatory systems that employ external price justifications for new drug products use different pricing criteria. Where the product under review is already marketed in other countries, these systems compare prices directly based on dose, strength, and pack size considerations. Where the product is not widely marketed elsewhere, countries develop comparative "market baskets" of drugs with the same therapeutic indication. The contents of these market baskets vary from system to system depending on which comparator drugs are included and whether generics are part of the package. The result is that the "fair" price for a given drug product will vary from country to country (Bloor 1996; Anis and Wen, 1998).

By whatever means a country sets the initial drug price, there is also the question of subsequent price changes. All governments that use direct drug price controls require approval for any product price increases after market introduction. (Le Pen 1996; Earl-Slater 1997; Anis and Wen, 1998)

In place of direct product-by-product price controls, some regulatory systems use a method known as "reference pricing". In such a system, drug prices are compared by three different approaches: the same drug chemical, the same drug class, or therapeutically equivalent drugs that work via different mechanisms of action.² Dickson and Redwood (1998) define reference pricing as the maximum reimbursement ceiling (reference price) set by the insurer for defined drugs. If the drug costs more than the reference price, the patient or supplementary private insurers are responsible for the difference (Dickson and Redwood 1998). Reference pricing differs from direct price controls in that the pharmaceutical firm can sell the

² An example of drugs within the same chemical class would be all brands of Tagamet® available on the market. An example of drugs within the same drug class would be all H2 antagonists such as Zantac® and Tagamet®. An example of different drugs used to treat the same medical condition would be all drugs used to treat ulcers such as Zantac®, Tagamet®, Prilosec® and Prevacid®. These drugs have similar effects but they use different methods to effect change. Under reference pricing would be considered equivalent (Narine et al. 1999).

product above the reference price if it believes that the patient is willing to pay the cost difference. The selling price is not strictly regulated on a product-by-product basis. Rather, reference pricing regulates groups of identical or similar drugs. Although reference-pricing systems differ greatly across countries they share four common objectives:

- Modify physicians' prescribing patterns to prescribe less expensive drugs.
- Influence patients to accept cheaper drugs or higher copayments.
- Pressure the pharmaceutical industry to lower prices in order to remain competitive.
- Control expenditures of the payer's drug budget. (Dickson and Redwood 1998; López-Casasnovas and Puig-Junoy 1999)

Reference pricing has been enacted in countries throughout the world, including Germany and British Columbia, Canada. It has become increasingly popular among private payers and Medicaid programs in the United States. The maximum allowable cost (MAC) pricing approach, used by many private insurers and Medicaid, uses reference pricing for drugs that are chemically identical. The effectiveness of reference pricing in influencing market prices depends upon several factors, including:

- The purchasing power of the buyer
- The scope of drugs covered under the reference pricing system
- Consumer's willingness to purchase the product at a given price
- The availability of substitutes for drug therapy, such as surgery or physical therapy (López-Casasnovas and Puig-Junoy 1999).

The general consensus is that reference pricing is effective in controlling drug costs, but the financial savings are short-term and subject to the law of diminishing returns. Initially, a significant reduction occurs in prices for referenced products resulting in short term savings for the insurer. Over time, the cost saving effect diminishes as pharmaceutical companies, physicians, and patients alter prescription consumption towards greater use of the reference-priced product (Dickson and Redwood 1998; Dickson 1992; Bloor 1996; López-Casasnovas and Puig-Junoy, 1999).

Some countries regulate the profits of pharmaceutical manufactures rather than the prices they may charge for their products. Britain and Spain both use this approach. Profit is defined by different methods including the rate of return on capital attributable to sales in that country or negotiated profit margins for each company (Bloor 1996). At regular intervals, a target profit rate is negotiated between each pharmaceutical company and the government. Profit regulation permits companies to price products at their discretion. If a company's profits are above the negotiated profit rate, the excess is either remitted to the government or prices are reduced (Dickson 1992; Towse 1996; Lecomte and Paris 1998).

4.5 Country Specific Cost Control Approaches

The following sections present more detailed discussion of the drug cost control mechanisms used in Canada, Germany, France, and the UK.

4.5.1 Canada

In Canada, the provinces have responsibility for assuring their citizens access to health care under a Federal mandate that establishes general eligibility and benefit standards. All provinces provide some level of prescription coverage for the elderly and social assistance recipients. Coverage for the remainder of the population varies by province. Many of the consumer-oriented cost control techniques used in the United States are also used in Canada, such as formulary management, drug utilization reviews and copayments (Angus and Karpetz 1998).

In addition to consumer-oriented cost control mechanisms, Canada regulates the entry price of newly patented pharmaceuticals through the Patented Medicines Prices Review Board (PMPRB). The primary mandate of the board is “to prevent brand name firms from abusing their monopoly position during the market exclusivity period” (PMPRP 1998). The PMPRB is responsible for regulating the maximum prices charged by manufacturers for all patent-protected prescription and non-prescription drugs sold in Canada. The board has no authority over the prices charged further down the distribution chain by wholesalers or retailers. Furthermore, once a drug goes off patent its price is no longer regulated by the PMPRB. (Angus and Karpetz 1998; Anis and Wen 1998; PMPRB 1998).

The PMPRP issues pricing guidelines that defines “excessive” drug prices for three categories of products:

1. Line extensions of existing medications, such as different strengths of the same product. A price is presumed to be excessive if it does not bear a reasonable relationship to the price of other strengths of the same drug sold by the company.
2. Breakthrough drugs. A price is presumed to be excessive if it is greater than the prices of all other medications in the same therapeutic class and exceeds the median factory price charged for the same strength and dosage form in Germany, France, Italy, Sweden, Switzerland, the United Kingdom, and the United States.
3. New chemical entities offering moderate, little or no therapeutic improvement. Price is presumed excessive if it exceeds the prices of all other medications in the same therapeutic class (Anis and Wen 1998; López-Casasnovas and Puig-Junoy 1999; PMPRB 1994).

The PMPRB also regulates prices of patent-protected products already on the market. In this case, a price increase is considered excessive if it exceeds the rise in the general consumer price index (CPI) (Angus and Karpetz 1998; Anis and Wen 1998; Dickson 1992;

PMPRB 1994). If the price is found to be “excessive” the PMPRB can negotiate or order a price reduction. The company may appeal this decision through the court system. If the PMPRB and the company are unable to reach an agreement the PMPRB can revoke the patent on the product (Dickson 1992; PMPRB 1994).

Although Canada has the second lowest per capita spending on pharmaceuticals in the G7 nations, there is still an ongoing struggle for the government and drug benefit plans to contain costs. Provincial governments employ a number of drug cost control approaches such as patient copayments and formularies. The British Columbia government has instituted a policy of reference pricing for select therapeutic categories (López-Casasnovas and Puig-Junoy 1999). Initial research findings suggest that the regulation has produced a shift toward prescribing of the reference product in each therapeutic class and that drug expenditures within the targeted therapeutic categories have declined as a result (Narine 1999).

4.5.2 Germany

Over the past decade, the German government has introduced a number of substantial health care reforms affecting the sales of pharmaceuticals. Germany uses a combination of cost control mechanisms to manage its national drug budget. Both negative and positive “Lists of Reimbursable Drugs” (comparable to open and closed formularies) are used in formulary management (Schöffski 1996). In addition, Germany uses office-based physician drug budgets and prescription copayments along with reference pricing. Office-based physicians receive an annual budget for drug expenditures based on the number of patients under their care. Similar to a capitation system, this regulation places physicians at financial risk for their prescribing behavior.

The German government uses reference pricing to help control prices for drugs for which there are exact or close substitutes on the market. The reference price system assigns covered products to one of three levels:

- Level 1: Those products with identically active substances.
- Level 2: Those products with pharmacologically similar active ingredients
- Level 3: Those products with similar therapeutic effects (therapeutic reference pricing)

In 1993, the government introduced further reforms that froze drug prices and set an aggregate cap on drug reimbursements. If expenditures exceed the cap, financial penalties could be imposed on the medical professional associations and the pharmaceutical industry. Evaluations of the reform found some dramatic effects. After the cap was imposed, physicians prescribed more generics, decreased their prescribing of products with unproven efficacy, and increased referrals to specialists and hospitals. The cap did not affect drugs administered in hospitals where specialists had a significantly higher cap. Use and price of drug products not covered by the National Insurance system also increased after the cap was imposed. Finally, some generic manufacturers increased their prices to the reference price level (Schöffski 1996; Lecomte and Paris 1998; Ulrich and Wille 1996; von der Schulenburg and Uber 1997; von der Schulenburg 1997; Drummond 1997; López-Casasnovas and Puig-Junoy 1999).

4.5.3 France

Compared to other members of the OECD, the French pharmaceutical market is characterized by low prices complemented by high demand (Le Pen 1996). Pharmaceutical firms are free to set prices for all drugs not covered by the National Insurance plan, the Sécurité Sociale. The pricing committee, Comité Économique du Médicament (CEM) sets prices of covered drugs sold through non-hospital channels. The Ministry of Health determines the list of reimbursable drugs and the level of coverage for each drug. The CEM determines drug prices based on anticipated therapeutic benefit, anticipated sales volume, and other considerations. During the 1990's, the French government instituted a number of innovations in an attempt to control drug expenditures. These included:

- A series of mandatory "good practice procedures" for physicians called Références Médicales Opposables (RMOs);
- An agreement between the state and the industry (Syndicat National de l'Industrie Pharmaceutique or SNIP); and
- A definition of enforceable regional spending targets (objectifs opposables) (Le Pen 1996; Lecomte and Paris 1998; Pauriche and Rupprecht 1998).

The agreement between the industry and the state was designed to reduce sales volumes in exchange for price increases. This agreement was negotiated with each pharmaceutical company and outlined the conditions for permitting price increases. In return, the companies agreed to reduce promotional expenditures, promote "proper drug use" and provide information about its activities. The regional targets (objectifs opposables) represented negotiated agreements between the Sécurité Sociale and the physician associations. Separate targets were negotiated for specialist and general practitioner fees and drug prescriptions. In case of regional overspending, local physicians could be required to compensate the Sécurité Sociale for the excess spending. Despite the reforms, the French remains heavy consumers of prescription drugs relative to their OECD neighbors. The principal impact of the reforms appears to have been a slight shift toward less expensive drug products for treatment of medical conditions where RMOs have been implemented (Le Pen 1996; Lecomte and Paris 1998; Pauriche and Rupprecht 1998).

4.5.4 United Kingdom

The United Kingdom uses a variety of different methods to control drug costs. The primary method is through regulation of manufacturer profits. The Pharmaceutical Price Regulation Scheme (PPRS) regulates the rate of return on capital attributable to pharmaceutical sales in Britain. The government and the Association of the British Pharmaceutical Industry (ABPI) negotiate a target rate of return for each company based on brand-drug sales to the national health plan, known as the National Health Service (NHS). To reach the target rate (currently between 17 to 21 percent), the amount of research and development (including promotional expenditures) is set at about 9 percent of sales. Since the PPRS does not regulate prices per se, it permits the company significant flexibility in the launch price of new products. Once a product is marketed, any subsequent price increases require prior NHS authorization.

In the event a manufacturer surpasses the target profit rate, it is permitted a 25 percent margin above the target rate, called the “gray area”. If the company earns more than the permitted “gray area” it must provide either reimbursement to the NHS or reduce the price. The PPRS does not address the pricing of generic products or products not reimbursed by the NHS (Lecomte and Paris 1998; Towse 1996; Bloom and van Reenen 1999; Burstall 1997; Burstall 1999).

Most prescription drugs available in the UK market are eligible for reimbursement from the NHS, but a few are included on a “Selected List” that prohibits government payment. Most drugs covered by the NHS are provided free of patient charge. Copayments are charged to certain segments of the population but more than half of all individuals are exempt. In all, only about 12 percent of prescriptions filled in the UK require a copayment, and for this reason copays contribute little in cost savings to the NHS drug budget (Towse 1996; Burstall 1997; Freemantle and Bloor 1996).

Another policy used in Britain to control drug spending targets doctors' prescribing of drugs (Towse 1996; Burstall 1997; Freemantle and Blood 1996). The NHS has introduced the Prescribing Analysis and Cost Information System (PACI) in an attempt to alter physician-prescribing patterns. This policy allows physicians to compare their prescriptions with a “theoretical” practice of patients with similar demographic characteristics. The practice guidelines are reported monthly. The PACT data have recently started to include price information on generics in order to encourage their use. Britain has also introduced voluntary drug budgets for general practitioners, called general fund holding practices.

Although the latest reforms in drug cost control in the UK have yet to be evaluated, the combination of control mechanisms is generally considered to have contributed to the fact that Britain has the lowest level of pharmaceutical expenditures per capita among the G7 nations (Burstall 1997).

4.6 Conclusion

Comparisons of prescription drug prices between the United States and other developed countries generally show that prices are higher here. That said, we end where we began with four major questions: (1) How much higher are drug prices in the US? (2) For which drug products are the differences the greatest? (3) Why are drug prices lower elsewhere? and (4) What can be done about it?

The primary difficulty in assessing the true magnitude of international drug price differentials arises from the fact that methodological problems make meaningful comparisons difficult. Different methods produce different results, as the Danzon and Kim (1998) study results show so dramatically. For this reason, it is critical that future research employ sensitivity analysis to test the robustness of study results to alternative assumptions regarding the types of drug products compared, their relative importance in terms of domestic consumption, and how they are priced.

Clearly, if we cannot answer the first question, the answer to the second is also unknown. Nonetheless, the findings from the Danzon and Kim (1998) study offer some clues and some lessons for future research. Their analysis of cardiovascular drugs found that prices were consistently higher in the US than in Europe regardless of alternative pricing and product matching criteria used in the study. However, the comparisons between the US and Canada and Japan showed that prices were lower in the US if a certain set of pricing/product matching conventions was used, but higher otherwise. The lesson here is that future research should concentrate on price comparisons of products within defined therapeutic classes.

Finding (and verifying) cross-national drug price variation is just the first step. Explaining why variation occurs is equally if not more important. The most important reasons are probably the country's wealth and the extent of prescription coverage offered to its citizens. Other important factors include cultural mores and medical practice norms. Demographic differences play a role. The size and characteristics of a nation's pharmaceutical industry matter. Drug price regulation surely plays a role. However, there is no body of empirical research that tells us which of these actors is the most important. This represents an important field for future investigation once we have better answers to the question of where drug price differentials are the greatest.

The last, and arguably most important question of what the US does about rising drug prices and expenditures is only tangentially related to the issue of whether Americans pay more for the drugs they use. Other countries in the OECD and elsewhere did not look at the American experience when deciding to embark on drug price and profit controls. Those decisions were based on domestic concerns. The same should be true here. Having good information about the effects of drug price controls (both positive and negative) is important, and the European experience is instructive in this regard. However, the US is unique in the size and innovativeness of its pharmaceutical industry. Most economists would agree with the pharmaceutical industry's contention that current levels of pharmaceutical research and development in the US would decline under administered pricing. There is considerable disagreement about the magnitude of the potential drop. However, research and development is not the only matter of importance. All developed countries struggle to achieve a balance between health care expenditures, provider prices, and the rate of medical innovation. The key is to take explicit account of the tradeoffs.

5. Bibliography

American Association of Retired Persons (1997) *Profile of Older Americans*.
<http://aarp.org/general/profile97.html>

Angus D. Karpetz H. (1998) Pharmaceutical Policies in Canada. *Pharmacoeconomics*. 14 (Suppl. 1): 81-96.

Anis A. Wen Q. (1998) Price Regulation of Pharmaceuticals in Canada. *Journal of Health Economics*. 17:21-38.

Anon. (1999) Mail Order Drug Sales Leap 10 Percent. *American Druggist*. July: 1.

Anon. (1999) Relief for the Rx Blues. *Consumer Reports*. October: 38-46

Atherly A. (1999). The Effect of Medicare Supplemental Insurance on Medicare Expenditures. Department of Health Policy and Management. School of Public Health. Emory University. Atlanta. GA. Unpublished Paper.

Barents Group LLC. (1999) *Factors Affecting the Growth of Prescription Drug Expenditures*. National Institute for Health Care Management Research and Educational Foundation.

Berndt ER. Cockburn IM. Cocks DL. et al. (1998). Prescription Drug Prices for the Elderly. *Monthly Labor Review* September: 23-34.

Bettelheim A. (1999) Drugmakers Under Siege. *CQ Researcher*. 9(33): 753-776.

Bloom N. Van Reene J. (1999) Regulating Drug Prices: Where do we go from here? Institute for Fiscal Studies. L5, L6, D4. 19 (3): 321-342. London. England. (<http://www.ifs.org.uk>)

Bloor K. Freemantle N. (1996) Lessons from International Experience in Controlling Pharmaceutical Expenditure II: Influencing Doctors. *British Medical Journal*. 312(7045): 1525-1527.

Bloor K. Maynard A. Freemantle N. (1996) Lessons from International Experience in Controlling Pharmaceutical Expenditure III: Regulating Industry. *British Medical Journal*. 313 (7048): 33-35.

Burstable. M. (1997) The Management of the Cost and Utilization of Pharmaceuticals in the United Kingdom. *Health Policy*. 41 (Suppl): S27-S43.

Burstable M. Reuben B. Reuben A. (1999) Pricing and Reimbursement Regulation in Europe: An Update on the Industry Perspective. *Drug Information Journal*. 33: 669-688.

Call K. Dowd B. Feldman R. Maciejewski M. (1999) Selection Experiences in Medicare HMOs: Pre-Enrollment Expenditures. *Health Care Financing Review*. 20(4): 197-209.

Carroll NV. Miederhoff PA. Waters LW. (1996) Profitability, Third Party Reimbursement, and Access to Community Pharmacies. *Clinical Therapeutics*. 18 (4): 702, 703-715.

Cartwright WS. Hu TW. Huang LF. (1992). Impact of Varying Medigap Insurance Coverage on the Use of Medical Services of the Elderly. *Applied Economics*. 24: 529-539.

Center for Drug Evaluation and Research (CDER). (1998) *Report to the Nation: Improving Public Health through Human Drugs*. Food and Drug Administration. U.S. Department of Health and Human Services. Washington D.C.

Center for Drug Evaluation and Research (CDER). (1998) *Approved Drug Products with Therapeutic Equivalence Evaluations*. 18th ed. Food and Drug Administration. United States Department of Health and Human Services. US Government Printing Office. Washington DC.

CibaGeneva. (1996) *Pharmacy Benefit report: 1996 Trends and Forecasts*. CibaGeneva Pharmaceuticals. Summit. NJ.

Cohen K. (1995) Glossary. Principles and Practices of Managed Care Pharmacy. Foundation for Managed Care Pharmacy. Alexandria. VA.

Cohen RA. Bloom B. Simpson G. et al. (1997) Access to Health Care. Part 3: Older Adults. National Center for Health Statistics. Vital Health Statistics 10 (198).

Copeland D. (1999) Prescription Drugs: Issues of Cost, Coverage, and Quality. *EBRI Issue Brief*. 208.

Coulson NE. Stuart, BC. (1995) Insurance Choice and the Demand for Prescription Drugs. *Southern Economic Journal*. 61(4): 1146-1157.

Crystal S, Harman J, Sambamoorthi U, Johnson R, Kumar R. (2000) Out of Pocket Health Care Costs Among Older Americans. *Journal of Gerontology: Social Sciences*, In press.

Danis M. Biddle AK. Henderson G. Garrett JM. DeVellis RF. (1997) Older Medicare Enrollees' Choices for Insured Services. *Journal of the American Geriatrics Society*, 45(6): 688-94.

Danzon PM. (1997) *Pharmaceutical Price Regulation: National Policies versus Global Interests*. The AEI Press. Washington DC.

Danzon P. Kim J. (1998) International Price Comparisons for Pharmaceuticals: Measurement and Policy Issues. *Pharmacoeconomics*. 14 (Suppl. 1): 115-128.

Davis M. Poisal J. Chulis G. Zarabozo C. Cooper B. (1999) Prescription Drug Coverage, Utilization, and Spending Among Medicare Beneficiaries. *Health Affairs*. 18(1): 231-43.

- Dickson M. (1992) The Pricing of Pharmaceuticals: An International Comparison. *Clinical Therapeutics*. 14 (4): 604-610.
- Dickson M, Redwood H. (1998) Pharmaceutical Reference Prices: How Do They Work in Practice? *Pharmacoeconomics*. 14(5): 471-479.
- Drummond M. Jönsson B. Rutten F. (1997) The Role Of Economic Evaluation in the Pricing and Reimbursement of Medicines. *Health Policy*. 40: 199-215.
- Earl-Slater A. (1997) A Study of Pharmaceutical Policies in the EU. *Policy Studies*. 18 (3/4): 251-267.
- Hillman A. Pauly M. Escarce J. Rippley K. Gaynor M. Clouse J, Ross R. (1999) Financial Incentives and Drug Spending in Managed Care. *Health Affairs*. 18 (2): 189-200.
- Ettner S. (1997) Adverse Selection and the Purchase of Medigap Insurance by the Elderly. *Journal of Health Economics*. 16: 543-562.
- Families USA. (1999) *Hard to Swallow: Rising Drug Prices for America's Seniors*. Publication No. 99-107. November.
- Freemantle. N. Bloor. K. (1996) Lessons from International Experience In Controlling Pharmaceutical Expenditure I: Influencing Patients. *British Medical Journal*. 314(7044): 1469-1470.
- Ganther JM. Kreling D. (1999) Effect of a Change in Third Party Reimbursement Rate on Prescription Gross Margin. *Journal of the American Pharmaceutical Association*. 39(3): 346-352.
- Gardner T. (1986) Structuring Drug Benefits. In final report of APhA Commission on Third-party Programs.
- Gebhart F. (1998) Annual Rx survey: The New Golden Age. *Drug Topics*. March 16: 71-83.
- Generic Pharmaceutical Industry Association (GPIA). (1998) Facts and Figures. Washington, DC. (<http://www.gpia.org>)
- Gibson M. Brangan N. Gross D. et al. (1999) *How Much Are Medicare Beneficiaries Paying Out-Of-Pocket For Prescription Drugs?* Washington DC: AARP Public Policy Institute.
- Glaser M. (1999) Boom year. *Drug Topics* April 5: 47-53.
- Gluck ME. (1999) *A Medicare Prescription Benefit*. National Academy of Social Insurance. (<http://www.nasi.org/medicare/medbr1.html>.)

Gold M. et al. (1999) *Medicare Managed Care: Preliminary Analysis of trends in Benefits and Premiums, 1997-1999*. Mathematica Policy Research. Washington D.C.

Grabowski H. Mullins CD. (Aug 1997) Pharmacy Benefit Management, Cost-Effectiveness Analysis and Drug Formulary Decisions. *Social Science Medicine*. 45(4): 535-44.

Gross DJ. Alexih L. Gibson MJ. Corea J. Caplan C. Brangan N. (1999) Out-of-Pocket Health Spending by Poor and Near-Poor Elderly Medicare Beneficiaries. *Health Services Research*, 34(1 Pt 2): 241-54.

Hamilton BH. (1999) HMO Selection and Medicare Costs: Bayesian MCMC Estimation of a Robust Panel Data Tobit Model with Survival. *Health Economics and Econometrics*. 8: 403-414.

Hejna Chester Pharmacy Networks: Origins, Functions and Future Directions. (1995) *Principles and Practices of Managed Care Pharmacy*. Foundation for Managed Care Pharmacy. Alexandria. VA: 119.

Hellinger F. (1995) Selection Bias in HMOs and PPOs: A Review of the Evidence. *Inquiry*. 32: 135-148.

Hensley S. (1999) Prescription Costs Harder to Swallow. Providers and Payers Get a Big Dose of Reality with Explosive Spending and Patient Demand for New Drugs. *Modern Healthcare*. 29(34): 30-4.

Hewitt Associates (1999) *Retiree Health Coverage: Recent Trends and Employer Perspectives on Future Benefits*. Menlo Park, CA: The Henry J. Kaiser Family Foundation.

Horn SD. Sharkey PD. Tracy DM. et al. (1996) Intended and Unintended Consequences of HMO Cost Containment Strategies: Results from the Managed Care Outcomes Project. *American Journal of Managed Care*. 2: 253-64.

Hurd MD. McGarry K. (1997). Medical Insurance and the Use of Health Care Services by the Elderly. *Journal of Health Economics*. 16: 129-154.

Jacobzone. S. (1999) *How can Pharmaceutical Policy Reconcile Social Objectives and Industrial Efficiency? A View from the Recent Experience of OECD Countries*. Organization for Economic Cooperation and Development (OECD). Paris France.

Johnson RE. Goodman MJ. Hornbrook MC. Eldredge MB. (1997) The Impact of Increasing Patient Prescription Drug Cost Sharing on Therapeutic Classes of Drugs Received and on The Health Status of Elderly HMO Members. *Health Services Research*.32(1):103-22.

Kane. N. (1997) Pharmaceutical Cost Containment and Innovation in the United States. *Health Policy*. 41(Suppl): S71-S89.

- Laschober M. (1997) *Health and Health Care of the Medicare Population: Data from the 1993 Medicare Current Beneficiary Survey*. Rockville MD. Westat, Inc.
- Laschober M. Olin G. (1996) *Health and Health Care of the Medicare Population: Data from the 1992 Medicare Current Beneficiary Survey*. Rockville MD. Westat, Inc.
- Le Pen C. (1996) Drug Pricing and Reimbursement in France: Towards a New Model? *Pharmacoeconomics*. 10 (Suppl. 3): 26-36.
- Lecomte T. Paris V. (1998) Controlling Drug Expenditures in France, Germany, and the United Kingdom. *Économie et Statistique*. 312-313: 109-124.
- Lillard LA, Rogowski J. Kington R. (1997) Long-Term Determinants of Patterns of Health Insurance Coverage in the Medicare Population. *The Gerontologist*. 37(3): 314-323.
- Lillard LA. Rogowski J. Kington R. (1999) Insurance Coverage for Prescription Drugs: Effects on Use and Expenditures in the Medicare Population. *Medical Care*. 37(9): 926-936.
- Long S. (1994) Prescription Drugs and the Elderly: Issues and Options. *Health Affairs*. 13(2): 157-74.
- Long S. Gordon N. (1989) Updated Estimates of Medicare's Catastrophic Drug Insurance Program. Congressional Budget Office (CBO). Washington D.C.
- López-Casanovas G. Puig-Junoy. J. (1999) Review of the Literature On Reference Pricing. Working Paper. Research Center on Health and Economics. Department of Economics and Business. Universitat Pompeu Fabra. Barcelona Spain. February.
- Lutchmie N. Mahil S. Smith T (1999) Evaluating Reference-Based Pricing: Initial Findings and Prospects. *Canadian Medical Association Journal*. 161(3): 286-288.
- Lyles A. Palumbo FB. (1999) The Effect of Managed Care on Prescription Drug Costs and Benefits. *Pharmacoeconomics*. 15(2): 129-140.
- McArdle F. Copock S. Yamamoto D. et al. (1999) Retiree Health Coverage: Recent Trends and Employer Perspectives on Future Benefits. The Henry J. Kaiser Family Foundation: Menlo Park, CA.
- Manning WG. Newhouse JP. Duan N. et al. (1987). Health Insurance and the Demand for Medical Care: Evidence from a Randomized Experiment. *The American Economic Review*. 77 (3): 251-327.
- Minority Staff Report. (1998) *Prescription Drug Pricing in the United States: Drug Companies Profit at the Expense of Older Americans*. Committee on Government Reform. United States House of Representatives. Washington DC.

National Pharmaceutical Council (NPC) (1998) *Pharmaceutical Benefits Under State Medical Assistance Programs*. NPC. Reston VA.

Novartis, (1999) *Pharmacy Benefit Report Facts and Figures: 1999 Edition*. Novartis Pharmaceutical Company. East Hanover NJ.

National Wholesale Druggists' Association (NWDA) (1999) *Industry Profile and Health Care Fact Book*. Addendum.

Office of Inspector General. (1997) *Experiences of Health Maintenance Organizations with Pharmacy Benefit Management Companies*. United States Department of Health and Human Services. Washington D.C. April. Report Number OEI-01-95-00110.

Olin G. Liu H. (1998) *Health and Health Care of the Medicare Population: Data from the 1994 Medicare Current Beneficiary Survey*. Rockville MD. Westat Inc.

Organization for Economic Co-operation and Development (OECD). (1998) *Social and Health Policies in OECD: A Survey of Current Programmes and Recent Developments*. Paris France.

Pauriche P. Rupprecht F. (1998) Pharmaceuticals in France: a Review of Current Trends. *Économie et Statistique*. 312-313:7-20.

Pharmaceutical Care Management Association (PMCA) (1999) *Facts and Figures, 1999*.

Pharmaceutical Research and Manufacturers Association. (PhRMA) (1999) *Pharmaceutical Industry Profile 1999*. Washington D.C. (<http://www.phrma.org>)

Pharmaceutical Research and Manufacturers Association. (PhRMA) (1998) *Pharmaceutical Industry Profile 1998*. Washington D.C.

Pharmaceutical Research and Manufacturers Association. (PhRMA) (1995) *PhRMA Facts: Current Drug Price Increase Below General Inflation: GAO Says Past Increases Much Lower Than Reported*. June. (<http://www.phrma.org>)

Physician Payment Review Commission (PPRC) (1996). *Annual Report to Congress*. ProPAC. Washington D.C.

Poisal JA. et al. (2000) Medicare Beneficiaries And Drug Coverage. *Health Affairs*. (forthcoming).

Poisal JA. Murray LA. Chulis GS. Cooper BS. (1999) Prescription Drug Coverage and Spending for Medicare Beneficiaries. *Health Care Financing Review*. 20(3): 15-27.

Riley G. Tudor C. Chiang YP. et al. (1996) Health Status of Medicare Enrollees in HMOs and Fee-for-Service in 1994. *Health Care Financing Review*. 17(4): 65-76.

Rowgowski J. Lillard LA. Kington R. (1997) The Financial Burden of Prescription Drug Use Among Elderly Persons. *Gerontologist*, 37(4): 475-482.

Sager A. Socolar D. (1999) *Affordable Medications for Americans: Problems, Causes and Solutions*. Prescription Drug Task Force. United States House of Representatives. Washington D.C.

Sasich L. Torrey E. Wolfe S. (1999) *International Comparison of Prices for Antidepressant and Antipsychotic Drugs*. Public Citizen's Health Research Group. Washington DC.

Schöffski O. (1996) Consequences of Implementing a Drug Budget for Office-Based Physicians in Germany. *Pharmacoeconomics*. 10 (Suppl. 2): 37-47.

Schulman KA. Rubenstein LE. Abernathy DR. et al. (1996) The Effect of Pharmacy Benefit Managers: Is It Being Evaluated? *Annals of Internal Medicine*. 124: 906-13.

Schweitzer S. (1997) *Pharmaceutical Economics and Policy*. New York: Oxford University Press.

Smith H. (1975) *Principles and Methods of Pharmacy Management*. Lea and Febiger. Philadelphia PA.

Smith S. Freeland M. Heffler S. et al (1998) The Next Ten Years of Health Spending: What Does the Future Hold? *Health Affairs*. 17(5): 128-140.

Stuart B. Coulson NE. (1994) Use of Outpatient Drugs as Death Approaches. *Health Care Financing Review*. 15(3): 63-82.

Stuart B. Grana J. (1998) Ability to Pay and the Decision to Medicate. *Medical Care*. 36(2): 202-211.

Stuart B. Grana J.(1995) Are Prescribed and Over-the-Counter Medicines Economic Substitutes? A Study of the Effects of Health Insurance on Medicine Choices by the Elderly. *Medical Care*, 33(5): 487-501.

Stuart B. Shea D. Briesacher B. (2000) *Prescription Drug Coverage For Medicare Beneficiaries: Coverage and Health Status Matter*. The Commonwealth Fund. New York.

Stuart B. Zacker C. (1999) Who Bears the Burden of Medicaid Drug Copayment Policies? *Health Affairs*. 18(2): 201-12.

Towse A. (1996) The UK Pharmaceutical Market. *Pharmacoeconomics*. 10 (Suppl. 3): 14-25.

Ulrich V. Wille E. (1996). Healthcare Reform and Expenditure on Drugs: The German Situation. *Pharmacoeconomics*. 10(Suppl. 2): 81-88.

U.S. Department of Health, Education and Welfare. (1968) *Task force on Prescription Drugs. Approaches to Drug Insurance Design: Background Papers*. Washington, DC. Office of the Secretary of Health.

U.S. Department of Health and Human Services Office of Inspector General. (1997) *Experience of Health Maintenance Organizations with Pharmacy Benefit Management Companies*. Washington, D.C. Government Document #OEI-01-00110.

U.S. General Accounting Office. (1992) *Prescription Drugs: Companies Typically Charge More in the United States than in Canada*. Washington D.C. Report Number GAO/HRD-92-110.

U.S. General Accounting Office. (1994) *Prescription Drugs: Companies Typically Charge More in the United States than in the United Kingdom*. Washington D.C. Report Number GAO/HEHS-94-29.

U.S. General Accounting Office. (1994) *Prescription Drugs: Spending Controls in Four European Countries*. Washington D.C. Report Number GAO/HEHS-94-30.

U.S. General Accounting Office. (1995) *Pharmacy Benefit Managers, Early Results on Ventures with Drug Manufacturers*. Washington D.C. Report Number GAO/HEHS-96-45.

U.S. General Accounting Office. (1996) Health, Education and Human Services Division, *Pharmacy Benefit Managers, Early results on Ventures with Drug Manufacturers*. Washington D.C. Report Number GAO-96-45.

U.S. General Accounting Office. (1997) *Pharmacy Benefit Managers: FEHBP Plans Satisfied with Savings and Services, but Retail Pharmacies Have Concerns*. Washington D.C. Report Number GAO/HEHS-97-47.

U.S. General Accounting Office. (1999) *Prescription Drug Benefits - Implication for Beneficiaries of Medicare HMO Use of Formularies*. Washington D.C. Report Number GAO/HEHS-99-166.

United State House of Representatives, Committee on Government Reform and Oversight, Minority Staff Report (1998) *Prescription Drug Pricing in the United States: Drug Companies Profit at the Expense of Older Americans*. Washington, D.C.

von der Schulenburg J. (1997) Management of Cost and Utilization of Pharmaceuticals in Germany. *Health Policy*. 41(Suppl): S45-S53.

von der Schulenburg J. Uber A. (1997) Current Issues in German Healthcare. *Pharmacoeconomics*. 12(5): 517-523.

Walser BL. Ross-Degnan D. Soumerai SB. (1996) Do Open Formularies Increase Access to Clinically Useful Drugs? *Health Affairs*. 15(3): 95-108.

Wolfe JR Goddeeris JH. (1991) Adverse Selection, Moral Hazard, and Wealth Effects in the Medigap Insurance Market. *Journal of Health Economics*. 10: 433-459.

Ya-Chen T. (1999). Effects of Insurance on Prescription Drug Use by ESRD Beneficiaries. *Health Care Financing Review*. 20(3): 39-54.

6. Abstracts

The articles abstracted below represent some of the best sources of material found during the course of this study. The source of the abstract is listed at the end of each study summary. If no source is listed, it is the authors' original abstract.

American Association of Retired Persons (1997) *Profile of Older Americans*.
<http://aarp.org/general/profile97.html>

This AARP report provides a socioeconomic profile of older Americans' in the United States for 1996. These variables include population in U.S. and by state, projected population growth, living arrangements, racial and ethnic composition, geographic distribution, income and poverty, employment, education, health and health care. It identifies older population-persons as 65 years of age and older at 33.9 million, representing 12.8%. Projections for future growth show the most rapid increase is expected between the years of 2010 and 2030 when the "baby boom" generation reaches 65. The study projects that older persons will represent 20% of the population by 2030, an increase of 100% from 1996 (staff).

Bloom N. Van Reenen J. (1998) *Regulating Drug Prices: Where Do We Go from Here?*
Institute for Fiscal Studies, L5, L6, D4.19(3): 321–342.

This paper examines the arguments for changing the ways that UK drug prices are regulated. In the UK, NHS pharmaceutical expenditures on branded drugs, currently worth about £3 billion a year, have been regulated by the Pharmaceutical Price Regulation Scheme (PPR) since 1978. We argue that, in publicly funded healthcare systems, pharmaceutical price regulation is necessitated by a tendency towards excessive government expenditure because of over prescription and the monopoly power of firms with on-patent drugs. We briefly explain the operation of the PPRS, which is based on rate-of-return regulation, and discuss its merits and drawbacks. We then consider five alternative pricing systems: free pricing, therapeutic benefit pricing, international reference pricing, therapeutic reference pricing and RPI – X price regulation. However, we reject all these alternatives in favour of a reformed PPRS. We suggest three potential reforms of the PPRS: an RPI – X cost allowance if feasible or a widening of the rate-of-return bands otherwise; the introduction of a marketing innovation allowance; and greater regulatory transparency.

Carroll NV. Miederhoff PA. Waters LW. (1996) *Profitability, Third-Party Reimbursement, and Access to Community Pharmacies*. *Clinical Therapeutics*, 18(4): 702, 703-715.

The purpose of this study was to analyze the extent to which third-party reimbursement programs have affected the profitability and availability of community pharmacies. Data were taken from records maintained by the Virginia Board of Pharmacy and a survey of 177 community pharmacies. Between 1989 and 1994, 258 outpatient pharmacies opened and 342 closed. Chain and independent pharmacies suffered net losses, and supermarket and mass

merchandise pharmacies experienced net increases. Few significant changes occurred in the distribution of pharmacies over the study period. Fifty-nine chain and independent pharmacies and 1 supermarket pharmacy chain provided usable profit and reimbursement data. These pharmacies experienced declines in profits and increases in the percentage of prescriptions reimbursed by private third-party prescription programs over the last several years. Regression analyses indicated that higher ratios of sales of private third-party prescriptions to private-pay prescriptions were associated with lower profits. All respondents indicated that changes in private third-party reimbursement had substantially reduced profits over the past 5 years. The results indicate that the growth of private third-party payment has led to lower pharmacy profits but has not yet resulted in problems of consumer access.

Cohen RA. Bloom B. Simpson G. et al. (1997) Access to Health Care. Part 3: Older Adults. National Center for Health Statistics. *Vital Health Statistics* 10(198).

This report uses data from the 1993 Access to Care, the 1993 Health Insurance, and the Year 2000 surveys of the National Health Interview Survey to describe access to care for older adults. The findings indicate that health insurance status played a key role in an individual's ability to obtain health care services. Elderly persons with Medicare only were 3 times as likely to go without prescription medicine or glasses as those with Medicare and private insurance coverage. Approximately 600,000 elderly persons were unable to get prescription medicine. (Staff)

Danis M. Biddle AK. Henderson G. Garrett JM. DeVellis RF. (1997) Older Medicare Enrollees' Choices for Insured Services. *Journal of the American Geriatrics Society*, 45(6): 688-94.

RESERACH OBJECTIVES: The aim of this study was to: (1) explore the possibility of allowing Medicare enrollees to choose limited insurance packages personally; (2) identify which services elderly adults would like insured; and (3) elucidate the reasons for their choices. **STUDY POPULATION:** We recruited 118 patients (77% response rate) receiving non-urgent care from the general internal medicine practice of a major teaching institution. **STUDY DESIGN:** We used in-person interviews and an innovative instrument as part of an anonymous, cross-sectional survey. The instrument, a "puzzle-like" board and 12 benefit cards, simulated the health insurance purchase decision by presenting information about premium costs and covered services to allow study subjects to "purchase" coverage for desired services. **PRINCIPAL FINDINGS:** Only 2% of subjects selected the package currently offered by Medicare; 52 different packages were chosen. Twenty-one percent of subjects selected a package that included coverage for hospital, intensive care unit, home care, outpatient care, prescription drugs, and either vision care (13%) or preventive services (8%). Only 9% elected to purchase coverage for long-term care services. Although there was some variation, costs and current or anticipated need were the most frequently cited reason for selection of coverage. Individuals forgoing long-term care coverage deemed other services as more essential (40%); did not anticipate a need (17%); or would rely on family for care (21%). **CONCLUSIONS:** The preferences expressed suggest that a majority would purchase a different combination of

coverage than is currently offered; coverage for prescriptions was highly desired.

RELEVANCE TO POLICY: These results suggest that patients can understand the need for limiting resource use and would rather not defer these decisions entirely to policy makers. Care must be taken in designing benefit packages, requiring, at minimum, coverage of certain core services. (HealthSTAR)

Davis M. Poisal J. Chulis G. Zarabozo C. Cooper B. (1999) Prescription Drug Coverage, Utilization, and Spending Among Medicare Beneficiaries. *Health Affairs*, 18(1): 231-43.

Outpatient prescription drugs are not a covered benefit under Medicare. There have been proposals in the past to expand Medicare benefits to include drug coverage, and current discussions dealing with "modernizing" the Medicare benefit package have raised the issue again. Using data from the 1995 Medicare Current Beneficiary Survey (MCBS), we describe the sources and extent of drug coverage among Medicare beneficiaries. The data show that 65 percent of Medicare beneficiaries have some level of drug coverage--a figure much higher than previous published numbers--and that 95 percent of Medicare health maintenance organization (HMO) enrollees have drug coverage. The data provide a baseline to observe future changes in the level of coverage, particularly among Medicare managed care plans.

Dickson M, Redwood H. (1998) Pharmaceutical Reference Prices. How Do They Work in Practice? *Pharmacoeconomics*, 14(5): 471-9

Reference pricing systems are reimbursement ceilings set by payers in an effort to constrain pharmaceutical expenditure for a private or public drug benefit. In recent years, many governments have adopted reference pricing either as a replacement or in addition to product specific price controls. Program administrators should consider whether these policies are providing the intended benefits or whether there may be a more effective method. This article provides a review of reference pricing in Europe, North America and other countries. There are many similarities in the reference price policies but the markets to which they apply are more likely to be different. The European experience gives a 'once-for-all' lowering effect on pharmaceutical expenditure, often at the expense of compromises on prescribing. In Germany and The Netherlands, reference pricing has been relatively ineffective in lowering expenditure which has led to a succession of other interventions to achieve expenditure control goals. The US also has reference pricing, but it occurs in a very competitive market which may be responsible (at least in part) for the relatively modest growth in expenditure compared with European countries. The review of countries with reference pricing policies suggests that such policies are less effective than competitive markets in moderating pharmaceutical expenditure. Nonetheless, governments continue to pursue reference pricing strategies.

Ganther JM. Kreling DH. (1999) Effect of a Change in Third Party Reimbursement Rate on Prescription Gross Margin. *Journal of the American Pharmacy Association*, (Wash) 39(3): 346-52

OBJECTIVE: To measure the effect of a change in an insurance company's reimbursement formula on prescription department gross margins for all prescriptions and subgroups of prescriptions. **DESIGN:** Retrospective descriptive analysis. **SETTING:** Wisconsin. **PARTICIPANTS:** Two units of a chain pharmacy. **INTERVENTION:** Reimbursement changed from usual and customary price to average wholesale price less 10% plus a \$2.00 dispensing fee for single-source products, and maximum allowable cost plus a \$2.00 dispensing fee for multisource products. **MAIN OUTCOME MEASURE:** Gross margins for prescriptions dispensed in the month before and after the reimbursement change. **RESULTS:** The average estimated gross margin decreased 26.9% after the change in reimbursement, and the effect on the average gross margin for generic prescriptions was nearly twice that of the effect on the average gross margin for brand name prescriptions. The effect of the reimbursement change on different therapeutic classes ranged from an increase of 0.7% in the cardiovascular class to a decrease of 68.2% in the eyes, ears, nose, and throat class. The effect of the reimbursement change was greater for low-cost prescriptions than for high-cost prescriptions. **CONCLUSION:** The large effect of the reimbursement change, combined with continued growth in third party prescriptions, raises concerns about whether pharmacies can accept third party contracts with low reimbursement rates and still maintain current profitability and service levels.

Grabowski H. Mullins CD. (1997) Pharmacy Benefit Management, Cost-Effectiveness Analysis and Drug Formulary Decisions. *Social Science Medicine*, 45(4): 535-44.

Pharmacy benefit management companies (PBMs) have evolved over the past decade in response to the increased demand for health care cost containment. Their activities include the implementation of drug formularies and the negotiation of rebates from manufacturers. Our analysis of this industry is based on interviews and materials provided by the top five ranked PBM companies which account for over 80% of beneficiaries covered within formulary plans. The formularies of these companies are relatively inclusive, but they are becoming more restrictive over time. At present the use of cost-effectiveness (C-E) studies in the formulary decisions of PBMs has been limited. In this regard, the surveyed PBMs emphasized that most C-E studies have not compared therapeutic substitutes in populations with characteristics that are similar to those of their clients. Pharmacy benefit management companies also have had strong incentives to focus narrowly on drug costs because they typically manage drug benefits on a "carved-out" basis. However, PBMs anticipate a growing future role in the integrated management of patient care (disease management) for certain high cost chronic diseases and conditions. All of the leading firms we surveyed have disease management programs in development. The importance of C-E studies to PBM decisions is expected to increase significantly as disease management programs are implemented. The data infrastructure inherent to the PBM industry and the increasing number of employees with advanced training in pharmacoconomics will permit firms to perform their own internal C-E studies. They are also establishing various alliances and joint ventures with drug manufacturers, health maintenance organizations, and academic institutions to perform these analyses. The leading PBMs tend to favor active participation in the development of methodological approaches to C-E studies over government regulations such as those proposed by the FDA in 1995.

Gross DJ. Alexih L. Gibson MJ. Corea J. Caplan C. Brangan N. (1999) Out-of-Pocket Health Spending by Poor and Near-Poor Elderly Medicare Beneficiaries. *Health Services Research*, 34(1 Pt 2): 241-54.

OBJECTIVE: To estimate out-of-pocket health care spending by lower-income Medicare beneficiaries, and to examine spending variations between those who receive Medicaid assistance and those who do not receive such aid. **DATA SOURCES AND COLLECTION:** 1993 Medicare Current Beneficiary Survey (MCBS) Cost and Use files, supplemented with data from the Bureau of the Census (Current Population Survey); the Congressional Budget Office; the Health Care Financing Administration, Office of the Actuary (National Health Accounts); and the Social Security Administration. **STUDY DESIGN:** We analyzed out-of-pocket spending through a Medicare Benefits Simulation model, which projects out-of-pocket health care spending from the 1993 MCBS to 1997. Out-of-pocket health care spending is defined to include Medicare deductibles and coinsurance; premiums for private insurance, Medicare Part B, and Medicare HMOs; payments for non-covered goods and services; and balance billing by physicians. It excludes the costs of home care and nursing facility services, as well as indirect tax payments toward health care financing. **PRINCIPAL FINDINGS:** Almost 60 percent of beneficiaries with incomes below the poverty level did not receive Medicaid assistance in 1997. We estimate that these beneficiaries spent, on average, about half their income out-of-pocket for health care, whether they were enrolled in a Medicare HMO or in the traditional fee-for-service program. The 75 percent of beneficiaries with incomes between 100 and 125 percent of the poverty level who were not enrolled in Medicaid spent an estimated 30 percent of their income out-of-pocket on health care if they were in the traditional program and about 23 percent of their income if they were enrolled in a Medicare HMO. Average out-of-pocket spending among fee-for-service beneficiaries varied depending on whether beneficiaries had Medigap policies, employer-provided supplemental insurance, or no supplemental coverage. Those without supplemental coverage spent more on health care goods and services, but spent less than the other groups on prescription drugs and dental care-services not covered by Medicare. **CONCLUSIONS:** While Medicaid provides substantial protection for some lower-income Medicare beneficiaries, out-of-pocket health care spending continues to be a substantial burden for most of this population. Medicare reform discussions that focus on shifting more costs to beneficiaries should take into account the dramatic costs of health care already faced by this vulnerable population. (Medline)

Hillman A. Pauly M. Escarce J. Rippley K. Gaynor M. Clouse J, Ross R. (1999) Financial Incentives and Drug Spending in Managed Care. *Health Affairs*. 18(2): 189-200.

This study estimates the impact of patient financial incentives on the use and cost of prescription drugs in the context of differing physician payment mechanisms. A large data set was developed that covers persons in managed care who pay varying levels of cost sharing and whose physicians are compensated under two different models: independent practice association (IPA)-model and network-model health maintenance organizations (HMOs). Our results indicate that higher patient copayments for prescription drugs are associated with lower drug spending in IPA models (in which physicians are not at risk for drug costs) but have little effect in network models (in which physicians bear financial risk for all prescribing behavior).

Johnson RE. Goodman MJ. Hornbrook MC. Eldredge MB. (1997) The Impact of Increasing Patient Prescription Drug Cost Sharing on Therapeutic Classes of Drugs Received and on The Health Status of Elderly HMO Members. *Health Services Research*. 32(1):103-22.

OBJECTIVE: To assess the impact of increased prescription drug copayments on the therapeutic classes of drugs received and health status of the elderly. **HYPOTHESES TESTED:** Increased prescription drug copayments will reduce the relative exposure to, annual days use of, and prescription drug costs for drugs used in self-limiting conditions, but will not affect drugs used in progressive chronic conditions and will not reduce health status. **STUDY DESIGN:** Each year over a three-year period, one or the other of two well-insured Medicare risk groups in an HMO setting had their copayments per dispensing increased. Sample sizes ranged from 6,704 to 7,962. **DATA SOURCES/DATA COLLECTION:** Automated administrative data systems of the HMO were used to determine HMO eligibility, prescription drug utilization, and health status. **ANALYSIS DESIGN:** Analysis of variance or covariance was employed to measure change in dependent variables. **FINDINGS:** Relative exposure, annual days of use, and prescription drug costs for drugs used in self-limiting conditions and in progressive chronic conditions were not affected in a consistent manner across years by increases in prescription drug copayment. Health status may have been adversely affected. Larger increases in copayments appeared to generate more changes. **CONCLUSIONS:** Small changes in copayments did not appear to substantially affect outcomes. Large changes in copayments need further examination.

Lecomte T. Paris V. (1998) Controlling Drug Expenditures in France, Germany, and the United Kingdom. From *Économie et Statistiques*, no. 312-313 Insee Studies no. 30.

In the 1990s, France, Germany, and the United Kingdom have all tested procedures to curb the growth of public expenditures on pharmaceuticals. Their diversity reflects the major differences between the three countries' healthcare systems. France combines a consensual regulation of drug prices with incentives to foster greater restraint in doctors' prescriptions (through the guidelines known as *Références Médicales Opposables*). Germany has introduced competitive mechanisms via regulations based on groupings of equivalent products. In the United Kingdom, a series of reforms has opened up the traditionally State-controlled healthcare sector to market rules aimed at promoting cost-conscious behavior among system players. The main innovation consists in giving doctors the opportunity to manage a budget tailored to the size of their practice. The success of these policies varies considerably from one country to another. France combines a higher individual expenditure with a lower co-payment by the State. The national differences concern not only the overall consumption level, but also the type of medicine: the French consume more anti-anxiety drugs, while the British consume more analgesics. Consumption volume appears to be a more powerful engine of spending growth than prices.

Lillard LA. Rogowski J. Kington R. (1999) Insurance Coverage for Prescription Drugs: Effects on Use and Expenditures in the Medicare Population. *Medical Care*, 37(9): 926-936.

BACKGROUND: Although Medicare covers most of the elderly, they potentially face large out-of-pocket costs for their health care because of excluded services. Aside from nursing home care, the exclusion of prescription drugs is one of the most significant. Several earlier policy initiatives have proposed adding prescription drug coverage to the Medicare program. To determine the effects of such an expansion, one must account for the potential increase in the demand for prescription drugs from providing insurance coverage. **METHODS:** The study uses a new data source, the RAND Elderly Health Supplement to the 1990 Panel Study of Income Dynamics (PSID). The endogeneity of insurance coverage is tested using instruments that exploit the longitudinal nature of the data. Equations are estimated on 910 persons (> or = 66 years) using a two-part model. **RESULTS:** Insurance coverage for prescription drugs significantly increases the probability of use, but not of total expenditures, among those who use prescription drugs. However, insurance coverage significantly lowers out-of-pocket expenditures, thereby decreasing the financial burden on elderly households associated with prescription drug use. Medicaid coverage has effects that are smaller than those for private insurance do, but the magnitude is less precisely estimated. These findings imply that if prescription drug coverage were added to Medicare, expected expenditures on drugs would rise by on average \$83 for each elderly Medicare beneficiary (in 1990 dollars), although this increase is significant only at the 90% level. If the benefit had been included under Medicare expected spending on prescription drugs by the elderly would have risen by approximately 20%, or \$2.6 billion in 1990. (Medline)

López-Casasnovas G. and Puig-Junoy J. (1999) Review of the Literature on Reference Pricing. Research Center on Health and Economics. Department of Economics and Business. Universitat Pompeu Fabra. Barcelona Spain. February.

This paper reviews the literature on reference pricing (RP) in pharmaceutical markets. The RP strategy for cost containment of expenditure on drugs is analyzed as part of the procurement mechanism. We review the existing literature and the state-of-the-art regarding RP by focusing on its economic effects. In particular, we consider: (1) the institutional context and problem-related factors which appear to underline the need to implement an RP strategy; i.e., its nature, characteristics and the sort of health care problems commonly addressed; (2) how RP operates in practice; that is, how third party-payers (the insurers/buyers) have established the RP systems existing on the international scene (i.e., information methods, monitoring procedures and legislative provisions); (3) the range of effects resulting from particular RP strategies (including effects on choice of appropriate pharmaceuticals, insurer savings, total drug expenditures, prices of referenced and non-referenced products and dynamic efficiency; (4) the market failures which an RP policy is supposed to address and the main advantages and drawbacks which emerge from an analysis of its effects.

Lyles A. Palumbo FB. (1999) The Effect of Managed Care on Prescription Drug Costs and Benefits. *Pharmacoeconomics*, 15(2):129-40.

This review discusses the approaches to prescription drug payment practices taken by managed care to influence drug use and costs, and presents the research evidence supporting these interventions. In the US, drugs were infrequently covered as an ambulatory benefit under fee-for-service indemnity insurance; however, health maintenance organizations almost always provide outpatient drugs and consequently have developed approaches to influence drug use and manage its costs. Managed care as a set of tools and as an organizational form is moving toward more restrictions on direct access to pharmaceuticals as a covered benefit. Options for influencing drug use and cost may address access, ingredient costs, dispensing fees and cost sharing. The formulary process is the foundation for a managed pharmacy benefit and integrates these options. The limited empirical evidence for an effect of managed care on drug costs and use is reviewed. A proposed research agenda includes evaluation of the effects of restrictive formularies, capitation, disease management and other programs to influence the cost and use of pharmaceuticals.

McArdle F. Copock S. Yamamoto D. et al. (1999) Retiree Health Coverage: Recent Trends and Employer Perspectives on Future Benefits. The Henry J. Kaiser Family Foundation: Menlo Park, CA.

This study uses the Hewitt Associates client database of large employers' benefits plans to show trends in retiree health plans. The analysis showed that the overall health insurance coverage has declined between 1991 to 1998: there was a 13-percentage point drop in portion of large employers offering health coverage to age 65+ retirees. More than 95% of large employers offer prescription benefits to retirees. Prescription drug expenditures account for 40 to 60 percent of retiree plan costs. (Staff)

Poisal JA. Murray LA. Chulis GS. Cooper BS. (Spring 1999) Prescription Drug Coverage and Spending for Medicare Beneficiaries. *Health Care Financing Review*, 20(3):15-27.

Very little is known about which persons within the Medicare population have drug coverage from other sources. Using 1995 data from the Medicare Current Beneficiary Survey (MCBS), the authors present information on who has coverage by various sociodemographic categories. The data indicate higher-than-average levels of coverage for minority persons, beneficiaries eligible for Medicare because of disability, and those with higher incomes. (HealthSTAR).

Rowgowski J. Lillard LA. Kington R. (1997) The Financial Burden of Prescription Drug Use Among Elderly Persons. *Gerontologist*, 37(4): 475-82.

This study, using a new data source, the 1990 Elderly Health Supplement to the Panel Study of Income Dynamics (PSID), demonstrates that, among elderly persons, insurance coverage for drugs reduces the fraction of household income spent on prescription drugs by 50 percent. Groups most likely to benefit from insurance coverage are elderly women and those with common chronic conditions, low incomes, and rural residences. (Medline)

Sager A. Socolar D. (1999) *Affordable Medications for Americans: Problems, Causes and Solutions*. Prescription Drug Task Force. United States House of Representatives. Washington D.C.

The authors define certain existing problems with the high costs of prescription drugs and make recommendations to redistribute financial resources in order to make prescription drugs more cost effective and accessible to the American public. According to the report, ¼ of all Americans do not have prescription drug coverage. Yet, current expenditures on prescription drugs in the U.S. are more than sufficient to purchase all the medications that Americans need. U.S. retail prescription drug spending is predicted to rise to \$103 billion in 1999 and \$143 billion by 2002. The cost of prescription drugs is rising about three times as fast as overall health costs. According to the authors, reasons for such high expenditures include: lack of government regulation of drug pricing activities; drug manufacturers charge Americans higher prices than they do to other countries. They assert that it may be a myth that the funds are needed for research activities. . The costs of pharmaceutical research ought to be shared globally. Pharmaceutical drugs in 1998 were the most profitable industry, and maintained remarkably high profits for seven decades. The profits of this industry exceed research costs in many of the top 10 U.S. drug firms. Some solutions recommended by the authors include: 1) lowering drug prices to raise demand, thus offsetting some revenue loss for drug makers, 2) pooling statewide buying power to negotiate discounts and rebates with drug manufacturers, 3) federal and state governments to negotiate “in-kind” donations with drug manufactures, 4) partnering public and private efforts to more efficiently manage expenditures related to drug manufacturers’ advertising, public relations, and lobbying, and 5) financing should be planned cooperatively among all stakeholders. In light of these recommendations, the authors advocate for comprehensive reform of the prescription drug manufacturing industry in order to contain expenditures and make prescription drugs more affordable and accessible to the American public. (Staff)

Schulman KA. Rubenstein LE. Abernethy DR. Seils DM. Sulmasy DP. (1996) The Effect of Pharmaceutical Benefits Managers: Is It Being Evaluated? *Annals of Internal Medicine*, 124(10): 906-13 .

Over the last decade, the number of pharmaceutical benefits managers has increased, and their influence has expanded rapidly. These managers now provide prescription drug coverage to more than 100 million Americans. The effect of pharmaceutical benefits managers on health care delivery remains unclear. We review the development of these organizations, their current role in the delivery of pharmaceutical therapies to patients, and their relationship with pharmaceutical manufacturers. We discuss potential advantages and disadvantages of pharmaceutical benefits manager practices and suggest ways in which these organizations can be made more accountable to the employer groups that hire them.

Stuart B. Grana J. (1998) Ability to Pay and The Decision to Medicate. *Medical Care*. 36(2): 202-211.

OBJECTIVES: It is widely recognized that ability to pay affects access to hospital and physician services. Much less is known about the economic determinants of prescription drug use, particularly among the elderly. The authors hypothesize that persons with higher incomes and better health insurance coverage are more likely to medicate common health problems than those with lower incomes and less comprehensive coverage. **METHODS:** A random sample of 4,066 elderly Pennsylvania Medicare beneficiaries were asked to complete a mail survey on health insurance, income, and medicine use for 23 common health problems. The relationship between ability to pay and medication decisions was analyzed using logistic and Poisson regression models with covariates for socio-demographic characteristics and health status. **RESULTS:** A strong and consistent relationship was found in the hypothesized direction. Other things being equal, elderly persons with Medicare supplementation were between 6% and 17% more likely to use prescription medicine to treat their health problems than are persons with Medicare coverage alone. The presence of prescription drug coverage significantly increased the odds of prescription treatment for 10 of the 22 conditions examined. The insurance effects were generally--but not exclusively--more pronounced for less serious compared with serious health problems. Income also was shown to have a strong independent effect on medication decisions. Elderly with annual incomes greater than \$18,000 were 18% more likely to treat problems with prescription drugs than were persons with annual incomes less than \$6,000. **CONCLUSIONS:** In sum, economic factors appeared to play an important role in medication decisions by the elderly. The magnitude of the impact was sufficiently high that it could have major negative consequences on the health of elderly persons who are poor and lack drug coverage. (Medline)

Stuart B. Grana J. (1995) Are Prescribed and Over-the-Counter Medicines Economic Substitutes? A Study of the Effects of Health Insurance on Medicine Choices by the Elderly. *Medical Care*, 33(5):487-501.

Insurance coverage on the selection of over-the-counter (OTC) and prescribed (Rx) medicines in treating less serious health problems. Because health insurance policies typically provide no coverage for OTC products, a low list price for an OTC may exceed the after-insurance expense associated with a much higher-priced prescription. Under these circumstances, rational individuals with insurance will choose prescribed medicines even if OTCs are equally effective. Ten common health problems typically managed with either Rx or OTC medicines were selected for analysis. The study population consists of elderly Pennsylvanians surveyed during 1990 who reported suffering one or more of these conditions (N = 2,962). Multivariate analysis confirmed that 1) people with prescription coverage are significantly more likely to medicate a given problem than are those without it; and 2) given the decision to medicate, the presence of insurance significantly increases the level of Rx use and significantly reduces the level of OTC use. As expected, the effect was strongest among people with the most complete prescription insurance coverage. The article discusses the implications of these findings in the context of national health reform and Food and Drug Administration policy regarding Rx-to-OTC switches. (Medline)

United States Department of Health and Human Services Office of Inspector General. (1997) *Experience of Health Maintenance Organizations with Pharmacy Benefit Management Companies*. Washington, D.C. Government Document #OEI-01-00110.

This report focuses on the experience of HMO's in using Pharmacy Benefit Managers (PBMs). As enrollment in managed care continue to grow, and because PBMs can significantly affect patients' use of prescription drugs, it is important for the Health Care Financing Administration (HCFA), as well as private payers, to be informed about the HMOs experiences with them. The data used in this report are derived from a mail survey of all HMOs in the country. The response rate was 71%. Information collected also drew from discussions with staff of the U.S. Department of Health and Human Services (HHS) and several state Medicaid agencies, non-government experts, and a literature review. The report had three recommendations: 1) the HCFA should take steps to ensure that its Medicare HMOs are sufficiently accountable for the quality of the services their PBMs provide to beneficiaries, 2) State Medicaid agencies should take steps to ensure that their Medicaid HMOs are sufficiently accountable for the quality of the services their PBMs provide to beneficiaries, and 3) HCFA, the Food and Drug Administration (FDA), and the Health Resources and Services Administration (HRSA), should work together with external organizations to develop quality measures for pharmacy practice that can be used in managed care settings. (Staff)

U.S. General Accounting Office (1996), *Pharmacy Benefit Managers, Early Results on Ventures with Drug Manufacturers*, Washington D.C. Report Number GAO-96-45

This GAO report responds to congressional concerns over recent trends among the largest pharmaceutical manufacturers in merging or forming alliances with some of the largest pharmacy benefit management companies (PBMs). Questions raised by the study focused on four general areas including: 1) the role of the PBMs in the health care industry; 2) the objectives of these ventures; 3) specific concerns about the effect of these ventures on competition in markets served by drug manufacturers and PBMs; and 4) the extent, if any, to which the PBMs have given preference to their manufacturer partners' drugs after a merger. Information was collected through discussions with Wall Street analysts, pharmaceutical economists, health plan sponsors, pharmaceutical trade associations, and PBMs. The results indicate that drug manufacturer have merged or allied with PBMs to help maintain and/or increase the manufacturers' profits at a time of increasing competition. It is believed that PBMs have substantial market power due to their increasing special role in health care by administering prescription drug benefits for health plan sponsors. They also have been able to affect substantial cost savings through their ability to negotiate drug discounts and rebates from both drug manufacturers and pharmacies. The objective of the manufacturers' ventures with PBMs was to bolster profits, increase market share for their drugs, and develop new programs for treating specific diseases. While the number of people covered by PBMs has increased significantly, the market for PBMs services continues to involve a small number of firms. Although there are over 40 PBMs in the U.S., the 5 largest manage benefits for over 80% of the health plan enrollees covered by PBMs. They include PCS Health Systems, Medco, Value RX, DPS, and Caremark International Inc.'s Prescription Service Division. (Staff)

U.S. General Accounting Office (1999) *Prescription Drug Benefits - Implication for Beneficiaries of Medicare HMO Use of Formularies*. Washington D.C. Report Number GAO/HEHS-99-166.

This GAO report is a study of the impact of drug formularies on beneficiaries in Medicare HMOs. Medicare HMO enrollees face complex issues in selecting a plan to best meet their needs because formularies within different HMOs vary and can affect their drug benefits as well as their out-of-pocket costs. Plans are not required by HCFA to notify beneficiaries of formulary changes and may also make it difficult for physicians to obtain exceptions to allow patients to remain on their existing medication at no additional cost if it is dropped from the formulary. Ten of the 16 HMOs studied use closed formularies that limit coverage to certain drugs. Twelve of the 16 HMOs require the use of generic drugs when available. Seven of the 16 use variable co-payments, with a larger amount charged for brand-name drugs than for the generics. Currently, Medicare beneficiaries can join or leave an HMO plan on a monthly basis. However, in 2002, making informed choices among health plans will become even more important because under the Balanced Budget Act of 1997 (BBA) (Staff)

U. S. General Accounting Office (1997), *Pharmacy Benefit Managers, FEHBP Plans Satisfied with Savings and Services, but Retail Pharmacies have Concerns*, Washington D.C. Report Number GAO -97-47

The Office of Personnel Management (OPM) estimates that nearly 9 million federal employees, retirees, and dependents are covered by a Federal Employees Health Benefits Program (FEHBP). Additionally, they estimated that pharmacy benefit payments for the five largest FEHBP plans amounted to about \$2 billion in 1995, and accounted for an increasing share of the total FEHBP health care costs –growing from 12% in 1990 to 19% in 1995. In order to control prescription drug costs, FEHBP plans contract with PBMs to manage pharmacy benefits on behalf of plan sponsors. As a result, the role of PBMs in managing pharmacy benefits for federal enrollees is growing. The report raised four basic questions: (1) why FEHBP plans have contracted with PBMs to provide pharmacy benefits, (2) what types of services and savings the PBMs provide FEHBP plans, (3) how FEHBP plans evaluate PBM customer service, and (4) the concerns of retail pharmacists about the quality of PBM pharmacy services and the effect of some PBM practices on the retail pharmacy business. The range of cost control services offered by PBMs to FEHBP plans include negotiating lower prices on prescription drugs, developing mechanisms that support lower drug costs such as mail order pharmacy sales, checking prescriptions for adverse drug reactions, and customer services, etc. Reimbursement mechanisms employed by PBMs include industry standards such as the drug's usual and customary price, average wholesale price (AWP), or maximum allowable cost (MAC), plus a dispensing fee. The PBMs also require network pharmacies to substitute generic drugs for brand name drugs when possible. In directing market share of certain drug formularies, manufacturers give rebates to the PBMs amounting to over \$113 million collectively in 1995. These rebates accounted for between 2% and 21% of plans' estimated savings. Because the FEHBP plans use open formularies, enrollee reimbursement is not limited to the drugs listed on the formularies. Other cost saving interventions used by the PBMs

include drug utilization review (DUR), generic and therapeutic interchange programs, and disease management programs. (Staff)

U.S. House of Representatives, Committee on Government Reform and Oversight, Minority Staff Report, (1998). *Prescription Drug Pricing in the United States: Drug Companies Profit at the Expense of Older Americans*. Washington D.C.

This report summarizes investigations of prescription drug pricing conducted by the minority staff in 20 congressional districts. The findings indicate that many older Americans pay high prices for prescription drugs and have a difficult time paying for the drugs they need. Large corporate and institutional customers with market power are able to purchase at discounted prices, but seniors and individual customers who pay for drugs out of pocket must pay at a much higher price. By one estimate, more than one in eight older Americans has been forced to choose between buying medications and food. Case studies conducted in several states illustrate these hardships. The staff recommendations include legislation to reduce the cost of prescription drugs for seniors. (Staff)

Walser BL. Ross-Degnan D. Soumerai SB. (1996) Do Open Formularies Increase Access to Clinically Useful Drugs? *Health Affairs*. 15(3): 95-109.

Before 1990 many state Medicaid programs maintained "restrictive" formularies, which denied reimbursement for unlisted prescription drugs. This type of formulary has been criticized for denying important medications to poor, medically needy persons. As part of the Omnibus Budget Reconciliation Act of 1990, restrictive formularies in Medicaid programs were disallowed. Based on research into the 200 top-selling prescription drugs in the United States, we conclude that eliminating Medicaid restrictive formularies improved access to a subset of the 200 best sellers, but that the majority of these products offered only questionable or no additional therapeutic benefit.