

THE 13TH ANNUAL
HERBERT LOURIE MEMORIAL LECTURE ON HEALTH POLICY
**Pharmaceuticals: Access, Cost, Pricing,
and Directions for the Future**

*Patricia M. Danzon and
Stephen B. Soumerai*

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Policy Brief

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Introduction

Prescription drug expenditures make up less than 10 percent of total personal health care expenditures in the United States, but over the last decade the amount that Americans spend on prescription drugs has grown much faster than any other component of personal health care (see Appendix Figures 1 and 2). For example, between 1999 and 2000, hospital care costs rose about 5 percent, physicians and clinical services 6 percent, while prescription drug expenditures climbed more than 17 percent. In dollar amounts, prescription drug expenditures doubled, from \$61 billion to \$122 billion, between 1995 and 2000.

Is this an unwarranted expense that needs to be controlled, or does it represent increased value, as pharmaceuticals substitute for older, more costly treatments? What is the prevalence of health insurance coverage for prescription drugs, and how does this affect specific populations who have limited or no drug benefits? What are the components of drug prices? And what do we need to consider when we design health care policy?

Stephen Soumerai and Patricia Danzon look at several aspects of pharmaceutical drug usage and pricing in the United States, illustrating their observations with their published research findings. They then briefly review recent legislative proposals to broaden public insurance coverage for prescription drugs and make their own policy recommendations.

Stephen Soumerai

There is a strong economic and public health rationale for guaranteeing access to prescription drugs. For many people, access to prescription drugs is highly correlated with adequate insurance coverage for outpatient prescription drugs. If we look only at the aggregate growth of insurance coverage, we don't see the problems that certain subgroups of Americans have obtaining adequate health insurance: older people, poor people, and those who are underinsured.

Uninsurance

An estimated 38.7 million Americans (14 percent of the total population) were without any form of health insurance in 2000, down slightly from the previous year (U.S. Census Bureau 2001). This decline in lack of coverage was widespread and affected most demographic groups, with one significant exception: among Americans with income between the poverty line and 125 percent of poverty, the share without health insurance increased two percentage points, from 25 to 27 percent, between 1999 and 2000. And the share of poor and minority Americans without health insurance remained well above the national average: 19 percent of African Americans, 32 percent of Hispanics, and 30 percent of poor Americans lacked health insurance of any kind in 2000.

Underinsurance

The original Medicare, the public health insurance program that covers virtually all older Americans, was designed to provide coverage for the big health care expenses that people faced in 1965, mainly hospitalization and doctors' treatments. But it does not include outpatient prescription drug benefits. Extremely low-income Medicare beneficiaries may qualify for Medicaid, which covers prescription drugs. Other Medicare beneficiaries who want drug coverage have to purchase supplemental insurance (Medigap), switch from fee-for-service Medicare to a Medicare HMO, or qualify for prescription discounts under one of the state sponsored plans (like New York's Elderly Pharmaceutical

Insurance Coverage, EPIC). Some pharmaceutical manufacturers have begun to offer their own discount plans for low-income seniors (Pear and Petersen 2002). Yet a disturbing number of Medicare beneficiaries have limited or no drug benefits.

Bruce Stuart and his colleagues, using data from the Medicare Current Beneficiary Survey, analyzed the sources and duration of prescription coverage maintained by Medicare beneficiaries in 1995 and 1996. They chose a two-year period to distinguish true losers and gainers from those who move into and out of coverage over time, and to capture changes at the beginning of the calendar year (Stuart, Shea, and Briesacher 2001). They found that although about 70 percent of all beneficiaries had coverage at some time in the first year, and even more had coverage at some time over both years, fewer than half (46.3 percent) had continuous drug coverage over the full two-year period. Thus, about 30 percent of the sample had gaps in their prescription coverage at some point during the two years.

Even the 46 percent who have continuous coverage don't always have access. Some Medicaid programs cap the number of prescriptions as low as three per month. Two-thirds of Medicaid programs require copayments ranging from \$0.50 to \$5.00 per prescription (National Pharmaceutical Council 2000). The three standard Medigap policies with drug benefits (H, I, and J) have a \$250 deductible, 50 percent coinsurance, and a \$1,250/\$3,000 annual cap (HCFA 2001). Even Medicare HMOs, to which many Medicare beneficiaries have turned for drug benefits, are starting to clamp down on those benefits in an effort to stay afloat (Rector 2000).

Appendix Table 1 illustrates out-of-pocket costs per year for pharmaceutical drugs under different types of insurance coverage, based on a hypothetical total of \$2,000 per year over 55 prescriptions (DHHS 2000, Table 2-23). The Medicaid recipient, with a \$2.00 copay per prescription, pays \$110; the Medicare beneficiary with Medigap H, I, or J pays an average of \$1,125; and the Medicare beneficiary with no supplemental insurance pays the entire \$2,000 out of pocket.

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Copays, coinsurance, caps, and other limits on prescription drug coverage are particularly burdensome for three vulnerable populations: the elderly, the poor, and those with multiple chronic health problems. As Adams, Soumerai, and Ross-Degnan wrote in 2001, “A Medicare drug benefit that includes high cost sharing without catastrophic coverage is likely to miss the poorest and sickest” (p. 276).

Adverse Impact of Limited Drug Coverage on Vulnerable Populations

What are the adverse effects of limited drug coverage, based on the evidence from the best controlled studies? In low-income populations, it reduces use of clinically important medicines like insulin and cardiac medications, and it increases use of institutional services like hospitalization and nursing home admissions, which tend to be permanent among the elderly. Among schizophrenic patients and other groups with chronic mental illnesses, it increases day hospital use and acute mental health and emergency mental health care. A series of three studies in *The New England Journal of Medicine* (Soumerai et al. 1987, 1991, 1994) strongly suggest that coverage limits increase total health care costs for these at risk patients.

Soumerai and colleagues conducted several analyses comparing changes in prescription drug usage of both essential and nonessential drugs, among Medicaid beneficiaries in New Hampshire under two different regimes in the 1980s (a three prescription per month cap during one year, replaced by a \$1 copayment the following year) and New Jersey, which had no cap (Soumerai et al. 1987, 1991, 1994; Fortess et al. 2001). Their first study (1987) used data from 48 months of claims in both states, including a baseline period. Among more than 10,000 continuously enrolled patients in New Hampshire, the imposition of a monthly three-prescription cap reduced the number of prescriptions filled by 30 percent; no change was noticed during the same time period in the comparison state. Those who used multiple prescriptions, predominantly female and elderly or disabled, were hardest hit; their filled prescriptions dropped by 46

percent. When a \$1 copayment replaced the cap, most prescription fills returned to nearly the same level as before the cap, but not for patients receiving multiple drugs.

In 1991 Soumerai and colleagues reported the effects of the same New Hampshire Medicaid drug benefit cap on the health of Medicaid recipients aged 60 and older who were taking three or more medications per month before the cap, including at least one maintenance drug for certain chronic diseases, compared to a similar sample in New Jersey. Again, prescription drug usage declined substantially, by 35 percent, among the New Hampshire sample when the cap was imposed. This decline was associated with a significantly increased risk of admission to nursing homes, although not to hospitals. When the cap was discontinued, the use of medications returned to nearly pre-cap levels, and the added risk of admission to a nursing home ceased. However, nothing could turn back the clock: the authors note that, “in general, the patients who were admitted to nursing homes did not return to the community” (p. 1072). This was the first time that a study actually demonstrated a link between coverage policies and an outcome like permanent institutionalization.

Three years later they looked at the effects of the New Hampshire Medicaid cap on the use of psychotropic drugs and acute mental health care services by permanently disabled, noninstitutionalized Medicaid recipients diagnosed with schizophrenia, ages 19 through 60 years of age (Soumerai et al. 1994). Imposition of the cap resulted in “immediate reductions (range 15 to 49 percent) in the use of antipsychotic drugs, antidepressants and lithium, and anxiolytic and hypnotic drugs....It also resulted in coincident increases of one to two visits per patient per month to [community mental health centers] (range of increase 43 to 57 percent)...and sharp increases in the use of emergency mental health services and partial hospitalization (1.2 to 1.4 episodes per patient per month), but no change in the frequency of hospital admissions. After the cap was discontinued, the use of medications and most mental health services returned to base-line levels.” During the cap there was an increased use of emergency mental health services that are only provided in New Hampshire,

a special service to prevent institutionalization for people who are having a psychotic episode. This indicates that a coverage cap can actually cause psychotic episodes among schizophrenic patients, because these services were only provided for people who had severe schizophrenic illness occurring at that time. Furthermore, in this study the cap clearly had a negative effect on overall Medicaid program costs: “the estimated average increase in mental health care costs per patients during the cap (\$1,530) exceeded the savings in drug costs to Medicaid by a factor of 17.”

Tamblyn and colleagues took a somewhat different approach, looking specifically for adverse events, “defined as the first occurrence of acute care hospitalization, long-term care admission, or death” (2001, 424), among low-income and elderly beneficiaries of a Canadian public insurance program in the 1990s. In 1996, the province of Quebec legislated mandatory drug insurance coverage for all residents. To finance their program, they instituted a deductible and 25 percent coinsurance for all recipients, including low-income and elderly persons who had previously received free prescription drugs. (Bear in mind that the current legislative proposals in the U.S. Congress are more like 50 percent cost sharing.) The random sample included 94,000 elderly persons and 55,000 low-income adults with Medicaid benefits. Data were drawn for periods before and after the deductible and coinsurance requirements were imposed. After cost sharing was introduced, use of both essential and nonessential prescription drugs dropped in both populations, although not as significantly as in the New Hampshire samples. The authors observed that “increased cost sharing for prescription drugs had the desired effect of reducing the use of less essential drugs but also the unintended effect of reducing the use of drugs that are essential for disease management and prevention” (p. 427). The rate of serious adverse events associated with reduced use of essential drugs increased from 5.8 per 10,000 person-months to 12.6 in the elderly sample, and from 14.7 to 27.6 in the low-income sample. Emergency department visit use rates associated with reductions in the use of essential drugs also increased by 14.2 per 10,000 person-months in elderly persons

and by 54.2 among the low-income persons (Tamblyn et al. 2001).

Policy Recommendations

The Kaiser Family Foundation has published a comparative study of all of the proposals for drug benefits for Medicare beneficiaries that are being discussed in Congress (Kaiser Family Foundation 2001). We're dealing here with political viability. We're dealing with Democrats who want to have universal coverage, and Republicans who want more private coverage and more selective coverage for vulnerable people. What has happened, however, is that the majority of proposals now favor thin, which means not very good, universal coverage. Why? Political exigencies are forcing us to cover everybody, but we can't afford it. It's as simple as that.

Congressional proposals say, in a nutshell, let's provide really thin coverage to everybody, even those people who don't necessarily need it. High deductibles, and catastrophic coverage so that after \$4,000 to \$6,000 of out-of-pocket costs people then will get coverage. Rely on the self-purchase private insurance market, despite the fact that these private plans have very high cost sharing and result in less use of essential medications. All of these systems are voluntary, which are political realities, I guess.

In 1999, Dennis Ross-Degnan and I wrote in *The New England Journal of Medicine* that the time was ripe for "a federal-state program to cover poor, near-poor, and low-income Medicare beneficiaries who are ineligible for Medicaid....Such an incremental approach would target the elderly and disabled persons with the greatest economic and clinical need, would build on existing federal-state programs, and would be affordable" (page 722). We referred to the demise of the Catastrophic Coverage Act as a missed opportunity, the failed Clinton Plan for health care as a missed opportunity, and now we've got a new opportunity. Let's not blow it again. We need a bipartisan compromise. We went to Washington and talked to a lot of senators and aides about this problem; they said we've got to

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compromise or else nothing's going to happen. At that time, we said that with the current budget surplus, as well as bipartisan concern about drug costs and coverage, it's time to act responsibly and aggressively.

Have we missed our chance? I hope not. There was a big chance a couple of years ago, but there was no compromise. I'm hoping that there will be a chance again soon.

Ideally, everybody in Medicare—elderly, disabled people—should have access to prescription drugs, and other people as well. But available solutions are controversial, and we need compromise.

Our first principle is that poor and low-income people, maybe up to 200 percent of poverty, have an urgent need for an immediate unlimited benefit, because these are the people—we have data now from many environments and countries—for whom limited access to prescription drugs actually affects their health and ultimately their ability to live independently. Limited drug coverage, especially for low-income people, reduces uses of essential medications that doctors clearly do not want to see reduced, nor does the clinical literature. It increases adverse costly outcomes such as institutionalization, hospitalization, and even mortality.

So what should be the priorities in coverage? To quote from our recent article in the *Journal of General Internal Medicine*:

We recommend an approach that recognizes the urgent need of low-income beneficiaries for an unlimited benefit with low copayments. We estimate that a substantial portion of the costs of providing coverage to this group, whose lack of economic access to drugs results in low utilization and undertreatment of important chronic illnesses, would be offset by reduced use of institutional services. In addition, no one should become impoverished by the need for essential medications. The second priority

should be to provide universal protection against very high drug costs (e.g., after \$3,000 in out-of-pocket costs). Such an approach will have a larger impact on health than thin coverage for everyone, including those who do not currently need any public assistance. (Soumerai, Adams, and Ross-Degnan 2001, 865)

An approach like this will have a larger impact on health than the so-called thin coverage that's being promoted for all beneficiaries, with up to 50 percent cost sharing and huge deductibles. Even so, there are still going to be people at the borderline who will not get their medications.

Patricia Danzon

My doctorate is in economics, which is known as the dismal science. So, after the heartwarming and caring concern expressed by Steve, it is my less pleasant task to talk about some of the hard numbers, the business side of things. Both perspectives are very important, and I think that our views of the solutions are quite similar.

Pharmaceutical Drug Spending Growth

If we step back to ask what actually drove the increase in spending that was described in the introduction, and which has been quite out of line in the 1990s compared with previous trends, our analysis suggests:

- *the single most important factor driving this growth in spending is the growth of insurance coverage.*

The proportion of Americans with some form of health insurance, 86 percent, has remained fairly constant for more than a decade. In 2000, about 238 million people in the United States were covered by some form of health insurance, including virtually everyone age 65 and older. But over the same time period an increasing fraction of both the under 65 and the over 65 population obtained some drug coverage, primarily as private

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insurers added outpatient prescription drugs to their standard benefits.(Danzon and Pauly 2001; Briesacher and Stuart 2002, Table 1).

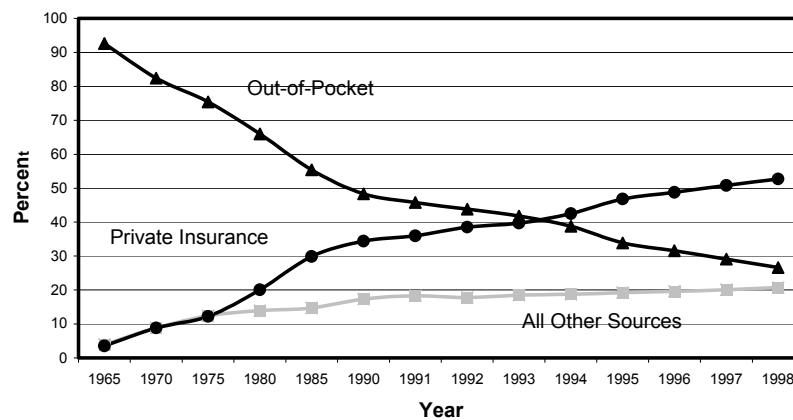
When we compared two population surveys, one done in 1987 and the other in 1996, and we looked at the under 65 population, those who had at least one prescription and some insurance coverage increased from 51 percent to 83 percent. Most of the people in the under 65 population who had a prescription now do have coverage (Danzon and Pauly 2001). And the people who don't have prescription drug coverage are primarily the people without any health insurance coverage, some of whom are young adults, ages 18 to 24. They were the least likely to have health insurance coverage, 72.7 percent, versus 86 percent overall, in 2000 (U.S. Census 2000). Interestingly, in the senior population we also found that there was a dramatic increase in the percentage with coverage; this may have declined recently with the exit of HMOs from Medicare Plus Choice.

Between 1965 and 1998, the proportion of prescription drug expenditures covered by private insurance increased from virtually nothing (3.5 percent) to slightly more than half (52.7 percent), while the proportion paid out of pocket declined from nearly the entire amount (92.6 percent) to about one-quarter (26.6 percent) (Figure 1). By comparison, over the last decade the share of total personal health expenditures, hospitals, and physicians paid out of pocket, has remained steady, at about 17 percent, 3.2 percent, and 12.5 percent respectively (HCFA 2000). This massive shift from direct to indirect payment for prescription drugs is a major underlying cause of expenditure growth, as consumers and prescribing doctors become less aware of and less sensitive to the financial impact.

I'm not saying that lack of drug benefits is not a problem. I *am* saying that during the 1990s there was an increase in coverage, which contributed significantly to the growth in spending. The fact is that when people have insurance they spend more, they use more prescriptions, and they have higher costs per prescription. To some extent this reflects what economists call the *moral*

hazard effect of insurance. We don't mean it is immoral; we simply mean that when somebody else pays, you use more expensive drugs. And to some extent it reflects the fact that people, especially in the under 65 population who need coverage or need drugs, are more likely to buy coverage. This is called *adverse selection*, the tendency for people who need drugs or other medical services to buy insurance coverage for that service.

Figure 1. Percentage of Drug Spending by Source of Payment: Private Insurance, Out-of-Pocket, and All Others, 1965-1998



Source: DHHS 2000, Table 2-30.

We estimate that about one-quarter of the real spending growth for outpatient pharmaceuticals between 1987 and 1996 is attributable to growth in insurance coverage (Danzon and Pauly 2001). Although the United States is still far from having universal coverage, in fact there has been a big increase and that has, not surprisingly, contributed to the growth in spending.

Volume, Mix Upgrade, and Unit Price

In addition to the overall effect of increased prescription drug insurance benefits, three other factors contribute to increases in prescription drug spending:

- **Volume (utilization)**, the average number of prescriptions per capita, has increased.

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- **Mix upgrade**, from older, less expensive drugs to newer, more expensive drugs. Some of these newer drugs replace existing treatments, and some treat diseases that were previously untreatable. Between 1986 and 1999, the number of New Molecular Entities (NMEs) approved by the U.S. Food and Drug Administration increased (FDA 2001). Among these are such drugs as Gleevec (for chronic myeloid leukemia, approved in 2001; for gastrointestinal stromal cancer, 2002), several new AIDS medications, Singulair (for asthma, 1998), Celebrex and Vioxx (arthritis, 1998 and 1999), Xenical (obesity, 1999), and of course Viagra (erectile dysfunction, 1998). Newer drugs tend to have higher prices, and the switch to new drugs raises expenditures. Of course many of these newer drugs offer improvements in long-term health and quality of life, but they also cost more.
- **Price inflation of existing drugs**, which on average contributes the least to spending growth.

Affordability

Turning to the issue of affordability, we hear a lot about the prices of drugs. But for seniors the main issue is not prices but drug coverage. If seniors were able to enroll in managed drug plans, they would benefit from the same discount on prices as those of us who are already in managed drug plans.

You may not be aware of this, but so-called *pharmacy benefit managers* (PBMs) negotiate significant discounts on prices with manufacturers. They also negotiate significant discounts on the pharmacy dispensing fees, all of which significantly reduce the price per script for people with managed drug coverage relative to people without. The anomaly in the United States is that the people without coverage pay relatively high prices and relatively high dispensing fees compared to those with coverage. That comes about simply because of the negotiating power of these pharmacy benefit managers and other managed care institutions that manage the pharmacy benefit. If seniors received this type of

managed benefit, they would benefit from lower prices. This is the way to approach the problem of affordability, as opposed to controlling prices, because pharmacy benefit managers do a good job of negotiating discounts, which makes price controls unnecessary.

But if we expand coverage, then we have to recognize that insurance is a mixed blessing. While insurance gives people financial protection, the flip side is higher usage. In every type of medical service, people with insurance use more. We have to expect that as we expand insurance coverage, there will be more utilization, which will drive up expenditures. That is part of the battle going on in Washington; they recognize that having insurance coverage will drive up drug spending.

Of course, there are ways to control costs once we have insurance coverage. The early generation managed care plans used tightly controlled *formularies*. They negotiated with the drug manufacturers for discounted prices and limited the number of products that were covered to those on the formulary.

With the managed care backlash, there is now reluctance to have closed formularies, so PBMs are switching to greater reliance on *copayments* to control costs. The plans now use triple tier copayments, which require, say, \$5.00 copayment for a generic drug, say \$15.00 for a preferred brand, and maybe \$25.00 or \$30.00 for a nonpreferred brand. In some ways this managed care backlash is unfortunate, because we are moving to a form of insurance coverage that has a lot of copayment, hence more financial exposure for patients, rather than relying on the other controls that managed care once used.

Research and Development in the Pharmaceutical Industry: An International Issue

The single most important factor that distinguishes pharmaceuticals from other industries is the importance of R&D. The pharmaceutical industry spends 15 to 20 percent of their sales on R&D, compared to an industry average of about 4

percent (PhRMA 2001a). The average cost of bringing a new drug to market is now estimated at \$800 million and upwards (DiMasi 2001). The reason the cost is so high is partly the cost of discovery and clinical trials to show that drugs are safe and effective. But it is also the cost of the failures, the so-called dry holes, that has to be averaged in with the cost of the successes. It takes a long time, 6 to 15 years, to take a drug all the way from discovery through clinical trials to market launch.

The good news is that R&D now uses new technologies to develop new drugs. With biochemistry and genomics and rational drug design, new drug targets have enormous promise. But all of this is expensive, so the costs of R&D are projected to increase.

The significant thing about the R&D costs, for purposes of pricing, is that *R&D is a fixed and sunk cost*. In other words, the cost must be incurred before the drug can be marketed, and then there is no incremental cost for every additional patient served. By contrast to the high cost of R&D, the marginal cost of serving additional patients, the cost of producing another pill, is very low. So the industry relies on patents to stop prices from falling because if prices fall to marginal cost, just the cost of production, nobody is paying for R&D and manufacturers would have no incentive or ability to invest in R&D for the future. Thus, intellectual property protection is crucial to the viability of the research-based pharmaceutical industry.

R&D is also a joint cost, which is not just an issue for the United States but is also an enormous international dilemma. R&D, once done, can serve consumers anywhere in the world. So the question is, who will pay? There is no way of attributing R&D to the Italians or the U.S. or the U.K. For each country, there is a great incentive to free ride, to wait for somebody else to pay, and that is indeed what some countries with very tough price regulation do. They pay relatively low prices and contribute very little to R&D. But if everybody pays only marginal costs, then no one pays for the joint costs, and there will be no R&D.

The economic question is, what is the best way of organizing the payment for this joint cost of R&D? When you have a joint cost such as pharmaceutical R&D, or electric utility capacity, the most efficient pricing—the form of pricing that gives the highest overall social welfare—is *differential pricing*. Everybody does not pay the same price; prices differ across different patient groups, depending on their price sensitivity, or price elasticity of demand. Elasticity is measured by answering the question, how much would you cut back if you faced a higher price? The principle of differential pricing is that price sensitive consumers or countries should pay lower prices, and less price sensitive consumers should pay higher prices (Danzon 2001).

Price Sensitivity

It's very difficult to measure price sensitivity, but in general it is highly correlated with income. Thus, one practical implication of this principle is that it is appropriate for higher income countries to pay higher prices for drugs, and for lower income countries to pay less.

Differential pricing does not imply cost-shifting. As I wrote in 1999:

Simple economic theory shows that if a firm serves two separate customer groups, say A and B, that differ in their price sensitivity, the firm would maximize its overall net revenue by charging different prices in the two markets. It would charge a higher price in the market that is less price-sensitive, say market A, other things being equal. If demand in market B now becomes more price-sensitive, the firm will lower its price in that market. But the price to the less price-sensitive market A is unaffected—indeed, to raise price to group A would actually reduce net revenue, since by assumption it had already set the price to maximize net revenue in that market. By analogy, increased price-sensitivity in the managed care market has led suppliers to offer discounts in

that market, but this does not affect prices to other customers. (p. 23)

A few years ago I reviewed studies that compared prices for pharmaceuticals in the United States and other countries (Danzon 1999). The most recent studies claimed that the United States had prices 70 percent higher than Canada, or 102 percent higher than Mexico. But these widely cited price comparisons use small, unrepresentative samples—typically, 10 top branded products—and faulty methods that lead to biased conclusions. These studies overstate U.S. prices because they do not include rebates given to managed care and government purchasers. Furthermore, more than 42 percent of drug purchases in the United States are generics, yet these are omitted from most price comparisons.

We are undertaking a study at Wharton to look at a large sample of products, including the generics and the branded products. We have included all the different presentations and packs, calculated appropriate measures of price indices to compare prices, and looked at both manufacturer-level prices and the prices to final consumers. Unfortunately, we do not measure the discounts; they are confidential. It is too early to give the detailed results of that study, but I can give you some general findings. The first conclusion from our analysis is that there is no single right measure: we cannot accurately say that Canada is X percent cheaper than the U.S. But the general conclusion is that the previous studies have overestimated the average differences. The U.S., on average, has higher prices for new originator products, but the U.S. has the lowest generic prices in our sample of nine countries. The U.S. also has the lowest over-the-counter drug prices. So when you average it all in, the differences are smaller. Another finding is that countries with regulation have much less competition and do not have large generic shares or low generic prices. Regulation undermines competition. Interestingly, when we compare Canada not just to the U.S. but to other European countries, we find Canada has among the lowest prices. This reflects in part the decline in the Canadian dollar over the last decade.

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Our final interesting finding was that although the U.S. does have higher prices somewhat on average than other countries, our differential for drugs is less than the differential on prices of other medical services such as hospital care and physician services. So the U.S. has higher prices for all types of medical care, not just drugs.

Unfortunately, current policies are undermining the price differences that exist. The European Union permits *parallel trade*, in other words, wholesalers can import products from countries that charge lower prices to countries that charge higher prices for the same products. We in the United States are talking about permitting reimportation, in other words, permitting wholesalers to import products from countries with lower prices. Further, governments increasingly are regulating their domestic prices based on prices in other countries. This means that the low prices in lower income countries are now spilling over to higher income countries, which has the unfortunate effect of eliminating the low prices for low-income countries. Manufacturers are rationally becoming much less willing to give low prices in low-income countries.

This issue received broad coverage in the context of AIDS drugs in Africa, where the prices seem way out of line with the very low income levels there. The affluent countries look at the prices in these other countries and say “We want those low prices.” When that happens, manufacturers are unwilling to give anyone low prices. My conclusion is that uniform pricing is not efficient or equitable, and it leads to the severe problem of unaffordably high prices in lower income countries.

This still leaves a question and a concern for the vulnerable populations who are low-income in this country. They also can not pay high prices in this country. We therefore have to be a lot more serious about finding a drug coverage program that really allows those people access. If we could get seniors into managed pharmacy coverage, they would benefit from the discounts that those with drug coverage already have, and they would not be facing prices as high as they currently do.

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Furthermore, we should not address the problem of higher prices in this country by trying to import lower prices from abroad, which would very adversely affect lower income countries. We may well, because of the political process, find a way to pay lower prices in the United States, but if we do we will get less R&D and fewer new drugs.

Policy Recommendations

The examples that Steve has showed us tend to be from vulnerable populations who, if faced with copayments, will cut back on their use of drugs. For the more affluent populations, we know from studies of other types of medical care that as much as 30 percent of the procedures done are inappropriate and not necessary. It suggests that insurance, which makes consumers/patients insensitive to cost, leads to overutilization and unnecessary use. The challenge in designing a drug benefit is providing enough coverage to benefit people who are really vulnerable, without encouraging overutilization or excessive switching to expensive, unnecessary drugs.

There is no perfect solution. We agree that using copayments is inappropriate for the low-income and needy. However, it is a very appropriate way of giving choice to higher income people while constraining the overuse that results from moral hazard. Copayments should be targeted at upper income people who can afford them, while lower income people should be protected.

We also agree that the coverage proposals proliferating in Washington, which would give seniors 50 percent copay up to about \$4,000 or \$5,000 worth of coverage, provide a very poorly designed drug benefit. A better drug benefit would give full coverage to lower income people, have significant cost sharing for higher income people, and catastrophic coverage. That is Insurance 101: insurance is supposed to protect people from expensive unpredictable events, not cover routine costs you can afford.

You may ask yourself, is it just that people in Washington do not understand these obvious principles of insurance? The unfortunate reality is that the reason they design these plans to be 50 percent copay is that if instead a plan has a big deductible with no coverage until, say, \$500 is spent, then the great majority of seniors would not see any benefit from their coverage. Therefore they would choose not to buy the plan.

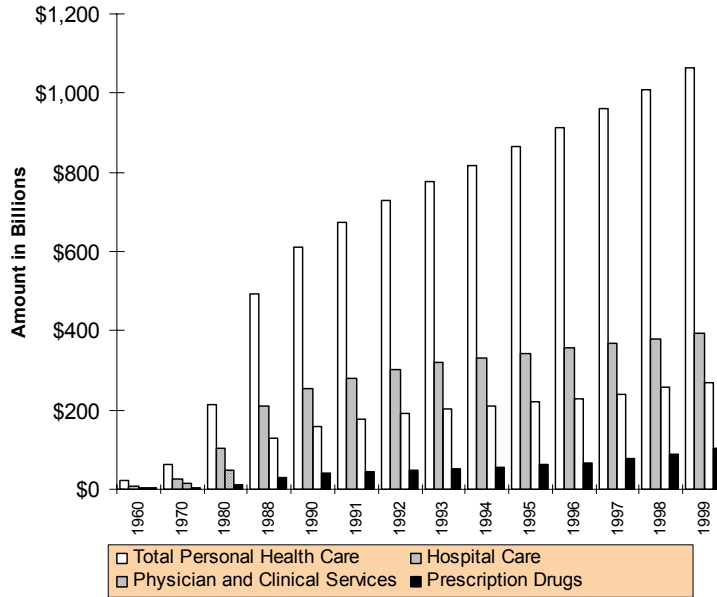
Everybody seems to agree that the coverage should be voluntary, not mandatory, because of the 1988 Medicare Catastrophic Coverage Act fiasco, which was a mandatory drug benefit. Many seniors opposed that vehemently because they did not want mandatory coverage in that form. Now, all the plans offer voluntary coverage. But if coverage is voluntary, then it is necessary to design the benefit so that the lower risk people will choose to buy the coverage. Otherwise only the sickest people will join the plan, which makes it costly and perhaps unstable. Politically it is not appealing if your political opponent can say “Your plan will only cover 50 percent of the people.”

The fact that the plan only pays benefits to 50 percent of the people is not a design defect, because most people will not have drug expenses high enough to reach the limit of the deductible, which triggers benefit payment.

Unfortunately, political constraints are leading us toward a very poorly designed drug benefit. The worst case scenario could be that we have a poorly designed benefit, which is very comprehensive for some people, and then we add price controls because the cost escalates beyond budgeted levels. That would be a very unfortunate resolution of the drug coverage debate. But political forces, as opposed to ignorance of insurance principles, are driving us in that direction.

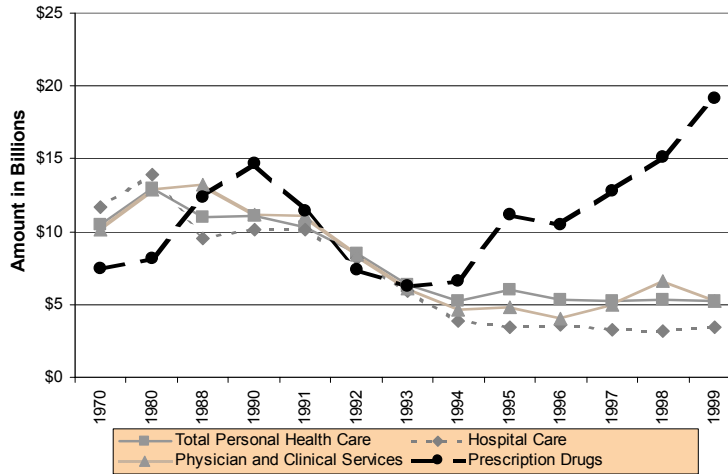
Appendix Tables and Figures

Appendix Figure 1. Personal Health Care Expenditures, Aggregate Amounts, by Type of Expenditure



Source: HCFA 2000, Table 2.

Appendix Figure 2. Personal Health Care Expenditures, Average Annual Percentage Change, by Type of Expenditure



Source: Authors' calculations, using HCFA 2000, Table 2.

Appendix Table 1. Illustration of Out-of-pocket Costs under Different Coverage Sources for a Beneficiary with Total Spending of \$2,000

Source of drug coverage	Deductible	Copay	Over cap	Total out-of-pocket	Percent paid out-of-pocket
HMO (\$7.50 copay, \$1,500 cap) ¹	--	\$412	\$88	\$500	25%
Medigap H/I/J (\$250 deductible, \$1,250 or \$3,000 cap, 50% coinsurance) ²	\$250	\$875	--	\$1,125	56%
Employer (\$7.50 copay) ¹	--	\$412	--	\$412	21%
Medicaid (\$2 copay) ¹	--	\$110	--	\$110	6%
Medicare FFS only	--	--	--	\$2,000	100%

Notes:

¹For non-Medigap plans, typical cost sharing rules are assumed; there are plans with higher and lower cost sharing. The \$2,000 spending was divided by the average cost of prescriptions for Medicare beneficiaries with drug coverage (\$36.37) to generate the number of prescriptions (55) used for the examples in this table. The cap on HMO payments applies to spending by the plan.

² For Medigap plans, out-of-pocket spending in this table is calculated directly from the dollar amount of spending (\$2,000). After the beneficiary has met the \$250 deductible, Plans H and I will cover 50% of \$2500 in total spending, for a total plan payment of \$1250. Plan J will pay a total of \$3000.

This table does not attempt to account for premiums paid or the different purchasing power that \$2000 might have under different discount arrangements negotiated by HMOs, employers, and Medicaid.

Source: DHHS, Report to the President: Prescription Drug Coverage, Spending, Utilization, and Prices, April 2000, Table 2-23.

Bibliography

- Adams, Alyce S., Stephen B. Soumerai, and Dennis Ross-Degnan. 2001. "Use of Antihypertensive Drugs by Medicare Enrollees: Does Type of Drug Coverage Matter?" *Health Affairs* 20(1) (January/February): 276-286.
- Berndt, Ernst R. 2001. "The U.S. Pharmaceutical Industry: Why Major Growth in Times of Cost Containment?" *Health Affairs* 20(2):100-114.
- Briesacher, Becky, and Bruce Stuart. 2002. "Drug Coverage for Medicare Beneficiaries: Why Protection May Be in Jeopardy." Issue Brief 505. New York: The Commonwealth Fund. January. http://www.cmwf.org/programs/medfutur/briesacher_medicaredrug_ib_505.pdf.
- Corea, John, and Lisa Alexih. 1998. *Current Knowledge of Third Party Outpatient Drug Coverage for Medicare Beneficiaries*. Falls Church, VA: The Lewin Group. November 6.
- Danzon, Patricia M. 2001. "More Equitable Pricing for Essential Drugs: What Do We Mean and What Are the Issues?" Background paper for the WHO-WTO Secretariat Workshop on Differential Pricing and Financing of Essential Drugs, April 8-11. 2001, Høsbjør, Norway, March 30. http://www.wto.org/english/tratop_e/trips_e/who_background_e.pdf.
- Danzon, Patricia M. 1999. "Price Comparisons for Pharmaceuticals: A Review of U.S. and Cross-National Studies." The Wharton School, Knowledge@Wharton. Philadelphia: University of Pennsylvania. <http://knowledge.wharton.upenn.edu/PDFs/154.pdf>.
- Danzon, Patricia M., and Mark V. Pauly. 2001. "Insurance and New Technology: From Hospital to Drugstore." *Health Affairs* 20(5): 86-100.
- DiMasi, Joseph A. 2001. "New Drug Development Study (press packet)." Boston: Tufts Center for the Study of Drug

- Development. November 30. <http://www.tufts.edu/med/csdd/Nov30CostStudyPressRelease.html>.
- Dubois, Robert W., Anita J. Chawla, Cheryl A. Neslusan, Mark W. Smith, and Sally Wade. 2000. "Explaining Drug Spending Trends: Does Perception Match Reality?" *Health Affairs* 19(2) (March-April): 231-239.
- Ernst & Young. 2001. "Pharmaceutical Industry R&D Costs: Key Findings about the Public Citizen Report." Ernst & Young LLP. August 8. <http://www.phrma.org/press/newsreleases/2001-08-11.277.pdf>.
- Fortess, E.E., S.B. Soumerai, T.J. McLaughlin, and D. Ross-Degnan. 2001. "Utilization of Essential Medications by Vulnerable Older People after a Drug Benefit Cap: Importance of Mental Disorders, Chronic Pain, and Practice Setting." *Journal of the American Geriatrics Society* 49(6): 793-797.
- Harvard School of Public Health. "Cost-Utility Analysis Database." Produced by the Harvard Center for Risk Analysis, a single electronic compilation of original cost-utility analyses gleaned from MEDLINE, HealthSTAR, CancerLit, Current Contents, and EconLit. It can be used to compare the cost-effectiveness of a broad range of interventions using standardizing cost-utility ratios, and to investigate variations in the methods used in their estimation. <http://www.hsph.harvard.edu/organizations/hcra/cuadatabase/intro.html>, accessed January 2002.
- Health Care Financing Administration. 2001. *2001 Guide To Health Insurance For People With Medicare: Choosing a Medigap Policy to Supplement the Original Medicare Plan*. Washington, DC: Government Printing Office. <http://www.medicare.gov/Publications/Pubs/pdf/guide.pdf>
- Health Care Financing Administration. 2000. "National Health Care Expenditures." <http://www.hcfa.gov/stats/nhe-oact/>.
- Kaiser Family Foundation and Sonderegger Research Center, University of Wisconsin-Madison. 2000. *Prescription Drug Trends: A Chartbook*. Washington, DC: Kaiser Family Foundation. <http://www.kff.org/content/2000/3019>.

Lourie Lecture Policy Brief

- Kleinke, J. D. 2001. "The Price of Progress: Prescription Drugs in the Health Care Market." *Health Affairs* 20(5) (September-October): 43-60.
- Kleinke, J. D. 2000. "Just What the HMO Ordered: The Paradox of Increasing Drug Costs." *Health Affairs* 19(2) (March-April): 78-91.
- Lichtenberg, Frank R. 2001. "Are the Benefits of Newer Drugs Worth Their Cost? Evidence from the 1996 MEPS." *Health Affairs* 20(5) (September-October): 241-251.
- National Pharmaceutical Council. 2000. "Pharmaceutical Benefits under State Medicaid Programs." Reston, VA: NPC. <http://www.npcnow.org/productlist/PDF/assistpro/benefit2000.zip>; <http://www.npcnow.org/productlist/PDF/assistpro/Introduction.pdf>.
- Neumann, Peter J., Eileen A. Sandberg, Chaim M. Bell, Patricia W. Stone, and Richard H. Chapman. 2000. "Are Pharmaceuticals Cost-Effective? A Review of the Evidence." *Health Affairs* 19(2) (March-April): 92-109.
- Patented Medicine Prices Review Board. 2001. "Annual Report 2000." Ottawa, Canada: PMPRB. May. http://www.pmprb-cepmb.gc.ca/english/06_e/06ann00_e.htm. The PMPRB is an independent quasi-judicial body, created in 1987 under the Patent Act to protect consumer interests in light of increased patent protection for pharmaceuticals. The annual report compares prices in Canada and the United States.
- Pear, Robert, and Melody Petersen. 2002. "Pfizer to Offer Drug Discount to Low-Income Elderly." *New York Times*. January 16, p. F1.
- Pharmaceutical Research and Manufacturers of America. 2001a. "Research and Development: The Key to Innovation." *Pharmaceutical Industry Profile 2001*. Washington, DC: PhRMA, Chapter 2. <http://www.phrma.org/publications/publications/profile01/chapter2.phtm>.
- Pharmaceutical Research and Manufacturers of America. 2001b. *The Value of Medicines 2001*. Washington, DC: PhRMA. <http://www.phrma.org/publications/publications/value2001/value2001.pdf>.

- Rector, Thomas S. 2000. "Exhaustion of Drug Benefits and Disenrollment of Medicare Beneficiaries from Managed Care Organizations." *Journal of the American Medical Association* 283(16) (April 26): 2163-2167. <http://jama.ama-assn.org/issues/v283n16/rpdf/jpp00001.pdf>.
- Soumerai, Stephen B., Alyce S. Adams, and Dennis Ross-Degnan. 2001. "Medicare Prescription Coverage and Congressional Gridlock: Time for Compromise." *Journal of General Internal Medicine* 16 (December): 864-866.
- Soumerai, S.B., T.J. McLaughlin, D. Ross-Degnan, C.S. Casteris, and P. Bollini. 1994. "Effects of a Limit on Medicaid Drug-Reimbursement Benefits on the Use of Psychotropic Agents and Acute Mental Health Services by Patients with Schizophrenia." *New England Journal of Medicine* 331(10) (September 8): 650-655.
- Soumerai, S.B., D. Ross-Degnan, J. Avorn, T.J. McLaughlin, and I. Choodnofskiy. 1991. "Effects of Medicaid Drug-Payment Limits on Admission to Hospitals and Nursing Homes." *New England Journal of Medicine* 325(15) (October 10): 1072-1077.
- Soumerai, Stephen B., Jerry Avorn, Dennis Ross-Degnan, and Steven Gortmaker. 1987. "Payment Restrictions for Prescription Drugs under Medicaid: Effects on Therapy, Cost, and Equity." *New England Journal of Medicine* 317(9) (August 27): 550-556.
- Stuart, Bruce, Dennis Shea, and Becky Briesacher. 2001. "Dynamics in Drug Coverage of Medicare Beneficiaries: Finders, Losers, Switchers." *Health Affairs* 20(2): 86-99.
- Tamblyn, Robyn, Rejean Laprise, James A. Hanley, Michael Abrahamowicz, Susan Scott, Nancy Mayo, Jerry Hurley, Roland Grad, Eric Latimer, Robert Perreault, Peter McLeod, Allen Huang, Pierre Larochelle, and Louise Mallet. 2001. "Adverse Events Associated with Prescription Drug Cost-Sharing among Poor and Elderly Persons." *Journal of the American Medical Society* 285(4) (January 24-31): 421-429.

Lourie Lecture Policy Brief

- U. S. Census Bureau. 2001. "Health Insurance Data."
<http://www.census.gov/hhes/www/hlthins.html>, accessed
February 2002.
- U.S. Congress, Office of Technology Assessment. 1993.
Pharmaceutical R&D: Costs, Risks and Rewards. OTA-H-
522, GPO stock #052-003-01315-1, NTIS order #PB93-
163376. 0-16 -041658-2. Washington, DC: Government
Printing Office. February. [http://www.wws.princeton.edu/
~ota/disk1/1993/9336_n.html](http://www.wws.princeton.edu/~ota/disk1/1993/9336_n.html).
- U. S. Department of Health and Human Services. 2000. "Report to
the President. Prescription Drug Coverage, Spending,
Utilization, and Prices." Washington, DC: Government
Printing Office. April. [http://aspe.hhs.gov/health/reports/
drugstudy/](http://aspe.hhs.gov/health/reports/drugstudy/), accessed February 2002.
- U. S. Food and Drug Administration. 2001. "Approval Times for
Priority and Standard NMEs, Calendar Years 1993-2001."
Created by FDA/Center for Drug Evaluation and Research.
Last updated January 24, 2002. [http://www.fda.gov/cder/
rdmt/NMEapps93-01.htm](http://www.fda.gov/cder/rdmt/NMEapps93-01.htm) (1993-2001) only.
[http://www.fda.gov/cder/rdmt/
CY00NDAAP.HTM](http://www.fda.gov/cder/rdmt/CY00NDAAP.HTM)
(accessed 11/5/2001; subsequently pulled from web.).
- Venis, Sarah. 2002. "Huge Increase in Patients Eligible for Lipid-
Lowering Drugs." *The Lancet* 359(9302) (January 19): 233.
[http://www.thelancet.com/journal/vol/iss/full/
llan.359.9302.news.19145.3](http://www.thelancet.com/journal/vol/iss/full/llan.359.9302.news.19145.3), accessed February 2002.