

HEALTH INSURANCE AND THE GROWTH IN PHARMACEUTICAL EXPENDITURES*

PATRICIA M. DANZON and MARK V. PAULY
University of Pennsylvania

ABSTRACT

This paper examines the contribution of insurance coverage to the recent unprecedented growth in spending on pharmaceuticals. Trends in drug spending over time closely paralleled the growth in drug coverage. Most of the coverage growth reflects an increase in the number of people with coverage, 65 percent from 1987 to 1996, rather than increased depth of coverage. The direct moral hazard effect of this insurance growth accounts for between one-fourth and one-half of the increase in drug spending. Technological change contributed to these changes, because both the flow of new drugs increased the demand for insurance and information technologies enabled the development of pharmacy benefit management, which reduced the real price of drug coverage. It is plausible that insurance growth also stimulated drug promotion. The only obvious source of inefficiency is the tax subsidy, which may lead to excessive insurance and promotion. This applies to all health care, not just pharmaceuticals.

I. INTRODUCTION

THE rapid growth of spending on pharmaceuticals in recent years has captured the attention of managers, policy makers, consumers, and analysts. Spending on outpatient drugs grew at a rate of 17 percent in 1999, compared with 8.2 percent in 1990 and 1.1 percent in 1980, whereas total health spending grew at a rate of 3.3 percent in 1999, 6.4 percent in 1990, and 5.6 percent in 1980. Consequently, the share of total health spending accounted for by outpatient drugs increased from 4.9 percent in 1980 to 8.5 percent in 1999. Drug spending is also blamed for a resumption of increases in health insurance premiums, from .8 percent in 1996 to 8.3 percent in 2000.¹ Previous analyses of these trends have provided an accounting decomposition of the growth in drug spending and have distinguished increases in volume of prescriptions (scripts), shifts to more expensive products, and price increases for existing products. In the 1990s, the dominant contributors to spending growth are

* The authors thank Edward Buckley for research assistance.

¹ Bradley C. Strunk, Paul B. Ginsburg, & Jon R. Gabel, Tracking Health Care Costs: Growth Accelerates Again in 2001, Health Aff. Web Exclusive (September 2002) (<http://www.healthaffairs.org/WebExclusives/2106Strunk.pdf>).

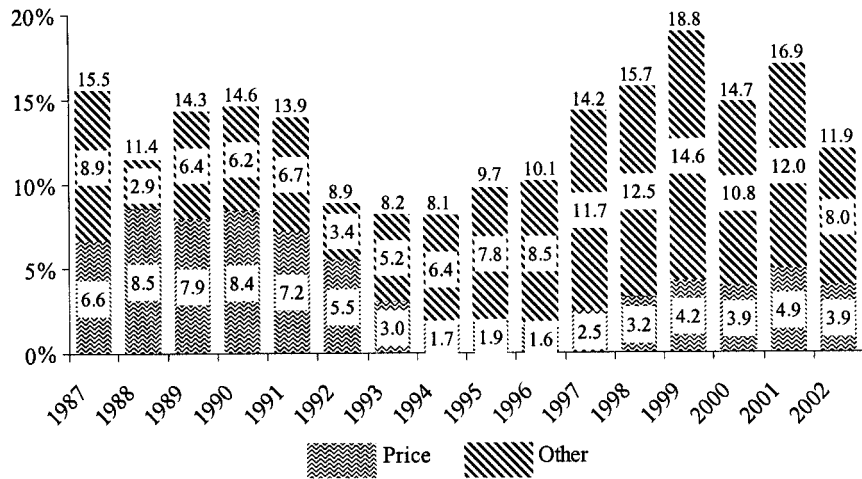


FIGURE 1.—Growth in spending due to price versus volume and innovation (other). Year over year percentage changes are shown. Data are from IMS Health, Retail and Provider Perspective (February 2003).

more prescriptions and shifting to more expensive products, which together account for 75 percent of total drug-spending growth in the 1994–99 time period, with price increases accounting for only 25 percent of the total (see Figure 1).

The purpose of this paper is to analyze the causes of the unprecedented rise in outpatient drug use in the 1990s and, in particular, to examine the role of growth in insurance coverage, which paralleled the acceleration of drug spending. The share of outpatient drug expenditures paid out-of-pocket declined from 69.4 percent in 1980 to 59.1 percent in 1990, with a more rapid decline to 33.4 percent in 1999. Standard theories of insurance and moral hazard suggest that this increase in drug coverage would trigger some growth in utilization. Ernst Berndt identifies the growth in insurance as one of four contributors to drug-spending growth, along with new products, the relaxing of the rules governing direct-to-consumer (DTC) advertising in 1997, and “the importance of being unimportant,” a spending share too small to attract the interest of cost controllers and one that has already self-corrected.² Robert DuBois et al. discuss the role of new products. Neither of these prior studies quantify the direct effect of insurance growth, nor do they discuss the connection between insurance and these other contributing factors.³

² Ernst R. Berndt, *The U.S. Pharmaceutical Industry: Why Major Growth in Times of Cost Containment?* 20 *Health Aff.* 100 (March/April 2001).

³ Robert W. DuBois et al., *Explaining Drug Spending Trends: Does Perception Match Reality?* 19 *Health Aff.* 231 (March/April 2000).

In this paper, we analyze both the direct effect of insurance on drug use (the moral hazard effect) and several indirect channels whereby growth of insurance can contribute to growth in drug spending. Specifically, we first decompose the growth in overall insurance coverage to provide evidence on how much of the decline in the percent paid out-of-pocket reflected an increase in the number of people covered and how much reflected an increase in the depth of coverage (fraction of spending covered) for those with insurance. Second, we use empirically based demand elasticity measures to estimate how much of the spending growth might reasonably be attributed to the direct or moral hazard effect of these insurance changes. We conclude that these direct effects alone may account for one-fourth to one-half of the growth in drug spending. Third, we discuss more qualitatively the possible indirect effects of insurance, through incentives for research and development (R&D) and hence the flow of new products, through incentives for DTC and other forms of drug promotion, and through prices.

We also take the inquiry one step further back, to examine reasons for the unprecedented growth in drug insurance during the 1990s. Several previous authors (for example, Burton Weisbrod) have hypothesized that an increase in insurance coverage can lead to a higher rate of technological change and hence to a higher rate of change in spending and that there may be some feedback effect from spending on demand for insurance.⁴ In the case of drugs, we argue that the reverse effect is more likely, that technological change, in the form of new drug therapies and new insurance technologies, contributed to the growth in level and type of drug coverage, which in turn played a major role in drug-spending growth. In conclusion, we offer some comments on whether these trends are likely to continue and some preliminary normative analysis of whether the increases in coverage and in drug spending is efficient.

II. TRENDS IN DRUG EXPENDITURES AND COVERAGE

Table 1 documents the time trends in expenditures and insurance coverage for drugs relative to other medical services in the United States for the period 1960–98. Over this long time frame, spending growth shifted from the inpatient sector to the outpatient sector. For the first 2 decades, drug spending grew less rapidly than hospital spending. Consequently, the drug share of total spending declined from 10 percent in 1960 to about 5 percent in 1985. In the last half of the 1980s, hospital spending growth declined relative to both drug spending and physician spending. Since 1990, drug spending has outpaced all the other major spending components. In real terms, drug-spending growth, although higher than the growth of real gross domestic

⁴ Burton A. Weisbrod, *The Health Care Quadrilemma: An Essay on Technological Change, Insurance, Quality of Care, and Cost Containment*, 29 *J. Econ. Literature* 523 (1991).

TABLE 1
TRENDS IN EXPENDITURES AND INSURANCE COVERAGE, 1960–99: PHARMACEUTICALS AND OTHER MEDICAL SERVICES

	1960	1970	1980	1990	1995	1996	1997	1998	1999
Expenditure share categories (%):									
Hospital care	34.4	37.8	41.3	36.5	34.7	34.2	33.7	33.0	32.3
Physician services	20.1	19.1	19.2	22.6	22.3	22.1	22.1	22.3	22.2
Prescription drugs	10.0	7.5	4.9	5.8	6.1	6.5	6.9	7.6	8.5
All other	35.5	35.5	34.6	35.1	36.9	37.3	37.3	37.1	37.0
Growth rates:									
Prescription drugs:									
Real annual expenditure growth ^a	N.A.	4.6	1.1	8.2	6.0	8.4	11.2	13.6	17.0
% paid out of pocket	96	82.4	69.4	59.1	42.7	39.5	36.8	34.9	33.4
Average annual change in % paid out of pocket	N.A.	-1.4	-1.3	-1.0	-3.2	-2.7	-2.7	-1.9	-1.5
Average annual % change in proportion paid out of pocket	N.A.	-1.4	-1.8	-1.5	-6.2	-6.6	-7.0	-5.3	-4.3
Total personal health spending:									
Real annual growth ^a	N.A.	7.3	5.6	6.4	4.8	3.4	3.7	3.9	3.3
% paid out of pocket	55.2	39.7	27.1	22.5	16.9	16.7	16.9	17.3	17.4
Average annual % change in proportion paid out of pocket	N.A.	-2.8	-3.2	-1.7	-5.0	-1.2	1.2	2.4	.5

SOURCE.—Health Care Financing Administration, Historical National Health Expenditures by Type of Service and Source of Funds: Calendar Years 1960–2000 (September 17, 2002) (<http://cms.hhs.gov/statistics/nhe/default.asp>).

NOTE.—These figures differ from those in table 2 in Patricia M. Danzon & Mark V. Pauly, Insurance and New Technology: From Hospital to Drug Store, 20 (5) Health Aff. 86 (2001), because they reflect substantial revisions in government estimates of health expenditures and, especially, prescription drug coverage.

^a Deflated by GNP implicit price deflator; continuous growth rates.

product (GDP), decelerated until about 1980, then began to pick up and grew at double-digit rates from 1997 onward.⁵ These trends no doubt reflect many causes, including technological change, that enabled the shift of care from inpatient to outpatient settings. However, the bottom seven rows of Table 1 suggest that trends in insurance coverage may have played a role.

Trends in insurance coverage for outpatient drugs move in close parallel to these trends in drug expenditures, growing slowly initially and then accelerating in the 1990s. The center four rows of Table 1 show that for each decade from 1960 to 1990, the proportion of aggregate drug expenditures paid out-of-pocket fell about 12 percentage points per decade, from 96 percent in 1960 to about 59 percent in 1990, then dropping to about 33 percent in 1999. But measured as an annual percentage change in the out-of-pocket share, which takes into account the decline in the base coverage level over time, the rate of growth of coverage has accelerated from less than 2 percent per year through the 1960s, 1970s, and 1980s to 6–7 percent per year in the mid-1990s. Thus, the acceleration of drug spending in the 1990s coincides with a dramatic acceleration in the rate of growth of drug coverage. By contrast, the percent paid out-of-pocket for other personal health spending leveled off and then slightly increased in the late 1990s (Table 1).

This overall pattern for the last 40 years of positive correlation between trends in growth in drug insurance coverage and (slightly lagged) drug-spending growth is consistent with the hypothesis that changes in spending are positively related to changes in insurance coverage. But correlation, of course, does not establish causation in any event.

With regard to the components of the drug-spending growth, as indicated in Figure 1, on the basis of IMS Health data, the increase in drug spending in the 1990s was associated primarily with increases in the volume of prescriptions or units per capita and shifts toward more expensive products, which together comprise about 80 percent of the growth in drug spending over this period. Only about 20 percent (or less, depending on the year) is attributable to rising prices for existing products;⁶ of this, over half is due to economy-wide inflation, leaving a very small share attributable to excess

⁵ The measures of drug expenditures reported in the National Health Accounts (NHA) do not include drugs purchased during a hospital stay, physician or clinic visit, or some nursing home stays, because these expenditures are classified as revenues of the institution that received payment. The NHA drug-spending estimates are also reduced to reflect rebates from drug manufacturers to insurers. For these and other reasons, total drug spending as reported in the NHA may differ from the drug-spending total reported by IMS Health.

⁶ The contribution of price increase may depend on the type of index used—base-weighted Laspeyres or chained Divisia. The source is unclear on this point. IMS Health, Retail and Provider Perspective (February 2003) (<http://www.imshealth.com>).

inflation of drug prices.⁷ This predominant role for volume growth and mix upgrade are consistent with insurance being an important inducement to spending growth because of the moral hazard effects of coverage on volume. Although some forms of insurance could also induce price growth, the managed care form that predominated has plausibly controlled price growth relative to what it might have been under indemnity insurance, but the structure of managed drug benefits may have contributed to mix upgrade, as discussed below.

Cross-national comparisons provide a rough way of distinguishing the role of new technologies relative to other contributors to health-spending growth. Specifically, if new technologies diffuse to the same degree in countries at similar levels of income and industrialization, then cross-national differences in spending growth among these countries might provide a very rough indicator of the role of country-specific differences in insurance coverage growth. The recent trends in drug spending are not unique to the United States; several other industrialized countries (for example, the United Kingdom, Canada, and Germany) have also experienced more rapid growth of spending on drugs than on physician and hospital services. However, in countries such as Germany or the United Kingdom that already had universal drug coverage by the early 1990s, the differential between expenditure growth on drugs and other services is less than in the United States, where there was significant expansion of coverage over this period. Moreover, in Germany, prices and volume of scripts have remained flat or have fallen since 1993, with all the spending growth coming from a shift to more expensive, including new, products. Thus, the more rapid growth of drug spending in the United States compared with other countries and the large role of volume growth in the United States are consistent with the hypothesis that growth in insurance coverage has played a significant role.

III. MORE PEOPLE WITH COVERAGE, MORE COVERAGE PER PERSON?

The evidence above suggests that rising insurance coverage has something to do with the relatively rapid increase in pharmaceutical spending in the United States. Evidence from both the United States and other countries suggests that new products have played a major role in drug-spending growth. Ideally, we would like to quantify the individual contributions of insurance and new products to the expenditure growth. This decomposition is problematic, even conceptually, because insurance is expected to have both direct

⁷ Prices of existing products actually declined in real terms in 1994 and 1995, when coverage was expanding most rapidly. Although this could partly reflect the market power of the new pharmacy benefit managers (PBMs), their market share increased over time, whereas price increases trended upward. The 1994–95 drop in drug prices could also reflect the anticipation that managed care buyers would be more powerful than they in fact turned out to be, as well as the political climate associated with the Clinton health care debate.

and indirect effects on the uptake of new products, including increased volume of scripts per capita and shift of mix from old to new products, which in turn affects price per unit and per script. Moreover, reverse effects are likely; that is, the expansion of range and expected cost of drug treatments increases the demand for insurance coverage, as discussed below.

Before turning to estimates of the direct effect of insurance on drug-spending growth, in this section we provide some evidence on the decomposition of insurance growth into number of people with coverage and depth of coverage per person. The next section provides rough estimates of the potential direct effect of this insurance growth on spending growth. Subsequent sections then discuss the indirect effects of insurance, including the stimulus of insurance to R&D and hence number of new products and the reverse effect of new products on demand for drug coverage; advertising; price levels for new products; and price change for old products.

How was the increase in the overall percentage of drug expenditures paid by insurance—from about 40 percent in 1990 to over 75 percent in 1999—distributed between growth in the number of people with coverage and increase in the depth of coverage for those with coverage? Broad trends in health insurance coverage suggest a mix of both effects. In the 1980s and 1990s managed care insurance in its various forms (health maintenance organizations (HMOs), preferred provider organizations, and others) largely replaced traditional indemnity insurance for general health insurance. Traditional indemnity insurance covered hospital and physician services but typically did not cover outpatient prescription drugs. Thus, the Medicare program for seniors, which was modeled on the typical private indemnity insurance plan of the mid-1960s, does not cover outpatient prescription drugs. Indemnity insurers relied on patient copayments to control moral hazard but were otherwise largely passive payers for whatever covered expenses patients incurred. The defining feature of managed care plans was the use of incentives and controls targeted at providers to control moral hazard, in particular, selective contracting, negotiated discounts, and risk-sharing forms of reimbursement for providers (such as capitation) and prior authorization and utilization review to determine *ex ante* whether expensive procedures would be covered. These managed care techniques were applied to outpatient drugs, often by specialized pharmacy benefit managers (PBMs). Managed drug benefits were included in most managed care plans, and many indemnity plans subsequently added a managed drug benefit, usually contracted out to PBMs, especially for employee coverage. Drug coverage also became more available to some seniors through employer-based retiree benefits and the managed plan options offered under the Medicare+Choice alternative to traditional Medicare.⁸ Given these trends in the types of insurance products

⁸ Possibly offsetting these trends toward more people with drug coverage could be a decline in the percent of retirees with employer-based coverage, as employers supposedly reduced their postretirement health benefits in response to Federal Accounting Standard (FAS) 106.

available, some increase in the number of people with coverage is expected. At the same time, an increase in depth of coverage is also possible, as managed plans relied less on patient copayments and more on other cost control strategies. Through the mid-1990s, managed drug benefits typically had either a single copayment per script or a two-tier copayment per script (\$5 for a generic, \$10 for a brand). This structure is expected to offer somewhat deeper coverage than indemnity plans, which typically included a drug-specific deductible and 20 percent cost sharing above the deductible if they covered drugs at all.

For several reasons, it is not simple to provide rough quantitative estimates of the changes in number of people with coverage and average depth of coverage. The best available data are from household surveys of insurance coverage, specifically, the 1986–87 National Medical Expenditure Survey (NMES) and the 1996 Medical Expenditure Panel Survey (MEPS). These surveys ask respondents whether they have specific types of health insurance (private, Medicare, Medicaid, and others), but neither these nor other surveys asked respondents whether they had outpatient drug coverage. Indeed, the concept itself is potentially ambiguous since policies could cover some drugs in some circumstances but not in others. For example, would a catastrophic policy that provides full coverage of medical services above a \$10,000 deductible be said to “cover drugs”? Or a policy that explicitly provides coverage for only certain expensive or life-saving drugs? Respondent error is also a potential problem if household respondents do not know or have forgotten what their insurance covers.⁹ Moreover, individuals may be eligible for some forms of third-party payment that they may or may not define as insurance; for example, some states have special drug programs for low-income seniors and other needy groups, and most drug manufacturers have charity programs that provide drugs free or at discounted prices to needy individuals.

In order to avoid these definitional ambiguities, we define people with drug insurance as those who report a self-pay amount less than the total drug expense, conditional on having positive outpatient drug expense. Similarly, we define the insurance payment as this residual difference between the total drug and the self-pay amount. Depth of coverage is the ratio of the insurance payment to total drug expense. By means of the measures that were calculated for the 1987 NMES survey and the 1996 MEPS survey, we calculate the growth in the number of people with coverage and the growth in depth of coverage. These estimates are no doubt subject to imperfect information on the part of survey respondents and recall bias; however, as long as the average errors do not change between the two surveys, our measures of growth should

⁹ Matching expenses reported by the household to plan provisions is not easy. The MEPS survey ran into problems trying to obtain plan documents from employers to verify whether some type of expense might ever be covered by the employee’s insurance plan.

TABLE 2

DRUG SPENDING AND INSURANCE: THE 1987 NATIONAL MEDICAL EXPENDITURE SURVEY (NMES) VERSUS THE 1996 MEDICAL EXPENDITURE PANEL SURVEY (MEPS), EXCLUDING PEOPLE WITH MEDICAID AND OTHER PUBLIC INSURANCE, AGES 25–64

	% with Rx Expense	Expense/Capita (\$)	Benefit/Capita (\$)	Benefit/Expense (%)	% with Insured Rx Expense
With private health insurance:					
1987 NMES	57.8	110.93	50.43	45.46	29.5
1996 MEPS	68.5	264.56	160.82	60.79	57.1
	ALL INSURED, EXPENSE/CAPITA (\$)	INSURED WITH INSURED RX EXPENSE			ALL UNINSURED, EXPENSE/CAPITA (\$)
		Expense/Capita (\$)	Benefit/Capita (\$)	Benefit/Expense (%)	
1987 NMES	110.9	261.35	170.88	65.4	65.33
1996 MEPS	264.6	437.25	282.64	64.6	132.92
		INSURED WITH RX EXPENSE		UNINSURED WITH RX EXPENSE	
	Insured Rx Expense	No Rx Insurance			
Prescriptions per capita:					
1987 NMES	10.23		5.54	8.19	
1996 MEPS	12.6		4.64	10.22	
Expense/prescription:					
1987 NMES	25.55		21.55	19.93	
1996 MEPS	34.7		29.19	29.93	

NOTE.—Rx: prescription.

be unbiased (more on this below). Defining the change in the number of people with drug coverage by the change in the number who report positive drug insurance payment, conditional on drug expense, could yield an upward (downward) biased estimate of the true increase in percent of people with drug coverage if the probability of obtaining a prescription, conditional on having coverage, increased (decreased) between 1987 and 1996.

Tables 2 and 3 show trends between 1987 and 1996 in various indicators of drug use and insurance coverage. Table 2 represents the population aged 25–64, excluding those who report being covered by public insurance programs (Medicaid, Medicare, the Veterans Association, Champus). This is the population potentially likely to buy private insurance. Table 2 shows trends in drug use and coverage for all persons with private health insurance and reports trends in use for subgroups of the population by health insurance and drug insurance status. Table 3 shows trends in drug use and coverage for the over-65 population. Although outpatient drug coverage is not included in traditional Medicare, seniors may obtain drug coverage from one of several sources: Medicaid covers drugs for the lowest-income seniors in all states, and some states have developed additional drug programs for needy seniors

TABLE 3
 DRUG SPENDING AND INSURANCE: THE 1987 NATIONAL MEDICAL EXPENDITURE
 SURVEY (NMES) VERSUS THE 1996 MEDICAL EXPENDITURE
 PANEL SURVEY (MEPS), AGE 65 AND OVER

	% with Rx Expense	Expense/ Capita (\$)	Benefit/ Capita (\$)	Benefit/ Expense (%)	% with Insured Rx Expense
1987 NMES	81	333.43	102.06	30.6	35.7
1996 MEPS	87.8	709.95	313.52	44.2	64.4
With insured Rx expense:					
1987 NMES		530.37	286.25	54.0	
1996 MEPS		909.23	487.02	53.6	
		Insured Rx Expense	No Rx Insurance		
Prescriptions per capita:					
1987 NMES		21.97	14.83		
1996 MEPS		25.37	16.62		
Expense/prescription:					
1987 NMES		24.14	22.13		
1996 MEPS		35.84	32.03		

NOTE.—Rx: prescription.

not eligible for Medicaid; employer retiree policies usually cover drugs if drugs are included in the coverage for active-duty employees; some Medigap policies include drug coverage (these are supplementary policies to traditional Medicare and are subject to strict regulation and severe adverse selection); and most Medicare HMOs offer some drug coverage, although both the number of Medicare HMOs and the level of drug coverage offered have declined since 1997.

For the under-65 group with general health insurance, the proportion with positive drug expense increased from 57.8 in 1987 to 68.5 percent in 1996, a 18.5 percent increase. By contrast, the proportion with drug insurance (measured as those reporting insured drug expense) increased by 93.6 percent, from 29.5 percent to 57.1 percent. Thus, conditional on having positive drug expense, the percent of the health-insured under-65 population who also had drug insurance increased from 51 percent in 1987 to 83.3 percent in 1996, a 63 percent increase.¹⁰ For the over-65 population, the trends are similar. The proportion of seniors with positive drug expense increased slightly, from 81 percent to 87.8 percent, while the percent with insured drug expense increased 80.6 percent. Thus, conditional on positive drug expense, the percent of seniors with insurance coverage increased from 44 percent to 73 percent, which implies a 66 percent increase in the percent with drug coverage, conditional on positive drug expense. Thus, the percentage growth in the number of people with coverage is similar for the under-65 and over-65

¹⁰ $29.5/57.8 = 51$; $57.1/68.5 = 83.3$.

populations, despite the differences in coverage options available to each group.

In contrast to this striking increase in the number of people with coverage, there was essentially no change in depth of coverage (percent of expense covered). For those with health insurance who also had insured drug expense, the percent of their drug expense (Benefit/Expense) that was covered by insurance remained at roughly 65 percent for the under-65 population, while for the over-65 population, the percent of expense covered by insurance was stable at 54 percent.

Overall, there is significant growth in spending per person with insured prescription (Rx) expense, in both the number of Rxs and the cost per Rx in constant 1996 dollars. For the under-65 population with health insurance and drug coverage, the number of scripts per capita increased 23 percent, from 10.2 in 1987 to 12.6 in 1996. By contrast, those who had no drug insurance but had positive Rx expense show a decline in number of scripts per capita, from 5.5 to 4.6. A plausible explanation for this apparent decline in utilization by those with health insurance who did not have drug coverage is that the growth of drug coverage has been subject to biased selection: those with higher expected demand for drugs were more likely to buy drug coverage, and only those least likely to need drug coverage remained without drug insurance by 1996.

By contrast, for those uninsured for general health expenses, those with positive Rx expense had a level and rate of increase in number of scripts per capita, from 8.2 to 10.2, that are only slightly lower than the level and rate of increase for those with drug coverage. This suggests that, to the extent that gaps in drug insurance remain a problem for the under-65 population, severe financial exposure occurs predominantly for those who are also uninsured for other health expenditures, not for those who have health insurance but choose not to buy drug coverage. This conclusion is confirmed by the evidence in Table 4, which shows that the out-of-pocket expense for those in the top quartile of drug expense (\$865) is almost twice as high for those who are uninsured for other medical expenses than it is for those who have general health insurance but lack drug coverage (\$443).

In addition to the modest increase in the number of scripts per capita, the larger factor contributing to growth in spending per person with drug insurance is expense per script, which increased by 36 percent for those with drug insurance. For the uninsured, the absolute increase in expense per script is similar (about \$10) but the percentage increase is greater (50 percent) because the absolute cost per script is lower for the uninsured. This high number of scripts as well as expense per script for both the health- and drug-insured population and the health- and drug-uninsured population with Rx expense suggest that moral hazard is far from the whole story behind the growth in expense per script. Rather, drug therapies have become increasingly valuable

TABLE 4
 MEAN DRUG EXPENSE AND COVERAGE FOR TOP QUARTILE USERS,^a
 CONSTANT 1996 DOLLARS

	NMES 1987 ^b	MEPS 1996
Ages 25–65:		
With health insurance:		
With insured Rx expense:		
Total	756	1,317
Insurance	497	875
% covered	65	66
No insured Rx expense:		
Total	179	151
Insurance	0	0
Rx expense, no Rx insurance:		
Total	352	443
Insurance	0	0
Uninsured:		
With Rx expense:		
Total	500	998
Insurance ^c	100	133
Over 65:		
With insured Rx expense:		
Total	1,271	2,463
Insurance	694	1,366
% covered	55	55
Rx expense, no Rx insurance:		
Total	835	1,543
Insurance	0	0

NOTE.—MEPS: Medical Expenditure Panel Survey; NMES: National Medical Expenditure Survey; Rx: prescription.

^a Mean expense for fourth quartile of distribution of drug expenditures.

^b 1987 dollars adjusted to 1996 using the gross domestic product deflator.

^c Insurance defined as Total – Self-Pay shows some positive amounts for those who report that they are uninsured.

forms of treatment that are demanded by those without insurance as well as by those with insurance.

In real terms, drug expense per capita for people under 65 increased by 128 percent in this 9-year period, from \$107 in 1987 to \$244 in 1996 in constant 1996 dollars (figures not in Table 2). For those with health insurance (with and without drug insurance), the rate of increase is 138 percent, from \$111 in 1987 to \$265 in 1996, whereas for those without health insurance, the increase is 103 percent, from \$65 to \$133. Among those with health insurance, per capita drug spending appears to have grown more slowly for those with drug coverage, although it started at a higher level—a 67 percent increase, from \$261 to \$437. This lower apparent rate of increase in expense per capita for those with drug insurance than for those without probably reflects biased selection in the growth of drug coverage. Specifically, if the sickest people are the first to purchase drug insurance, then as coverage increases over time, the drug-insured population expands to include more

who are intrinsically low risk. This shift in risk profile within the group with health insurance would bias down the estimate of change in average expense per capita for those with insurance. Thus, without risk adjustment, we cannot accurately estimate from these aggregate data the increase in use for those with insurance compared with those without. Mean drug expense per capita remains much lower overall for those without health insurance than for those with health insurance. Since most (83 percent) of those with health insurance also had drug insurance by 1996, if they had drug Rx, this overall differential is consistent with a moral hazard effect from insurance, both from general insurance and drug insurance. This moral hazard effect appears to be due mostly to a lower probability of any positive Rx expense for those without health insurance (this has increased slightly over time, from 40 percent in 1987 to 43 percent in 1996). For the uninsured with Rx expense, the number of scripts and expense per script are only 15–20 percent lower than for the insured who also have drug insurance and Rx expense.¹¹

The finding of no increase in depth of coverage for those with drug coverage and positive expense is somewhat surprising, given the fact that traditional indemnity plans generally had sizeable deductibles plus 20 percent or more copayments, whereas PBM plans generally have no deductible and a modest copayment per script, say \$5 for a generic and \$10 for a brand. It is possible that PBM coverage is more likely to have upper limits or exclusions, but we know of no evidence to support this. It is also possible that there is greater underreporting of the amount paid by insurance in 1996 because of the growth in managed pharmacy benefits, which are card-based plans. In such plans, consumers pay only their copayment and hence may be unaware of the amount reimbursed by the plan to the pharmacy. Since card-based plans were a much larger fraction of total coverage in 1996 than in 1987, if systematic underreporting of covered expense occurs in card-based plans, the resulting underestimate of the amount paid by insurance would be greater in 1996, which would lead us to underestimate the growth in depth of coverage.

To address the question of whether the new forms of coverage provide better catastrophic coverage, we examined coverage and out-of-pocket expense for those in the top quartile of drug expenditures. For individuals under 65 with drug insurance and in the top quartile of the overall distribution of drug expense, the mean percent covered by insurance increased very slightly, from 65 in 1987 to 66 percent in 1996 (see Table 4), which is very similar

¹¹ In an earlier version of this paper, presented at the American Economics Association meetings in January 2001, we reported rather different estimates of the growth in spending attributable to an increase in the number of people with insurance versus expenditure per insured person. Those estimates defined everyone who reported insured expense as “insured,” whereas the present estimates distinguish between people who report having health insurance and the uninsured and then define insured expense as the difference between total and self-paid expense.

to the overall mean level of coverage of 65 percent for those in this age group with insured Rx expense in both periods. Similarly, for the over-65 population, the average coverage rate for those with insured Rx expense was 55 percent in both years, which is very close to the overall mean of 54 percent in both years. Thus, there is little evidence of an increase (or decrease) in catastrophic coverage, which seems to refute the hypothesis that the finding of no increase in depth of coverage or average co-insurance rate is due to more or lower caps on coverage, which could have offset the lower up-front copayments.

Although rough, these numbers do suggest conclusions about the role of insurance coverage in the growth in spending. The largest contributors to spending growth were the increase in the proportion of those with Rx expense who had insurance for this expense, the increase in expense per person with Rx expense (both of which increased by about 66 percent), and the higher average spending for those with insurance than those without. Conditional on positive Rx expense, mean spending per person with drug insurance was much higher than for the uninsured. This evidence is highly consistent with the hypothesis that having drug insurance coverage tends to increase drug spending compared with being uninsured. However, these simple means may not provide an unbiased measure of the moral hazard effects of insurance coverage because they do not control for other risk characteristics of the populations with and without drug insurance. How much of the growth can reasonably be attributed to the traditional moral hazard volume effect is discussed in Section V below.

IV. THE FEEDBACK BETWEEN INSURANCE AND RESEARCH AND DEVELOPMENT

The diffusion of new, more expensive drugs, both as innovative new therapies and as more modest improvements over older, less expensive drugs, is a major descriptive driver of drug-spending growth in all countries. Figure 2 shows the number of new molecular entities (NMEs) launched in 1990–2001. The number of NMEs launched per year more than doubled between 1994 and 1996 and then declined again to the earlier level by 2001. Since the absolute numbers are so small, inferences about trends are tentative. With that caveat, these data suggest an upward trend in the first half of the 1990s, followed by a decline in the later years. This pattern, in particular the mid-decade bulge, may reflect the reduction in the time required to obtain Food and Drug Administration (FDA) approval following the introduction of user fees in 1992. This could generate a one-time increase in the rate of new product introductions, after which the new product flow would return to steady state. Whatever the cause of this mid-decade acceleration in new drug launches, it no doubt contributed to the 1997–99 acceleration in spending growth, while the decline in new drug launches in 2000–2001 contributed

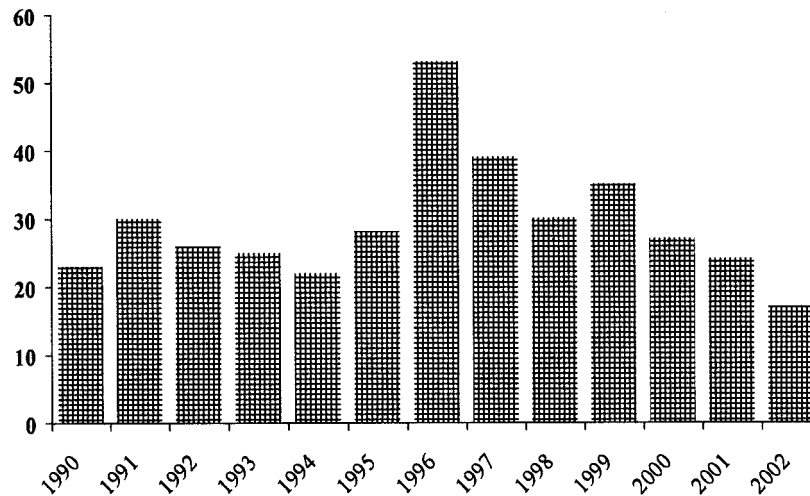


FIGURE 2.—Total number of new molecular entities approved in the United States. Data are from the Food and Drug Administration, Approval Times for Priority and Standard NMEs (<http://www.fda.gov/cder/rdmt/NMEapps93-02.htm>), and Food and Drug Administration, FDA Drug Approvals List (<http://www.fda.gov/cder/da/da.htm>).

to the decline in spending growth in 2000–2002. A full analysis of the contribution of new drugs to spending growth would have to also consider biologics, new formulations, and new indications for existing drugs, which are not reflected in Figure 2 and which are quantitatively the majority of new drug launches. Conversely, patent expirations on major drugs can affect spending levels, as generic entry dramatically reduces price levels relative to brand prices prior to patent expiry. Patent expirations on several major products have been a significant contributor to the recent slowing of drug-spending growth.

Given the growth of drug insurance, an obvious question is the potential impact of insurance on R&D and hence on the rate of new drug introductions. Previous analyses of growth in health care spending more generally have identified technological change as the major driver of spending growth and have speculated on the role of insurance in driving technological change. Pharmaceutical R&D, like any product investment decision, is no doubt influenced by the expected demand for the product, which is positively related to insurance coverage. Research and development spending grew both absolutely and as a percent of sales, from 15.1 percent of sales in 1985 to 20.0 percent of sales in 1998, and then dropped to roughly 17.7 percent of sales in 2001.¹² However, the link between drug insurance and pharmaceutical

¹² Pharmaceutical Research and Manufacturers of America, *Pharmaceutical Industry Profile* (2002).

R&D spending and hence new product launches is complex, lagged, and stochastic. The average total drug development time from synthesis to approval in the United States was 14.2 years in the 1980s.¹³ Thus, the new product flow in any year presumably reflects demand projections over the prior 14 years. It seems unlikely that the 1990s surge in insurance coverage could have been anticipated in the 1980s when the 1990s products were initiated. Moreover, since major drugs diffuse globally, the relevant market demand is total expected global, not just U.S., sales and profits.

A second and very important factor complicating inferences about the incentive effects of insurance on R&D and new product flows is the role of exogenous new technology breakthroughs. These may come from basic research related to medicine, such as research sponsored by the National Institutes of Health on mapping the human genome, or from other sciences—for example, informatics and robotics play a major role in drug discovery. The importance of exogenous technology breakthroughs (plus luck) is evident in the fact that new products tend to come in waves associated with specific new therapeutic category breakthroughs—for example, the nonsteroidal anti-inflammatory drugs (NSAIDs) in the 1970s; H₂-antagonists and beta blockers in the 1980s; and lipid lowerers, ACE inhibitors, antidepressants in the 1990s.

Although exogenous technology shocks were clearly critical in the expansion of the new product frontier, insurance coverage probably plays a significant role in the number of drugs in each category and the number of formulations and indications per molecule. When manufacturers make the “go/no go” decision at various points during drug development, the incentive to proceed with commercialization of a drug that will be sixth in class is clearly greater the larger the potential sales for the class. Insurance coverage expands the market for any indication by making patients more likely to seek drug therapy and switch from older, cheaper drugs to newer, improved, and more costly products. Insurance is therefore likely to make it worthwhile for companies to launch more new drugs per therapeutic class and to develop more formulations and indications per molecule.

If the causal link from insurance to new drugs is lagged and complex, the converse causal link from technological breakthroughs to demand for insurance coverage is clear and more immediate. The new drugs that were launched in the late 1980s and 1990s offer improved treatment options for a number of very prevalent disease categories, including treatments for chronic conditions, such as depression and hyperlipidemia, and for acute conditions. These improvements in available treatment technologies and hence in the mean and variance of expected medical expense are predicted to increase the demand for insurance.

Suppose that technology increases the number of disease states that can

¹³ Kenneth I. Kaitin & Joseph A. DiMasi, *Measuring the Pace of New Drug Development in the User Fee Era*, 34 *Drug Inf. J.* 673 (2000).

be effectively treated with drugs. As long as the available drugs treat only a small number of disease states and would entail relatively small total expense, the value to a risk-averse person of pooling this risk may be less than the administrative cost of coverage. This is true a fortiori with moral hazard. If new drugs become available to treat other disease states and if administrative costs increase less than increases in expected expense, the demand for drug coverage will rise. The predicted increase in insurance demand is greater the more expensive the new drugs are (which increases the financial risk should illness strike) and the greater the tax subsidy to purchasing insurance (which effectively offsets the loading charge).

For medications for chronic conditions, the expected treatment expense is less stochastic; hence the risk-pooling rationale for insurance is weaker. However, the tax subsidy to employer contributions to health insurance implies that middle- and upper-income employees would be better off having these expenses covered through insurance instead of paying out-of-pocket. Actual pharmaceutical innovation in the 1990s surely satisfies this criterion of increased expected expense, for both acute and chronic conditions, relative to insurance loadings, net of the tax subsidy.

In addition to this stimulus to insurance demand from the technological change in drug therapies, technological change in insurance systems has probably also contributed to the growth of insurance coverage. In the late 1980s and 1990s, improvements in information systems made possible the offering of managed pharmacy benefits that use more cost-effective strategies for providing drug insurance than did traditional indemnity coverage. Pharmacy benefit managers use formularies of preferred drugs, with incentives to patients and physicians to use on-formulary drugs, and networks of pharmacists that agree to discounted dispensing fees. The use of drug formularies and selective pharmacy networks enables PBMs to negotiate discounts on manufacturer prices and pharmacy dispensing fees that together are estimated to reduce the cost of coverage by about 20–30 percent. Pharmacy benefit managers also require that participating pharmacies be equipped to do on-line, point-of-service verification of patient eligibility, to confirm whether a drug is covered by the patient's formulary, and to do drug utilization review (DUR) to check for interactions and contraindications with other drugs the patient may be taking. Patients are issued "smart" cards. These systems enable the pharmacy to verify coverage and formulary compliance before the purchase and to bill the plan directly, which leaves the patient to pay only the copayment. By contrast, under traditional indemnity insurance, the patient had to pay in full and then submit forms to the plan for reimbursement, which could be rejected on grounds the service was not covered. Drug utilization review may also improve quality and reduce the risk of drug interactions and other Rx errors. Pharmacy benefit managers also launched the use of mail-order dispensing, particularly for chronic medications, which further improves formulary compliances and reduces pharmacy and patient

time costs. These PBM strategies reduce the administrative costs of controlling moral hazard costs and reduce patient time and hassle costs, while the negotiated discounts on drug prices and pharmacy dispensing fees reduce the actual cost of drugs, relative to being either uninsured or having indemnity drug coverage. Managed drug benefits thus reduce the real price of insured drug coverage, relative to indemnity insurance, and reduce the real cost of drugs relative to being uninsured.

Our hypothesis is that while new products increased both the mean and variance of expected drug expense in the 1990s, which increased the demand for drug coverage, at the same time the development of managed drug benefit programs offered a significantly improved form of drug insurance, with lower money and time price for beneficiaries. These technology-driven trends are a major reason why coverage grew so rapidly. Consistent with this, PBMs (or similar means of in-house managed benefits) are used not only by virtually all types of managed care plans, but now they are also used by indemnity plans, which offer managed drug benefits as an addition (carve out) to the traditional indemnity coverage of physician and hospital services. Similarly, most proposals for a Medicare drug benefit would use PBMs to administer the coverage.

V. THE DIRECT EFFECT OF INSURANCE ON UTILIZATION

The dramatic increase in drug insurance coverage over this period—much larger than for other components of medical spending—suggests that the moral hazard effects of coverage growth may have made a major contribution to the increase in drug utilization documented above and hence to the growth in drug spending. Simple moral hazard theory implies that, given an estimate of the reduction in out-of-pocket price (dP) and the demand elasticity (E), we can estimate the predicted increase in volume dQ , other things being equal: $dQ = E \times dP$. The average out-of-pocket price fell at a rate of 20–60 percent per decade from 1970 to the present, with the most rapid decline in the 1990s. Empirical price elasticities for Rx drugs from cross-section data are roughly -3 .¹⁴ These estimates imply that the increase in drug insurance can account for an increase in utilization and hence in spending of 1.0–2.5 percent per year, assuming no effect on manufacturer prices nor on type of drugs used. With 1.75 percent as an estimate of annual growth due to coverage and 8 percent as an estimate of the real (consumer price index (CPI) adjusted) growth in drug spending per capita since the mid-1980s, this would imply that about one-fourth to one-fifth of this drug-spending growth was due to the volume effects of increased insurance coverage.

¹⁴ A. Hillman *et al.*, Financial Incentives and Drug Spending in Managed Care, 18 Health Aff. 189 (March/April 1999); Congressional Budget Office, Issues in Designing a Prescription Drug Benefit for Medicare (2002) (<http://www.cbo.gov/showdoc.cfm?index=3960&sequence=0&front=0>).

This estimate, that the insurance-induced reduction in average user price accounts for one-fourth to one-fifth of the growth in drug spending, implicitly assumes a benchmark of zero spending growth in the absence of insurance growth. An alternative benchmark is that drug spending would have grown at the same 5 percent real rate per capita as did spending on other types of medical care, which experienced a much smaller increase in coverage but were subject to influences of income growth, technological change, and the like. Using this 5 percent benchmark, the 8 percent drug-spending growth implies 3 percent excess drug spending, over and above the growth attributable to the general drivers of medical spending. Thus, our estimate of a 1.75 percent annual increase in drug utilization due to increased drug insurance “explains” about half of the excess spending growth on outpatient drugs.

These estimates assume that the growth in insurance coverage simply reduced the average out-of-pocket price of drugs. In fact, the drug coverage growth also entailed a shift to managed drug benefits, and managed care plans replaced indemnity plans for other medical services. These changes in the structure of insurance coverage probably also contributed in several ways to the increase in drug spending, which suggests that our simple *ceteris paribus* estimates are a lower bound on the full effect of insurance on drug-spending growth in the 1990s.

First, the full user price of an Rx drug includes not only the out-of-pocket money price of the drug, which was the basis for the above estimates, but also the out-of-pocket price of a physician visit (if an extra visit is necessary to obtain an Rx), plus the patient’s time cost for the physician visit and the trip to the pharmacy. The 1990s shift from indemnity insurance to managed care and managed pharmacy benefits reduced these other components of the full user price for drugs, in addition to cost sharing for the drug. Managed care plans generally charged lower copayments for physician visits and for drugs than did indemnity plans in the 1990s. Managed drug benefits also reduced the patient time cost of getting a reimbursed Rx by the use of pharmacy cards and mail order, as described earlier.¹⁵

Second, these elasticity estimates are based on responses to small changes in price for those people who already have some coverage. They may not be appropriate estimates of the effect of going from no coverage to fairly comprehensive coverage. Third, the structure of most managed drug plans, at least through the mid-1990s, may have encouraged the “mix upgrade” toward more expensive drugs, conditional on having an Rx, which is the second major driver of drug spending. Patient cost sharing under these first-

¹⁵ Conditional on the number of filled Rx’s, pharmacy cards may increase the percent of scripts paid by insurance by eliminating the “shoe box” effect that leads patients to hoard rather than file potentially reimbursable claims under indemnity insurance plans. This is one reason why drug-spending growth as reported by insurers may exceed total drug-spending growth as reported in national accounts.

generation managed drug plans was typically either a fixed copayment per script or a two-tier structure, say \$5 for a generic and \$10 for a brand. Since the copayment was invariant with the price of the brand, the patient faced no financial penalty for preferring newer, more expensive (and perhaps only marginally better) products over older, less expensive products, as long as both were on the formulary.¹⁶ For all these reasons, our estimates that drug insurance growth accounts for one-fourth to one-half of total drug-spending growth are probably a lower bound on the full impact of the 1990s insurance changes.

These estimates are lower than might be inferred from the simple cross-sectional evidence in Table 2, which suggests that drug expense per capita was roughly three times as high for those with both health and drug insurance as it was for those with neither health nor drug insurance (\$437 vs. \$133 in 1997). However, as discussed earlier, the cross-sectional evidence in Table 2 cannot provide unbiased estimates of the effect of insurance on drug utilization for a given risk type because of biased selection in insurance demand. That is, if higher-risk individuals are more likely to buy coverage, the observed differences in drug spending between those with and without drug insurance overstate the moral hazard effect of coverage for an individual of a given risk type.¹⁷

Other evidence suggests that people with managed drug benefits have higher drug use than people with indemnity insurance.¹⁸ Several factors may contribute to this outcome, in addition to the lower patient cost sharing for both physician visits and drugs and lower patient time and hassle cost with managed plans, as described above. Managed plans have generally encouraged substitution of outpatient services, including drug therapies, for inpatient care, and physicians in managed care plans may substitute drug therapy for their own time, in response to managed care's practice of paying either lower fees or capitation.¹⁹ It has also been suggested that managed care plans have been quicker to realize that drugs can be cost-effective relative to alternatives: "The cost-effectiveness of outpatient drug care relative to inpatient hospital

¹⁶ Only a minority of managed plans used closed formularies that required patients to pay in full for off-formulary drugs.

¹⁷ A study of drug use by seniors (Department of Health and Human Services, Report to the President: Prescription Drug Coverage, Spending, Utilization, and Prices (April 2000) (<http://aspe.hhs.gov/health/reports/drugstudy/>)) suggests that insurance increases use disproportionately for more costly and brand-name drugs and for therapeutic categories with important innovative products for common diseases (antidepressants, statins, proton pump inhibitors for ulcers). This suggests that insurance contributes to mix upgrade, hence higher cost per script, in addition to volume of scripts; however, this cross-sectional evidence may also be biased by insurance selection effects.

¹⁸ Alan Lyles & Francis B. Palumbo, The Effects of Managed Care on Prescription Drug Costs and Benefits, 15 *Pharmacoeconomics* 129 (1999).

¹⁹ The anecdotal evidence from Germany and Japan, two countries with fee for service and very short physician visits, is that physicians use Rx's as a way to bring a visit to a close.

care (when it can be substituted) has been recognized by managed care” and “managed care organizations encourage the use of Rx drugs by including them in their benefit design.”²⁰

An alternative hypothesis is that managed care plans experienced economies of scope in applying managed care techniques and information systems to drug coverage. The basic selective contracting techniques used by PBMs and HMOs—demanding discounts on drug prices in return for putting a drug on the formulary and discounts on dispensing fees in return for admitting a pharmacy to the preferred pharmacy network—are similar to the selective contracting used for physician and hospital services. Some variants of drug formularies are designed to encourage use of low-priced drugs and deter mix upgrade—in particular, incentives for generic substitution and higher copayments or noncoverage of nonpreferred drugs. Most of these techniques focus on switching between drugs rather than on reducing total volume. Thus, the traditional PBM copayment structure was not well designed to deter moral hazard, at least prior to triple-tier copayments. Similarly, managed care’s copayment structure for physician visits was generally a low, fixed payment per visit, which seems less optimal for moral hazard control than the coinsurance percentage used by traditional indemnity plans. Why managed care used this apparently inefficient copayment structure for both physician visits and drugs is beyond the scope of this paper. We simply note that it may have contributed to both the increase in the number of Rxs and the shift to more expensive drugs under managed drug benefits.

Thus, we conclude that the direct effect of increased coverage on drug-spending growth was at least one-fourth to one-half of the total, with the larger figure being more likely if the reduction in the nondrug price component of the full user price (patient time cost, copay on physician visits) was at least as large as the reduction in cash price of the drugs or if other characteristics of managed care and the managed drug benefit structure increased the use of outpatient drugs, conditional on user price.

VI. INDIRECT EFFECTS OF INSURANCE ON DRUG-SPENDING GROWTH

A. *Promotion and Direct-to-Consumer Advertising and Other Drug Promotion*

Previous authors²¹ cite the 1997 relaxation of FDA regulations of DTC advertising as a major driver of the growth in drug spending in the late 1990s. These regulatory changes permitted drug manufacturers to mention the name of the drug and its purpose or indication without having to cite the full list

²⁰ Joshua P. Cohen, PBMs and a Medicare Prescription Drug Benefit, 55 Food & Drug L. J. 311 (2000).

²¹ See note 3 *supra*.

of side effects and contraindications listed in the approved label.²² Although manufacturers are still required to provide “balance” in their listing of risks and benefits, these changes presumably increased the expected positive impact of DTC advertising on demand, thereby increasing manufacturers’ expected returns to DTC investments.

We hypothesize that the spread of insurance coverage further increased manufacturers’ expected returns on drug advertising by making the consumer’s demand for insured drugs more inelastic. This effect is especially likely if cost sharing is in the form of copayments rather than co-insurance. The Dorfman-Steiner condition for optimal investment in advertising implies that the optimal advertising budget relative to sales (A/PQ) is inversely related to the demand elasticity with respect to price $E_{q,p}$ and positively related to the demand elasticity with respect to advertising $E_{q,a}$: $A/PQ = E_{q,a}/E_{q,p}$.

In the simple case of insurance with a 50 percent copayment, the elasticity of an insured linear demand curve would be 50 percent lower at any gross price than the uninsured demand curve. Other things equal, such lower elasticity could imply a doubling of the optimal advertising-to-sales ratio. In reality, since most of the growth of coverage was in managed benefits, which typically used a \$5 or \$10 copayment per script, the implied reduction in demand elasticity is even greater than in the example here. Moreover, if managed drug coverage reduced the patient’s time price and/or other components of the full user price, this would shift the own demand curve and thereby further reduce own price elasticity.²³

This insurance stimulus to drug promotion applies not only to DTC advertising but also to other forms of promotion, including the quantitatively more important detailing of physicians. Physicians are necessary, if not primary, “customers” for Rx drugs. If physicians act as reasonably good agents for their patients, then their demand presumably reflects the demand of the patient, including his or her insurance coverage. Thus, the increase in insurance coverage that makes patient demand for drugs more inelastic should also make the physician’s demand more inelastic, under plausible agency assumptions. Consistent with this, detailing of drugs to physicians has significantly increased in the latter half of the 1990s. Thus, insurance growth may have stimulated all forms of advertising, not just DTC.

Direct-to-consumer advertising is allegedly also used to counteract managed care’s attempts to control moral hazard through restrictive formularies. It enables manufacturers to reach consumers directly to inform them about the drugs that are available to treat specific conditions. By encouraging pa-

²² The full listing of side effects and contraindications must be available through an 800 telephone number or a Web site.

²³ Of course, a constant elasticity demand curve has the same elasticity at a user price of $.2P$ as at P , but the reduction in other components of the full user price would reduce elasticity even in this case.

tients to request specific drugs by name, DTC has allegedly limited managed care's ability to exclude highly advertised drugs from formularies. This assumes that patient dissatisfaction with the formulary is costly to the HMO, either because physicians complain that they incur time costs to discuss possible substitutes for off-formulary drugs or because the HMO's enrollment is responsive to patient satisfaction with the formulary. Thus, DTC may be one reason why managed pharmacy benefits have not been as restrictive as initially expected. Whether this is good or bad is beyond the scope of this paper.

Much heat but less light has been shed on whether drug promotion in general and DTC advertising in particular is excessive. This is a complex issue. Given the rapid rate of change of drug technologies, including both new compounds and new formulations and indications for old compounds, patients and physicians need information as new products become available. Advertising by drug companies, in all its forms, is the main vehicle for this. Some informational advertising is clearly potentially beneficial, and some promotion clearly does expand the total market, while some appears to be designed to steal share from competitor products. We do not attempt a normative evaluation of drug promotion here. We simply make the positive observation that the spread of insurance coverage—especially insurance coverage in managed care form because of the relatively low copayments (for drugs and for physician visits needed to get a script)—would stimulate the use of DTC and other forms of promotion to increase consumer and physician demand for drugs directly, thereby counteracting the constraints that formularies try to impose.

Note that this tendency for insurance to stimulate promotion by making consumer demand less elastic is not confined to drugs—it applies to all insured medical services. However, the effect on drugs may be greater because of other characteristics of drugs. Drugs are used by the average consumer more frequently than hospital visits or even physician visits; drugs offer a relatively painless form of cure and/or improvement in quality of life compared with most other medical services; hence the elasticity of consumer demand in response to advertising may be greater for drugs than for heart surgery, for example. Further, drugs typically have very low marginal costs and relatively high price–marginal cost margins (reflecting, in part, the high fixed costs of R&D, production capacity, and so forth), which makes generating additional sales through advertising more profitable for drugs than for lower margin products and services. These characteristics plausibly make drug advertising more responsive to insurance than advertising of other medical services.

Quantifying this indirect effect of insurance on drug expenditures would require estimates of the insurance-induced increase in advertising and the effect of advertising on drug utilization and prices. Neither of these components can be estimated from readily available data. Other studies have

inferred a strong causal effect of advertising on drug spending from the fact that several of the highest-volume products are among the most heavily promoted. But the direction of causation in this relationship is unclear at best. Clearly, the payoff to advertising is greatest in large markets, given the large fixed costs of advertising.

B. Prices

Insurance may affect both the launch price of new drugs and the postlaunch rate of price increase. To address the latter first, both theory and evidence suggest that managed drug benefits may have slowed the rate of postlaunch price growth. The average rate of excess drug price inflation (that is, drug price growth in excess of the CPI) has been much less in the 1990s than in the 1980s. Thus, although the spread of insurance might be expected to make demand more inelastic, this has not been reflected in higher rates of post-launch price growth for established products. In the case of managed pharmacy benefits, the manufacturer's overall demand is presumably more influenced by the PBM's demand in negotiating price discounts in return for formulary status than by the consumer's demand, which may be price inelastic because of the fixed copayments. One important function of a PBM is to act as an intermediary to negotiate drug prices for beneficiaries. The use of formularies enables PBMs to shift market share toward drugs that offer large discounts. This use of formularies effectively makes the demand facing the manufacturer more elastic. The slowing of the rate of drug price increase in the 1990s compared with the 1980s is consistent with this hypothesis that PBMs made demand more elastic. Further evidence confirming that PBM demand is more price elastic is the prevalence of discounts that PBMs receive relative to cash-paying or indemnity-insured consumers.

Estimating the effect of insurance coverage on launch prices of new drugs is empirically more problematic. The empirical decomposition of drug-spending growth in Figure 1 only identifies postlaunch price inflation. Any tendency for new drugs to be launched at higher prices than new drugs in prior years is subsumed in the residual that includes increased volume and shift to more expensive drugs. Conceptually, a valid comparison of the launch prices of new drugs launched in the 1990s with the prices of new drugs launched in the 1980s would require hedonic adjustments that would almost certainly be imperfect because the types of drugs were different. This would remain an "apples to oranges" comparison.

Although we have no empirical basis for estimating the effect of insurance coverage on prices for new drugs, controlling for their intrinsic but unmeasured value, conceptually it seems reasonable to assume that the price elasticity effects discussed above in relation to postlaunch price growth would apply equally to launch price levels for new drugs. If so, to the extent that PBMs have more elastic demand than cash-paying individuals or indemnity-

insured individuals, the growth of PBM coverage should have moderated launch prices for new products as it moderated the rate of growth of prices for established products. In conclusion, since the growth in insurance coverage was associated with a change in its form, from unmanaged indemnity to managed benefits with formularies, there is no strong theoretical basis for concluding that the growth in insurance contributed to higher prices; in fact, the contrary is more likely.

VII. CONCLUSIONS

The unprecedented spread of insurance coverage for outpatient drugs in the 1990s was almost exclusively in the form of managed drug benefits and coincided with the shift to managed care for other forms of health insurance. This evolution of managed pharmacy benefits was made possible by developments in information technologies, which enabled formularies, smart cards, point-of-service DUR, and verification of coverage to be conducted, in addition to mail order. These innovations in insurance design significantly reduced the true cost of drug coverage (measured as the net loading relative to no insurance) and reduced both the time price to patients and the real cost of drugs through negotiated discounts on drugs and on pharmacy dispensing fees. This downward shift in the supply price of drug insurance coincided with an increase in the demand for drug coverage due to the flow of major new products, including drugs for several widespread chronic conditions. The net effect was that most people under 65 with health coverage added drug coverage to their insurance policies, while coverage also increased for seniors through a variety of public and private plans. We estimate that for both the under-65 population and seniors, the percent with drug insurance increased 63–66 percent between 1987 and 1996. The reduction in consumers' out-of-pocket price and time price of obtaining drugs in turn led to more scripts and higher expense per script as people shifted from older drugs to newer, more expensive medicines. We estimate that the direct (moral hazard) effect of this growth in insurance coverage accounts for between one-fourth and one-half of the total growth in drug spending over this period. By making consumer demand less price elastic, insurance also probably stimulated manufacturer investments in DTC and other forms of promotion, adding a further indirect effect of insurance on demand (assuming such investments are rational).

A full normative evaluation of these trends is beyond the scope of this paper, but some simple observations are possible. Growth in coverage due to technological changes in insurance administration and new medical products may well be welfare increasing. One obvious distortion is the tax subsidy to health insurance, which presumably stimulates some inefficient coverage for drugs, as it does for other forms of health care. Since this subsidy applies equally to all medical services but there was no increase in the aggregate

rate of insurance coverage for medical services other than drugs, it seems unlikely that increases in marginal tax rates contributed to the growth in drug coverage. However, the tax subsidy does make it worthwhile to buy coverage for routine and chronic medications that are a predictable expense if the rate of subsidy more than offsets the insurance loading, which is likely for most middle-class taxpayers. Increases in coverage due to the large and growing tax subsidy to the middle class do not appear to reflect an efficient use of resources. However, since we tolerate this for other medical services, there may be no reason to single out drugs for black marks.

The fact that insurers have been surprised by the rapid growth in drug expenditures suggests that they misestimated the effects of different benefit designs. In that case, our interpretation of the 1990s experience, as an equilibrium growth path for insurance design and associated spending, may be overly optimistic. The post-1997 growth of triple-tier copayment structures, which raise copayments for preferred-brand drugs and add an even higher third-tier copayment for nonpreferred brands, does suggest that PBMs have learned from experience that more sensitive copayment structures are needed to control moral hazard. But this cannot all be blamed on imperfect foresight. Managed care plans are shifting from supply-side controls to more copayment/demand-side controls for other services, not just drugs, partly in response to the managed care backlash, which may make supply-side controls politically ineffective, even if economically viable. Thus, although the increased moral hazard from more insurance coverage accounted for a sizeable proportion of drug-spending growth, other than the tax subsidy, which applies to all forms of medical care, there is no obvious basis for labeling the insurance-induced rise in drug expenditures as inefficient relative to other health care spending.

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