

The U.S. Pharmaceutical Industry: Why Major Growth In Times Of Cost Containment?

Four factors affecting drug use have driven costs upward since 1994, but their future role is uncertain.

by Ernst R. Berndt

ABSTRACT: Growth in utilization rather than price, particularly since 1994, has been the primary driver of increased pharmaceutical spending. In this paper I focus on four factors that have increased utilization, even as cost containment efforts have flourished: (1) “the importance of being unimportant”; (2) increased third-party prescription drug coverage; (3) the introduction of successful new products; and (4) aggressive technology transfer and marketing efforts by pharmaceutical firms. I also consider the roles that these four factors are likely to play in the future.

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FOR MOST MEDICAL CARE INDUSTRIES in the United States, the 1990s were turbulent, as managed care and other cost containment efforts flourished, rooting out overutilization, altering incentives, and affecting health care quality in ways not yet well understood. Yet during this same decade the U.S. pharmaceutical industry experienced relatively high rates of domestic sales growth. Why such significant growth in times of cost containment?

■ **Recent spending growth patterns.** In terms of average annual growth rates in pharmaceutical sales, while the rate of 12.8 percent for the more recent 1994–1999 time period is only slightly larger than the rate of 11.9 percent for 1987–1994, the composition of this spending growth has changed dramatically (Exhibit 1).

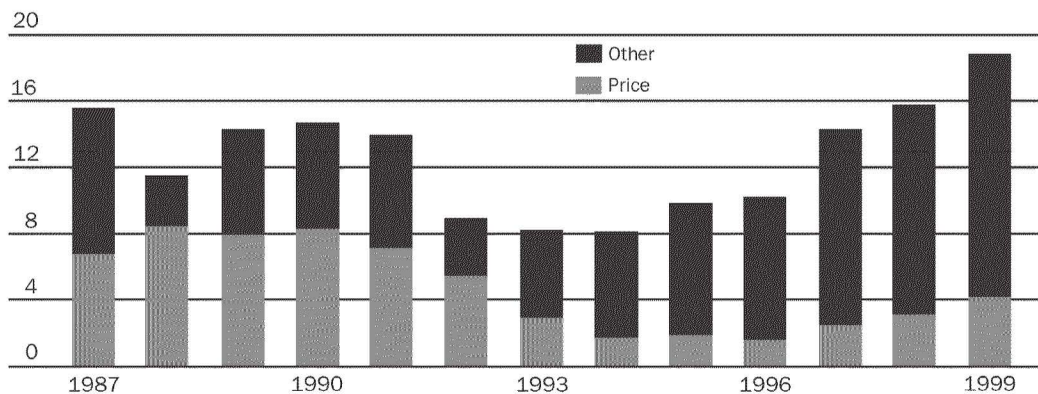
Using price index formulae analogous to those used by the U.S. Bureau of Labor Statistics, IMS Health regularly decomposes prescription drug expenditures into those attributable to price (the change in spending if last year’s mix of drugs were purchased today), those attributable to spending on new products (defined as less than

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EXHIBIT 1

The U.S. Prescription Pharmaceutical Market: Total Annual Sales Growth And Its Sources, 1987-1999

Percent growth rate



SOURCE: IMS Health, "Retail Provider Perspective, 2000," reproduced in *Pharmaceutical Industry Profile 2000: Research for the Millennium* (Washington: Pharmaceutical Research and Manufacturers of America, 2000), Figure 4-11.

NOTE: Annual averages were as follows. Sales growth: 1987-99, 12.6 percent; 1987-94, 11.9 percent; 1994-99, 12.8 percent. Price growth: 1987-99, 4.8 percent; 1987-94, 6.4 percent; 1994-99, 2.5 percent. Residual growth: 1987-99, 7.8 percent; 1987-94, 5.8 percent; 1994-99, 10.3 percent.

a year old), and the residual (those attributable to volume and mix on incumbent products). Hereafter I refer to the latter two nonprice factors as "utilization" components. From 1987 through 1994, of the 11.9 percent average annual rate of spending growth, about half reflected the direct effects of increased prices, while the remaining half is attributed to utilization growth. In contrast, from 1994 through 1999 the growth rate remained in double digits, but only about one-fifth was directly attributable to price changes; nearly 80 percent of increased drug spending was related to growth in utilization.¹

In this paper I offer four hypotheses to help explain why use of pharmaceuticals has continued to grow even as managed care and other cost containment efforts have flourished. The four factors on which I focus, not necessarily in order of importance, are (1) "the importance of being unimportant"—pharmaceuticals' modest share of total U.S. health care costs; (2) the dramatic growth of third-party prescription drug coverage; (3) the successful new product innovation emerging from the pharmaceutical industry; and (4) pharmaceutical firms' aggressive technology transfer and marketing efforts.

Factor 1: 'The Importance Of Being Unimportant'

Alfred Marshall, a famous nineteenth-century economist, reasoned that certain characteristics of goods and services made their demand more or less price-responsive, or more or less immune to cost-cutting efforts. Among the four laws of demand that Marshall enunciated, one has been dubbed "the importance of being unimportant."

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To Marshall, if spending on some good or service is perceived to be only a small portion of total costs, that good or service will not be as likely to be on cost cutters' radar screens; instead, they will tend to focus more on big-ticket items. Although Marshall provided no analytic basis for this argument, it is plausible to argue that, other things being equal, it may be rational for budget managers to focus most of their attention on the largest budget items.

Hospital spending (outpatient plus inpatient) continues to be the single largest component of health care costs (Exhibit 2). Despite the shift from inpatient to outpatient settings, total hospital costs are still the largest single health care component. The second-largest spending item has consistently been physician services, whose share of total health care spending has remained relatively constant over the past four decades at about 20 percent.

In third or fourth place is spending for outpatient prescription drugs. Even at their current 8 percent share, prescription drug costs are still relatively unimportant. However, this 8 percent represents an average, and the variance across subpopulations is considerable. For example, data from the 1995 Medicare Current Beneficiary Survey (MCBS) indicate that while Medicare beneficiaries' average total spending on prescription drugs was \$536, the variance was \$741.² Also, it is likely that the prescription drug share is larger for payers that cover the nonelderly working population, a subgroup with relatively low rates of hospitalization.

Within the past decade, as the prescription drug cost share has grown, pharmacy benefit management (PBM) tools have been developed and have flourished. These tools include drug utilization review, generic substitution, prior authorization, step-care protocols, therapeutic interchange, increasingly restrictive formularies, three-tier copayment structures, academic detailing, and various physi-

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EXHIBIT 2
Health Care Expenditure Cost Shares, By Category, 1960–1998

Category	1960	1970	1980	1990	1995	1996	1997	1998
Hospital care	34.6%	38.3%	41.5%	36.7%	34.9%	34.6%	34.0%	33.3%
Physician services	19.7	18.6	18.3	20.9	20.3	20.1	20.0	20.0
Prescription drugs	10.0	7.5	4.9	5.4	6.1	6.6	7.2	7.9
Nursing home care	3.0	5.7	7.1	7.3	7.6	7.7	7.8	7.6
All other	32.7	29.9	28.2	29.7	31.1	31.0	31.0	31.2
Total health care expenditures (billions)	\$26.9	\$73.2	\$247.3	\$699.4	\$993.3	\$1,039.4	\$1,088.2	\$1,149.1

SOURCES: K. Levit et al., "National Health Spending Trends in 1996," *Health Affairs* (Jan/Feb 1998): 35–51 (for 1960–1990 data); and K. Levit et al., "Health Spending in 1998: Signals of Changes," *Health Affairs* (Jan/Feb 2000): 124–132 (for 1995–1998 data).

NOTE: "All other" includes dental and other professional services, home health care, nonprescription drugs and medical durables, vision products, net cost of private health insurance, government public health activities, and research/construction.

“The information technology revolutions have contributed to the diffusion of drug coverage into benefit plans.”

cian capitation schemes. While use of these PBM tools has undoubtedly constrained drug spending growth, a detailed analysis of their impacts is beyond the scope of this paper.

It is worth noting, however, that formulary compliance by physicians involves information gathering and monitoring costs. Such costs are likely to be higher the larger the number of payers with which a physician contracts. Relatively few physicians today have only one managed care contract. Based on data from the 1996–97 Community Tracking Survey of Physicians, Nancy Beaulieu reports that 61 percent of primary care physicians and 64 percent of specialists surveyed had six or more managed care contracts.³ The ability of any one payer to greatly affect prescribing decisions is constrained when physicians simultaneously interact with so many different payers and their formularies.

Thus, until recently prescription drug costs have not on average been as important as the health care cost shares of hospital and physician services. In the context of nonpharmaceutical expenditures, there is some evidence suggesting that managed care has had a much larger impact on prices paid for health care services than on their use.⁴ This may be particularly true for drugs, whose average cost share in 1998 was still relatively unimportant at 8 percent.

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Factor 2: Growth In Third-Party Drug Coverage

Prescriptions dispensed at retail pharmacies have been paid for in a variety of ways. Historically, for consumers with private third-party drug coverage, the drug recipient initially made a full cash payment to the pharmacy and then was reimbursed in whole or in part by the insurer. Until the 1990s this somewhat cumbersome procedure was the norm. The transaction costs—first saving and storing prescription receipts in shoe boxes, then gathering them together, and finally filling out forms and sending them off to claims processors—were considerable, for both beneficiaries and insurers.

■ **Impact of information technology.** Recent technological progress, particularly involving information technology and telecommunications equipment, has dramatically changed the way in which third-party drug claims are processed at pharmacies, making covered insurance transactions much more convenient and less costly than they were a decade ago. Today, for example, the privately insured beneficiary usually pays a copayment or coinsurance to the

pharmacy upon receipt of the prescription. After monitoring the pharmacy claim request to ensure compliance with formulary provisions, the third-party insurer then seamlessly reimburses the pharmacy electronically for the remainder, based on their contractual arrangement. For publicly provided drug insurance such as Medicaid, even when there is a copayment, the entire transaction is typically processed instantaneously and electronically.

Technological developments involving electronic transactions have also facilitated inexpensive, instantaneous monitoring for safety and formulary compliance by PBMs. Indeed, it could well be argued that the very existence of PBM techniques owes much to the revolutions in information technology and telecommunications.⁵

But what do these technological revolutions have to do with increased drug use? Undoubtedly the tight U.S. labor market in the past decade has contributed enormously to enhanced employee compensation in the form of more generous prescription drug coverage. However, because they have reduced pharmacies' and insurers' costs; offered consumers increased convenience and less bookkeeping; and enabled PBMs to monitor transactions, enforce formulary provisions, and perform drug utilization reviews at very low cost, the information technology revolutions have contributed as well to the diffusion of drug coverage into benefit plans.

■ **Changing role of third-party insurance.** The Health Care Financing Administration (HCFA) has produced data that document the changing role of third-party coverage in paying for prescription drugs (Exhibit 3). As seen in this exhibit, in 1965 (prior to the 1967 precedent-setting agreement between Ford Motor Company and the United Auto Workers enshrining drug insurance benefits as part of employees' benefit package), private insurance

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EXHIBIT 3
Share Of Prescription Drug Spending, By Source Of Payment, Selected Years
1965–1998

Year	Private insurance	Out-of-pocket	Medicaid	All other
1965	3.5%	92.6%	0.0%	3.9%
1970	8.8	82.4	7.6	1.2
1975	12.2	75.4	10.8	1.6
1980	20.1	66.0	11.7	2.2
1985	29.9	55.4	11.8	2.9
1990	34.4	48.3	13.5	3.8
1995	46.8	33.9	15.8	3.4
1996	48.8	31.6	16.1	3.5
1997	50.8	29.1	16.5	3.6
1998	52.7	26.6	17.1	3.6

SOURCES: Health Care Financing Administration (HCFA) National Health Accounts; and *Report to the President: Prescription Drug Coverage, Spending, Utilization, and Prices* (Washington: DHHS, April 2000), Table 2-30.

covered only about 3.5 percent of prescription drug spending. Moreover, in 1965 Medicaid did not yet exist. By 1980 the nonreimbursed cash share had fallen to 66.0 percent, the private third-party portion rose to 20.1 percent, and Medicaid grew from nothing to 11.7 percent. By 1995 the private third-party portion surpassed that of out-of-pocket cash payments. In 1998, the last year for which HCFA data were available, the out-of-pocket share had fallen to about a quarter, while the portion covered by private and public insurance was almost 70 percent. Although the rate of increase has fallen recently, it is clear that the predominant form of payment for prescription drugs has changed dramatically from uninsured cash to electronically processed third-party insurance coverage transactions.

■ **Relationship of use and coverage.** But why is this change significant for understanding increased use of prescription drugs? At least since the RAND Health Insurance Experiment in the 1980s, it has been widely understood that per capita drug use is strongly associated with the extent of drug coverage.⁶ For example, in the RAND experiment, when patient coinsurance rates for prescription drugs fell from 95 percent to 25 percent, per capita prescription drug spending increased 33 percent (per capita prescriptions increased 22 percent). Furthermore, when the patient coinsurance rate fell to zero (free to the patient), per capita drug spending relative to the 25 percent coinsurance rose another 32 percent (per capita prescriptions increased another 22 percent).

A caveat is worth noting. The RAND experimental data are now several decades old, and since the experiment involved simultaneously changing coinsurance rates for drugs and nondrug health care services, rather than adding drug coverage to existing health benefits, their quantitative values may not provide reliable guidance in the current policy environment. Moreover, because of selection problems into insurance plans, in nonexperimental settings it is difficult to quantify the extent to which increased drug coverage has contributed to increased drug use. Thus, for example, evidence that in the 1990s elderly Americans with drug coverage used drugs considerably more intensively than did those without such coverage does not help us to quantify reliably what drug use would be if drug benefits were added to Medicare.⁷

■ **Decreasing copayments.** Increased drug use has also been associated with decreased copayments as a share of costs. In 1996, 1997, and 1998, for example, as private health insurers' payments for prescription drugs increased by 17.5 percent, 18.7 percent, and 19.7 percent, respectively, beneficiaries' out-of-pocket payments increased by only 5.3 percent, 4.9 percent, and 5.4 percent, respectively.⁸ In such an insurance-protected environment, it is not at all

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surprising that employees' prescription drug use has surged.

■ **Deceleration ahead.** Growth in the insured drug coverage share has decelerated considerably in the past few years, however (Exhibit 3). Whether the 70 percent insurance coverage portion will continue to increase in the future depends in large part on public policy decisions such as those involving Medicare universal drug coverage. Absent such developments, there does not appear to be any compelling reason to expect further growth in the impact of drug coverage on use, particularly if the U.S. labor market softens.

Factor 3: Introduction Of Successful New Products

While the first two factors identified above operate essentially by affecting demand, the third factor functions primarily through the supply side—namely, the successful introduction of new pharmaceutical products. These new products are the fruits of substantial research and development (R&D) efforts. Some of the recent innovations have provided effective therapies where previously very few had existed (for example, the protease inhibitors for acquired immunodeficiency syndrome [AIDS], the human growth hormone Protropin, and Viagra for erectile dysfunction). Others have been new entrants in already crowded therapeutic classes, but their manufacturers have claimed lower prices and greater cost-effectiveness (for example, Lipitor, a statin lipid-lowering agent, and Protonix, a proton pump inhibitor).⁹ Yet other sets of innovative pharmaceutical products have offset nonpharmaceutical costs, such as third- and fourth-generation antidepressants that have facilitated reductions in the intensity of costly psychotherapy, and the beta-blockers and blood pressure medications that have reduced costs of cardiovascular-related hospitalizations and surgeries.¹⁰ Finally, increases in the variety of products within therapeutic areas facilitate a better matching between idiosyncratic patients and their medications.

■ **Approval time falling.** In recent years the number of new molecular entities (NMEs) approved by the U.S. Food and Drug Administration (FDA) has increased considerably. From 1987 through 1993 the FDA approved on average twenty-four NMEs per year. In the past six years, however (1994–1999), this approval rate increased by almost 50 percent to 35.5 NMEs per year. Part of the reason more new drugs are coming onto the U.S. market each year is that the mean approval time at the FDA has fallen. From 1987 through 1993 the mean approval time was 26.3 months, but by 1999 it had fallen to 12.6 months.¹¹

■ **Clinical testing time rising.** At the same time, however, the mean time in the clinical testing phase of drug development increased from 5.5 years in the 1980s to 6.7 years in 1990–1996; the

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number of clinical trials per new drug application (NDA) increased from sixty in 1989–1992 to sixty-eight in 1994–1995; and the mean number of patients involved in each NDA increased about 20 percent, from 3,567 in 1989–1992 to 4,237 in 1994–1995. Clinical trials take longer and are more costly. This is partly the result of the FDA's and providers' demands for more information on patient subpopulations and on interactions with other drugs, necessitating larger and more complex multisite trials.¹²

■ **Impact of new products on spending.** How important are new pharmaceutical products as drivers of increased drug spending? The answer to this question depends in part on what one means by a “new” pharmaceutical product, and on this there is inherent ambiguity. IMS Health defines a “new product” as any product having a new National Drug Classification (NDC) code and launched during the twelve months ending with the last calendar quarter. Although a one-year window is rather narrow, new NDCs include all new products, such as new generics, new brand-name products, and new line extensions of existing molecules. While it would be preferable to have a new-product definition that excluded new generic drugs having comparable brand-name presentations and strengths, spending on new generic drugs is typically much less than that for new brands, and thus the IMS definition is a reasonable first-cut estimate of the impact of new products on drug spending.

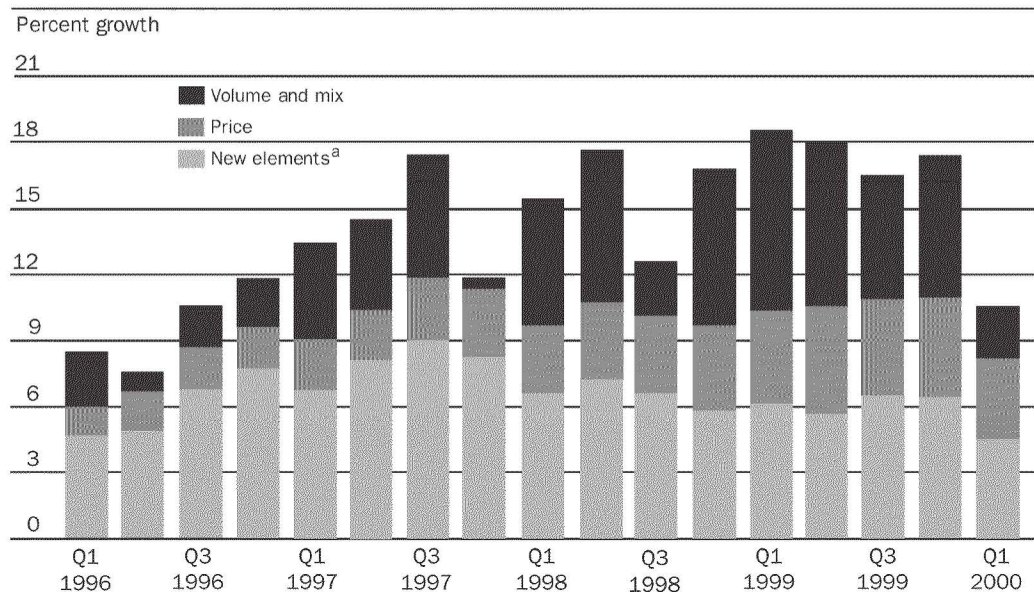
Since 1997 about 46 percent, on average, of drug spending growth can be attributed to growth in new elements, about 32 percent to volume and mix changes involving older drugs, and 22 percent to the price growth of older drugs (Exhibit 4). The role of successful new products in increasing drug spending is therefore a significant one.

■ **Role of patent protection.** Pharmaceutical products differ from many other consumer products in the critical role of patent protection on sales. For pharmaceuticals, once patent protection and market exclusivity expire, generic entry typically cuts sharply into the pioneer's revenues. A year after patent expiration in mid-1997, for example, pharmacy costs for brand-name Zantac (generic name ranitidine) fell to about 15 percent of their prepatent expiration level, and a year later to only about 10 percent of that level. The generic share sold increased from 0 percent to about 80 percent (one year) and 90 percent (two years). For Tagamet (generic name cimetidine), during the first year following patent expiration, expenditures also fell about 80 percent, and at twelve months after expiration the generic share already reached slightly more than 80 percent.¹³ While not all brand-name drugs experience such rapid drops in revenues following patent expiration (for some, reputation and brand-name loyalty effects persist), for others such as Capoten

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EXHIBIT 4

Trends In Growth Rates In The U.S. Prescription Pharmaceutical Market, By Component And Quarter, 1996-2000



SOURCES: IMS Health, "Retail Provider Perspective, 2000."

^a Includes products and line extensions launched during the twelve months ending with the latest calendar quarter.

(generic name captopril), the revenue reduction following patent expiration was apparently even more dramatic.¹⁴

In this context of patent expiration and generic penetration, two points are worth noting. First, in the ten years following passage of the Drug Price Competition and Patent Term Restoration Act (the Hatch-Waxman Act) in 1984, the generic share of dispensed prescription drug units in the United States more than doubled, from 18.6 percent to 41.6 percent. Since 1994 this share has increased at a more modest rate, reaching 47.1 percent in 1999.¹⁵ Hence, today roughly half of all prescription drug units dispensed in the United States are off-patent generic drugs.

Second, a substantial number of brand-name drugs are expected to lose patent protection and market exclusivity in the next few years and are likely to experience sharp losses in revenues as generics enter and capture market share. Among these are blockbuster drugs such as Vasotec, Prozac, Pepcid, Augmentin, Mevacor, Claritin, and Prilosec. According to one set of industry analysts, based on their total 1998 annual U.S. sales, drugs expected to lose patent protection in 2000 will result in annual revenue reductions to brand-name firms of about \$6.5 billion, slightly less than the \$6.7 billion for those drugs whose patents are due to expire in 2001.¹⁶ The cumulative effect of these revenue reductions over time is of course even larger.

“Post-launch research can greatly alter treatment guidelines, medical practice, and the demand for pharmaceuticals.”

Factor 4: Aggressive Technology Transfer And Marketing Efforts

Even though prescription drugs are becoming increasingly “user-friendly” (having fewer side effects, fewer adverse interactions with other drugs, more convenient dosing, and enhanced tolerability), these drugs are still complex “high-tech” products, and their appropriate and wise use requires a great amount of knowledge-base development and technology-transfer information. Marketing plays a critical role in this information-sharing process.

■ **Post-launch research.** After new products are launched, pharmaceutical firms often undertake or help to support long-term studies to compare alternative therapies, to assess whether preemptive treatment is efficacious, or to compare outcomes among subpopulations. As does basic research, post-launch research incorporates multilateral information flows among researchers in the drug industry, academe, and government. The findings from such studies, typically involving interactions with large numbers of physicians and patients, can greatly alter treatment guidelines, medical practice, and the demand for pharmaceuticals. It is useful to consider several examples and their impacts on medical practice.

Cholesterol-reducing drugs. Based on a number of widely publicized studies documenting the benefits of more aggressive treatment, in the mid-1990s the National Cholesterol Education Program adopted new treatment guidelines for patients with coronary heart disease, lowering the target for treatment from a low-density lipoprotein (LDL) level of less than 130 to less than or equal to 100.¹⁷ Treating high cholesterol more aggressively has benefited patients and has undoubtedly increased the use of cholesterol-lowering medications.

Treatment after heart attacks. A second example involves post-heart attack treatment with beta-blockers, which have been shown to be effective in reducing morbidity and mortality associated with heart disease, as well as in decreasing the probability of having a second heart attack. In 1992, as part of the Cooperative Cardiovascular Project, HCFA initiated a study in which the use of beta-blockers was monitored following a myocardial infarction. In 1992, data indicated that only 31.8 percent of eligible patients received this treatment. In 1996 the National Committee for Quality Assurance (NCQA) implemented a measure of beta-blocker use among health plans it audited, and later it set a 90 percent post-heart attack

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beta-blocker treatment rate as a benchmark requirement for health plans to obtain the NCQA “excellent” quality rating accreditation. According to the NCQA, the average treatment rate among its audited health plans rose from 62.2 percent in 1996 to 79.9 percent in 1998.¹⁸

Diabetes diagnosis. A third example concerns altering the criterion for a diabetes diagnosis. Based on pivotal clinical studies, in 1997 the American Diabetes Association recommended that a person be considered to have diabetes if his or her fasting blood glucose level was above 126, a decrease of 10 percent from the level of 140 that had been the previous diagnostic criterion.¹⁹ This added to the number of persons considered to have diabetes and surely has increased use of medications to control diabetes.

In each of these examples, post-launch studies have changed the knowledge base concerning the appropriate and effective use of new drugs. Although a somewhat nontraditional form of marketing, the fostering and facilitation of research that promulgates new diagnostic criteria and treatment guideline standards both benefits patients and on balance increases the use of pharmaceuticals.

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■ **More traditional marketing.** Other technology transfer and marketing efforts involving pharmaceuticals are much more traditional. In this context, it is informative to examine a widely used measure of advertising intensity—advertising-to-sales ratios, measured in current dollars—for common over-the-counter (OTC) medications. Advertising for OTC drugs entails spending on various print media, radio, television, and billboards. For pain medications, 1993 advertising-to-sales ratios were 17 percent for Tylenol, 26 percent for Advil and Bayer, and 21 percent for Excedrin. For antacids, the ratios were 33 percent for Alka-Seltzer, 24 percent for Mylanta, and 20 percent for Tums.²⁰ Are these ratios low or high?

Search goods versus experience goods. Marketing science researchers have long noted that the magnitude of advertising-to-sales ratios varies systematically across goods, depending in part on how one obtains information about the likely impact of the good or service on a given person.²¹ This research distinguishes “search goods” as polar opposites of “experience goods.” The characteristics and effectiveness of search goods can be determined simply by searching their specifications, which often can be quantified. A pure search good does not require one’s own consumption experience to gain information on its characteristics. By contrast, the characteristics and effectiveness of experience goods are to a great extent idiosyncratic and unpredictable for a given person. An experience good, therefore, requires a person to consume it directly to obtain reliable information on its performance. Not surprisingly, other things being equal,

advertising-to-sales ratios tend to be higher for experience goods than for search goods, since firms need to continuously entice a consumer to engage in a trial with the experience good and to remind him or her of previous successful consumption experiences so that he or she won't defect to another product. Brand loyalty tends to be stronger for experience goods than for search goods.

Although precise demarcation between search and experience goods and their attributes is not possible, the distinction is useful and informative, and it helps us to interpret advertising-to-sales ratios for pharmaceuticals. In 1998, for example, ratios for primarily "search good" companies were Home Depot, 1.6 percent; Phillips Electronics, 2.4 percent; American Express, 3.2 percent; Circuit City, 4.5 percent; Sony Corporation, 4.7 percent; and Intel, 5.8 percent. In contrast, 1998 ratios for "experience good" companies were Ralston Purina, 14.9 percent; Wendy's International, 16.7 percent; Coors, 18.8 percent; McDonald's, 21.1 percent; Estée Lauder Cosmetics, 22.2 percent; Revlon, 24.0 percent; and L'Oréal, 26.5 percent.²²

Clearly, prescription drugs are predominantly experience goods, and thus one would reasonably expect that advertising-to-sales ratios for them would be relatively high. Moreover, since physicians primarily make prescribing decisions, much pharmaceutical marketing is focused on them, with detailers providing information and free samples to physicians to encourage them to experiment with their product. How one measures total marketing expenditures and ratios for prescription drugs is inherently ambiguous and problematic, particularly when marketing involves traditional and less traditional promotions. If one includes as components of marketing journal advertising, detailing to physicians, product samples, and direct-to-consumer (DTC) marketing, ratios of 10–20 percent are not unreasonable estimates. Using this definition of marketing, IMS Health estimates that in 1999 drug companies spent \$13.9 billion on marketing, which when combined with IMS Health final sales estimates of \$113.0 billion, yields a marketing-to-sales ratio of 12.3 percent. This is a higher ratio than for, say, Sony at 4.7 percent, but is lower than that for McDonald's at 21.1 percent.

In the past decade, U.S. drug companies have marketed their experience goods aggressively. Marketing provides technology-transfer information to patients and providers on efficacy in the treatment of specific medical disorders based on clinical trial data; the incidence of side effects, adverse interactions, and contraindications; pharmacokinetic properties involving half-life and dosage; and, in the naturalistic environment outside the clinical trial setting, effectiveness information on post-launch product surveillance evidence, actual dosages, off-label usage (when appropriate), subpopu-

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lation differentials, tolerability, and cost-effectiveness. Pharmaceutical marketing is subject to regulation by both the FDA and the Federal Trade Commission. Nonetheless, it is frequently the focus of considerable controversy involving the extent to which appropriate information for physicians or patients is fully disclosed.

DTC marketing. In 1997 the FDA announced guidelines that relaxed restrictions on prescription drug advertising, particularly for television. Since then, DTC marketing has risen sharply. DTC drug advertising appears primarily to involve products that deal with conditions that are chronic or episodic rather than acute, are not life-threatening, have widespread incidence, and are likely to be undertreated. In most cases, the first drug that is advertised directly to the consumer is the market sales leader in that therapeutic class. At \$1.8 billion in 1999, total DTC advertising spending for pharmaceuticals was up 40 percent from 1998. In 1999 about 58 percent of DTC marketing dollars involved television, 40 percent magazines, and 2 percent newspapers.²³ Research on the effects of DTC marketing on health status, physician/patient relationships, and pharmaceutical use is still rather lean and deserves high priority.

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■ **More aggressive marketing ahead.** I expect that we are likely to see even more aggressive and intense pharmaceutical marketing in the future. There are several reasons for this. First, the U.S. population is aging, and people are now living to an older age when new or different illnesses afflict them, with many of these illnesses requiring medications. Some medications are needed simply to offset the side effects of others.

Second, many new products will continue to be launched, and since marketing efforts are particularly intense at the time of new product launch, overall marketing intensity will grow. Moreover, many of these new products will be entering therapeutic classes with one or more existing products, and it is well known that marketing-to-sales ratios tend to be successively higher for subsequent entrants that have to overcome others' early-mover advantages.²⁴ Information concerning differential patterns of side effects and adverse interactions, not just on efficacy, will likely be stressed. In such contexts, marketing rivalries are likely to be particularly intense.

Third, new drugs will increasingly be "lifestyle" products, such as Propecia and Rogaine for hair loss, and Viagra for erectile dysfunction. Since third-party insurance often declines to cover such products, DTC marketing will be particularly important. Finally, we live in an era in which consumers are demanding more information, consumer empowerment is promoted, and consumers are increasingly focused on self-medication. Consumers want more information, and such an environment induces more, not less, marketing.

WHILE A SIMPLE RETROSPECTIVE decomposition of past growth in utilization is not feasible, I speculate on which of the four factors discussed here are likely to be prominent in the future. With respect to “the importance of being unimportant,” I believe that the days of benign neglect are over, although at 8 percent the prescription drug share of total health care costs is still modest. In terms of continued growth in insurance coverage for prescription drugs, I do not foresee much growth in private insurance coverage (particularly if the U.S. labor market softens), but the role of public coverage, such as Medicare, could increase sharply depending on congressional and state policy developments. As to continued successful new product innovations, the amount of R&D being undertaken by pharmaceutical and biotechnology firms is enormous, aided in part by interactions among the genomic and information technology revolutions. While uncertainty always figures prominently in the success of pharmaceutical and biotech R&D, the sheer massive amount of R&D in process bodes well for new product introductions in the near future. Over the longer term, however, the amount of R&D efforts undertaken will depend critically on the extent to which governments will exercise buying power and effectively control prices. That, too, is now being debated. Finally, with respect to drug marketing efforts, the future is, I believe, much less uncertain—you can bet they will be there in full force.

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5. See R. Levy, *The Pharmaceutical Industry: A Discussion of Competitive and Antitrust Issues in an Environment of Change* (Washington: Federal Trade Commission, March 1999).
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