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Prologue: America’s pharmaceutical industry, which year in and year out has been among the most profitable sectors of the economy, is being subjected to a variety of strong pressures that could squeeze its bottom line. One of these pressures is the evolution of system that integrate the financing and delivery of appropriate health care services, which have come to be labeled “managed care.” Under this rubric are a diverse variety of entities ranging from health maintenance organizations (HMOs) to modified fee-for-service programs that closely examine the professional behavior of providers through utilization review and case management, and provide financial incentives for patients to use the plan’s providers. In this paper, Michael Pollard examines how the managed care enterprise is changing the pharmaceutical industry. Pollard, a partner in the Washington law firm of Michaels and Wishner, formerly worked for the Pharmaceutical Manufacturers Association (PMA) as director of its Office of Policy Analysis (1983–1988). He counts among his current law clients a third-party drug claims processor and mail service pharmacy and several pharmaceutical companies. Before joining PMA, Pollard, who holds graduate degrees in law and public health from Harvard University, worked at the Federal Trade Commission (1978–1983), concluding his experience there as assistant director for service industry practices of the Bureau of Consumer Protection; and at the Institute of Medicine (1974–1978). As Pollard points out, the pharmaceutical industry, long multinational in its orientation, has become much more concentrated in the past several years as the consequence of eight major mergers. One reflection of the dramatic change in attitude of these companies toward managed care is that five years ago many of them refused to deal with HMOs that demanded drug price concessions. Today, all major U.S. manufacturers have created marketing units to deal with managed care clients.
The U.S.-based pharmaceutical industry is robust and profitable. But, as are other sectors of the economy, the industry is undergoing profound changes that will influence how it develops and markets new products. These changes have come about in reaction to several environmental factors, including marked changes in European markets, consolidation of the U.S. hospital industry, the growth of health maintenance organizations (HMOs) and other forms of managed care in the United States, greater sophistication on the part of the purchasers of prescription drug benefits, and the aging of populations in all developed countries. The pharmaceutical industry has responded by allocating more resources to research, particularly for geriatric products, and by expanding marketing activities geared toward managed care clients. Discounting, especially to large customers such as hospital systems and HMOs, is occurring throughout the industry for the first time. Also, eight major mergers have been completed during the past four years, thereby enhancing the capacity of the “new” companies to compete across several product lines both domestically and abroad.

Here I address the long-term effects of efforts to contain health care costs in the pharmaceutical industry, particularly those efforts that can be described as “managed care.” For purposes of this article, managed care includes prepaid health plans and those fee-for-service insurance programs with active utilization review and case management. I explore the implications of these market forces on industry consolidation, research priorities, marketing, and future participation by industry in government-sponsored prescription drug benefit programs.

### Recent Developments In The Pharmaceutical Industry

**Legislative developments.** In September 1984, Congress passed the Drug Price Competition and Patent Term Restoration Act (P.L. 98-417), which accelerates the approval of generic versions of brand-name drugs once the patents expire. The act also restores up to five years of patent life for those drugs for which it can be shown that regulatory approval by the U.S. Food and Drug Administration (FDA) delayed introduction into the market for at least that long. The 1984 legislation, once implemented, led to the rapid approval of scores of generic products and resulted in precipitous declines in sales for a few popular brand-name medications once their patents expired. This change in regulatory policy had severe dislocating effects on certain firms and in some cases, such as at Hoffman-LaRoche, led to large reductions in personnel.

Recently, FDA policies and procedures have come under scrutiny for abuses that occurred during the review and approval of the generic
products that were cleared for marketing shortly after the 1984 act. The "generic drug scandal" of 1989 called into question the safety and effectiveness of generic versions of several drugs that were approved since 1985. While only a handful of generic manufacturers have been implicated in the scandal, it has undermined the credibility of the entire generic drug industry.

In April 1988, Congress passed the Prescription Drug Marketing Act (P.L. 100-293), which severely limits the sampling activities of drug manufacturers and imposes stiff penalties for failure to observe safeguards against diversion of free drug samples into regular sales or illegal drug distribution channels. This legislation, combined with the growth of managed care programs, stimulated many pharmaceutical manufacturers to rethink their marketing and sales strategies. By 1989, one survey showed that 56 percent of practicing physicians belonged to at least one managed care program and that over one-third of physicians reported receiving drug prescribing guidelines from an HMO or a preferred provider organization (PPO) in which they participate. Thus, tried and true marketing efforts targeted on individual physicians are becoming less effective in moving products because physicians often do not make the ultimate decisions in selecting drugs.

**Introduction of formularies.** Until quite recently, pharmaceutical manufacturers were able to develop and market new products to physicians without much, if any, interference from third-party payers. Despite sustained growth in third-party payment for prescription drugs, most programs during the 1970s did not pressure physicians to prescribe certain drugs or to use generic versions of multisource products. However, these halcyon days for the pharmaceutical industry came to an end in the 1980s, as employers and government programs began to monitor health costs more closely and adopted incentives for or imposed restrictions on drug product selection. This process began in hospitals through the use of drug product formularies, which are lists of drugs approved for use in the hospital by a pharmacy and therapeutics committee. The growth of HMOs expanded the use of drug formularies to ambulatory care outside of an institutional setting. State Medicaid programs also clamped down on prescription drug benefits through their own maximum allowable cost and formulary programs. Last year, third-party payment accounted for 41.5 percent of retail prescription drug sales. Some of these payers aggressively enforce generic and therapeutic substitution prescribing protocols.

**Utilization review.** Utilization review of prescription drugs also came of age in the latter half of the 1980s, enabling insurers, managers in hospitals and HMOs, and drug claims processors to develop sophisticated
profiles of both physicians and patients. These profiles may become the basis for physician education programs (so-called counter-detailing) and hold great potential for future patient-oriented education. Numerous reports of inappropriate drug use and the low level of patient compliance with prescribed drug regimens were published. Mechanisms to deal with these problems were developed and are used by some providers, such as patient package inserts, telephone advisories, and preprogrammed reminder devices.

**Effect of drug wholesalers.** During the 1980s, drug wholesalers captured a much bigger share of sales, and direct sales by manufacturers to retail pharmacies declined proportionately. Today, wholesalers account for about 70 percent of all sales by manufacturers. This shift in the distribution of prescription medicines facilitated the current era of prescription drug discounting and multitiered pricing, the likes of which were previously unknown in the ethical pharmaceutical market. Because of the dominance of the wholesalers, the industry developed a complex network of rebates and value-added services to attract and retain sales to large purchasers, particularly in drug product classes with several competitors and marginal therapeutic differences among products in that class.

**FDA-approved over-the-counter drugs.** Last, but not least, FDA approved several prescription or legend drugs in the late 1980s for sale without a prescription, or “over the counter.” The significance of this development is twofold. First, it has big cost implications for third-party payers, most of whom do not cover over-the-counter drugs. Ibuprofen is an excellent example of a product that is available as a prescription drug and as an over-the-counter product. Many HMOs suggest that their physicians rely on the over-the-counter version of the drug as the first step in therapy for inflammation and pain. Subscribers buy the drug without a prescription, and the HMO does not have to pay for it under the prescription drug benefit.

Second, today’s consumers are much better informed about drugs, and for many conditions—such as allergies, pain, or skin problems—they prefer to self-medicate. Marketing a familiar prescription drug directly to these individuals as an over-the-counter product can be a highly effective technique for boosting sales once the product goes off patent or is eclipsed by a newer form of prescription drug therapy. As the power of physicians wanes in the area of drug product selection, smart manufacturers will be positioned to move prescription drugs into over-the-counter status, if possible, so that consumer advertising can be used to build brand identity and product loyalty, and ultimately boost sales.
The Tension Between Innovation And Cost Control

The pharmaceutical industry is rooted in the soil of innovation; new products, preferably patentable, are its cash crop. In the past, pharmaceutical firms could market new products simply by telling doctors about their superior therapeutic properties and ease of administration. Price was rarely discussed, because physicians did not pay for the drugs, patients did. As third-party payment has grown, both in government and private-sector programs, so has pressure for drug manufacturers to justify their prices for new products to third-party payers. Perhaps the most significant event for the industry in recent memory is the shift in the stance of insurers and government from simply processing prescription drug claims to becoming well-informed purchasers with a vested interest in getting the best price.

The development of new drugs is a costly and risky enterprise. With U.S. manufacturers plowing as much as 16 percent of their sales back into new-product research and development (R&D), the pharmaceutical industry is among a small number of industries that invest heavily in the future. The pharmaceutical industry is also among a small number of industries that spend heavily on marketing and sales.

The most recent industry-sponsored study of the cost of developing a new prescription drug claims that it costs $231 million in pretax 1987 dollars. The industry argues that the time required to test and obtain approval for newer, more complex medications targeted to the chronic ailments of the elderly is lengthening, thereby reducing the period during which manufacturers can enjoy market exclusivity and recoup their investments in developing these drugs. The industry also argues that modern medicines are the most cost-effective form of therapy and that the high cost of these medications is more than offset by the savings in even more costly surgical and medical interventions, reduction of time lost from work, and reduction in premature death.

The industry’s argument that high prescription drug prices are necessary to sustain expensive research endeavors may fail to evoke sympathetic responses from employers and insurers who are under intense pressure to cut their health care costs. The annual upward climb in the medical care component of the consumer price index is still outpacing general inflation by about twofold, and prescription drug prices are an increasingly visible component in these increases. The cost of several new therapies—such as zidovudine, or AZT, human growth hormone, cancer chemotherapies, and cholesterol-lowering agents—are highly visible manifestations of recent trends in pharmaceutical pricing. During the early 1980s, drug price increases were well into double digits, and it has
only been in the past two years that they have fallen just below 10 percent. The cumulative impact of this trend has fallen upon the elderly most acutely, many of whom take multiple maintenance medications and live on fixed incomes.

Currently, the pharmaceutical industry is investing heavily in cardiovascular research: almost 30 percent of U.S. pharmaceutical R&D is devoted to this product class. Neoplasms, central nervous system drugs, and anti-infectives are the next largest drug classes in terms of R&D spending. These four categories of drugs account for about 75 percent of all industry-sponsored pharmaceutical R&D in the United States.

Globalization Of The Industry

The pharmaceutical industry has long been multinational in scope, but eight recent mergers have brought home the increasingly global focus of corporate leadership. Three of the mergers have involved foreign companies as the acquirer—Beecham, Roche, and Rhone-Poulenc. However, even with the mergers among U.S.-based companies, the new management teams in several of these companies are weighted toward individuals with substantial experience in managing overseas operations.

The conventional wisdom in the industry is that a firm must be of sufficient size to be successful in both the United States and foreign markets. Currently, the threshold appears to be $3 billion in annual sales. However, recent mergers—such as Bristol-Myers and Squibb—have produced combined operations in excess of this threshold (Exhibit 1).

In the pharmaceutical business, there are economies of scale in two critical areas: research and marketing. If, in fact, the cost of developing new chemical entities is as high as the industry claims, then it makes sense to spread these costs over a bigger revenue base. It also makes sense to

<table>
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<th>Exhibit 1</th>
<th>Recent Consolidation In The U.S. Pharmaceutical Industry</th>
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<tr>
<td><strong>Acquiring firm</strong></td>
<td><strong>Purchased firm</strong></td>
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<tr>
<td>American Home Products</td>
<td>A.H. Robins Company</td>
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<tr>
<td>Beecham Group PLC</td>
<td>SmithKline Beckman</td>
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<tr>
<td>Bristol-Myers Company</td>
<td>Squibb Corporation</td>
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<td>Eastman Kodak Company</td>
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<td>Monsanto</td>
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<td>Rhone-Poulenc SA</td>
<td>Rorer Group</td>
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<td>Roche Holdings</td>
<td>Genentech</td>
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have more irons in the fire, given the number of promising new drugs that never make it beyond the first phases of human testing.

### Changes In Marketing And Sales

On the marketing front, the expansion of sales forces—which has been under way for the past five years, largely in response to new markets such as managed care systems—has created some excess capacity, which increases costs. The current wave of consolidations means that sales representatives will probably be expected to detail more products than previously and, when dealing with large purchasers such as hospitals or HMOs, may be expected to negotiate a full product-line agreement. In the context of managed care and large purchasers, it makes sense for manufacturers to have more products when the company’s sales representative makes a call. The cost of each of these visits is high, and the time with the physician or pharmacy manager is typically brief. Thus, the sales representative must be able to move quickly to other products if the customer’s reaction to the initial pitch is negative.

The groundwork for the consolidation of sales forces began a few years ago, when several major firms adopted a spate of comarketing and licensing agreements. These arrangements, short of a merger, provided firms with valuable field experience in offering an expanded product line. Today, as the result of mergers and still extant licensing or comarketing agreements, many pharmaceutical companies are or soon will be marketing a full product line under the banner of one corporation.

### Introducing Price Competition In Government Programs

The pharmaceutical industry, represented in Washington by the Pharmaceutical Manufacturers Association (PMA), has opposed any change in existing federal health programs that would restrict drug product selection or might lead to price controls. PMA staunchly opposed the Medicare catastrophic prescription drug benefit and came out strongly against the Medicaid reform legislation introduced 10 May 1990 by Sen. David Pryor (D-AR). Senator Pryor’s bill, the Pharmaceutical Access and Prudent Purchasing Act of 1990 (S. 2605), would enable state Medicaid programs to negotiate with pharmaceutical manufacturers for lower drug prices, in line with the discounts already obtained from manufacturers by hospitals, HMOs, mail service pharmacies, and the Department of Veterans Affairs (VA).

State Medicaid prescription drug programs have come under severe financial pressure because of the substantial increase in drug prices during
the 1980s. Most states have resorted to cost-cutting measures—such as using negative formularies, increasing coinsurance for recipients, limiting reimbursement to pharmacists, and excluding categories of drugs from coverage—that often have the perverse effect of reducing access to needed medicines for some Medicaid recipients. Senator Pryor’s bill is a bold reversal of roles for Medicaid, from being simply a vendor payment program to being a purchaser of prescription drugs, aggressively negotiating with manufacturers for the best possible price. This change in roles, if it occurs, would mirror the change that has been taking place among private insurers and providers.

The other controversial element of the Pryor bill is its recognition of therapeutic alternatives within therapeutic categories. If enacted, states would be encouraged to designate certain drugs as “preferred,” based on the prices that can be negotiated with manufacturers. The industry has long contended that each drug in a therapeutic class has unique qualities that make it impossible to restrict physicians’ choices to only a few drugs in that class. They are, in essence, saying that there are no therapeutic alternatives. If this were true, it would be very difficult for even large purchasers, such as state Medicaid programs, to achieve leverage with manufacturers. If they impose no restrictions on drug product selection, their purchases of any one drug would be much too small to warrant volume discounts. However, by limiting the number of preferred drugs in each therapeutic category to only a few, purchasers can greatly enhance their power to negotiate lower prices. Government agencies, hospital systems, HMOs, buying groups, and mail service pharmacies have been using variants of this technique to obtain significant discounts from drug manufacturers for the past few years.

### Industry Responses

Pharmaceutical manufacturers have adopted a variety of responses to the demands of cost containment and managed care. Five years ago, many pharmaceutical firms refused to deal with group- and staff-model HMOs because they imposed restrictions on sales representatives and demanded price concessions. Today, all major U.S. manufacturers have designated units within their marketing departments that deal with managed care clients. Three years ago, some manufacturers refused to discount their prescription drug products, claiming that they had a “one price policy.” Today, all U.S. manufacturers acknowledge that they discount and that the discounts can be substantial for certain product lines where competition is intense. In April 1990, PMA launched a major public relations and lobbying effort questioning the merits of Senator Pryor’s attempt to
make the Medicaid program a more prudent purchaser of prescription drugs. On April 19, Merck Sharp and Dohme unilaterally offered to cut its prices to state Medicaid programs down to its best discount, which is the price it charges to the VA.\textsuperscript{15} Shortly, four other manufacturers endorsed Merck’s offer.\textsuperscript{16}

The point of these examples is that pharmaceutical manufacturers are being called on to reexamine their positions on a number of business practices, and many companies are moving quickly to change long standing practices, to meet the demands of purchasers. This is a healthy sign. Over the long term, the techniques used by managed care will expand to all segments of the health care industry, placing new demands on providers and suppliers alike. The pharmaceutical firms that will survive in this environment will be large enough to sustain expensive research, diversified enough to rebound from the competition of new entrants into their product markets, flexible enough to adopt new marketing techniques in response to bottom-line decisionmakers and restrictions on product selection, and savvy enough to find opportunities in government-sponsored drug benefit programs instead of simply opposing anything that originates in Washington, D.C., or the state capitals.

**Future changes.** Managed care has profoundly changed the way in which pharmaceutical companies conduct their business. In the 1990s, more changes will occur. First, large employers and insurers will demand and receive even greater price concessions from prescription drug manufacturers as a number of high-volume, patented products go off patent. Manufacturers will gladly trade off margins on multiple-source products for volume, when the alternative is greatly reduced sales because of effective formulary management and utilization review. Second, profound changes are likely to occur in the distribution and monitoring of prescription drugs. Employers and insurers will accelerate their demands for pharmacy vendors who can provide sophisticated utilization review, change physician prescribing patterns, and enhance patients’ compliance with drug regimens. This will force consolidation in retail pharmacies, further stimulate the growth of mail service pharmacies, and, in turn, increase pressures on manufacturers to offer discounts to fewer, but substantially larger, pharmacy outlets. Third, intensive scrutiny by federal and state governments of pharmaceutical companies’ pricing policies and increased sophistication of governmental bodies as purchasers will make it difficult for the industry to sustain the pricing policies it employed during the 1980s. Public policymakers are aware of the concessions the industry makes to obtain the business of hospital groups, HMOs, and other large purchasers; they are unlikely to continue to accept less for the beneficiaries of public programs.
Pharmaceutical products have become a much more potent element in modern medical intervention but have achieved much greater visibility with policymakers because of their high cost. At the same time, the tools for monitoring and influencing the use of these products have become much more sophisticated and effective. Thus, it will be more difficult for pharmaceutical manufacturers to gain widespread acceptance of marginally improved therapeutic agents in a managed care environment. Even breakthrough therapies will have to demonstrate their cost-effectiveness in comparison to existing therapies before they are accepted for coverage. However, for those pharmaceutical companies with the vision to develop truly effective new medicines and the willingness to deal on price, the future will be bright indeed.

NOTES

1. For the second quarter of 1990, profits of several U.S. drug manufacturers were estimated to have increased by 18–20 percent, reflecting strong sales of premium-priced new drugs, general price increases, and a weakening dollar abroad. Eli Lilly and Company was the industry profit leader with a 25 percent increase for the first half of 1990 but was closely followed by Merck and Company and Bristol-Myers Squibb at 20 percent. M. Waldholz, “Drug Concerns Likely to Post Earnings Gains,” The Wall Street Journal, 6 July 1990, A3A.


3. In 1988, 94 percent of HMOs surveyed by the Group Health Association of America provided prescription drug benefits, usually with copayments and sometimes with limits on coverage. M. Gold and D. Hodges, “Health Maintenance Organizations in 1988,” Health Affairs (Winter 1989): 127. Forty percent of all HMOs had prescription drug formularies in 1988, with group- and staff-model plans relying on formularies more often than individual practice association (IPA)-type HMOs. HMOs impose other restrictions on drug benefits in an attempt to control costs, such as restricting choice of pharmacy, limiting the days’ supply of the drug, requiring utilization review, and mandating generic substitution for brand-name drugs that are off patent. Marion Managed Care Digest/HMO Pharmacy Edition, 1989.


9. See *Prescription Drug Prices: Are We Getting Our Money’s Worth?*, U.S. Senate Special Committee on Aging, Staff Briefing Paper (8 July 1989).


11. The Tufts University Center for the Study of Drug Development and the Pharmaceutical Manufacturers Association announced the results of this study of ninety-three drugs developed by twelve U.S. pharmaceutical companies at a joint press conference 19 April 1990 in Washington, D.C. The published report was not available when this article went to press.


14. PMA released a six-part series of advocacy papers titled “Medicine in Medicaid: Cost-Effective Health Care for America’s Poor” in April 1990. The papers—covering topics such as differential pricing, restrictive formularies, and therapeutic equivalence—were designed to challenge the assumptions underlying Sen. David Pryor’s legislation.

15. Merck’s April letter to all state Medicaid directors offered to match its federal government contract price in return for assurances that no single-source Merck products would be excluded from state drug formularies. *F-D-C Reports*, “*The Pink Sheet*” (23 April 1990): 2–6.