IMPACT ON THE PHARMACEUTICAL INDUSTRY OF CHANGES IN THE AMERICAN HEALTH CARE SYSTEM: A PHYSICIAN'S PERSPECTIVE†

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I. INTRODUCTION

Since ancient times, an array of natural and synthetic substances, administered orally or in other fashions, have been used in attempts to cure mankind's physical and mental afflictions. Individuals possessing special knowledge in the use of physic or medicines are known as physicians. To this day, the treatment of patients by their physicians almost invariably includes the prescription of medications. For this reason, the development, production, and appropriate use of drugs and medicinal substances is more than just of general interest to doctors; it is at the core of their profession.

Most practicing physicians have taken the pharmaceutical industry for granted. Physicians have an incomplete understanding of the research and development that leads to new drugs, and they are only moderately aware of the regulatory and oversight procedures governing the availability of drugs. The explanation for this lack of knowledge lies partly with the pharmaceutical industry itself. Until recently, the continuing growth and success of the pharmaceutical industry, both in a scientific and business sense, has allowed the industry to focus on the clinical attributes of its products, rather than on the complicated fiscal and regulatory issues involved in making medications accessible to patients. But changes in the economics and nature of medical practice, together with federal and state health care legislative initiatives, are sharply altering this state of affairs.

A. *The Thrust of Legislation*

A detailed discussion of proposed legislation to govern health care in the United States is beyond the scope of this Article. Moreover, because there are so many competing proposals before Congress, it is very difficult to predict the final outcome. A cardinal feature of almost all the legislative initiatives is that they would ensure health insurance for those individuals who, for reasons of affordability, pre-existing medical conditions, employment status, or personal choice, are not currently covered. Universal access to health care is a principle that has been widely embraced. It would be misleading, however, to assume that this praiseworthy motive is the chief goal of the legislative proposals now being considered. In

reality, the primary issue is cost, a matter of concern to governments, to industry, and to all others who have been witnessing the steady and apparently unabating increase in the costs of providing health care.

Legislation encouraging competitive managed care, which appears to be the most widely promoted approach to the cost problem, has already been preempted in key parts of the United States. In states such as California, more than fifty percent of patients receive their health care through health maintenance organizations (HMOs), preferred provider organizations (PPOs), or other structured systems designed to provide efficiency and cost saving in the delivery of care. Moreover, these organizations already are engaged in fierce competition, providing a foretaste of the price pressures that will be encountered in trying to provide medical care. This affects all facets of diagnosis and treatment and, very conspicuously, the provision of drugs and other pharmaceutical products.

In some respects, proposed legislation might simply codify what has already been taking place in the health care marketplace. It is also fair to say that the debate over health care legislation does not necessarily follow parochial political lines: much of what the current Administration is proposing was already coming into existence under previous administrations.

B. Hypothesis

This Article will examine the effects of changes likely in the health care picture on the pharmaceutical industry. Specifically, because this issue is being considered from the perspective of the physician, we will examine the following hypothesis: namely, that because the pharmaceutical industry is so integral to all facets of medical care, major changes in the industry, whether provoked by legislative or other forces, will markedly affect the professional activities of physicians and medical practices, medical schools, hospitals, insurers, health care organizations, governments, and especially patients.

The questions posed by this hypothesis will be considered under several headings: cost issues, fiscal responses by the pharmaceutical industry to health care changes, effects on research, the impact on patients and their care, and strategies likely to be followed by the pharmaceutical industry in the changing economic environment of health care.

II. COST ISSUES AND THE PHARMACEUTICAL INDUSTRY

Drug prices are driven downwards by the attempts of health care providers to minimize cost.[1] Quite apart from the formalized rules that might affect drug purchasing under the proposed health care legislation, several economic realities already are influencing drug use and selection.

Because of the availability of multiple alternative products within several of the major drug categories, including such commonly used groups as antibiotics, antihypertensives, and non-steroidal anti-inflammatories, purchasers often are able to enforce competitive bidding among pharmaceutical companies wishing to place their products on limited or restricted formularies.[2] Although competing products indicated for a particular condition might not be completely identical, they are often judged to be sufficiently similar to allow a formulary to select one or the other solely on the basis of price. This practice, which is used commonly by managed care organizations with in-house pharmacies or tightly

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[1] In its April 1993 report, the Boston Consulting Group reviewed in detail the actions of organized health care plans that have driven down drug prices. *The Changing Environment for U.S. Pharmaceuticals* (Boston Consulting Group, New York, N.Y.), Apr. 1993 [hereinafter *The Changing Environment*]. The report indicates that drug selection is no longer the sole prerogative of the physician, but that insurers, managed care organizations, pharmacists, major employers, and government agencies have moved to reduce overall health care costs by using their authority to select drugs for formulary listings that are less expensive than other available alternatives. *Id.* at 14. HMOs have been especially active in driving down the cost of pharmaceuticals. *Id.* at 17. In addition to restricted formulary availability for expensive drugs, the HMOs have employed such processes as drug utilization review (in which the cost effectiveness of physician prescribing habits is critically analyzed), generic substitution, and aggressive negotiations to ensure discounted drug prices from drug manufacturers. *Id.*

[2] "Formulary" is a formal and widely recognized term that denotes a list of drugs and pharmaceutical products available for prescription within a hospital, a health plan, or other system of medical practice. *Id.* at 18. The entirety of available drug products in the United states is listed formally in the *United States Pharmacopeia*, which is published every few years by the United States Pharmacopeial Convention, Inc. (Philadelphia).

Obviously, it is not practical for individual institutions or plans to carry the full array of products, many of which are old and no longer in common use. There are also multiple redundancies of drug types, and many cases where several manufacturers produce identical or closely similar agents. It is also not practical for pharmacies to carry the full range of drugs; indeed, the cost of capitalizing an unlimited selection, as well as the problems of stocking it, requires some degree of selection. *See The Changing Environment, supra* note 1, at 17. In most institutions, this selection is made by a Formulary Committee, which considers and votes upon the drugs to be made available to prescribing physicians. Administrators have been progressively excluding physicians from this selection process, replacing them with clinical pharmacists and managers with high awareness of the costs of drugs as well as drugs' therapeutic properties.

controlled external formularies, obviously can also be used by hospitals and major clinics.

A further influence on drug prices is the availability of generic products that can be marketed more cheaply than the original branded products once their patent protection has expired. Although the originating pharmaceutical company continues to market its product, inevitably it will be forced to offer marked price reductions to fend off generic competition. It has been claimed that manufacturers of generic drugs do not always adhere to the strict standards of manufacture and testing required by the Food and Drug Administration (FDA), but there has been a growing trend for the major pharmaceutical houses themselves to enter the generic drug business.[3]

A key to the successful marketing of new drug products is to inform physicians of their existence and to demonstrate how these innovative drugs might offer clinical advantages over previous agents. However, to minimize excessive use or awareness of newer drugs, which typically are more expensive to buy than existing products, many HMOs restrict pharmaceutical representatives' access to prescribing physicians.[4] Indeed, in some staff model HMOs, where clinical activity occurs physically within properties controlled by the HMO itself, pharmaceutical representatives often are denied entry.[5] Although there are other sources of information about new drug developments, it is by no means certain that busy physicians can keep up to date in these areas. Again, in HMOs or other similar settings, even the educational and scientific activities of the organization are carefully controlled and monitored by the managers.

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[3] Elyse Tanouye, *Drug Firms Share Risks With Care Givers*, WALL ST. J., Dec. 6, 1993, at B1, B1-B2.

[4] *See* George Anders, *Managed Health Care Jeopardizes Outlook for Drug 'Detailers,'* WALL ST. J., Sept. 10, 1993, at A1. This report describes pharmaceutical company representatives' highly limited access to physicians within HMOs. *Id.* at A6. Kaiser Permanente, one of the Unites States' leading organizations, has established thirty-two rules governing interactions between industry and Kaiser's physicians. *Id.* These rules include a prohibition against pharmaceutical representatives even discussing a drug that has not already been selected for the Kaiser Formulary. Moreover, the rules also forbid distribution at Kaiser facilities of written materials that do not meet Kaiser criteria. Drug manufacturers' representatives may meet with Kaiser doctors only after having prearranged an appointment. *Id.* Furthermore, in situations where more than one drug of a particular type is available on the Kaiser formulary, Kaiser administrators themselves will aggressively counter-detail their own physicians to encourage use of a preferred or cheaper drug. *Id.*

[5] *Id.*

A. An Ethical Dilemma

There is a yet more powerful technique used by administrators of HMOs and other such organizations to reduce drug costs. In essence, physicians are promised a monetary bonus if they prescribe drugs in such a way as to save money. Doctors are encouraged to use drug classes intrinsically less expensive than others, to maximize the use of generic products, and perhaps delay or even avoid the use of medications for certain conditions. Similarly, physicians practicing in their own offices, but who undertake to see patients under capitation contracts from HMOs,[6] are subject to withholds: payments of their annual patient care fees are completed only if they document compliance with corporate cost-saving mandates.[7]

This type of pressure, of course, does not apply only to drug selection. Other types of therapy, and especially the choice of diagnostic tests, can also be influenced by providing physicians with personal incentives to care for their patients in ways that are to the financial advantage of the organization. This can create a serious conflict for physicians, as shown in Figure 1. Indeed, this problem directly affects the fundamental basis of the physician's professional relationship with the patient.

In the traditional practice of medicine, doctors have usually chosen treatments and tests considered to provide the optimal advantage to their patients. This approach at times has been expensive and clearly has created part of the current concern over rising health care costs, but at least patients have not had to fear that quality of care is being compromised by forces external to their

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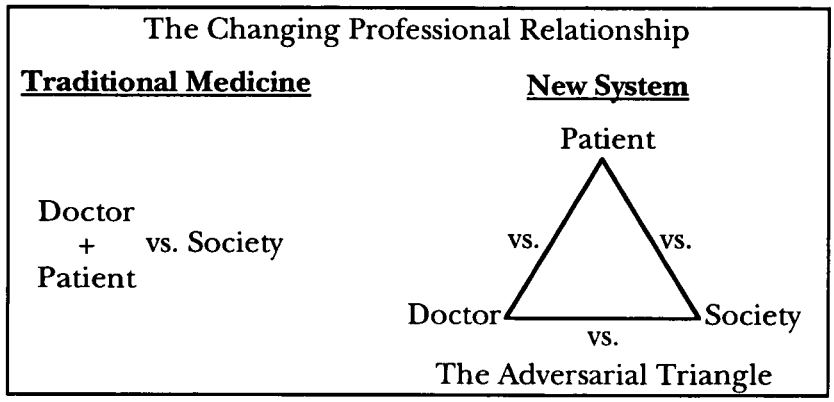
[6] Many HMOs do not directly hire their own physicians, but instead contract with outside individual physicians or medical groups to provide physician services. There are many variations in how these services are funded, but commonly the external physicians undertake to care for patients for an agreed-upon annual fee negotiated on a per-patient basis. This method of payment is termed capitation. Physicians then become responsible for providing full care for the patients allocated to their practices, regardless of the complexity or intensity of these patients' problems. The capitation often includes the primary care physicians' costs in referring patients to specialists, and additionally includes the costs of diagnostic tests. In general, however, the cost of hospitalizations are not included within the capitation agreements, and are carried directly by the HMO. *See generally* INTERSTUDY, COMPETITIVE EDGE: BIANNUAL REPORT OF THE MANAGED HEALTH CARE INDUSTRY (1993).

[7] *See generally Home Sweet HMO?*, AM. MED. NEWS, Aug. 16 1993, at 3. *See also* Elizabeth McCaughey, *No Exit*, NEW REPUBLIC, Feb. 7, 1994, at 21, 21. According to one source, HMOs such as MetLife, Aetna, and Prudential (though not Cigna) require physicians to meet targets of reduced tests, referrals, and hospitalizations. *Id.* at 22. If such reductions are not met, the physicians may face a withholding of between 10-25% of their annual compensation. *Id.*

FIGURE 1



relationship with the doctor. Under the new system, however, there might be very legitimate reasons for patients to feel apprehensive about being advised and managed by physicians whose personal income partly depends on their willingness to deny or avoid treatment options on the basis of price. Given this conflict of interest, there must be serious concern about the integrity of the doctor-patient relationship.

Drug selection is a very obvious part of this situation and, as will be discussed later in this Article, must become an issue of direct involvement by the pharmaceutical industry.

B. Potential Legislative Pressures on Drug Costs

The new federal health care legislation currently being proposed would put strong pressures on drug prices through rules governing the provision of drugs to patients under Medicare.[8] The impact of these rules on the pharmaceutical industry would be substantial, for the Medicare population represents a large proportion of health care expenditures in the United States.[9] Additionally, because there has been a strong trend for other third party payers to

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[8] Some of the details envisaged in the legislation proposed by the White House are listed in Table 1. A more detailed discussion of how some of the downward price pressures on new drug product introduction might have a deleterious effect on research and development is provided by McCaughey, *supra* note 7, at 21-22.

[9] *The Contribution of Pharmaceutical Companies: What's at Stake for America* (Boston Consulting Group, New York, N.Y.), Sept. 1993 [hereinafter *What's at Stake*]. The report explains: "On average, the elderly consume four times as much medical care as do people under 65 because they are ill more often, recover more slowly, and are more likely to suffer simultaneous illnesses, which complicates treatment." *Id.* at 11.

follow the rules and standards imposed for Medicare,[10] the new legislation could have even wider effects. Of course, it is difficult to predict the final form of legislation in this area, and it is quite likely that the original proposals will be watered down or even deleted.

It is not the intention of this Article to describe in detail the proposed Medicare rules, but Table 1 summarizes the benefits and responsibilities for individual patients in the Medicare prescription-drug benefit program, and also lists the requirements directly affecting the prices of drugs set by the pharmaceutical industry. This would not only influence the prices of currently available drugs, but would also govern the introductory prices of newly developed agents. In turn, this cost pressure would influence the decisions of pharmaceutical companies as to whether to develop and introduce innovative forms of therapy. This potential limitation on new developments in treatment justifiably could cause anxiety both to physicians and their patients.

TABLE 1
PROPOSED MEDICARE RULES FOR DRUGS

(i) Medicare Prescription Drug Benefit:
- Beneficiaries Pay 25% Overall
- 20% of Each Prescription
- Limit of $1000 Annually

(ii) Drug Companies Pay 17% Rebate of Average Manufacturer Price: Rebate Even Higher if:
- Bigger Discounts Already Offered to Non-Governmental Non-Retail Users
- Prices Rise Faster Than Inflation
- New Drugs Priced Higher Than Existing Comparables (Council on Breakthrough Drugs)

(iii) Emphasis on Generics

(iv) Prior Approval Required for Non-Cost-Effective Drugs

(v) Physician and Pharmacist "Education"

III. FISCAL RESPONSES BY THE PHARMACEUTICAL INDUSTRY

A. *Financial Pressures*

Current changes in the health care market, together with possible legislative actions, will potentially decrease pharmaceutical company income in two ways. First, competitive pressures will

[10] *See generally* Michael A. Palley, *Payment Changes Require Integrating Records*, HEALTHCARE FIN. MGMT., June 1990, at 52.

force companies to decrease the prices of their branded products. Second, generic competition can be expected to decrease the market share of several widely used branded drugs. This revenue loss is already evoking responses as companies develop strategies to preserve profitability by reducing expenditures. Some of the approaches they are using, especially those of interest to practicing physicians, are listed in Table 2.

TABLE 2
PHARMACEUTICAL COMPANIES: FISCAL RESPONSES

A. REDUCE NUMBER OF EMPLOYEES
- Sales Representatives—Middle Management—Research Personnel

B. REDUCE PRODUCT PROMOTION
- Journal Advertising (Could Be Fatal for Several Medical Journals)
- Mailing to Physicians
- Hospital and Society Exhibits

C. REDUCE EDUCATIONAL SUPPORT
- Grand Rounds and Visiting Professorships (Industry Now Supports Over 50%)
- Scientific Programs and Symposia of Major Medical Societies
- Donations and Corporate Memberships of Professional Societies

D. REDUCE RESEARCH
- Immediate Cash Savings Enhance Profitability and Protect Stock Prices

Many companies have already responded to the ongoing financial pressures by reducing their workforces. Industry wide, 30,000 jobs were cut in 1993.[11] Although this has occurred at all levels throughout the industry, it has become evident to practicing clinicians that there has already been a perceptible reduction in the number of pharmaceutical sales representatives. To some extent, this is not an adverse trend—except, obviously, for the unfortunate individuals who have lost their jobs—because there has been a strong feeling among physicians that they have been besieged by an excessive number of representatives. During the past ten to twelve years, most companies substantially increased the size

[11] *American Drug Firms: Kicking the Habit*, THE ECONOMIST, Dec. 25, 1993, at 90, 90.

of their sales forces, in some instances two- or three-fold.[12] Thus, the current trend to decrease the number of representatives by ten to thirty percent could be regarded as an appropriate rationalization of the sales effort.

B. Promotion and Education

Some of the cost reduction strategies being undertaken by the pharmaceutical industry could have clearly negative impacts on medical, educational, and scientific activities. Advertising in medical journals, which during the past several months has been reduced by at least thirty percent,[13] has long been a financial mainstay for many leading peer-reviewed scholarly journals of medicine. In essence, drug advertising provides a subsidy for these publications, and the survival of the less economically robust journals, including some with strong scientific value, might be jeopardized. Another form of pharmaceutical support for medicine comes through product-related exhibits, often at a substantial fee, at hospital meetings or at clinical societies' scientific sessions. A reduction in this type of promotion also will adversely affect educational activities for practicing and academic physicians.

A reduction in drug companies' direct support for education can also be expected. At present, industry directly sponsors at least fifty percent of grand rounds[14] and visiting professor programs at hospitals and medical academic institutions.[15] Indeed, for many community hospitals the expenses and honoraria required to sup-

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12 *See* C. Marshall Paul, *Time to Cut Back on Detailing*, MED. MARKETING & MEDIA, Oct. 1993, at 94, 94 ("There was a 50 percent increase in the number of pharmaceutical representatives during the 80's . . . . Increases in salesforce size continued into the 90's at the rate of 12 percent per year . . . .") (quoting Larry Levin, President of Scott-Levin Associates, Newton, Pa.).

13 *See The PERQ Report* (PERQ Research Corporation, Wilton, Conn.), Spring 1994.

14 The term "grand rounds" is generally used within the medical profession to describe a formal educational program. Typically, grand rounds are held weekly, and are the most important lecture or teaching event for medical departments. Historically, grand rounds were practical demonstrations and discussions of interesting or instructive patient problems, but more recently grand rounds have become predominantly didactic sessions. In many institutions the grand round is a requirement, or at least there is a strong expectation that all affiliated physicians attend. An interesting history of grand rounds has recently been published. *See* John D. Stobo, *Medical Grand Rounds at Hopkins*, 261 JAMA 3164 (1989).

15 Formal documentation of this 50% figure is not easily obtained. In the author's personal experience, however, as a lecturer and audience member at several hundred grand rounds during the past 20 years at medical schools, academic medical centers, and community hospitals, it appears that markedly in excess of 50% of these programs are provided by direct pharmaceutical industry sponsorship or through educational grants provided by the industry.

port these programs almost invariably are provided by industry sources. Just as importantly, scientific programs and symposia at major medical meetings frequently are sustained by the pharmaceutical industry. Even though this support often is done with the intention of providing visibility for specific products, the majority of pharmaceutical companies have been willing to provide full financial backing for programs that are predominantly scientific and educational in their content. There has been a perceptible drop off in the number of sponsored symposia at major medical meetings during the last year. In addition, pharmaceutical companies often serve as corporate members of major medical professional societies; their gifts, although relatively small in the context of the overall financial position of industry, nevertheless are of great importance to the viability of several scientific professional societies.

IV. Effects on Research

The pharmaceutical industry has made a large financial commitment to research, and a reduction in research activity—even if temporary—has the immediate effect of conserving drug companies' cash resources. In turn, this enhances the companies' profitability and, at least in the short-term, helps protect stock prices. This is potentially a dangerous strategy, however, with negative implications both for the industry and for the whole medical enterprise. Maintaining adequate research in the face of changes in the health care system is a critical issue for academic and clinical medicine, and the nation as a whole.

A. The High Cost of Research

There has been a dramatic increase in the cost of bringing a drug to market during the past several years. The total cost of bringing a drug to market in 1976 was $54 million.[16] It was $125 million in 1984,[17] $231 million in 1987,[18] and $350 million by the early 1990s.[19] The drug development pyramid has an enormous base; to produce one drug for the marketplace, 5000 molecules with clinical potential must be conceived, synthesized, and evaluated by the industry's scientists.[20] Of these, about 500 are found to be worthy of examining in organ preparations; and, in turn, 250

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16 Joseph A. DiMasi et al., *Cost of Innovation in the Pharmaceutical Industry*, 10 J. Health Econ. 107, 114 (1991).

17 *Id.*

18 *The Changing Environment*, *supra* note 1, at 40.

19 *Id.*

20 *See generally* Sol I. Rafjer, *Perspective of the Pharmaceutical Industry on the Development*

are tested in animals.[21] The huge pre-clinical development process ultimately is able to reduce the original 5000 molecules to 5, or 0.1% of the original quantity, that are eligible for evaluation in humans.[22] Even at this advanced stage, only one of these five drug candidates will ultimately be placed on the market.[23]

To some extent, it is possible to attribute this enormous commitment, and the resultant high cost, to regulatory requirements promulgated by the FDA. But it is also likely that with so many drugs already available, it is becoming progressively more difficult to produce new products that genuinely represent much-needed progress. At the same time, concerns about liability have forced the industry to be especially diligent in evaluating all possible safety issues with their new products, including expensive long-term surveillance.

B. Research Pressures: Pharmaceutical Company Perspective

It is difficult to summarize the ways in which pharmaceutical companies are dealing with research issues in the current environment, for it is still too early to focus a clear picture of the strategies being employed to enhance the efficiency of research activities. At present, the pharmaceutical companies appear to spend more of their income on research than any other major industry. It is estimated that approximately one-sixth of industry revenues are directly reinvested into research activities.[24] Because of the current price pressures on drugs, as well as likely limitations on introductory prices of new products, the industry inevitably will be conservative in deciding which new products appear worthy of research investment.

At present, most companies are continuing to support prod-

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of New Drugs for Heart Failure, 22 J. AM. C. CARDIOLOGY 198A-200A (1993); *What's at Stake*, *supra* note 9, at 92.

21 *What's at Stake*, *supra* note 9, at 92.

22 *Id.*

23 *See* OFFICE OF TECHNOLOGY ASSESSMENT, PHARMACEUTICAL R&D: COSTS, RISKS, AND REWARDS 76 (1993) (explaining that "[u]ltimately . . . only 20 of the 100 [new drug] candidates jump all the hurdles and reach the market").

24 *See The Changing Environment*, *supra* note 1, at 35 (pointing out that research and development spending constituted 17% of pharmaceutical sales during the 1980s). A review of spending on research and development by the pharmaceutical industry in the United States has indicated an almost 10-fold increase between 1968 and 1992 based on data provided by the Pharmaceutical Manufacturers Association. *Id.* According to the investigation performed by the Boston Consulting Group, research and development as a percent of gross sales is approximately 17% at the present time. *Id.* The Boston Group also points out that the electronics industry, by comparison, invests less than six percent of its sales in research and development. *Id.*

ucts already on the market, or approaching release, with prudent clinical trials. There is less enthusiasm, however, for truly new products that might demand very expensive research and development budgets. One option for the major pharmaceutical companies is to acquire highly promising products by obtaining licenses to market the products from smaller innovative companies. An extension of this approach, also in evidence, is for the major companies to actually acquire smaller companies that appear to have promising drug pipelines.

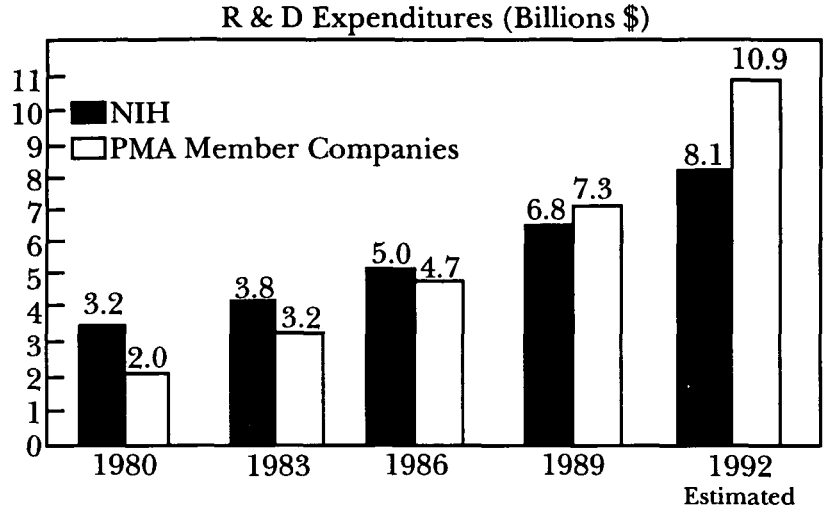
These short-term strategies do not fully address one fundamental research dilemma that the industry will soon face. Quite independent of economic or legislative factors, basic medical science, especially molecular biology, has provided a new understanding of the genetic basis of disease. In turn, highly specific products tailored to selectively treat diseases resulting from abnormal or undesirable genetic characteristics can now be developed. It is likely that the cost of this type of research will be high, and it is also probable that the prices of these types of products will also be greater than those being charged for current state-of-the-art drugs. Clearly, this creates a situation of high risk for the pharmaceutical industry.

Other aspects of pharmaceutical products, however, are unchanging. For the most part, drugs primarily are intellectual property. Their worth is linked to the research that has created them; they have relatively little intrinsic material value. Thus, once a drug is no longer innovative, or its patent has expired, the drug has relatively little commercial value to its manufacturer. The industry has no choice other than to continue with research activities, for without creative work there can be no new products; and without new products, the pharmaceutical industry cannot exist in any meaningful fashion.

C. Research Pressures: Academic Perspective

A large part of the pharmaceutical industry's research and development investments is spent at academic centers, chiefly medical schools. Figure 2 illustrates that research and development expenditures by the major pharmaceutical companies already outstrips the contributions to medical research of the National Institutes of Health (NIH). Although it is difficult to accurately quantify the drug industry's specific funding of projects at academic medical centers, it appears reasonable to estimate that as much as fifty percent of research funding within clinical depart-

FIGURE 2



Source: National Institutes of Health and PMA Annual Survey

ments at medical schools originates with industry.[25]

To a substantial extent much of the industry's investment in medical schools is in support of projects, either basic or clinical, related to the development of pharmaceutical products. But from the perspective of the academic institution, this expenditure by the pharmaceutical industry is of far greater importance than could be envisaged simply by a routine contractual relationship. Much of this funding, although project directed, supports the academic careers of faculty members and is used to subsidize research activities that may be unrelated to the drug projects. Drug trials, for example, are often performed by clinical departments as a means of attracting revenues that sustain basic science laboratories, provide salaries for research fellows who are gaining experience in clinical or basic research, and augment other sources of research support. To some extent, the majority of academic physicians depend on support from industry. In turn, this source of funding plays a

[25] Although firm data are not readily available, it is author's experience that funding for general research activities at clinical departments in the author's own academic institution is derived substantially from industry sources. Personal communications with senior faculty at other comparable institutions suggest a similar state of affairs. A careful survey of the sources of research funding for academic clinical work would be of much interest to industry, health care observers, and the institutions themselves.

meaningful role in maintaining the research, teaching, and clinical trinity that underlies the careers of most academic clinicians.

Two trends now threaten to undermine this important relationship. First, the general reduction in research expenditure by the pharmaceutical industry will inevitably result in fewer dollars being invested in clinical trial activities. Second, in an environment of rigorous cost constraints, private research centers and medical practices can often underbid academic centers and preferentially receive contracts from the industry or its contract research organizations, thus squeezing out the major academic institutions.

The implications of these trends not only portend adverse effects on academic institutions, but have national implications as well. New developments in the basic sciences, molecular biology, applied biology, and human physiology are all seriously threatened by the diminishing income from industrial sources. Despite the important contributions of the NIH and other governmental or public sources of research funding, the pharmaceutical industry has gradually assumed a key role in providing support for advances in medical care—even those that are not directly related to drug development.

V. Impact on Patients

A. *Beneficial Effects of Changes in the Health Care System*

As discussed earlier, patients can derive three general benefits from the proposed legislation. First is the promise of universal access to health care, making such care available to all regardless of financial or employment status. Second is the promise that this universal health care access cannot be limited by previous or ongoing medical conditions. And third, despite expecting individuals to carry a partial financial responsibility for their care, there are limits on the overall burden that could fall to any one individual or family. Clearly, these commitments are all praiseworthy, but they comprise only a small part of the impact and motivation for the overall changes that are envisaged.

B. *Negative Effects from the Patient's Perspective*

Because the relationship between the doctor and patient traditionally has been the cornerstone of medical care, some of the issues affecting physicians, detailed earlier, would have similarly negative connotations for patients.

The issue of drug availability, although quantitatively a relatively small proportion of overall health care cost issues, lends itself

to analysis and is also of obvious relevance to the interests of the pharmaceutical industry. One obvious cost-saving measure is to enforce or encourage the use of less expensive drugs. In turn, from the patient's perspective, this could mean receiving a less-than-optimal treatment choice. This cost-saving can be achieved formally or informally within individual plans, or it can be governed by major central forces.

The proposed rules for Medicare have already been discussed, but major commercial participants in this process already exist. For example, Medco is a corporation providing pharmaceutical services to a large number of health plans. In addition to being a major wholesaler of drugs, Medco advises health plan organizations on their formulary[26] selections, and provides—typically at discounted prices—an array of pharmaceutical products to the health plan participants. To aid in acquiescence with their recommended drugs, Medco employs a large number of pharmacists whose job is to continually call and persuade—or jawbone—prescribing physicians to conform with the Medco range of products. A fascinating complication recently has arisen because of Medco's acquisition by one of the nation's largest pharmaceutical corporations, the Merck Company, for six billion dollars.[27] Clearly this enormous investment provides Merck with an opportunity to promote its products, especially when they are closely similar to brands offered by competitors.

Another way in which HMOs or other plans limit patient access to expensive drugs is by the bottleneck technique. Conditions that require relatively expensive drugs—for example cholesterol abnormalities or Alzheimer's Disease—are often directed to low ca-

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26 See *supra* note 2 for an explanation of institutional formularies and the manner in which drug products are made available to prescribing physicians.

27 Michael Waldholz & George Anders, *Merck to Purchase Medco in $6 Billion Transaction*, WALL ST. J., July 29, 1993, at A3. This highly unusual purchase by Merck & Co., a pharmaceutical company, indicates that the alliance with Medco, America's largest marketer of discount prescription drugs, would certainly shake up the pharmaceutical industry. According to Waldholz & Anders, Merck's purchase

> is certain to intensify price competition among drug makers, which in the past year has pushed down drug company revenues, profit growth, and share prices.
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> . . . .
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> . . . Medco manages the prescription-drug benefit plans for many corporate and government employees through a discount mail-order business and retail pharmacy insurance program. Recently, Medco has become particularly effective in wringing sharp discounts from drug makers and signing up corporate customers by passing on the price savings.

Id.

pacity specialty clinics. Only the doctors assigned to these clinics have the authority to prescribe the appropriate drugs. Moreover, other doctors wishing to refer patients to these clinics must first document that they have exhausted all the more simple remedies before their patients can become eligible for the "specialist" care. Inevitably, the referring physician's frustration, and the long, inconvenient delays that patients must endure while waiting for an appointment to become available, effectively limit utilization of the more expensive modern treatments.

A second recent issue attracting much publicity was the decision of the Kaiser HMO not to include the recently marketed agent tacrine (Cognex) in its formulary.[28] Cognex is the first drug approved by the FDA for the treatment of patients with Alzheimer's disease.[29] In its approval process, which is acknowledged to be the most meticulous and rigorous in the world, the FDA acknowledged that Cognex had a favorable efficacy and safety profile. Cognex cannot prevent the ongoing deterioration associated with Alzheimer's disease, but through both psychometric testing and physician assessment, Cognex clearly improved intellectual function. Despite the FDA approval and recognition of potential beneficial effects of this agent, the Kaiser formulary decided that the benefits of treating its patients with this drug were not worth the price of three dollars per day.[30]

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[28] See *supra* note 2 for a definition of formulary.

[29] *See* 55 F-D-C REPORTS—THE PINK SHEET (Chevy Chase, Md.) Sept. 13, 1993:

> Warner-Lambert's Cognex (tacrine) was approved Sept. 9 by FDA for the treatment of patients with 'mild to moderate dementia of the Alzheimer's type.' Cognex is the first drug approved specifically to treat symptoms of Alzheimer's, which the FDA estimates affects four mil[lion] people in the U.S. and results in the deaths of 100,000 people annually.

Id.

[30] Harvey Schwartz, *HMO's—Another Road Block for Alzheimer's Drug*, WALL ST. J., Oct. 5, 1993 at A16. This report describes the approval by the FDA of the drug for Alzheimer's disease, Cognex, and indicates that fee-for-service physicians "no doubt will write prescriptions for patients they think may be helped by Cognex." *Id.* But Schwartz points out that two major HMOs, the Northern California Kaiser Permanente and the Group Health Cooperative of Puget Sound, have shown great reluctance to make the drug available to their patients. *Id.* Northern California Kaiser decided to ban Cognex from its formulary, and has planned to issue an information sheet explaining to its members why it is not making this drug available. *Id.* The Puget Sound Group has made a similar decision, but since it is a cooperative that is ultimately governed by its patient members, this decision may well be overturned. *Id.* Schwartz also points out that this drug would cost between $1300 to $1500 per year for each patient. *Id.* Moreover, the article discusses the economic basis for Kaiser's decision, indicating that the addition of any new form of treatment must be offset by an accompanying saving in another area if the HMO is to maintain a constant expenditure on its services. *Id.*

Regardless of the scientific and clinical aspects of this issue, Kaiser's decision to withhold access to Cognex, despite the FDA's approval, must inevitably provoke concern and a reaction by its patients. Indeed, Kaiser may well be forced to modify its decision, but the impact of this important precedent remains. This situation leads to some interesting further questions.

For example, will other HMO plans make the opposite decision and add Cognex to their formularies, thus demonstrating in a highly competitive marketplace that their plans offer a greater depth of care and compassion than Kaiser's plan? Or, will the competing HMOs take a more passive stance and follow the lead of the Kaiser formulary in denying patients access to treatment with Cognex?

A further issue, albeit not directly drug related, recently arose in dramatic fashion when the Health Net HMO in California withheld therapy from a woman with breast cancer.[31] The patient died after the HMO had decided not to provide bone marrow treatment for her advanced disease.[32] In the Riverside (California) Superior Court, a jury awarded the patient's family $12.1 million in compensatory damages.[33] But of even greater weight, the jury then ordered the HMO to pay an additional seventy-seven million dollars in punitive damages.[34]

The most interesting aspect of this case was not the argument over the merits of the treatment, or even the legal obligations of the HMO or insurer. Rather, the case was characterized by the outrage of the jury upon learning that Health Net HMO, while denying treatment to the dying woman, provided their corporate ex-

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In an interesting argument, Schwartz points out that the majority of patients within an HMO, at any given time, are in good health; only a small minority have illnesses that would stimulate them to fight for an upgrade in their treatment. *Id.* Thus, while the majority of patients are disinterested and unorganized,

> the staff [in the typical HMO] usually has potent incentives to economize . . . . It is normal in HMOs for primary care physicians to have quotas as to how many tests they may order, how many outside consultants they may refer to, and how many prescriptions they may write. Moreover, bonuses are frequently offered to doctors who cut extra costs appreciably below their quota levels.

Id.

Parenthetically, it is possible that the drug could delay the need for nursing home placement—at approximately $30,000 per year—for some of these patients. Of course, Kaiser usually is required to pay for the drugs, but not for nursing homes.

31 Tom Gorman, *Jury Adds $77 Million Against HMO That Denied Coverage*, L.A. TIMES, Dec. 29, 1993, at A1.

32 *Id.* at A2-A3.

33 *Id.* at A1.

34 *Id.*

ecutives with financial incentives and bonuses for refusing to authorize expensive procedures and treatments.[35] Although this is a relatively extreme example, it indicates that the general public, most of whom sooner or later become patients, will not tolerate health care plans whose financial success or profitability appears to be predicated upon denying contemporary standards of treatment. The availability of modern drugs, which sometimes provides moderate advantages over older products but for a somewhat greater price, readily falls into this area.

In support of this trend, some articles[36] have reported results of questioning patients on those aspects of medical care that the patients would be least willing to sacrifice in any planned changes in the health care system. Out of several choices, access to new drugs and technology was listed as the most important attribute to preserve.[37] Access to health care regardless of age was second on the list, and third, the freedom of patients to choose their doctors.[38] Other choices, including malpractice limits or mandatory second opinions, were ranked lower.[39]

Although the top three selections are probably not really surprising, the results of this survey seem to send a strong message that patients, perhaps even more than physicians themselves, do not appear willing to accept compromises in the quality of their treatment with state-of-the-art pharmaceutical products and other therapeutic techniques.

C. *Cost-Effectiveness and Outcomes Research*

Health care economists are always careful to differentiate between the terms "cost saving" and "cost effectiveness." Cost saving generally implies a short-term strategy in which goods or services are acquired for the cheapest possible price, often without regard to long-term economic consequences and therapeutic results.[40] In

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35 *Id.* at A3.

36 *See, e.g., Health Care Crisis: Satisfaction and Sacrifice,* MED. BENEFITS, Aug. 30, 1992, at 7.

37 *Id.* at 6.

38 *Id.*

39 *Id.*

40 Robert M. Goldberg, *Pharmaceutical Price Controls: Saving Money Today or Lives Tomorrow?,* IPI POLICY REPORT No. 123 (Institute for Policy Innovation, Lewisville, Tex.), Sept. 1993 (Introduction). This article makes the argument that pharmaceutical products, even when relatively expensive, are net savers of health care dollars because they treat conditions that would otherwise require expensive surgery. *Id.* The report also provides data indicating that drug therapy for coronary artery disease costs approximately $1000 per year compared with $41,000 for bypass surgery; drug therapy for ulcers costs $900 compared with $25,000 for surgery; and drug therapy for

turn, the choice of an inexpensive cost-saving drug that fails to prevent a serious medical complication, which thereafter results in an expensive hospitalization, would be less cost-effective than a more expensive product that successfully achieves its goals.

Recently, the State of New Hampshire issued restrictive pharmaceutical guidelines for its Medicaid program: patients were each limited to a maximum of three drugs.[41] This cost-saving measure backfired. Nursing home admissions, which are a far more expensive proposition than drug therapy, rose in these patients, and almost certainly increased overall costs.[42]

Heart failure, which is the most common reason for hospital admissions in the elderly, provides a further illustration of the drawbacks of cost-saving initiatives. Effective outpatient treatment for heart failure usually requires the use of three separate drugs (a diuretic,[43] an ACE inhibitor,[44] and digitalis[45]), quite apart from the drugs needed to manage other concomitant problems. The combined cost of heart failure drug treatment is less than two dollars a day. The cost in 1989 of a typical hospitalization for heart failure, often necessitated by inadequate outpatient drug treatment, was $6,373.[46] Other research has shown that patients who reliably take their medications have significantly reduced needs for physician and laboratory services.[47] It is not difficult to argue that drug ther-

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depression costs $5000 per year compared with $73,000 to institutionalize an individual. *Id.* at 2. The basis for these numbers is not clearly explained, but it is possible that—if anything—the estimate of drug costs may actually be excessive. Unfortunately, without specific examples of drugs being given, it is not possible to form an accurate assessment. Nevertheless, the article appears, overall, to argue convincingly that drug therapy is a highly cost-effective alternative to other treatment modalities.

41 *What's at Stake, supra* note 9, at 145.

42 Stephen B. Soumerai, et al., *Effects of Medicaid Drug-Payment Limits on Admission to Hospitals and Nursing Homes*, 325 NEW ENG. J. MED. 1072, 1074 (1991).

43 Diuretics are drugs that have their primary actions within the kidney and facilitate elimination of sodium and water from the body.

44 ACE (angiotensin converting enzyme) inhibitors are drugs that work on the renin angiotensin hormone system, specifically blocking formation of angiotensin II. Because this hormone is responsible both for raising blood pressure and for increasing the resistance against which the heart has to pump, the ACE inhibitors are commonly prescribed for the treatment of hypertension (high blood pressure) and congestive heart failure.

45 Digitalis is an ancient medicinal product that is derived from the purple fox glove. Originally, the drug was administered as a powdered form of the plant leaf, but now is administered as tablets of the derivative, digoxin. This substance has a stimulatory effect on the contraction of the heart, and thus helps the heart to perform more effectively in patients who have congestive heart failure and certain other cardiac abnormalities.

46 Rajfer, *supra* note 20.

47 David A. Sclar et al., *Utility of a Transdermal Delivery System for Antihypertensive Therapy, Part 1.*, AM. J. MED., July 18, 1993, 1A-50S, 1A-5053S (Supp.).

apy appears to be the most cost-effective approach to overall medical care.

Outcomes research[48] has become the vogue expression to describe the evaluations of treatment, typically with pharmaceutical products, in terms of the treatment's ability to provide benefits that go beyond the obvious immediate pharmacologic actions of the drug. Of course, outcomes can be measured in medical and human terms as well as in economic or resources terms. But issues that so obviously mix human and economic variables often cannot be resolved satisfactorily, and can create conflicts between patients and health care providers.

One illustration is the controversy over performing surgery for prostatic cancer in men over a certain age. It is possible that this procedure, even if curative, may not be justified in terms of the cost of surgery, hospitalization, and rehabilitation because many of the men afflicted with this condition would, in any case, die of some other cause before their cancer proved fatal. Indeed, the argument can go one step further: if it is unlikely that cancer treatment for a man of a certain age would be offered, why even perform the examination or tests that might reveal its existence?

A similar situation could easily arise in the context of drug therapy. For example, effective treatment of cardiovascular risk factors in young people could markedly delay serious events. But for people already in old age, especially if other medical conditions are already present, the benefits of treatment—even if proven statistically—are clearly more modest in terms of prolonging life.[49]

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48 Bryan R. Luce & Kit Simpson, *Methods of Cost Effectiveness Analysis: Areas of Consensus and Debate*, PHARM. MANUF. ASS'N (Battelle Med. Tech. Assessment & Policy Res. Ctr., Washington, D.C.), Apr. 22, 1993, at iv. In general, evaluations of cost-effectiveness in medicine remain an area of controversy. Extreme examples are easily understood. An inexpensive vaccination of a child that prevents serious or fatal illnesses later in life clearly is an example of a highly cost-effective maneuver. On the other hand, spending tens of thousands of dollars on major diagnostic tests and procedures to minimally palliate or delay the inevitable and imminent outcome of a terminal illness would generally be considered not cost-effective. The difficulty in defining cost-effectiveness, however, lies in the more common intermediate situations. Can length of life be translated into dollar terms? What is a reasonable price to pay per year of life saved? How can we truly measure quality of life? How can we measure the negative emotional effects of treatment, or non-treatment, on sick patients and on their relatives and friends? If pursued to their logical conclusion, these issues—and many others like them—quickly go beyond the realm of medicine and economics, and involve religion, philosophy, ethics, personal beliefs, and societal values. Outcomes research tries to simplify this highly complex dilemma by looking for more simple solutions. Some of these approaches are discussed in the text.

49 R. D. Abbott & D. McGee, *The Probability of Developing Certain Cardiovascular Disease in Eight Years at Specified Values of Some Characteristics*, *in* THE FRAMINGHAM STUDY:

A recent controversy in the medical literature has focused on a Coronary Heart Disease Policy Model proposed by public health physicians to guide the cost-effective selection of drugs to prevent heart disease.[50] Disagreements over the interpretations and validity of clinical trials, availability of long-term data for some drugs but not for others, conflicting assumptions about the negative as well as the positive attributes of drugs, contentious statistical questions, and difficulties in measuring patient quality of life, all contributed to angry but inconclusive published exchanges among experts.[51] Rightly or wrongly, the reader was left with the concern that scientific method was being compromised by economic and political issues.

These types of questions, naturally seen by the patient in a different fashion from that of the health plan administrator, are likely to be confronted with increasing frequency in the area of drug products. The Cognex issue, discussed earlier, is an example of this phenomenon. Outcomes research, like any other research, provides data that must then be analyzed and interpreted. The critical question thus arises: how will the lay patient be able to follow the complexities of these issues and be informed adequately about the rationale for being offered certain forms of treatment but not others?

D. The Concept of Prevention

There are few ideas more beguiling than preventive medicine.

AN EPIDEMIOLOGICAL INVESTIGATION OF CARDIOVASCULAR DISEASE (W. B. Kannel et al. eds., 1987).

50 *See* Jonathan T. Edelson et al., *Long-Term Cost-Effectiveness of Various Initial Monotherapies for Mild to Moderate Hypertension*, 263 JAMA 407, 408-11 (1990) (describing the Coronary Heart Disease Policy Model).

51 *Compare* Norman M. Kaplan, *Cost-Effectiveness of Antihypertensive Drugs: Fact or Fancy?*, 4 AM. J. HYPERTENSION 478 (1991) *with* Lee Goldman & Milton C. Weinstein, *Reply to Kaplan*, 5 AM. J. HYPERTENSION 666 (1992).

As discussed in the text, there are many issues in this type of outcomes research that readily lend themselves to controversy. Indeed, the editorial by Dr. Kaplan, which criticized the original outcomes article by Edelson et al. (see *supra* note 50) and provoked the angry secondary response by Goldman et al., used the term "so-called experts" to describe the authors of the original article. *See* Kaplan, *supra*, at 478 ("We must counter these misleading figures whenever they appear from the so-called experts in cost-effectiveness."). Dr. Kaplan's point was not to diminish the integrity or scholarly standing of the authors, but to argue that outcomes research is still so speculative, lacking in guidelines, and poorly supported by credible data, that it is difficult for any authors—regardless of their stature or academic position—to be truly regarded as experts. These disagreements help to highlight the frustrations of many participants in the health care debate at the lack of consistently effective methods of outcomes research.

Vaccination is an excellent example of how a relatively simple and inexpensive procedure at an early age can prevent serious and life-threatening diseases later on. Preventive medicine has taken on broader meanings during the past few years. Persuading patients to stop smoking, for example, is an obvious means of reducing patients' risks of developing such conditions as lung cancer or heart disease.

Other strategies are less obvious in their benefits, and apparently more difficult to achieve. For example, losing weight, reducing the amount of fat or sodium in the diet, and increasing physical activity are strategies thought to be of benefit in helping to control such conditions as high blood pressure or cholesterol abnormalities.[52] One of the main rationales for the HMOs themselves—indeed, the use of the words "health maintenance" in their name—has been the encouragement of such strategies.

It could be argued that these lifestyle modifications help to give patients themselves an active part in being responsible for their own health. This attractive concept, when successful, is obviously pleasing to all concerned. In many instances, for reasons that are not always clear, and which usually do not indicate a lack of interest or commitment on the part of the patient, these lifestyle strategies are ineffective, and it becomes necessary for the physician to prescribe appropriate drugs to control such problems as high blood pressure or high cholesterol. Clearly these forms of treatment can at times be expensive, and it is noteworthy that governmental and other committees[53] have been at work to marshall

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[52] Joint National Committee on Detection, Evaluation, and Treatment of High Blood Pressure, *The Fifth Report of the Joint National Committee on Detection, Evaluation, and Treatment of High Blood Pressure (JNC V)*, 153 ARCHIVES INTERNAL MED. 154, 162-64 (1993).

[53] *See* National High Blood Pressure Education Program Working Group, *National High Blood Pressure Education Program Working Group Report on Primary Prevention of Hypertension*, 153 ARCHIVES INTERNAL MED. 186 (1993) (providing example of the work product of a committee formed to study modes of treatment in the medical profession). This Committee had been established under the aegis of the National Heart, Lung, and Blood Institute, which is one of the National Institutes of Health (NIH). The Committee is made up of experts, chiefly from the academic world, in the fields of cardiovascular medicine, hypertension, and lipid disorders, who have been selected by NIH officials to participate in generating guidelines and recommendations. Such committees are generally respected, especially as they tend to be composed of scholars enjoying high stature in their fields of study. On the other hand, these committees also are vulnerable to criticism, especially if the members are selected on the basis of their known commitments to certain points of view. Are the NIH officials, perhaps analogous to a trial lawyer, carefully selecting only those experts who will help them to make their case? In the case of hypertension recommendations, an editorial indeed has made such an assertion. *See* Michael A. Weber & John H. Laragh,

arguments in support of broad lifestyle modifications for large segments of the population.

Although attempting to modify lifestyle habits is a desirable goal, there is concern that these approaches, which have not yet been subjected to measurements of long-term outcomes, are being proposed more for their potential to save money for health plans, and not for an individual patient's health benefits.[54] It is quite likely, however, especially for chronic conditions such as hypertension, that pharmacologic treatment is more effective than life-style modifications,[55] and such treatment might even be less expensive. But whereas drug purchases usually are undertaken by the health plan, the expenses of dietary modifications and exercise programs are at least partly borne by the patient. Thus, preventive medicine can have the effect of transferring costs from the organization to its subscribers.

Preventive medicine, whether based on pharmaceutical agents or life-style modifications, is influenced by another hard reality. Vigorous competition among managed care plans, apart from putting pressure on premium costs, causes about twenty-five percent of patients to switch from one HMO to another every year. Despite their propaganda to the contrary, there is relatively little incentive for health plans to invest in true long-term prevention. In essence, each of the plans is playing a game of medical musical chairs, hoping that the patient who has a disabling stroke will have it while enrolled with one of its competitors.

E. Who Sets the Rules?

Until recently the choice of drugs or other forms of treatment was made by physicians on a case by case basis for each of their patients. Unless these treatments were potentially dangerous, or perhaps so new as to be yet incompletely understood except by experts, drug selection would be made by doctors on the basis of their own knowledge and experience. The influences of restricted formularies, cost cutting incentives, and jawboning techniques by external pharmaceutical consultants have all markedly altered this freedom of selection.

Who protects the patient in this setting and ensures that ade-

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Hypertension: Steps Forward and Steps Backward, 153 ARCHIVES INTERNAL MED. 149, 151-52 (1993).

54 Weber & Laragh, *supra* note 53, at 149-51.

55 *See* James D. Neaton et al., *Treatment of Mild Hypertension Study: Final Results*, 270 JAMA 713 (1993).

quate state-of-the-art treatment is still being provided? It is becoming more difficult to apply so-called community standards of care in a rapidly changing system, and the major professional medical societies—although recognizing a need to issue guidelines—are not always sufficiently organized or widely based to assume the authority of true leadership in setting standards of care.

The proposed federal health care legislation envisages that certain standards and practices will be conceived and regulated centrally. One recent experience, with interesting implications for the use of drugs, is currently stimulating intense debate in the field of hypertension. Hypertension is very prevalent in the United States, and the NIH (Department of Health and Human Services) helped establish a committee under its aegis referred to as the Joint National Committee (JNC) on the Detection, Evaluation, and Treatment of High Blood Pressure. The JNC, composed of external experts carefully selected by officials of the NIH, has issued therapeutic recommendations on hypertension to the medical community at four-year intervals during the past twenty years.[56]

The recommendations of 1988 (referred to as JNC IV because it was the fourth report of the Committee) included four groups of drugs: beta blockers, diuretics, ACE inhibitors, and calcium channel blockers. At that time, beta blockers and diuretics were already well established for the treatment of hypertension, but the ACE inhibitors and calcium channel blockers were newer classes of agents then becoming recognized as effective newer alternatives. Subsequently, these newer classes have started to dominate the field of hypertension treatment.

To the surprise of most experts in hypertension, the JNC V Report (in 1993), although still advising use of the same four drug classes, actually labeled the older groups—the beta blockers and diuretics—as "preferred."[57] The Committee, which clearly had highly contentious internal deliberations, argued that only the older drug classes have thus far had the opportunity of demonstrating beneficial impacts on morbidity and mortality during long-term follow-up.[58] The newer drugs, the Committee argued, although potentially as good as the older agents—or perhaps even

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56 The Joint National Committee's most recent report was published in 1993. *See* Weber & Laragh, *supra* note 53, at 149-51 (providing references to previous reports by the same committee that extend back twenty years).

57 *See* Joint National Committee, *supra* note 52, at 183.

58 *See id.* at 178 (pointing out that only beta-blockers and diuretics have been used in trials that showed a reduction mortality and cardiovascular morbidity).

better—have not yet been tested in the same way, and thus cannot yet be granted "preferred" status.

Not surprisingly, the JNC recommendation was greeted with dismay and sharp criticism.[59] This criticism stemmed from several well-known facts. First, the benefits demonstrated for the older drugs still are well short of ideal. Moreover, the newer drug classes, although admittedly not yet fully proven in the hypertension arena, have produced cardiovascular benefits that, by reasonable extrapolation, should make them the treatment of choice for hypertension. Finally, the JNC Report, which strongly stressed the needs for cost containment, appeared to have been strongly influenced in its therapeutic recommendations by the fact that its "preferred" drugs are older and cheaper than the newer alternatives.

Ironically, as discussed earlier, drugs that cost less to acquire may not be truly cost-effective. Diuretics, for example, while inexpensive in their generic form, cause unwanted changes in such blood measurements as potassium, uric acid, lipids, and glucose. Beta blockers also can provide metabolic changes. The costs involved in providing extra drugs to counteract these changes, as well as in additional laboratory tests and clinic visits, largely eliminate the apparent price advantages of these traditional agents over the newer drugs.

Equally fierce controversy, therapeutic benefit versus cost, also has arisen in the frequently encountered area of cholesterol abnormalities for which optimal treatment often requires the use of relatively expensive agents such as the HMG CoA reductase inhibitors.[60] But because of the high cost of this drug class—approximately $1.50 per day—institutions have already claimed that they realistically cannot afford to provide this type of treatment for the large numbers of patients who appear to need the treatment. From the point of view of the individual patient, the daily cost of providing such treatment is less than that of a pack of cigarettes; but formulary committees, looking solely at the drug acquisition components of their own budgets rather than at the big picture of

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59 *See generally* Weber & Laragh, *supra* note 53, at 149-52.

60 The HMG CoA Reductase Inhibitors are drugs that have been made available for general use during the past five years. Current examples are pravastatin, lovastatin, and simvastatin. These drugs are able to decrease the manufacture of cholesterol within the liver. This, in turn, provokes special molecules (scientifically termed "receptors") on the surface of the liver to increase their attraction for certain forms of cholesterol circulating in the blood. Thus, the liver is stimulated into removing substantial amounts of an undesirable form of cholesterol known as low density lipoprotein (LDL) cholesterol from the blood, thereby decreasing the risk to patients of damage to critical arteries such as the coronaries which serve the heart.

long-term health outcomes, are likely to impose restricted access to this type of treatment.

F. The Role of the Food and Drug Administration

The FDA is a federal regulatory agency that has been guided by a clear philosophy in deciding which new drugs to approve for marketing. In essence, the first requirement is that the new drug demonstrate efficacy that is either clearly superior to a placebo or is equal to that of other similar agents already available. Second, the drug must be shown to be safe, or to have adverse effects that are acceptable within the context of the drug's benefits.

The FDA has rarely, if ever, used cost-effectiveness as a criterion for new drug approval. The agency has based its decisions on safety and efficacy, and has assumed that physician and patient judgment, together with market forces, will govern the extent to which the drug is used. There is now some apprehension that the FDA may be taking a tougher stand, especially with "me too" drugs that, although differing slightly in their chemical structure from already available products, have similar therapeutic properties. It is also possible that the FDA could be instructed—perhaps along the lines recommended within the proposed new legislation regarding Medicare prescription benefits[61]—to take cost into account even when considering approval of truly new drug products. It is clearly important that the future role of the FDA in the drug approval process be clearly defined. Otherwise, patients again might have reason to fear that they may be denied access to state-of-the-art treatment. Furthermore, the future role of the FDA in governing product promotion and education by industry must be clarified.

G. Tort Reform

Health care economists, as well as physicians, have claimed for several years that a major part of health care costs results from problems with medical liability. The cost of malpractice insurance has become a substantial part of the expenses of practicing clinicians.[62] Moreover, physicians' perceived need to practice "defen-

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61 See *supra* note 8 and accompanying text for some insight on Medicare drug prescriptions.

62 Insurance companies or physicians' cooperatives that deal in selling medical malpractice insurance are reluctant to publicly publish their tariffs. One of the reasons for this is that they try, as far as possible, to individualize rates for physicians and to make some estimate of an appropriate premium based on risk. This takes into account doctors' personal histories in terms of training, formal qualifications, and

sive medicine," which entails expensive procedures performed primarily to protect against lawsuits rather than to help patients, adds yet further to the cost of providing care. Thus, imposing limits on the maximum size of judgments, and discouraging frivolous legal actions, has become an important issue for those seeking to change the health care system.

Some of the issues discussed earlier in this section, including the Health Net case, raise the possibility of an interesting paradox. It is now not the individual physician who will necessarily be responsible for choosing a patient's treatment, but rather a business entity that is operating a for-profit health plan. Certainly, the patient must have assurance that powerful and meaningful legal remedies will be available to protect not only against poor professional judgement, but, perhaps more importantly, against adverse business-dominated decisions. Physicians who value the individualization of patient care, and who put value upon their personal relationships with patients, might unexpectedly find themselves allied with attorneys in their fight to provide optimal care, including drugs, for their patients. Despite the enthusiasm of the White House and of many large health plans for tort reform, members of the medical profession and, perhaps, the pharmaceutical industry as well, might wish a delay in such changes.

VI. INDUSTRY RESPONSES: BEING CREATIVE IN A CHANGING ENVIRONMENT

Understandably, there is apprehension within the pharmaceutical industry as it contemplates widespread changes in the health care system. These concerns exist not only within the industry, for a marked devaluation of drug industry stocks has served to indicate that business observers and investors are expressing some caution over the future prospects of pharmaceuticals.[63] Numerous newspa-

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previous involvement with malpractice claims. More importantly, the type of specialty in which a physician is involved is a major determinant. For example, the plan with which the author is associated in Southern California has premiums that range from approximately $5000 per year for primary care physicians to approximately $100,000 per year for high-risk surgical specialties and certain types of obstetrical practices.

[63] During 1993, drug prices increased only 0.4 percentage points faster than the consumer price index (CPI) for all items, and much more slowly than the CPI for medical care. With rapidly escalating research and development costs, the moderation in drug prices has squeezed industry profitability. Pharmaceutical stocks fell by 22% in 1992 and declined at an annual rate of 25% during the first half of 1993, resulting in a $90 billion loss in market value. *Financial Trends in the Pharmaceutical Industry and Projected Effects of Recent Federal Legislation*, PHARMACEUTICAL MANUF. ASS'N (Price Waterhouse), Oct. 21, 1993, at 20.

per and business magazine articles have pointed out the pressures on the pharmaceutical industry.[64] But it should be remembered that the growth of pharmaceutical companies during the ten or twelve-year period before 1990 was so extraordinary that the more recent reductions in the rate of revenue growth, stock values, and employment could be interpreted, at least in part, as a predictable correction.

There are a variety of strategies that pharmaceutical companies could use to allow them to survive and grow in the type of health care environment we are likely to see during the next several years. For simplicity, these approaches can be subdivided into three main groups: business strategies; physician-based strategies; and patient-based strategies. It is the approach to the patient, who now more than ever must be regarded as the true consumer, that might offer some of the most creative opportunities to ensure both a viable industry and a high quality of health care.

A. *Business Strategies*

In a pharmaceutical marketplace where decisions on drug use by individual physicians are being at least partly replaced with corporate decisions by HMOs and other health care plans, the pharmaceutical industry clearly must develop methods for marketing their products to these high volume purchasers. The most simple competitive approach, of course, is to bid with low prices in order to obtain formulary selection within major health plans. This type of activity already represents an important marketing strategy for most of the major pharmaceutical companies.

B. *The Vertical Integration Approach*

Traditionally, the relationship between the pharmaceutical industry and the principal users of their products has been that of a vendor and a customer. However, as strategies based primarily on pricing may no longer be adequate in a progressively more competitive setting, alternative approaches are now being contemplated. The acquisition of Medco by Merck, discussed earlier, is one example of how a major pharmaceutical company has gone beyond being simply a supplier of pharmaceutical products, and is now providing services as well as drugs directly within the health care system.

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64 *See, e.g.*, Shawn Tully, *The Plots to Keep Drug Prices High*, FORTUNE, Dec. 27, 1993, at 120, 120-24; Doug Bandow, *Missing the Mark*, PRIVATE PRACTICE, Sept. 1993, at 29; Robert Goldberg, *The Myth of High Drug Costs*, WALL ST. J., Sept. 30, 1992, at A16.

One strategy that pharmaceutical companies might contemplate is to go even beyond the Medco model and form long-term relationships with major health plans. In essence, pharmaceutical companies could acquire major equity interests in health plans, creating a situation in which they can guarantee long-term use of their products. At least one of the major companies has looked seriously at creating such an alliance.[65] In a sense, there is already a precedent: several of the major health insurance carriers, also anxious to protect their long-term prospects, have acquired or created their own health plans.[66]

A less dramatic strategy than the "pharmaceutical services" or "ownership" models is the concept of "bundling." This requires that a large pharmaceutical company, with a broad range of products encompassing most of the common therapeutic areas, makes an arrangement for its entire product line to be used preferentially by major health plans. Making its full portfolio available in this fashion can be helpful to a pharmaceutical company, for by increasing the usage of some of its less popular products, it can then afford, in essence, to subsidize some of its more popular or expensive products. In practice, the range of necessary drugs required by a comprehensive health plan is so great that not even the largest pharmaceutical companies can come close to truly satisfying this need. However, consortiums of pharmaceutical companies could bid jointly to acquire comprehensive drug supply contracts from major plans.

Interestingly, these more complex bundling models may finish up by being similar in some respects to the Medco operation. Should these types of business solutions become more widespread than at present, there must inevitably be some ethical concern within the medical community. Certainly in a setting where a pharmaceutical manufacturer has as much financial interest in profitable health care delivery at the bedside as in its traditional sales of drugs, it could be feared that the critical processes of research and development might be driven by fiscal rather than by scientific and clinical forces.

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65 *See American Drug Firms: Kicking the Habit*, THE ECONOMIST, Dec. 25, 1993, at 90, 92 (pointing out that the Pfizer Corporation has been considering such an option).

66 Margie Freaney, *Aetna Boldly Remaking Itself*, BALTIMORE BUS. J., Oct. 1, 1993, at 1. This article discusses how Aetna, traditionally one of the major insurance carriers, has undergone a radical restructuring, and has decided that its future viability lies in its ability to exert tight cost-control over the health care that is provided under its aegis. *Id.* Accordingly, the formation of a tightly controlled HMO is a critical part of its planning. *Id.*

C. *Physician Strategies*

Much of this article has already discussed the close relationship that traditionally has existed between the pharmaceutical industry and physicians. Obviously, as health plans make business decisions regarding drug acquisition, this relationship is tending to become diluted by the interposition of formulary committees, pharmaceutical consultants, and other intermediaries.

But, ultimately, the physician remains—and for the foreseeable future will continue to remain—the person who will continue to have decision-making input for drug treatment in individual patients. As detailed in an earlier section of this Article, there has been a recent tendency for pharmaceutical companies to decrease their interactions with physicians. Sales calls have been reduced, and educational activities, either at local hospitals or through major medical societies, have also been reduced.

In an environment where medical decisions are being made progressively more by individuals trained primarily in business, it will become very important for physicians to be informed advocates for drug advances. Research into drugs and their use is a continuous process throughout the lives of drugs. New information is always being obtained, and there is a strong need to keep physicians aware of developments that can enhance and broaden the use of therapeutic agents in their patients. Moreover, even though aggressive marketing strategies might bring a particular product onto a formulary, this does not guarantee that physicians within the plan will use the drug, or if they use it, that it will be prescribed appropriately. Indeed, the provision of physician educational services, either informally as at present, or perhaps even on a structured or contractual basis, is an important obligation for pharmaceutical companies and a good opportunity to optimize the use of their products.

D. *The Patient Strategy*

In a world where the pharmaceutical industry is being squeezed by governments, insurers, and health plans, it is critical that, finally, direct communication with the true consumer, the patient, will open up. Indeed, at present the lay public's understanding of the pharmaceutical industry, and the whole process by which therapeutic drugs are provided, is so poor that the industry—despite the extraordinary contributions it has made to modern health care—has become an almost undefended victim of widespread criticism. Long-term prospects for the industry, and thereby for the

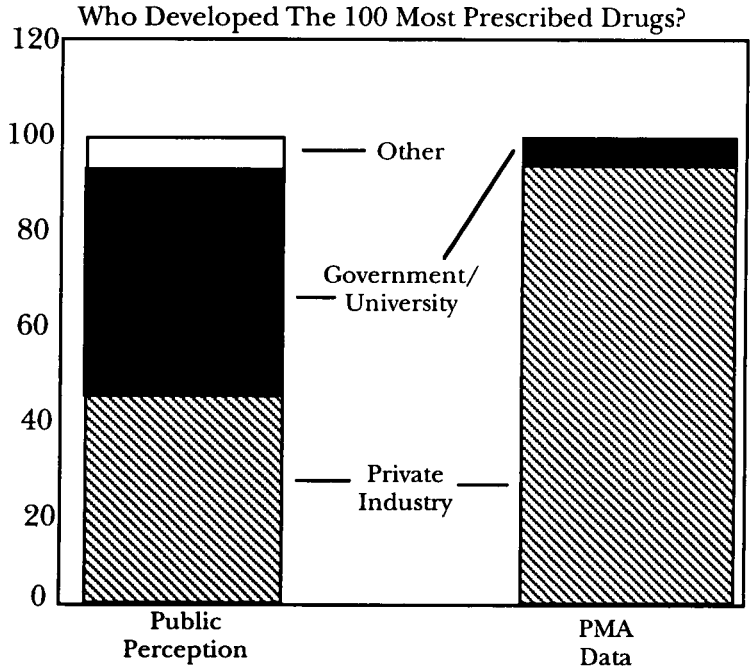
quality of health care, might depend very closely on its ability to educate the public. The following issues appear especially appropriate.

1. Where Do Drugs Come From?

It is likely that only a tiny fraction of the general population understands the extraordinarily complex, lengthy, and expensive process of providing new therapeutic products. It is likely that much of the information discussed earlier concerning the "drug development pyramid," which is not understood even by most physicians, would certainly surprise most members of the lay public. There is no real understanding of the concept that much of the price of drugs is not to make the pills, but to amortize the research and development costs.

One common misconception is shown in Figure 3. When considering the origins of the most commonly prescribed drugs in this country, the reality is that over ninety-five percent were developed by the pharmaceutical industry. The general public, however, has a completely erroneous perception of this process, and believes

FIGURE 3



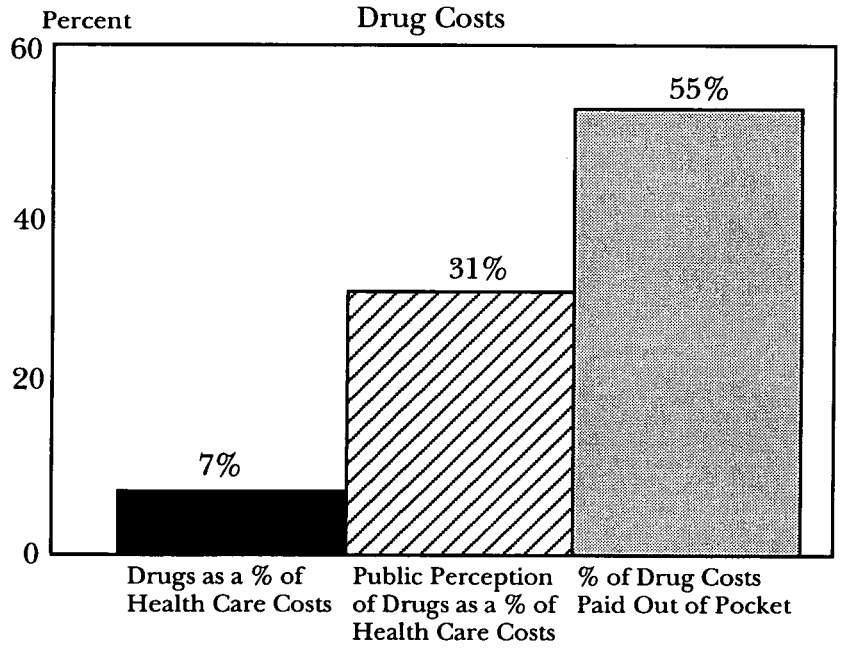
SOURCE: HARRIS POLL 1993 and PMA

that the majority of therapeutic breakthroughs have come from research by government or university investigators.[67] It is unfortunate for medical care overall that this type of misunderstanding exists; the blame, to be fair, belongs primarily to the pharmaceutical industry itself. Very simply, it has not spoken to its own customers.

2. What Drugs Cost

A further result of poor communication is shown in Figure 4. Although they are the cornerstone of most therapies, drugs in reality account for only about seven percent of total health care costs.[68] But in the minds of the public, drugs appear to have a far more dramatic importance, approaching one-third of overall costs.[69] This misconception is not totally surprising. Many patients, even those with good private insurance plans, are required to pay part or all of their own drug costs. In many instances, especially for

FIGURE 4



SOURCE: HARRIS POLL, 1993 and 1994

67 See Figure 3 for some support for this proposition.
68 *See supra* note 4.
69 *See* Figure 4.

patients who may be taking multiple drugs for chronic conditions, these out-of-pocket expenses can often dwarf their other personal health care expenses. For this reason, anti-industry rhetoric from Washington falls on receptive ears. Again, education is vital.

3. What Drugs Do

For many patients, especially the elderly who might simultaneously be affected by such common conditions as hypertension, diabetes, heart disease, or arthritis, it is inevitable and appropriate that they receive multiple drugs. Although no physician likes to prescribe more drugs than are necessary, these drug regimens are needed to prevent strokes, comas, or other complications of diabetes, severe pain, and major cardiac events. The cost of the drugs, albeit rather startling when a patient is asked to fill prescriptions for a month's supply of four or five differing medications, is still trivial when compared with the cost of hospitalization or other major interventions that would be required if the drugs were not used.

Unfortunately, for most lay patients, let alone formulary committees who ought to know better, there is a preoccupation with drug acquisition costs without an appropriate understanding of the total financial picture. Beyond education, one approach to lessening the personal financial impact on patients is to encourage expanded use of prescription benefit plans. These approaches, which are being offered more widely by several insurance carriers, and are even envisaged to some extent under the new Medicare rules,[70] limit out-of-pocket expenses and the total annual personal cost of drug products. Much or most of the drug costs are, in fact, then carried by the plan, which presumably has a clear understanding of how wise investment in modern drugs can actually save major expenses in other areas.

4. Quality of Drug Treatment

In a medical marketplace characterized by competitive health care plans, patients will be forced to evaluate the differing claims of rival plans when making choices for themselves or their families. Several factors might influence these decisions, including cost, convenience of the plan's physical facilities, or perhaps personal acquaintance with physicians or other personnel within a particular plan. But because the plans tend to be very complex and have several attributes that could influence their potential subscribers, it

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[70] See *supra* note 8 and accompanying text for a discussion of Medicare rules for prescription medicines.

is likely—and highly desirable—that detailed evaluations of the plans, on a feature by feature basis, be published regularly within each community by objective observers.[71]

It is critical for the pharmaceutical industry, and other advocates for high quality medical care, to ensure that plans compete on the basis of quality of their treatment—especially highlighting the availability of modern drugs—in addition to such other issues as cost. Choosing one plan over another because it offers a broader range of state-of-the-art drugs could be a legitimate way for educated patients to receive the best value for their health care investment.

VII. Final Comment

The pharmaceutical industry has already been impacted by a widely expressed desire to curtail health care costs. Because the industry has been perceived as successful and prosperous, it has been a ready target for those who claim to see excesses in current health care expenditures. Drugs remain the primary tools for treating most physical and mental illnesses, and there is legitimate concern that cost pressures on the pharmaceutical industry could reduce its incentive to develop innovative new products. The cost of drug research and development is extraordinarily high, and it is critical that physicians, health plan administrators, and especially patients, be made to understand the whole process of making therapeutic products accessible.

This Article has argued that the pharmaceutical industry, through its support of many aspects of medical research and education, is integral to quality health care. There are a number of strategies that individual pharmaceutical companies might follow to preserve their viability and growth in the changing health care market. But most important of all is a need for pharmaceutical companies to carefully educate their ultimate consumers—the patients—on the importance of demanding full access to contemporary drug therapy in a health care system dominated increasingly by the business objectives of health plan managers rather than by traditional doctor-patient relationships.

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[71] The type of rating scale used by *Consumer Reports* to judge products and services in the general marketplace is a good model for these evaluations.