Withdrawal/Redaction Marker
Clinton Library

DOCUMENT NO. AND TYPE	SUBJECT/TITLE	DATE	RESTRICTION
001. fax	Chris to Gene et al. re: phone number (partial) (1 page)	07/16/1999	P6/b(6)

COLLECTION:
Clinton Presidential Records
Domestic Policy Council
Devorah Adler
OA/Box Number: 20471

FOLDER TITLE:
Medicare [Folder 11]

2012-0463-S
rc790

RESTRICTION CODES

Presidential Records Act - [44 U.S.C. 2204(a)]

P1 National Security Classified Information [(a)(1) of the PRA]
P2 Relating to the appointment to Federal office [(a)(2) of the PRA]
P3 Release would violate a Federal statute [(a)(3) of the PRA]
P4 Release would disclose trade secrets or confidential commercial or financial information [(a)(4) of the PRA]
P5 Release would disclose confidential advice between the President and his advisors, or between such advisors [a)(5) of the PRA]
P6 Release would constitute a clearly unwarranted invasion of personal privacy [(a)(6) of the PRA]

C. Closed in accordance with restrictions contained in donor's deed of gift.
PRM. Personal record misfile defined in accordance with 44 U.S.C. 2201(3).
RR. Document will be reviewed upon request.

Freedom of Information Act - [5 U.S.C. 552(b)]

b(1) National security classified information [(b)(1) of the FOIA]
b(2) Release would disclose internal personnel rules and practices of an agency [(b)(2) of the FOIA]
b(3) Release would violate a Federal statute [(b)(3) of the FOIA]
b(4) Release would disclose trade secrets or confidential or financial information [(b)(4) of the FOIA]
b(6) Release would constitute a clearly unwarranted invasion of personal privacy [(b)(6) of the FOIA]
b(7) Release would disclose information compiled for law enforcement purposes [(b)(7) of the FOIA]
b(8) Release would disclose information concerning the regulation of financial institutions [(b)(8) of the FOIA]
b(9) Release would disclose geological or geophysical information concerning wells [(b)(9) of the FOIA]

Darlene Burgess
Vice President
Corporate Government Affairs

1 Ford Place, 3A/B
Detroit, MI 48202-3450
(313) 876-8484 Office
(313) 876-9252 Fax
Internet: Dburges1@hfhs.org

July 12, 1999

Christopher Jennings
Deputy Assistant to The President
for Health Policy
216 Old Executive Office Bldg.
Washington DC 20502

RE: Drug Coverage

Dear Mr. Jennings:

As promised, enclosed please find the Health Affairs article by Gail Warden that discusses the importance of drug coverage in the management of care of seniors. Some of the content came from what we learned from the Medicare Commission hearings, as well as the experience of our own Henry Ford Medical Group physicians and our Henry Ford Health Alliance Plan, Michigan's largest HMO. We have both Medicare and Medicaid managed care enrollees in HAP under global risk arrangements with HFMG.

Also enclosed is a white paper on pharmaceutical costs. The paper was prepared in an effort to gain attention on these important issues from the American Medical Association. It has been discussed by the AMA Group Practice Advisory Committee which is made up of physicians from the largest group practice organizations in the country, including HFMG, Mayo, Cleveland Clinic, Lahey and others. The AMA Advisory Committee will likely come to closure on recommendations to the AMA Board over the next few months. Many of these same physicians have leadership roles in the American Medical Group Association as well.

It was an honor to have the opportunity to discuss Medicare reform and other issues with you and Congressman Levin. As you know, in today's world we face a tough environment. We very much appreciate the interest and leadership you have shown and hope you won't hesitate to call on us if there are ways for us to help.

Sincerely,

Darlene Burgess

Withdrawal/Redaction Sheet
Clinton Library

DOCUMENT NO. AND TYPE	SUBJECT/TITLE	DATE	RESTRICTION
001. fax	Chris to Gene et al. re: phone number (partial) (1 page)	07/16/1999	P6/b(6)

COLLECTION:
Clinton Presidential Records
Domestic Policy Council
Devorah Adler
OA/Box Number: 20471

FOLDER TITLE:
Medicare [Folder 11]

2012-0463-S
rc790

RESTRICTION CODES

Presidential Records Act - [44 U.S.C. 2204(a)]

P1 National Security Classified Information [(a)(1) of the PRA]
P2 Relating to the appointment to Federal office [(a)(2) of the PRA]
P3 Release would violate a Federal statute [(a)(3) of the PRA]
P4 Release would disclose trade secrets or confidential commercial or financial information [(a)(4) of the PRA]
P5 Release would disclose confidential advice between the President and his advisors, or between such advisors [a)(5) of the PRA]
P6 Release would constitute a clearly unwarranted invasion of personal privacy [(a)(6) of the PRA]

C. Closed in accordance with restrictions contained in donor's deed of gift.
PRM. Personal record misfile defined in accordance with 44 U.S.C. 2201(3).
RR. Document will be reviewed upon request.

Freedom of Information Act - [5 U.S.C. 552(b)]

b(1) National security classified information [(b)(1) of the FOIA]
b(2) Release would disclose internal personnel rules and practices of an agency [(b)(2) of the FOIA]
b(3) Release would violate a Federal statute [(b)(3) of the FOIA]
b(4) Release would disclose trade secrets or confidential or financial information [(b)(4) of the FOIA]
b(6) Release would constitute a clearly unwarranted invasion of personal privacy [(b)(6) of the FOIA]
b(7) Release would disclose information compiled for law enforcement purposes [(b)(7) of the FOIA]
b(8) Release would disclose information concerning the regulation of financial institutions [(b)(8) of the FOIA]
b(9) Release would disclose geological or geophysical information concerning wells [(b)(9) of the FOIA]

DRAFT - 7/16/99 - DRAFT

Amendment by Senators Baucus and Conrad
Social Security and Medicare Lockbox

The tax cuts in the Chairman's mark will be reduced by an amount sufficient to allow one-third of the available on-budget surplus to be dedicated to Medicare as set forth below. The reductions in the tax cuts will be pro-rata, across-the-board, except that any extenders and pay-for items will be unaffected.

The Social Security and Medicare lockbox precludes any portion of the Social Security surplus *or* any portion of the surplus reserved for Medicare to be used for any purpose other than to strengthen and preserve these programs. Over the next 10 years, the lockbox will protect *100 percent* of the Social Security surplus in each year, and one-third of any available on-budget surplus for Medicare.

Amounts in Lockbox: The Social Security and Medicare lockbox contains: (1) the entire Social Security surplus in every year and (2) one-third of the available on-budget surplus in every year. The latter is reserved specifically to extend the life of the Medicare program, to provide Medicare beneficiaries with access to affordable, quality care and to modernize the Medicare benefit package, including coverage for prescription drugs.

Enforcement: The Social Security and Medicare lockbox will be enforced through new supermajority points of order that apply to the budget resolution, and all bills, amendments and conference reports.

Budget Procedures: Budget process procedures, including extension of the pay-go rules, should be included in legislation that protects Social Security and Medicare, and provides tax relief to working Americans.

To: Gene / Jeanne / Larry S.

Fr: Chris J.

Here's the Baucus Medicare lockbox draft amendment we discussed. It may be a very good idea but I'm not sure of structure. We should get back to them soon. Staff contact is Pat Bousliman -

H - P6/(b)(6) [001]
o 224-4353

Chi

A Crisis for U.S. Health Care:

The Growing Burden of Prescription Drug Costs

Health Policy White Paper

Henry Ford Health System
Lahey Clinic

May 27, 1999

A Crisis for U.S. Health Care:

The Growing Burden of Prescription Drug Costs

A new crisis for U.S. health care is brewing, catching policy makers and consumers unprepared. In late 1998, Blue Cross Blue Shield, one of the nation's largest health insurance companies, announced that for the first time in the history of group insurance, more of the health care insurance premium dollar would be spent in many states on prescription drugs than for hospital services. Inflation rates for drug costs since 1995 have been three times the growth for hospital services and two and one half-times the growth for physician services.

This is a success story gone haywire. On the one hand, the prescription bottle seems to promise the American public everything from youthful potency to wiping out the long-term debilitating affects of stroke. Americans spend billions each year on over-the-counter remedies and vitamins and are true believers in the miracles of pharmaceutical and herbal science. No one wants to forgo the benefits of research and the discoveries that make chronic illness bearable or transplantation miracle procedures successful. Life is precious and pharmaceutical advances contribute greatly to the quality of life in ways never thought possible prior to the end of this century.

With the unveiling of a whole new world of genetic information becoming available to medicine through the Human Genome Project, sometime early in the new millennium, the horizon seems unlimited. Drug companies are already busy mapping out drugs that can provide personalized medicines that will treat people based on their individual genetic makeup. The research is expensive, the clinical trials will be expensive, the drugs will be expensive, and demand will produce a new surge of uncontrolled cost.

No one wants to turn back the clock or kill the initiative that is spawning pharmaceutical miracles. But someone always pays the bill. In the U.S., costs for these advances are embedded in the health care insurance system, so every American pays in the form of higher insurance costs. There is a clear economic burden on employers and government who finance these costs for the American people.

Policy Framework

The purpose of this paper is to discuss the issues and recommend a new policy framework in U.S. health policy on pharmaceuticals. The new policy framework would have the following elements:

1. Federal government cost oversight should be expanded beyond the current emphasis on hospital, physician, nursing home and home care, to also encompass pharmaceuticals.

The federal government is currently heavily invested in regulating the efficacy, safety and protective licensing for pharmaceuticals. Specific oversight on cost should be added.

2. Expenditures by pharmaceutical companies on research, marketing, profits and other costs that are built into the price of prescriptions should be publicly disclosed.

3. Insurance companies and government purchasers should be empowered to control utilization of pharmaceuticals and share costs with an ever-demanding public through co-payments, deductibles and reduced coverage of certain drugs.

4. Medicaid and Medicare programs, as well as other government-funded insurance, should not cover quality of life drugs without contribution from the subscriber.

5. FTC-like monitoring and regulation of competition among pharmaceutical companies should be instituted.

6. Direct advertising should be banned unless the ad contains full disclosure of possible side-effects and likely efficacy. Advertising should be reviewed by a government agency prior to broadcast to assure compliance with guidelines.

7. Cooperation among pharmaceutical companies for large and expensive investigations, such as the search for genetically tailored drugs, should be required so that the American public is not forced to pay for this research many times over.

8. No physician should be placed in an ethically hazardous position through accepting risk for pharmaceutical costs. Insurance and managed care companies should be prohibited from requiring physicians to accept risk for pharmaceutical costs.

9. Explicit limits on investment for research, development and advertising should be implemented to force more collaboration and lower costs to consumers.

10. Each pharmaceutical company should be required to provide a certain amount of free products to needy individuals, depending on the amount of sales in each state. This program would enhance current free drug programs many states now administer. Make this an explicit obligation.

Policy-makers have a societal role and obligation to address the issue of cost increases in pharmaceuticals and the burdens this create for the American public. With the number of uninsured individuals nearing the 50 million mark and health care costs about to explode as baby boomers hit their highest health care consuming years, someone must apply the brakes. While physicians have been on the vanguard of improvements in medicine, physicians must also assume responsibility on behalf of the patients they serve to make health care more affordable and available for those unable to pay for care.

This paper represents a call by physicians to examine all aspects of the pharmaceutical miracle in America, including cost, and to construct guidelines that address broader social and ethical questions than simply whether the drug will work or may help some patients. It does little good to produce miracle drugs if no one can afford them, or if coverage of the drug squeezes out other needed services and subscribers.

It is unreasonable to assume that there can be no cost savings in pharmaceuticals and that there is no waste in current practices that support multiple research, competitive trials and advertising. This is a call for moderation, public enlightenment, as well as an assertion that pharmaceuticals are part of health care and must accept accountability to the broader goals, as others in health care do.

Executive Summary

Health plans and provider groups that serve patients under various forms of at-risk payment are caught between two powerful financial forces: the employer and government purchasers push for flat or declining premiums, and the unrelenting rise in costs of care, particularly for prescription drugs.

At the same time, an initiative to expand Medicare coverage to include ambulatory care prescription medications is bogging down with the question of how to make that coverage affordable, both to the Medicare program and to individual beneficiaries.

Individuals (especially seniors) who do not currently have a rich prescription drug benefit are often in an immediate and more powerful predicament -- the need to choose between paying for needed medications and paying for other essentials like food, housing, and transportation.

A key problem underlying all these issues is the rapidly increasing cost of prescription medications. As indicated in Figure 1, the costs of drugs are the most rapidly increasing element of overall health care costs. For many plans, they are about to reach a point where they are a larger expense category than hospital care.

Figure 1 here

Although health plans across the country have been seeking double-digit percentage increases in premiums for 1999, the experience for the past several years has been increases at or below the general level of inflation. For many plans and many market areas, this has meant premiums at stable or even declining levels in absolute dollar terms. At the same time, the essential costs of care have been rising at rates higher than general inflation, including the cost for prescription drugs.

Costs of prescription drugs and other kinds of treatment technologies are rising due to many factors:

1. Development of new patented drugs that provide either more effective treatment or fewer side effects in common chronic conditions for which relatively inexpensive therapies had been customary (Examples are: Claritin for seasonal allergies; a variety of non-steroidal anti-inflammatory agents for arthritis);

2. Trends towards more comprehensive prescription drug coverage under most through insurance plans, due primarily to increasing numbers of patients moving into managed care plans with relatively generous prescription drug coverage;

Annual Increase in National Health Care Expenditures, by Category

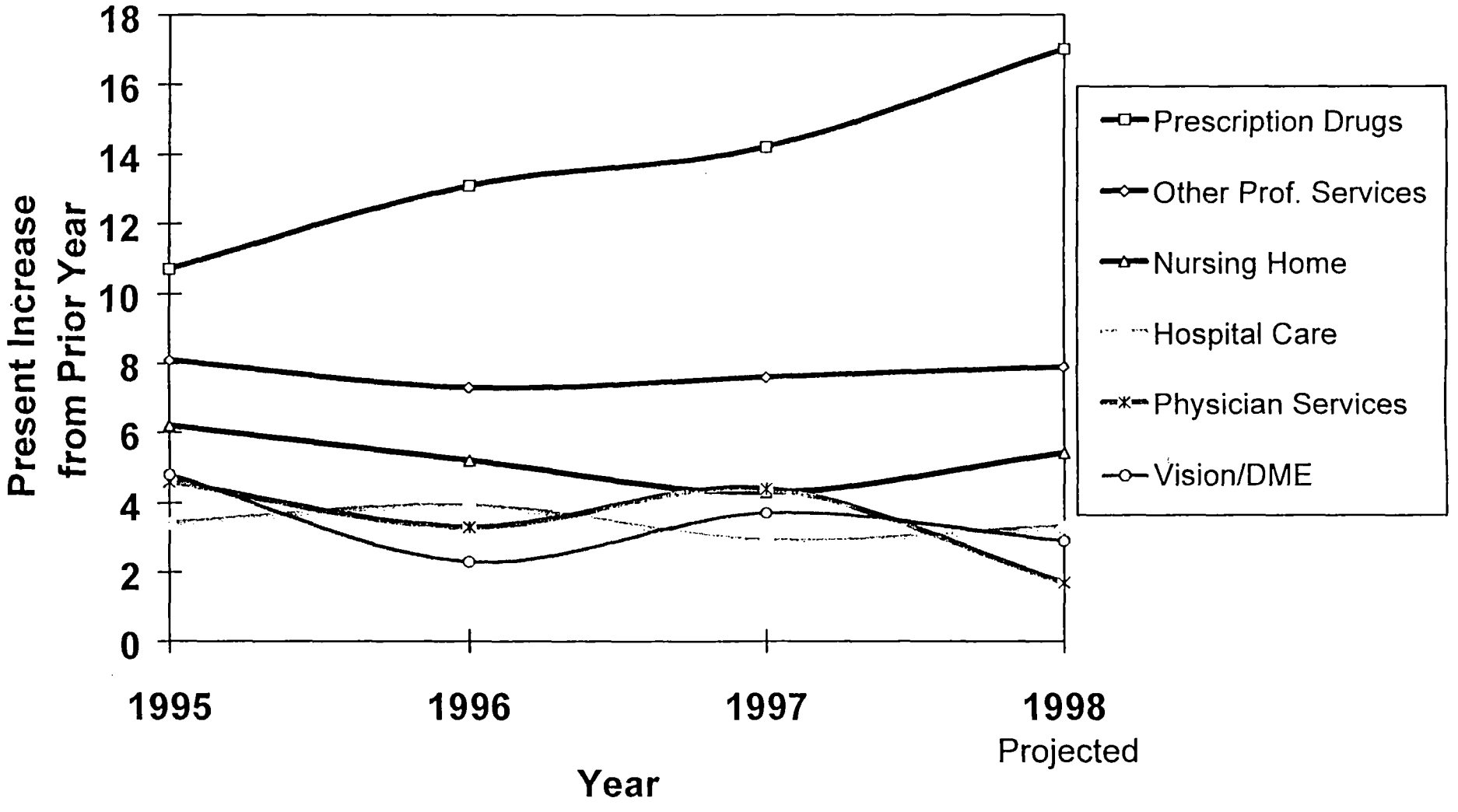
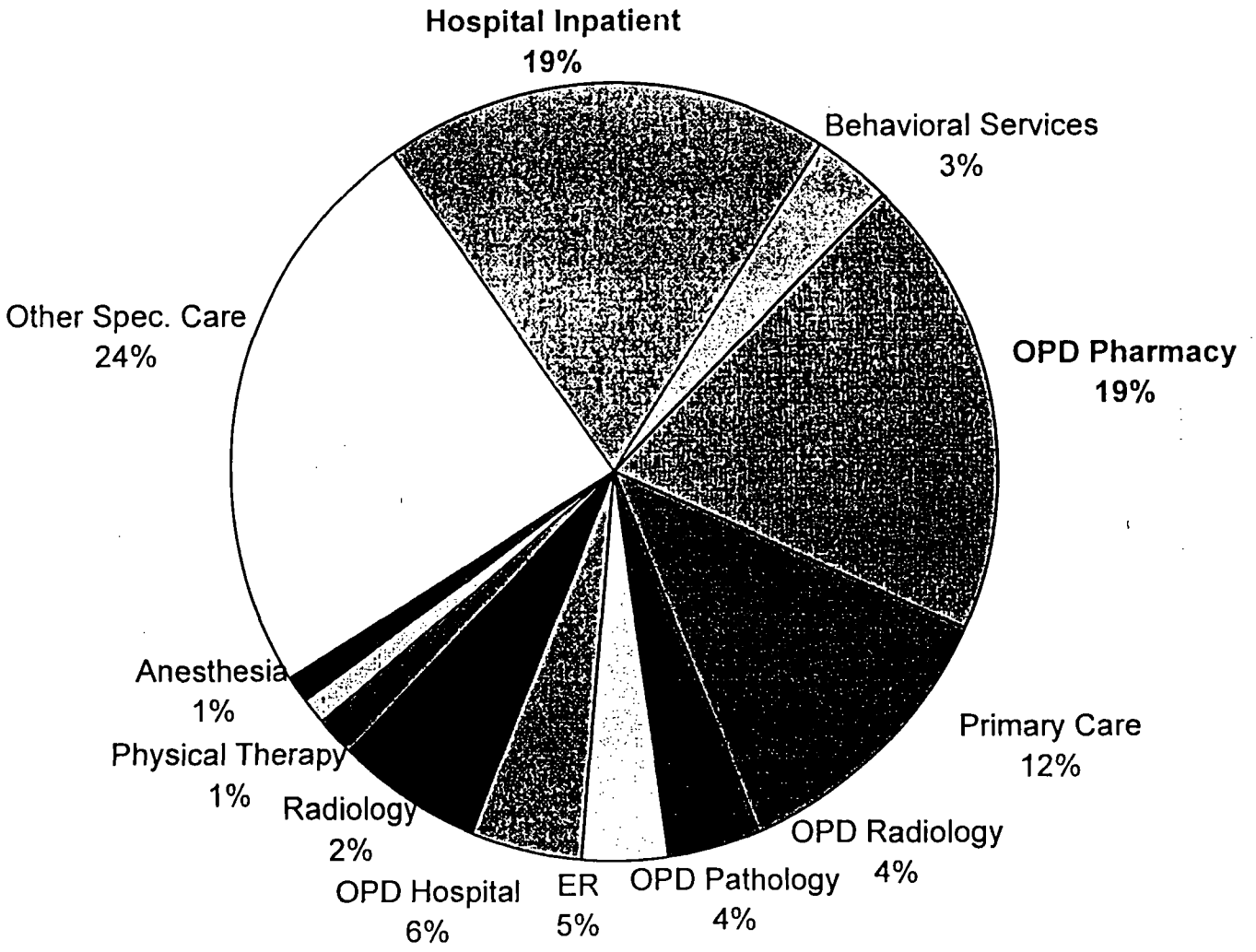


Figure 1

Source: Inglehart, JM, *NEJM*, Jan. 7, 1999

Multispecialty Group Practice / Integrated Health System
Projected Managed Care Expense Categories - 2002



3. Growth in numbers of elderly individuals with treatable chronic conditions, due in part to declining death rates for heart disease and other illnesses that were frequently fatal following relatively short periods of intensive care;

4. Direct marketing by pharmaceutical companies to consumers, raising expectations about prescription medications for conditions not previously thought to benefit from such treatment, and creating demand for name-brand vs. generic prescriptions;

5. Expanded sources of information to patients/consumers via the Internet, coupled with less trusting attitudes toward physicians and health plans, and more patient demands for the latest, most expensive medication available;

6. Development of new drugs to treat conditions that were previously not treatable or considered even to be "illnesses" (examples: antiviral "cocktails" for HIV/AIDS, Viagra for impotence; Propecia for baldness;);

7. Relatively high per-dose charges for new medications (examples: $7-10 per pill for Viagra; $11-15 per pill for Imitrex or Maxalt for migraine; $2,000 per treatment with infliximab (Remicade for Crohn's); $1,000 per treatment of etanercept (Enbrel) for rheumatoid arthritis);

8. Higher drug prices in the U.S. than in other countries; and

9. Increased costs of conducting clinical trials, not just to establish safety and efficacy of new medications, but to also establish marginal benefits over competing medications in either side effects/quality of life or range of indications.

A number of steps can and have been taken by health plans and physicians to control rising pharmacy costs. These include: establishment of formularies or preferred drug lists; development of financial incentives at the individual physician level for controlling prescription costs; establishment of variable co-pay rates that promote use of generic or less expensive options within the same drug class; "tiering" co-payments to increase patient sensitivity to price differences between generic and patented or formulary and non-formulary drugs; and raising co-payment levels in general. Although these steps have frequently been shown to have some measurable effect on control of costs, collectively they have not been able to prevent overall prescription drug costs from rising faster than any other category of medical expense.

Many of these strategies carry inevitable negative consequences for one or more of the parties involved or create serious ethical dilemmas. Higher co-pays simply shift the cost of medications from the health plan or provider group to the patient. Incentives to physicians can create powerful conflicts of interest, in which the physician has to balance the potential benefit of an expensive medication to one patient with the need to stay within a fixed capitation budget for a group of patients.

Pharmaceutical companies and some health care analysts point to the results of cost-effectiveness or "cost-offset" studies to argue that rising pharmaceutical costs are not necessarily bad. The essence of the argument is that prescription drugs are more effective, or more cost-effective, than alternative forms of treatment (e.g., medication vs. extended outpatient psychotherapy for patients with depression), and that rising drug costs should be more than outweighed by savings in other areas.

From the health plan or medical group perspective, the main problem with the cost-offset argument is that the costs are real, immediate, and clearly located within the plan or group, while the benefits or offsets are uncertain, in the future, and likely to accrue to another plan or group if there is significant turnover of patients year-to-year. There are relatively few situations where the use of a new, expensive medication has clearly identifiable cost savings.

Cost-effectiveness arguments can also be built for many prescription drugs, where the benefits are expressed in terms of enhanced functional status or quality of life. While these benefits may be worthwhile from a plan member, employer, or societal perspective, they do not usually translate into financial benefits at the health plan or at-risk provider group level. The costs, though, are very tangible, particularly if the new drugs are not effective on all cases treated, so that expenses must be incurred on many patients in order to benefit a few.

As patients, we all benefit from drugs that produce measurable benefits in duration or quality of life. We do not, however, benefit from rising costs, particularly if these costs relate to expenses that are unnecessary, wasteful, or not directly related to expenditures associated with essential development, production, and distribution of those drugs.

In a free market economy, producers' costs are generally not regulated from outside, but presumed to be controlled by the inevitable competitive pressures in the market to produce goods as efficiently as possible. Because of the peculiarities of health care economics and the U.S. preferred method of financing care through insurance, market forces have not controlled drug costs to date, and cannot be relied on to control costs in the future. The "normal" market rules of supply and demand, with competition among multiple sellers for the business of multiple willing, informed buyers do not apply. Some other sets of rules need to be created, which can have the effect of continuing the incentives for drug companies to develop and test new products, but also have the effect of controlling some of the costs of those products that do not really represent "value added" to individual patients and to society as a whole. The specific costs that need attention are:

- advertising, to physicians and direct to consumers;
- development of "me-too" drugs that enter already-crowded therapeutic fields offering little or no additional benefit;
- clinical trials that show small marginal benefits for marketing advantage but have little overall effect on health status of patients;

- price differences between the U.S. and other countries that have the effect of U.S. citizens subsidizing the development of drugs and their use in other countries.

Recommendations

Under a wide-open insurance financing health system, the costs of prescription drugs in the U.S. are rising at a rate, and to a level, where they threaten not only the affordability of medications themselves but the affordability of health insurance in general. Because of trends toward global risk, pharmacy costs also threaten the financial viability of health plans and provider groups. This issue has assumed crisis-level proportions. We recommend a set of steps at the federal level and within health insurance plans to get pharmacy costs under control:

Plan and Provider Initiatives

1. Institute separate budget line items and payment models for pharmacy, distinct from facility, technical, and professional payments in Medicare and other insurance systems; when this is not possible,

    a. allow adjustment of DRG payments to reflect the rising cost of inpatient pharmacy;

    b. encourage continued research and development on ambulatory case-mix models that reflect costs of prescription drugs, for use in capitated or other bundled payment models;

2. Establish continued upward adjustment of tiered co-payments and deductibles for prescription drugs to make patients sensitive to the relative price of drugs while not creating insurmountable financial barriers to effective treatment;

3. Expand any policies that promote stable, long-term relationships between patients and providers and plans, so that the same business entity will participate in both sides of a cost-offset tradeoff involving pharmacy costs now in exchange for savings on other forms of care in the future;

4. Encourage greater coordination among employers, health plans, and medical groups on issues of formularies and preferred drugs, with alignment or actual sharing of financial incentives for use of the "right" drugs in the "right" patients for the "right" indications;

Federal Policy Initatives

5. Establish continued examination by Congress, HCFA, and other large agencies representing public and private purchasers on the issue of differential pricing of medications between the U.S. and other countries, and on levels of profit associated with

patent monopolies. There is no obvious reason why the U.S. should subsidize the R&D costs of pharmaceuticals for the rest of the world, or contribute more than a fair share of the profits of companies that, in many cases, are multinational or primarily based in other countries.

6. Enact stronger regulation, by the same payment or regulatory agencies, of advertising and promotion of pharmaceuticals, to both professional and lay audiences;

7. Promote the concept of "full disclosure advertising", in which costs, side effects, complications, relative effectiveness, and strength of scientific evidence are all included in materials designed for direct consumer marketing.

8. Require examination, and possible regulation, by appropriate regulatory bodies, of costs of clinical trials, bonus payments to physicians who meet patient accrual targets in such trials, other issues related to the conduct and publication of results of trials, and the ultimate benefit of expenditures on clinical trials to the public.

Other Initiatives

9. Increase investment in public education programs about appropriate use of generic drugs, lack of benefit of antibiotics for viral infections, safety and efficacy of over-the-counter medications for common acute and chronic conditions, and possible adverse effects of unnecessary or inappropriate medication use;

10. Seek expanded visibility of AMGA, AMA, AHCPR, major medical specialty societies, and other national organizations as "trusted experts" to consumers on issues of effective use of prescription medications. Guidelines and recommendations about appropriate and inappropriate patterns of care, widely disseminated through print, television, and Internet media may serve as a counter to some direct marketing efforts by pharmaceutical companies.

A Crisis for U.S. Health Care:

The Growing Burden of Prescription Drug Costs

Introduction

More than a third of the 38 million people covered by Medicare have no prescription drug coverage, and many of those who are covered have limited coverage with substantial out-of-pocket costs (NY Times, May 10, 1999). It is not unusual for low-income elderly patients without drug coverage to have to choose between food, rent, and expensive medication needed to manage chronic conditions like hypertension or diabetes (Lagnado, 1998). Other insured individuals without a prescription drug benefit face the same pressures, and those who lack insurance at all simply can't afford the drugs that are prescribed for them.

Organized health care systems are not in a good position to offer relief. 1998 was a crisis year for many health plans and provider groups. Kaiser Permanente, for example, reported an operating loss of some $270 million. Henry Ford Health System in Detroit reported a net loss, including revenues from investments and other non-operating sources, for the first time in its history as an integrated health system. Organizations that are losing money cannot afford to expand benefits to take the burden off patients and health plan members.

Purchasers who had enjoyed several years of stable or slowly increasing health care premiums are now dealing with requests for double-digit premium increases. In many cases, these increases are not being passed on to providers to provide care to patients, but are being used to cover increasing costs at the plan, including costs of prescription drugs. While some large private employers have the negotiating leverage to push back and keep increases below 10%, many small and medium-size companies, particularly those with a recent history of adverse claims experience, may see increases in premiums of 20% or more (Frudenheim, 1998). These employers will find it difficult to expand or even maintain coverage for prescription drugs as they face their own competitive pressures and needs to control costs.

The major public payors, Medicare and Medicaid, have contributed to the economic problem, at least in the short run, by simply declaring reductions in payments to health plans, hospitals, or providers, and passing savings on to taxpayers in the form of lower (or at least gently rising) overall program costs. Increasing costs in an area like pharmacy have to be absorbed in a payment environment that has no slack.

Health plans and provider groups that accept capitation payments could conceivably accept flat or declining premium payments if they could keep underlying

costs of care stable or produce actual reductions. In spite of strenuous efforts driven by years of strong financial incentives, though, the cost curves are rising rather than falling. The average "medical loss ratio" (percentage of premium revenues paid out for medical care expenses) among HMOs rose from 89% in 1996 to 90.1% in 1997, and was not expected to decline in 1998 (Weiss Ratings, 1998).

The category of expense that has been identified most consistently as contributing to rising overall costs is prescription drugs (Levit, 1998). The increase in costs for 1997 compared to 1996 was 14.1% (compared, for example to 2.9% for inpatient services or 4.4% for physician services).

Figure 1 repeated here

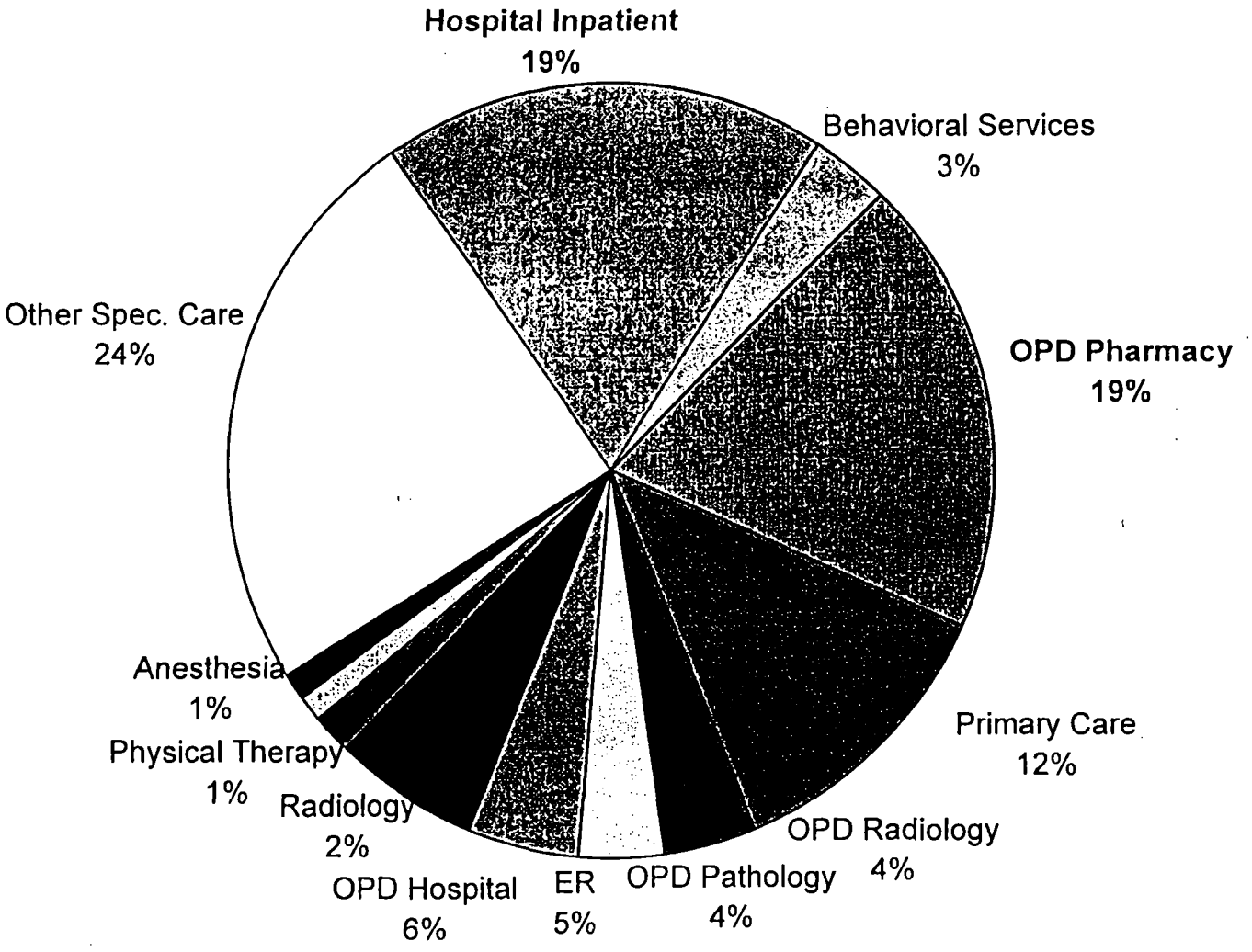
In addition to the general concerns just mentioned about rising costs and financial risks to health plans and provider groups, there are three specific reasons for concern about rising prescription drug costs and their impact on overall costs and the financial status of health care providers:

1. The ability of the Medicare program to expand coverage to include prescription drugs will depend a great deal on the total cost, and the rate of cost increase,of that benefit. Expensive medications, which now represent a crushing cost to many individual low-income beneficiaries, could represent an unbearable cost to an expanded Medicare program. Even if some costs are shifted to plans, providers, or patients, the program cannot tolerate an exponentially rising cost curve with no apparent upper limit.

2. From the purchaser perspective, all health care costs fall under the same general budget category (health benefits), so that monies spent on prescription drugs are monies that are not spent on hospital, physician, and other provider services. A strict arithmetic of rising pharmacy costs and fixed (or slowly increasing) premiums inevitably means fewer dollars available for other health care services.

3. Physician groups have been pressured, for economic reasons, by health plans to accept full-risk capitation, including capitation for prescription drug costs. In situations where capitation payments are inadequate to cover costs, providers are placed in an ethical quandary that is unfair to both them and their patients. Once some general formulary, generic substitution, and medication guideline measures are taken, further cost reductions may begin to come from the witholding of truly beneficial treatment. This scenario is most likely when a fixed pharmacy budget becomes strained by the sudden appearance of a new medication or new indication for an existing medication (e.g., Viagra, tamoxifen for prevention of breast cancer).

Multispecialty Group Practice / Integrated Health System
Projected Managed Care Expense Categories - 2002



Annual Increase in National Health Care Expenditures, by Category

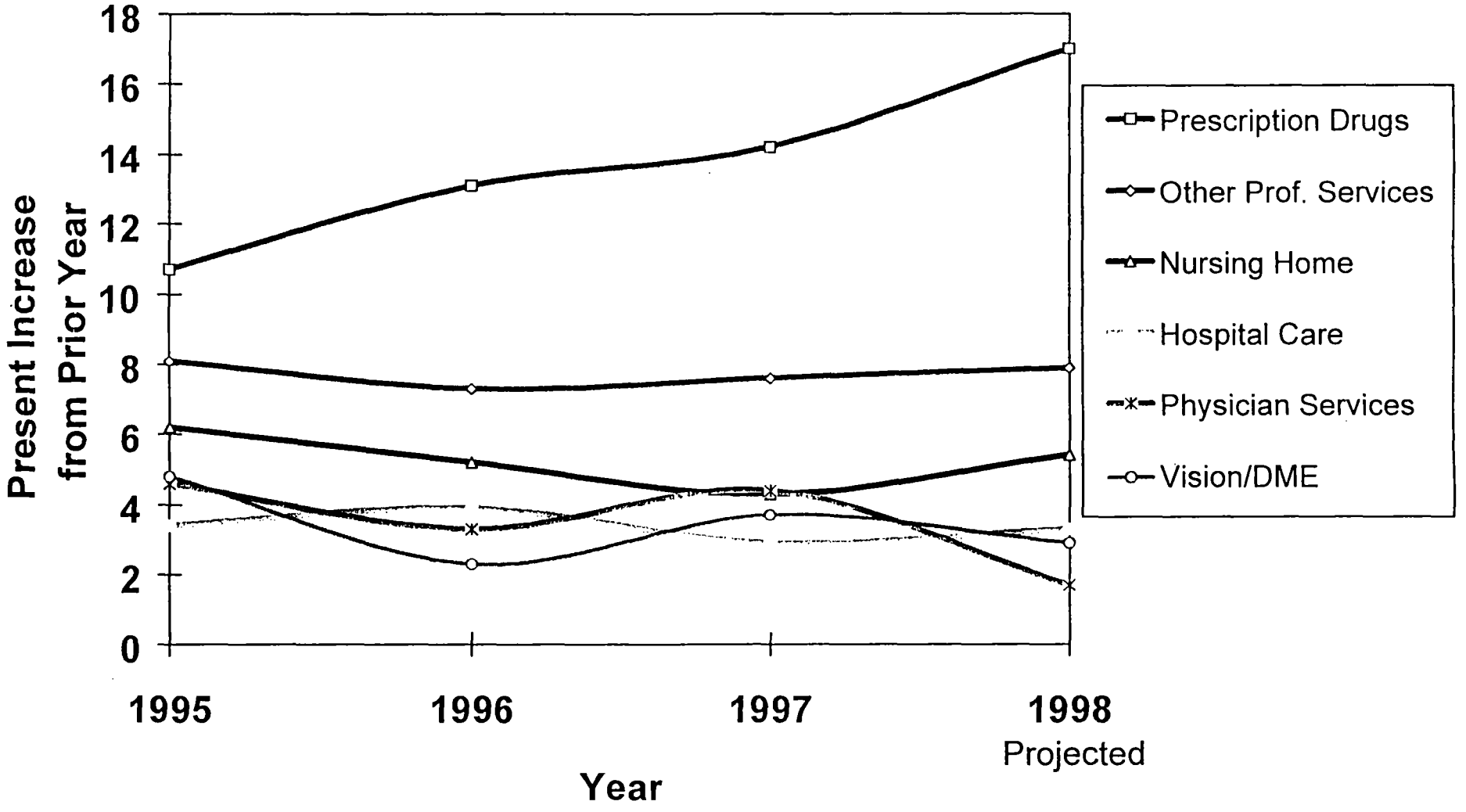


Figure 1

Source: Inglehart, JM, *NEJM*, Jan. 7, 1999

Background - Increases in Prescription Drug Costs

The basic numbers are straightforward:

- 14.1% annual increase in costs for prescription drugs in 1997, when the annual increase for total health spending was 4.8% and the overall level of inflation in the economy was lower yet (Levit, 1998);

- 17% estimated increase in costs for prescription drugs in 1998 (Kuttner, 1999)

- 2.7% rise in 1997 in the Producer Price Index for prescription drugs (suggests that only a relatively small part of the overall cost increase is related to price increases for the same "market basket" of drugs) (Mehl, 1998);

- for patients with AIDS, 16% of total costs of care related to prescription drugs in 1994, up from 5% in 1988 and 6% in 1990 (Hellinger, 1998);

- in the Henry Ford Medical Group, an increase of nearly 20% (from $16.62 pmpm to $19.87 pmpm) in prescription drug costs from 4th quarter 1997 to 4th quarter 1998, despite aggressive management of costs;

- at Empire Blue Cross and Blue Shield (NY), spending on prescription drugs up 20% in 1997.

If the increases are not due primarily to price increases for the same mix of drugs, what else is happening to drive up total costs? There is no single answer, but there are several factors that combine to account for such a large overall increase.

1. There is a constant stream of new drugs coming on the market, and the research and development costs for each drug can amount to several hundred million dollars. These costs have to be recouped by the manufacturer. Advances in basic science open up new possibilities for treatment and entire new classes of drugs, resulting in a never-ending supply of new drugs whose R&D costs are eventually aborbed by consumers.

Medications for depression are a prime example of this phenomenon. The selective serotonin reuptake inhibitors (SSRIs) did not exist as a drug class ten years ago and were relatively new as a class five years ago. Prozac, Zoloft, and Paxil ranked 8th, 10th, and 11th, respectively on the list of most frequently prescribed brand-name medications in April of 1998. If they had been a single drug, they would have ranked first, with over 2,260,000 new prescriptions in that month alone (Todd, 1999).

The same report indicated that Viagra had taken 13th spot on the list, with nearly 600,000 prescriptions in just its first month on the market. In the same month (possibly inflated, though, by some seasonal effects) Claritin and Claritin-D combined for second place with over 1,500,000 new prescriptions.

2. As effective treatments become available, or as treatments with fewer side effects or easier daily schedules become available, the number of individuals willing (or demanding) to take them increases. If these patients would have received more expensive alternative forms of treatment, there may be cost savings. On the other hand, though, patients who would have used over-the-counter treatments or less expensive (generic) prescription medications will now incur higher costs.

3. As more patients move into managed care plans with prescription drug coverage, there is a "moral hazard" phenomenon in which patients would prefer prescription drugs that are covered by the plan (even with a co-pay) to OTC medications that must be paid for out-of-pocket.

These three factors taken together all yield an increase in the number of prescriptions written, either for new drugs or for existing drugs. A recent study estimated that of the 14 % increase in expenditures for prescription drugs in 1997, 11.7% was due to increase in volume with only 2.5% due to increase in price. (Copeland, 1999)

4. Nearly half of the total cost increase for prescription drugs is in increased volume of existing drugs. This increasing volume reflects an aging population, broader indications for many medications, increasing use of medications for prevention as well as for treatment of disease (estrogen replacement therapy or Raloxifene to prevent osteoporosis, HMGcoA Reductase Inhibitors to prevent heart disease, tamoxifen to prevent breast cancer), and increasing dissemination of guidelines about use of existing medications that have the effect of increasing rates of use (e.g., beta blockers for patients after AMI).

5. Some possible price decreases that might help balance the other forces, such as the expiration of patents for popular drugs that can then become generics, have either not happened or happened more slowly than expected. A recent Time magazine article (March 8, 1999) described the legal battle between the Federal Trade Commission and Mylan Laboratories over a sudden increase in price for lorazepam (a popular tranquilizer) from $11 to $85 at retail for a one-month supply. Even though the drug in question is a generic, Mylan is accused of essentially "cornering the market" on the essential chemical supplies needed to produce it in order to drive competitors out of the market, raise prices, and maximize profits. Mylan argues that the price increase is necessary to allow it to stay in business as a generic manufacturer and alternative to even more expensive brand name, patented medications.

Several more specific drivers of increasing drug costs are discussed in the following sections.

I. "Quality of Life Drugs".

Not all drugs are used to save or prolong lives, or even to ameliorate pain and suffering associated with conditions like arthritis. Medications are being developed to address "quality of life" issues that are stretching the definitions of "treatable medical conditions".

Viagra is the most well-known example - a medical treatment for impotence that has created an entire new group of "patients": men who have erectile dysfunction but who had not been, and perhaps would never have been, seeking medical treatment. Viagra sold 600,000 prescriptions in its first month on the market, and the growth potential was so open-ended that major managed care plans like Kaiser either refused to cover it or placed limits on the number of pills (6-8 per month) that an individual could be covered for. It has been estimated that as many as 30,000,000 men suffer from impotence at least occasionally, but only 2.7 million consulted a physician for that complaint in 1997. A new patient group of 27 million men receiving treatment at $7-10 per pill would be an obvious and enormous driver of increasing prescription drug costs.

Propecia for baldness is another example, with a $50 per month cost. Alternative treatments for baldness (e.g., hair transplants) have generally not been covered by health insurance plans, as baldness itself has generally not been considered to be a "medical condition". The fact that the condition is treatable by a prescription medication, though, helps redefine it as medical and therefore under the domain of health insurance coverage.

The Wall Street Journal of May 3, 1999 contained another example, this time about an existing medication that has now been approved for an indication that stretches our conception of disease - "social phobia" or "social anxiety disorder". SmithKline Beecham is apparently about to receive regulatory approval to advertise its antidepressant Paxil for treatment of social phobia. While company officials pointed out that the disorder affects some 17 million people in the U.S. and is associated with alcoholism and suicide, there appears to be no clear line between a serious illness for which treatment might be well-justified and more ordinary cases of shyness and stage fright. The company plans to sponsor a series of public service announcements that will educate the physician community and the lay public on the problem of social phobia.

There is no theoretical upper bound to the potential for "lifestyle drugs". Drugs to increase metabolism or lose weight, drugs to eliminate age spots or facial wrinkles, drugs to make it easier to quit smoking, or drugs to eliminate facial hair on women are either already available or in development. Although it is impossible to predict the future cost consequences of these developments with any accuracy, the potential additional costs in this area are unlimited.

II. Changing Patient Demographics.

The aging of the American population is a well-documented phenomenon. The association between aging and use of health care services is also well-documented. At the national level, then, increases in prescription drug costs are an inevitable consequence of an aging population. "Savings" in the Medicare program, though, achieved through caps or actual reductions in payments to hospitals and health plans, must inevitably conflict with increasing costs associated with an aging population. Unless there are relatively large numbers of inefficiencies that can still be "squeezed out" of the health care system, a combination of increasing numbers of beneficiaries, rising costs per beneficiary, and lower levels of payment cannot possibly be sustained.

As Congress debates expanding Medicare coverage to include prescription drugs, the arithmetic comes into even sharper focus. A new benefit with an exponentially rising cost curve cannot possibly be covered within a program budget that is not also exponentially expanding. Costs of drugs must either be borne largely by out of pocket payments by individual beneficiaries, or must compete for funding with other parts of the health care program - doctor and hospital services.

At the health plan or medical group level, though, the issue is a little more complex than a rising number of individuals in the covered population and rising costs of a covered benefit. In the Medicare population, a key issue is the number of beneficiaries enrolling in managed care plans that offer prescription drug coverage, and the rising costs of that benefit coupled with caps on monthly premiums. There is a clear incentive for Medicare recipients taking multiple expensive medications to enroll in plans offering coverage for those medications. As the number of Medicare managed care enrollees increases, the number of elderly individuals with prescription drug coverage rises, and the financial risk of health plans and provider groups paid on a capitation basis rises in proportion.

In the commercially insured population, a demographic force pushing up drug costs may be the number of people insured in a generally strong economy, and the number insured in managed care plans offering prescription drug coverage who were either uninsured or insured in indemnity plans without drug coverage. Patients whose diabetes, hypertension or asthma were not well controlled because of limitations on coverage in a prior program may be more expensive to treat in a managed care plan than those who have been continuously enrolled and covered. A health plan taking in large numbers of new members is likely to find its pmpm drug costs rising faster than a plan with more stable membership, as it deals with a relatively larger number of members who need "tuning up" or more active forms of therapy for conditions that have been neglected in the past. A strong economy brings more people into insurance, and a general employer shift to managed care brings more people into plan with drug coverage.

A strong economy reduces the number of patients eligible for Medicaid, but many states are already turning to managed care as a means of controlling costs in their

Medicaid programs. Plans or provider groups paid on a capitation basis must absorb rising drug costs, but have no way to find savings elsewhere in the benefit package if the main features of the benefit package are contractually fixed and the payments are already at or below costs of providing care. A downturn in the economy that had the dual effect of expanding Medicaid rolls while reducing state government revenues could be the catalyst for crisis, as neither the health plans, provider groups, nor the State government could find the funds needed to pay for the relatively rich prescription drug benefit in Medicaid.

Treatment successes in diseases like cancer, AIDS, diabetes, or heart disease have the effect of increasing prescription drug costs by increasing the numbers of people living with a chronic, rather than acute and life-threatening, condition. An AIDS patient who would have died in approximately 18 months after diagnosis of HIV infection in 1989, for example, is now a person who can be maintained on an expensive regimen of antivirals for many years. A woman with breast cancer who might have died with only palliative treatment after metastasis is now a candidate for high-dose chemotherapy and bone marrow transplantation. A middle-aged man who might have died suddenly of AMI with essentially no health care costs 20 years ago is now likely to live a long and productive life on a regimen of beta blockers and cholesterol-lowering agents. Patients with diabetes on tight-control regimens live longer without complications, but may require a complex combination of insulin, ACE inhibitors, and other medications to control a wide range of risk factors.

III. Medicalization of Nearly Everything.

Viagra, Propecia, and various weight control medications have already been cited as examples of treatments for "problems" that have not traditionally been considered to be diseases or treatable medical conditions. Impotence, baldness, and obesity are just a part, though, of the list of human frailties or problems that are making their way into the medical arena. Other examples:

- The "common cold" - viral upper respiratory infection - is a legitimate disease, but one for which there is no effective medical treatment and one where self-management is the traditional approach. Antibiotic prescriptions for URIs are rising, even in the absence of a bacterial infection. Patients who expect and demand an antibiotic for URIs in themselves or their children are part of the prescription drug cost problem.

- A set of multi-symptom syndromes have emerged in recent years as treatable medical conditions. Chronic fatigue syndrome, multiple chemical sensitivity, fibromyalgia, "Gulf War syndrome", and others are probably not new conditions, but new labels for problems that were previously not considered medically treatable and perhaps not even brought to the attention of physicians. Although there are not clearly indicated pharmaceutical treatments for most of these conditions, a prescription can frequently be a preferred option for busy physicians who otherwise might face a series of long and unproductive office visits.

- Many mental health problems, particulary depression and anxiety, are diseases with known biological bases, but are also likely to have gone undiagnosed and untreated in the past. Prozac and the other SSRIs have opened up diagnosis and treatment to large numbers of people who in the past might not have been willing to accept other forms of therapy.

- Menopause is an example of a normal biological change that in the past was not automatically associated with medical care and pharmaceutical treatment, but is now likely to receive both. Estrogen replacement therapy or chemical prophylaxis for breast cancer with Tamoxifen are examples of treatments that are rising in frequency (and cost) for a condition that is not fundamentally a medical problem.

IV. Direct Marketing to Consumers.

Pharmaceutical companies have traditionally directed their advertising to physicians, and still do most advertising to physicians through medical journals, presence at professional meetings, detailing, and special meetings. A growing phenomenon, though, is direct marketing to consumers in one of two forms: (a) a "see your doctor" approach in which the drug is not named, but the message has to do with a new and effective treatment for a common problem; and (b) essentially the same kind of ad that is directed to physicians, in which the drug is named, and some of the information about indications and contraindications is provided. Examples:

- SmithKline Beecham is advertising LYMErix as "the world's first vaccine to prevent Lyme disease".

- Forest Pharmaceuticals is advertising oral Flumadine as an "antiviral medicine to fight the flu" in print ads in major metropolitan newspapers. The ad not only promises symptom relief, but asks patients to see a doctor within 48 hours of the onset of symptoms because the medication is only effective if given that early in the illness. The fact that viruses other than flu may causes the symptoms listed in the ad, or that not all strains of flu are treated effectively is not mentioned.

- Both Allegra and Claritin are heavily advertised in consumer publications, creating the impression that there is a clear advantage to prescription vs. OTC antihistamines.

- Sporonox is widely advertised as a treatment for toenail fungus, in spite of the fact that the treatment is expensive ($600-800 per treatment), offered for a condition that many patients have lived with for a long time, and associated with only a 20-30% cure rate.

- Astra Pharmaceuticals ran an expensive ad campaign in 1997 for Prilosec, using network television, cable, and magazine media. Prilosec is now the leading prescription drug in terms of sales; during the same time period, sales of ranitidine in generic form have fallen by 50%. The advertisements raised awareness of Gastroesophageal Reflux Disease (GERD) among consumers; perhaps not accidentally, the incidence of GERD as the diagnosis for which Prilosec was prescribed rose dramatically during the same time period. (Burton, 1998).

IMS Health estimated that direct-to-consumer marketing expenses would reach $1.3 billion in 1998, a 50% increase over 1997 levels. That follows a reported 42% increase in the prior year. Most spending (80%) in 1996 was in consumer magazines; for 1998 television advertising was projected to account for 50% of the total with magazines dropping to 40%.

As a result of increased direct-to-consumer marketing, the total marketing budget for pharmaceutical companies (including "detailing" to physicians and marketing in medical journals is rising to the point that is nearly as large as the R&D budget.

In order to target consumer messages more directly, some pharmacies are using their own prescription records to identify patients with particular conditions and then send advertising information from drug companies; drug companies themselves maintain 800 numbers that serve as vehicles for obtaining information from patients themselves that permit later mailings about specific products.

V. Limits on Physicians' Ability to Maintain Knowledge of Pharmaceuticals.

The pharmaceutical industry spends approximately $10 billion each year in advertising to clinicians to influence their choice of one medication over another, or to make them aware of the benefits of a particular medication (Tanouye, 1998)

This overall expenditure translates into $5,000 per physician per year of "behavioral modification" efforts to sell more drugs, including meals, trips, educational programs, pens, books, and other gifts or incentives. A typical drug representative is expected to produce 3-5 times their annual salary in drug sales.

This expense would not be objectionable if it reliably had the effect of directing physicians to prescribing the safest, most cost-effective medications for specific indications. In practice, though, expenses for "detailing" are incurred primarily by the companies promoting expensive patented drugs rather than generics, and are often specificially designed to promote sales of the patented drugs in situations where equally safe and effective generics are available. Calcium channel blockers for treatment of hypertension, for example, are promoted when cheaper, generic beta blockers and diuretics would work as well and are the only two classes of medications proven to reduce mortality in hypertension.

Data on the costs of "mis-use" of prescription drugs suggests that detailing to physicians, whatever its benefits to patients may be, does not result in a pattern of drug use that is safe and efficient. Examples:

- A recent study estimated the costs of drug-related morbidity and mortality for treatment in outpatient settings at $76.6 billion per year (Johnson, 1995).

- Another study estimated that, for every $1 spent on drugs for patients in nursing home settings, $1.33 in various health care resources was spent in the treatment of drug-related problems (Bootman, 1997).

- A third study estimated that as many as 32% of people over 65 living in community settings (i.e., not institutionalized) were receiving one or more inappropriate medications (Willcox, 1994).

- Finally, a study of two outpatient clinics treating elderly patients identified potential adverse drug interactions in 31% of patients whose charts were reviewed and actual adverse drug interactions in 21%. Twelve of the 86 documented adverse drug interactions required hospitalization (Schneider, 1992).

Clearly, not only are there high and rising costs associated with prescription drugs themselves, but there are also a set of "hidden" costs associated with misuse of drugs.

VI. Higher Prices in U.S. than Elsewhere.

Several studies have documented higher drug prices in the U.S. that in other countries. One estimate, from 1994, put the excess cost to U.S. consumers in a range between $12 and $35 billion annually Sager, 1997). The "beneficiaries" of differential pricing policies are not poor, underdeveloped countries that cannot afford higher prices, but rather countries such as Switzerland, Japan, Sweden, Germany, and the U.K. that have either publicly funded health care systems that can control prices as purchasers or other means of controlling prices.

As an example, a study by the Public Citizen's Health Research group in 1998, focused on eight specific medications for mental health conditions, found that the cost of a 30-day supply for all eight was higher in the U.S. than in 16 other countries of North America and Europe. The difference ranged from 1.7 times to 2.9 times higher across the eight medications, when comparing the U.S. to the average of the other countries. Differences were even larger when comparing the U.S. to specific low-cost countries. Clozapine, for example, cost $317 per month in the U.S., compared to the equivalent of $52 per month in Spain.

It is not clear that the difference in prices across countries is increasing over time, but higher prices in the U.S. than elsewhere contribute to the high current costs. The ability of national health insurance systems to negotiate with drug companies to set prices is one explanation for lower prices, but does not fully explain differences between the U.S. and countries that do not have single national health insurance programs (e.g., France, Germany).

Pharmaceutical companies occasionally deny the existence of the differences, but also explain and attempt to justify the differences by arguing that (a) U.S. consumers benefit by the new products that higher prices in the U.S. allow them to produce, regardless of price inequities; and (b) there is no better alternative that will still allow R&D spending at current levels. Drug companies themselves may not be either the source of this problem or the means to its solution. This is an area amenable to treaties between governments in the context of broader issues of trade and economic relationships.

VII. Rising Costs of Developing New Drugs.

U.S. pharmaceutical companies spent an estimated $21 billion in 1998 on domestic and foreign R&D. The expenditure of $17 billion in the U.S. is higher than the budget of the NIH ($13.6 billion for 1998) (Tanouye, 1998). That total represents a 10.8% increase over 1997; the rate of annual increase was actually higher than that through almost the entire past 20 years. A typical new drug introduced in 1990 cost $500 million to develop, and might have taken 15 years to work through the entire process from basic laboratory research through clinical trials. The high and rising costs of drug R&D represent the primary rationale provided by pharmaceutical companies for rising drug costs. A recent consulting firm study estimated that new drugs introduced by the leading pharmaceutical companies over the next seven years will have to earn $1-1.5 billion in profit each to support the companies' rising investment in R&D (Drug Topics, 1998).

Are all these expenses necessary? Perhaps, but the context of R&D for new medications has changed, with an inevitable rise in the cost of clinical trials. The key issue is whether new medications are researched to the point of proving safety and efficacy to meet requirements for FDA approval, or whether they are researched to the point of establishing a specific difference from competitors in the same basic drug class (e.g., fewer side effects, enhanced quality of life) that will offer a marketing advantage.

The former objective (safety and efficacy) is less time-consuming and less expensive, but still sufficient to meet all FDA requirements for bringing a drug to market. The latter objective, since it typically focuses on relatively subtle differences experienced by relatively small numbers of patients, is much more time-consuming and much more expensive, but is required in order to gain FDA approval for certain marketing claims.

According to a recent article in the *Wall Street Journal* (Langreth, 1998), as many as one-quarter of patients currently in clinical trials are in studies that are going on after initial FDA approval of a drug. An example of such a study is a $50 million, six-year trial of Pravachol supported by Bristol-Myers Squibb to establish that Pravachol reduced deaths and heart attacks rather than just lowered cholesterol. The study did demonstrate a significant effect, and the FDA did permit Bristol-Myers to advertise Pravachol as a protective agent against heart disease. Sales "soared" (according to the Wall Street Journal), even though Pravachol had been tested against placebo rather than against any competing cholesterol-lowering agent.

Similar studies by other companies are going on in "crowded" clinical areas like hypertension, female hormone replacement, arthritis, and congestive heart failure, where a number of safe and effective therapies are competing for lucrative gains in market share. New drugs seek to become the fourth or fifth entrant in a class, usually with no clear advantage in cost, safety, or efficacy, put perhaps a minor advantage in convenience or absence of a minor side effect. The studies required to document minor advantages involve sample sizes of 5-20,000, because nothing less than that has the statistical power

to show significant differences in incidence of relatively rare events like heart attacks or strokes or in already low-incidence side effects. A sort of "clinical trial arms race" begins to occur; as one company gains the ability to claim a competitive advantage for its medication, the competing companies must mount similar studies in order to keep up. Failure to keep up could mean ceding the market to the competitor and losing a large volume of sales.

A recent set of articles in the *New York Times* (5/16/99) documented some of the horrors associated with this race to complete clinical trials in order to gain market advantage, particularly when the trials involve incentive payments to community physicians for recruitment and monitoring of patients in studies. Inappropriate pressure on patients, "fudging" of eligibility and exclusion criteria to put more patients on study, inaccuracy of record-keeping, and pure fabrication of data and patient records are among the problems. Patient safety is compromised, results of studies are questionable, authorships on scientific papers are based on accrual of patients rather than actual scientific contribution to the studies, and the costs of the entire enterprise are passed on to consumers in the form of higher prices.

No Light at the End of the Tunnel

There is *no clear evidence of changes in the various forces described above that will reduce or eliminate the problem of rising prescription drug costs and stable or slowly rising reimbursements. There may actually be an increase in pressure.* Examples:

1. The general trend of expansion for new health care technologies of all kinds is gradual and continuous rather than sudden (Victor Fuchs, Health Affairs, 1999). There is no reason, based on experience with many other forms of medical technologies, to believe that the increases in the use of SSRIs, Viagra, NSAIDs, or other relatively new and expensive medications will taper off after an initial "burst". As physicians gain experience with medications and patients hear about benefits, use increases rather than decreases.

2. The "cycle time" for FDA approval of new molecular entities (NMEs) has dropped from 30 months to 19 months over the past 10 years. The FDA approved 39 NMEs and 10 "biologics" in 1997, down slightly from 1996 but higher than the average for the preceding ten years. (Neumann and Sandberg, Health Affairs, 1998). The "pipeline" for new medications is clearly flowing well.

3. Support for research and development in health care continues to rise, and the recent increases in NIH budgets promise to yield scientific findings that will assure a continued flow of new ideas and new medications through the FDA approval pipeline.

4. According to a 1997 survey of the pharmaceutical industry, there are 316 new medications being developed for cancer, 124 for AIDS, and 96 for stroke and heart disease. (Neumann and Sandberg)

5. We are just beginning to see an increase in the number of "biologics" approved for use that were developed out of genomics research.

6. There is significant research going on in the area of "delivery systems" for medications - pumps, implants, nasal sprays, skin patches, etc. All are designed for increasing patient convenience and acceptance of treatment; essentially none are designed to produce cost savings. In fact, the profits for many of the companies developing these technologies come from taking generic drugs whose patents have expired and packaging them with the new delivery technologies to create patentable combined products that can be sold at relatively high prices to consumers. The combination of old drug and new delivery mechanism is a "new product" that may be patentable or at least sold profitably for some time until competitors enter the market.

7. Patents on a number of very popular and profitable drugs - Zantac was a recent example - have expired or are due to expire this year. This creates even more pressure on the companies making them to develop new products to take their place. Based on these

trends, a study in the American Journal of Health System Pharmacy in 1998 estimated that the pace of new drug introduction would escalate at least through 2000, and that the drugs introduced would be "more effective and expensive than the pharmaceutical products they replace".

What Can Be Done?

The current pattern of rising costs suggests that the current mechanisms for controlling prescription drug costs are not sufficient to handle the continuing and increasing cost pressures. Some combination of strengthened efforts on the cost containment side, coupled with some acceptance among purchasers of increased premium rates, will have to come together to avoid financial catastrophe for at-risk health plans and providers. Some potential steps that providers and purchasers can take:

1. *Increased patient choice and accountability.* Pharmacy benefits can be structured in many different ways - some place a greater burden on patients than others. No one model will fit the needs and preferences of all, since those needs and preferences vary. Patients who desire the most comprehensive prescription drug coverage, with the fewest restrictions and the lowest out-of-pocket expense, should be able to find a plan offering that coverage, but expect to pay for it, either in higher premiums or in more restrictive coverage in other areas of the benefit package. Patients who are willing to accept fixed formularies, aggressive generic substitution policies, or higher co-pays should find those options as well, with either lower overall premiums or richer benefits in other parts of the package. Making the trade-offs in benefit costs more explicit will make patients more sensitive to rising costs.

2. *Stronger and more consistent formularies.* Organized health plans and provider networks can save money through creation and enforcement of formularies. The benefits are achieved through both channeling of prescribing patterns to more cost-effective medications, and negotiation of better prices through volume purchasing of preferred drugs. One key issue, though, is coordination. If a health plan has Prozac in its formulary because of a negotiated price with Lilly, and a provider group has Paxil in its formalary because of its findings of superior cost-effectiveness, the group's physicians are in a quandary when treating the health plan's members. Since the managed care environment seems to be moving away from, rather than toward, closed-panel or staff-model health plans, the issue of coordinating formularies will become more rather than less acute.

3. *More support for clinical effectiveness studies.* One factor in creating strong and consistent formularies is greater consensus about the relative cost-effectiveness of alternative medications in the same class. Medical groups and health plans are the ideal place to conduct comparative clinical trials and cost-effectiveness analyses using existing published data. The key issue is not price per se, but cost-effectiveness.

4. *Messages to consumers about medications.* Consumers may not trust health plans' communications about drugs and drug costs, because in the current anti-managed care climate, they are likely to believe that the plans are simply interested in saving money at the expense of good quality care. National organizations representing physicians, though (AMGA, AMA, various Board and Colleges of specialty physicians) may have greater credibility if they speak out on issues of over-medication (e.g., antibiotics for viral URIs)

or inappropriate medication ("rescue" medications rather than anti-inflammatories for children with asthma).

5. *Greater information coordination for patients with multiple medical problems.* Patients who see multiple physicians, using separate medical records systems, for multiple chronic and acute conditions, run a high risk of receiving either unnecessary or potentially dangerous combinations of medications. This is a problem of special significance in the elderly, but can occur for anyone with multiple medical needs. Pharmacies may be able to detect some possible interaction problems, but the number of patients admitted to hospital each year for adverse drug reactions is testimony to the failure of current methods of detecting interactions and other potential problems before they occur. One possible benefit of a large movement of people into organized managed care systems with good data bases would be the ability to automatically detect and avoid possible drug interactions.

6. *Higher health care premiums.* In the end, if consumers want to have antibiotics for every cold, flumadine when they have the flu, high-dose chemotherapy for advanced stage breast cancer, convenient pumps and skin patches for chronic care medications, and the latest prescription antihistamine or NSAID, either they or their employers will have to pay. Policies that promote greater price sensitivity among individual consumers (e.g., higher co-pays or deductibles for prescription drugs) may temper consumer demand, but it may be appropriate to spread costs of improved drug therapies over an entire insured group by incorporating those costs into higher premiums.

From the larger health policy perspective, we propose the following recommendations:

Plan and Provider Initiatives

1. Institute separate budget line items and payment models for pharmacy, distinct from facility, technical, and professional payments in Medicare and other insurance systems; when this is not possible,

   a. allow adjustment of DRG payments to reflect the rising cost of inpatient pharmacy;

   b. encourage continued research and development on ambulatory case-mix models that reflect costs of prescription drugs, for use in capitated or other bundled payment models;

2. Establish continued upward adjustment of tiered co-payments and deductibles for prescription drugs to make patients sensitive to the relative price of drugs while not creating insurmountable financial barriers to effective treatment;

3. Expand any policies that promote stable, long-term relationships between patients and providers and plans, so that the same business entity will participate in both sides of a

cost-offset tradeoff involving pharmacy costs now in exchange for savings on other forms of care in the future;

4. Encourage greater coordination among employers, health plans, and medical groups on issues of formularies and preferred drugs, with alignment or actual sharing of financial incentives for use of the "right" drugs in the "right" patients for the "right" indications;

Federal Policy Initatives

5. Establish continued examination by Congress, HCFA, and other large agencies representing public and private purchasers on the issue of differential pricing of medications between the U.S. and other countries, and on levels of profit associated with patent monopolies. There is no obvious reason why the U.S. should subsidize the R&D costs of pharmaceuticals for the rest of the world, or contribute more than a fair share of the profits of companies that, in many cases, are multinational or primarily based in other countries.

6. Enact stronger regulation, by the same payment or regulatory agencies, of advertising and promotion of pharmaceuticals, to both professional and lay audiences;

7. Promote the concept of "full disclosure advertising", in which costs, side effects, complications, relative effectiveness, and strength of scientific evidence are all included in materials designed for direct consumer marketing.

8. Require examination, and possible regulation, by appropriate regulatory bodies, of costs of clinical trials, bonus payments to physicians who meet patient accrual targets in such trials, other issues related to the conduct and publication of results of trials, and the ultimate benefit of expenditures on clinical trials to the public.

Other Initiatives

9. Increase investment in public education programs about appropriate use of generic drugs, lack of benefit of antibiotics for viral infections, safety and efficacy of over-the-counter medications for common acute and chronic conditions, and possible adverse effects of unnecessary or inappropriate medication use;

10. Seek expanded visibility of AMGA, AMA, AHCPR, major medical specialty societies, and other national organizations as "trusted experts" to consumers on issues of effective use of prescription medications. Guidelines and recommendations about appropriate and inappropriate patterns of care, widely disseminated through print, television, and Internet media may serve as a counter to some direct marketing efforts by pharmaceutical companies

Summary

It is not possible to sustain the current trends of rising drug costs (along with rising costs of other treatments and medical technologies) and flat or slowly rising health insurance premiums. Something has to give. There is no overall evidence of cost savings with new medications - such cost savings as might be documented in small-scale controlled studies are often more than offset by the increase in the number of previously untreated individuals seeking care when effective drugs (e.g., Viagra) become available.

It will be impossible to make prescription drugs affordable to the elderly through Medicare without some mechanism to control costs. Regardless of how costs are distributed between program benefits covered by premiums or out of pocket expenses, an exponentially rising cost curve will be impossible to sustain.

There are a number of steps that can be taken to moderate the rate of increase in prescription drug costs, but there is no obvious "magic bullet" than will solve the problem. Health plans and organized medical groups should adopt all the steps as fully as they can, but there still may be an unavoidable increase in health care costs due to prescription drugs that will have to be borne by employers and individual consumers if they want the benefits that the new drugs provide.

Sources

Bootman, JL, Harrison, DL, & Cox, E. The health care cost of drug-related morbidity and mortality in nursing facilities. *Archives of Internal Medicine*, 1997, *157*, 2089-2096.

Burton, TM. Why generic drugs often can't compete against brand names. *Wall Street Journal*, November 18, 1998.

Copeland, C. "Prescription Drugs: Issues of Cost, Coverage, and Quality" (EBRI Issues Brief # 208). Employee Benefits Research Institute, April, 1999.

Record r&d costs create challenges for drugmakers. *Drug Topics*, 1998, *42*, 1.

Frudenheim, M. Health insurers seek big increases in their premiums. *New York Times*, April 24, 1998.

Fuchs, VR. Health care for the elderly: How much? Who will pay for it? *Health Affairs*, 1999, *18(1)*, 11-21.

Hellinger, FJ. Cost and financing of care for persons with HIV disease: An overview. *Health Care Financing Review*, 1998 *(Spring)*.

Iglehart, JK. The American health care system: Expenditures. *New England Journal of Medicine*, 1999, *340*, 70-76.

Johnson, JA & Bootman, JL. Drug-related morbidity and mortality: A cost-of-illness model. *Archives of Internal Medicine*, 1995, *155*, 1949-1956.

Kuttner, R. The American health care system: Insurance coverage. *New England Journal of Medicine*, 1999, *340*, 163-168.

Lagnado, L. Drug costs can leave elderly with a grim choice: Pills or other needs. *Wall Street Journal,* November 17, 1998.

Langreth, R. Drug marketing drives many clinical trials. *Wall Street Journal*, November 10, 1998.

Levit, K, Cowan, C, Braden, B et al. National health expenditures in 1997: More slow growth. *Health Affairs*, 1998, *17(6)*, 99-110.

Mehl, B & Santell, JP. Projecting future drug expenditures - 1998. *American Journal of Health System Pharmacy*, 1998, *55*, 127-136.

Meyer, H. The pills that ate your profits. *Hospitals and Health Networks*, 1998, *72*(3), 18.

Neumann, PJ & Sandberg, EA. Trends in health care r&d and technology innovation. *Health Affairs*, 1998, *17(6)*, 111-119.

PhRMA - Pharmaceutical Research and Manufacturers of America. Industry Profile 1998. http://www.pharma.org.

Sager, A. & Socolar, D. The market needs a peace treaty. *Business and Health*, 1997, *14*, 51.

Schneider, JK, Mion, LC & Frengley, JD. Adverse drug reactions in an elderly outpatient population. *American Journal of Hospital Pharmacy*, 1992, *49*, 90-96.

Tanouye, E. U.S. has developed an expensive habit: Now, how to pay for it? *Wall Street Journal*, November 10, 1998.

Todd, JM Record-breaking Viagra claims 95% of market. The Health Care News Server. http://www.healthcarenewsserver.com.

Weiss Ratings, Inc. Nearly 60% of HMOs Lost Money in 1997. http://www.weissratings.com/

Willcox, SM, Himmelstein, DU, & Woolhandler, S. Inappropriate drug prescribing for the community-dwelling elderly. *JAMA*, 1994, *272*, 292-296. (See also, editorial in same issue, pages 316-317, and related article in USA Today, July 27, 1994.)

Zagorin, A. Who's really raising drug prices? *Time*, Marcy 8, 1999.