

CHAPTER 6: GOVERNMENT IN THE PHARMACEUTICAL MARKETPLACE



The mission of the research-based pharmaceutical industry is to save lives, cure disease, and improve the quality of life. The industry does this both through its business operations—by discovering, developing, and marketing life-saving, life-enhancing medicines—and through its extensive philanthropic endeavors—which make it a U.S. and world leader in charitable contributions.

Both the federal and state governments are major purchasers of pharmaceuticals. The Defense Department (DoD) and the Department of Veterans Affairs (DVA) buy drugs for their own health-care institutions and for beneficiaries of their health-care programs. The U.S. Public Health Service (PHS) sponsors a variety of programs that include pharmaceutical assistance. Medicaid, a federal-state partnership that serves as the nation's principal public health-care program for low-income individuals, provides outpatient prescription drug coverage in all 50 states. In addition to participating in Medicaid, states operate separate pharmacy assistance programs for low-income individuals, particularly the elderly. However, most government programs that cover prescription drugs mandate various forms of price controls, including rebates, discounts, caps on prices, and limits on price increases. Various restrictions are also imposed on beneficiaries' access to drugs.

Government-imposed procurement requirements include Medicaid rebates; discounts to PHS entities, DVA, DoD, the Indian Health Service, and the Coast Guard; and rebates to state-funded programs that assist low-income elderly patients in paying for prescription drugs.

Medicaid Rebates and Related Discount Programs

Medicaid provides prescription drug coverage in all 50 states. According to HCFA, it covered an estimated 32 million Americans in 1999.¹ In 1990, Congress required that, for a pharmaceutical company to have its drugs reimbursed by Medicaid, it would have to pay a rebate on these products.

For all innovator products, reimbursement requires (1) a rebate that is the greater of 15.1 percent of the average manufacturer's price (AMP) or the difference between the AMP and the manufacturer's "best price," and (2) an additional rebate for any price increase for a product that exceeds the increase in the Consumer Price Index (CPI) for all items since the fall of 1990. The "best price" is the lowest price offered to any other customer, excluding Federal Supply Schedule (FSS) prices, prices to state pharmaceutical assistance programs, and prices that are nominal in amount, and includes all discounts and

rebates. Reimbursement for generic drugs requires a rebate of 11 percent of each product's AMP.

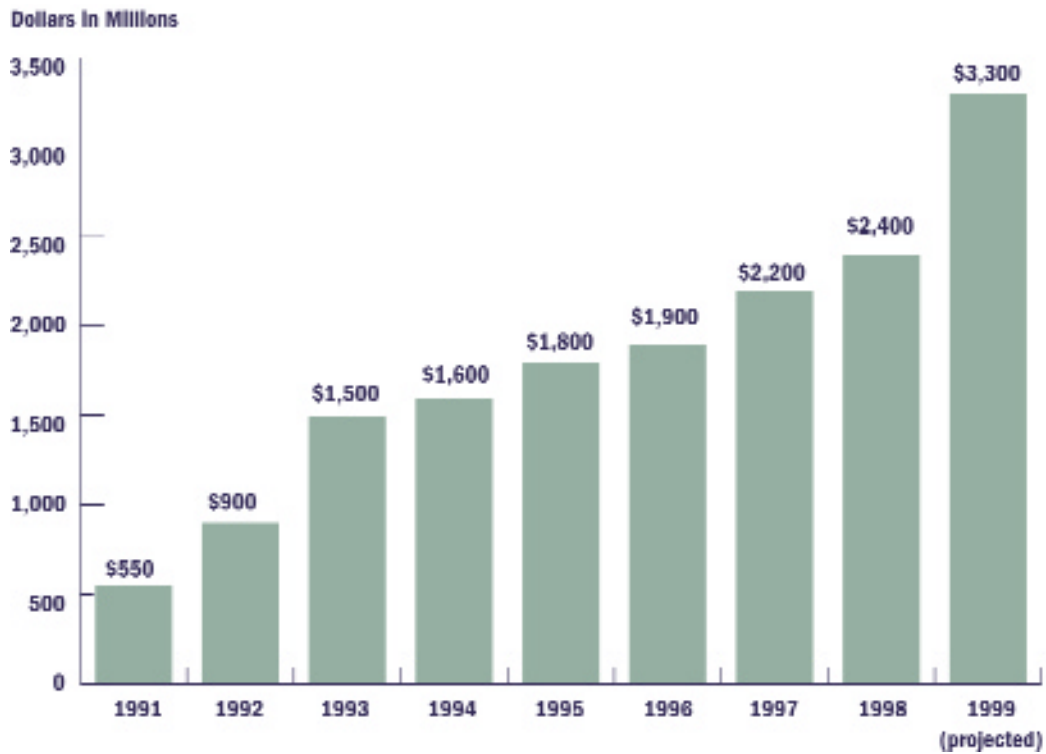
In 1999, manufacturers returned an estimated \$3.3 billion to the federal government and states—in effect an extra business tax [Figure 6-1].

In recent years, Congress mandated discounts for other federal procurement programs. The 1992 Veterans Health Care Act (VHCA) conditioned Medicaid coverage for a manufacturer's drugs on participation in three additional discount programs:

- **Federal Ceiling Price Program:** To have their products covered by Medicaid, manufacturers are required to sell innovator products to the DVA, the DoD, the PHS, and the Coast Guard at or below federal ceiling prices that are 24 percent below a manufacturer's average price to wholesalers for nonfederal customers, including hospitals and HMOs. There is no required discount for generic products.
- **Public Health Service Grantees:** Manufacturers also are required to sell to PHS grantees (e.g., community and migrant-health centers, hemophilia centers, Ryan White and AIDS drug-assistance programs) at discounted prices equal to the AMP minus the Medicaid rebate.
- **Federal Supply Schedule:** Brand-name manufacturers also must agree to list all pharmaceutical products on the FSS, a government-wide list of discounted products for procurement by federal agencies. No other industry is required to list its products to gain access to a separate, substantial market. In establishing the FSS price for a product, the government seeks to negotiate prices that do not exceed the price offered by a manufacturer to its most favored customers.

Another major government discount program is conducted by DoD. Unlike the rebate programs mandated by Congress in 1990 and discount programs mandated by the VHCA, the DoD purchasing program is not required for Medicaid reimbursement. The department negotiates the prices for purchases with manufacturers through its prime vendors, but these payments cannot exceed federal ceiling prices.

Figure 6-1
PHARMACEUTICAL MANUFACTURERS' REBATES TO MEDICAID



Sources: State Medicaid Programs; Muse & Associates, Washington, D.C., 1999, 2000.

State Pharmaceutical Assistance Programs

Because Medicare does not offer a prescription-drug benefit and many elderly individuals do not qualify for Medicaid, 24 states offer pharmaceutical assistance programs for low-income—primarily elderly and disabled—persons. Nineteen of these programs are operational, while five are still in the planning stage. The programs offer subsidized drug benefits to an estimated 2.4 million individuals.

Most of the programs were launched in the late 1970s and 1980s, when state budgets were healthy and large numbers of senior citizens had inadequate access to prescription-drug coverage.

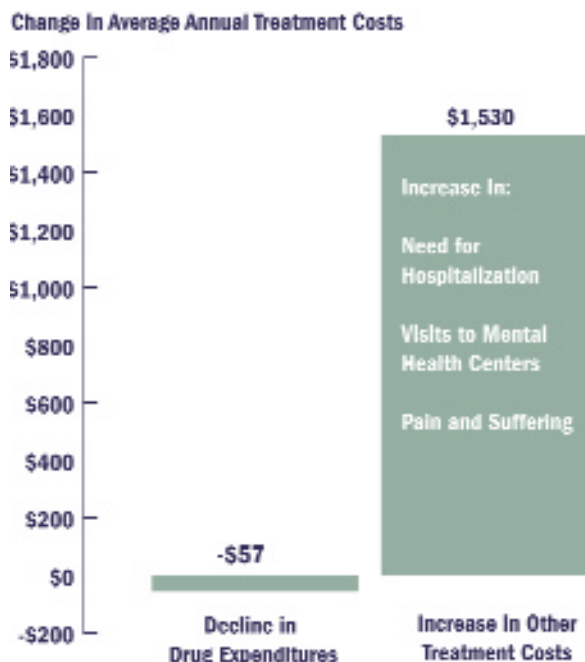
States soon found that these programs were more costly than anticipated, especially as public pressure forced them to expand eligibility and extend coverage. They have tried to contain costs by seeking increased taxes or

manufacturers' rebates, or by imposing access restrictions.

Federal Procurement Initiatives

Despite access to discounted prices through the federal ceiling-price program, the DVA is seeking additional savings by implementing a national formulary. The department views this formulary as essential to its evolution to an integrated health-care delivery system. However, the formulary is managed separately and relies on a cost-driven bidding process to include a product in many drug categories. The result of this bidding process severely limits physicians' choices to select the most appropriate drug products for their patients. There is concern that formulary limitations will not accommodate the special needs of veterans, who are disproportionately poor and suffer a higher rate of chronic disease than the general U.S. population.

Figure 6-2
EFFECT OF REIMBURSEMENT CAP ON
AVERAGE TREATMENT COSTS



Note: New Hampshire Medicaid program imposition of a three-drug reimbursement cap on psychotropic drugs to treat schizophrenia.

Sources: Soumerai, S.B., et. al., *New England Journal of Medicine*, September 1994; The Wilkerson Group, 1995.

DoD, which already uses a “TriService Formulary” to purchase prescription drugs for the three military branches, is now seeking to join the VHA purchasing operation.²

Restrictions on Access to Prescription Drugs in Medicaid and Other Government Programs

In addition to requiring rebates, the federal and state governments affect the pharmaceutical market in other ways. Many programs are imposing restrictions on physicians’ ability to prescribe drugs for their patients. Medicaid, the state pharmaceutical

assistance programs, and the other federal drug-purchasing programs are using restrictive drug formularies, prior authorization systems, and limits on the number of prescriptions or amount of any one drug that will be reimbursed.

Throughout the 1970s and into the early 1980s, many states offered a comprehensive and essentially unrestricted pharmaceutical benefit. However, as budgets became tighter, states began to look for ways to cut costs.

In 1981, states began to restrict drug coverage by limiting the number of prescriptions a patient could receive

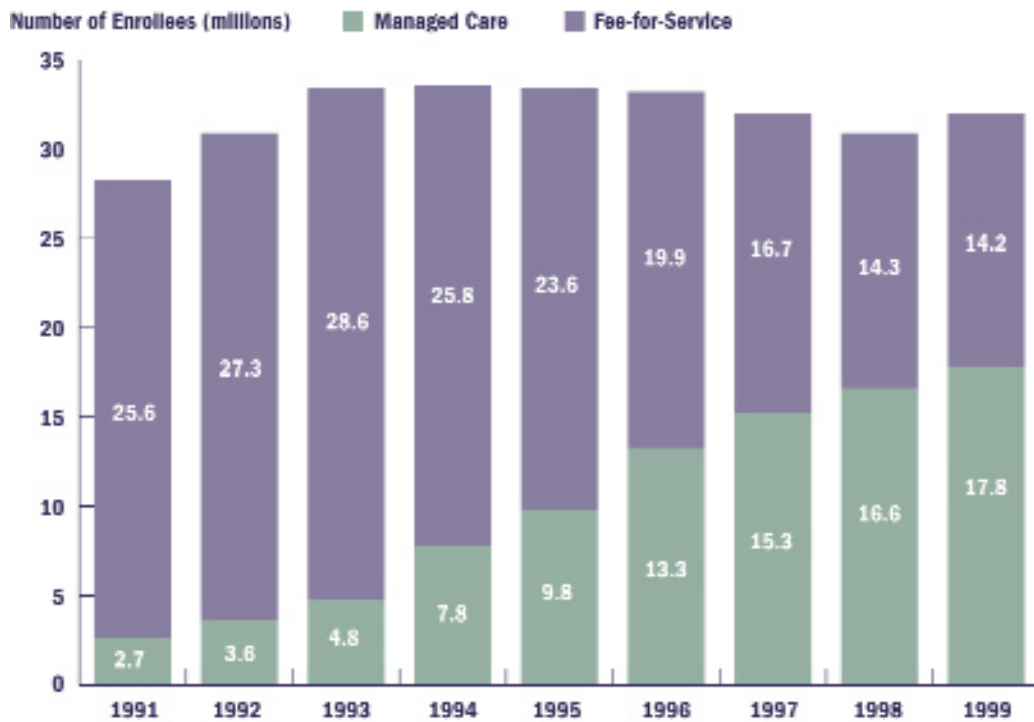
or the amounts that could be prescribed at one time, or by establishing restrictive drug formularies specifying the medicines for which Medicaid would provide reimbursement. By 1988, only four states offered Medicaid patients unrestricted access to all FDA-approved medicines.

Restrictive formularies and other access barriers deprive the nation’s poorest patients of the newest and most innovative medicines. Also such attempts to control drug costs frequently backfire. When Medicaid patients are deprived of access to cost-effective medicines, expenditures for other, more costly services often increase substantially.

A 1991 study published in *The New England Journal of Medicine* found that when New Hampshire restricted the number of prescriptions that could be reimbursed by Medicaid, the elderly entered nursing homes at a rate more than 60 percent greater than in a control state.³ Although drug utilization fell 35 percent, nursing-home admissions rose 60 percent and overall health-care expenditures increased. When the restrictions were lifted, nursing-home admissions decreased.⁴

A 1994 study in *The New England Journal of Medicine* by the same authors found that New Hampshire’s prescription-drug caps saved an average \$57 per year on drugs for schizophrenia patients—but added an additional \$1,530 per year in costs for visits to mental-health clinics and emergency rooms [Figure 6-2].

Figure 6-3
MEDICAID ENROLLEES, 1991–1999



Source: Health Care Financing Administration, Office of Managed Care, Managed Care Enrollment Report, 1999.

Other cost-containment/quality-control techniques used in Medicaid programs include Drug Utilization Review (DUR) and Disease Management. Under DUR, physicians' prescribing habits are systematically reviewed and physicians and pharmacists are educated about common drug interaction problems. As of 1996, automated DUR programs were in operation in 29 states and in the planning stages in 16 states. A study by the General Accounting Office found that these programs enhance safety and save money. In the five states studied, DUR programs saved a total of \$30 million in one 12-month period.⁵

Disease-management programs are an attempt to manage high-risk-disease populations by integrating all components of treatment to maximize health outcomes while controlling costs. In the private sector, managed-care programs have adopted such an approach in sev-

eral disease areas. A number of states are considering this approach for such diseases as asthma, heart disease, mental illness, and AIDS, which account for a significant part of overall Medicaid expenditures.

The Movement of Medicaid to Managed Care

State Medicaid programs are turning increasingly to managed care, which offers both a means of controlling costs and the potential for achieving greater coordination and continuity of care. In 1981, only about 280,000 beneficiaries—1 percent of the Medicaid population—were enrolled in HMOs. By 1999, 17.8 million beneficiaries—56 percent of all Medicaid enrollees—were enrolled in some type of managed care [Figure 6-3].⁶ And whereas in 1981 only four states—California, Maryland, Michigan, and New York—had substantial Medicaid managed-care

experiments under way, nearly every state had a program either in operation or in the planning stages by 1996.⁷

There are three basic types of Medicaid managed-care plans: full-risk capitation, partial capitation, and primary-care case management.

Over half of Medicaid beneficiaries covered by managed care are in full-risk capitation plans, the fastest growing managed-care model.⁸ Under this plan, states contract with HMOs or other managed-care plans to provide health-care services to participating beneficiaries for a fixed amount per enrollee per month. The plan is at risk for all the services provided, but may negotiate with providers for discounts.

Some Medicaid managed-care enrollees are in partial capitation plans.⁹ Under such programs, plans are paid for a limited number of services on a per-head basis and are reimbursed for other services on an actual-cost basis.

In fiscal year 1998, about 16.5 percent of Medicaid managed-care beneficiaries were in primary-care case management plans (PCCMs).¹⁰ Under this model, beneficiaries are assigned to case managers who provide basic medical care and act as gatekeepers, referring patients to specialists when considered appropriate.

Managed-care plans provide pharmaceutical benefits to enrollees in either of two basic ways. In some plans, pharmaceutical benefits are fully integrated into the per-person rate the state pays to the managed-care group. In other cases, the pharmaceutical benefit is “carved out” and administered separately by the state. This strategy appeals to some states because it allows them to retain access to federally mandated Medicaid rebates.

The first population groups targeted for enrollment in Medicaid managed-care programs have been the younger, less costly populations—the single-parent families eligible for welfare payments under Temporary Assistance for Needy Families and low-income pregnant women and children. In 1998, these groups accounted for about 72 percent of the 40.6 million Medicaid beneficiaries.¹¹ However, expenditures for these groups represent only about 26 percent of Medicaid spending.¹²

States are moving more cautiously to include elderly and disabled Medicaid recipients and residents of nursing homes in managed care, because these groups are high users of services. As a result, it is difficult for private-sector managed-care organizations to assume the risk of caring for them. Other groups that need special consideration include mentally ill individuals, substance abusers, AIDS patients, women with high-risk pregnancies, and individuals with chronic diseases such as diabetes.

Medicaid Waivers: Until 1997, states had to apply for waivers of certain requirements of the Social Security Act to move Medicaid patients into managed care. Two principal types of managed-care waiver programs are in operation throughout the country: “freedom of choice” waivers under Social Security Act Section 1915(b), and the more flexible Section 1115 “demonstration” waivers.

Under a Section 1915(b) waiver, states may direct beneficiaries to particular providers. However, they are limited with respect to the types of managed-care organizations with which they may contract. Moreover, they may not expand eligibility or change the scope of benefits they offer. During Fiscal Year 1998, 35 states and the District of Columbia operated 84 Section 1915(b) waivers. Because of the limitations on 1915(b) waivers, states have used the “health reform” Section 1115 waivers as a vehicle for more fundamental overhauls of their Medicaid programs. TennCare, a statewide managed-care program in Tennessee, is one such experiment. In 1998, 17 states operated statewide, comprehensive Section 1115 demonstrations.

In 1997, the federal Balanced Budget Act allowed states to enroll their Medicaid beneficiaries in managed-care organizations on a mandatory basis without applying for waivers. However, HCFA still retains oversight of these programs. In letters to state Medicaid directors, HCFA has indicated that it must approve all contracts between a state and managed-care organizations. It also ensures that states provide the increased beneficiary protections and quality standards that the Balanced Budget Act requires.¹³

If prescription drugs are included as an integral part of a comprehensive package of health-care services, man-

aged-care organizations may have an incentive to manage the whole patient and consider the total outcome of care, rather than to focus on separate budget items—such as prescription-drug costs—in isolation. However, if programs are not adequately financed, rates are set too low, or planning and oversight are inadequate, quality of care and access to prescription medicines could suffer.

Medicare and Prescription Drugs

Medicare is a nationwide federal program of health insurance for the elderly and certain disabled persons. In 1998, the program covered an estimated 39 million people, about 87 percent of whom are 65 or older. Seniors were projected to represent 13 percent of the population in the year 2000 and 20 percent by 2030. The largest increase will occur during 2010-2030, when “baby-boomers” reach 65. Concerns about the long-term solvency of Medicare have prompted calls to restructure the program for the needs of the 21st century.

On July 30, 1964, when President Lyndon B. Johnson signed the Medicare Act into law, there were approximately 20 million Americans 65 and older, about half the number today. Like the private-sector health care system of the day, Medicare was a “fee-for-service” program. Doctors, hospitals, and other providers were reimbursed for “reasonable and customary” charges. Outpatient prescription drugs, which were not covered by Medicare, were a relatively minor component of health care. The breakthrough drugs available today for heart disease, ulcers, depression, and other diseases had not yet been discovered. Surgery, lengthy hospitalizations, and doctor visits were the usual forms of care.

Since that time, health care has undergone a sea change. While the majority of Medicare beneficiaries are still in “fee-for-service” programs, about 80 percent of younger, employed Americans and their families are enrolled in managed-care programs. About 90 percent of the people in managed-care programs have some sort of coverage for outpatient prescription drugs. Because there are so many innovative medicines available today, and because insurers realize that drugs are the most cost-effective component of health care, medicines play a leading role in today’s health care. Drug utilization rose 8.7 percent last

year alone, according to IMS Health. A growing body of evidence indicates that medicines provide medical, social, and economic value of the highest order. They prevent and cure disease, save lives, relieve pain, and improve the quality of life. And they keep people out of the hospital, out of emergency rooms, and out of nursing homes—and in the home and on the job—often decreasing the total cost of medical care.

An estimated 73 percent of Americans 65 and older have prescription-drug coverage—either through employer-provided retiree health plans, Medicare HMOs, “Medigap” insurance plans, or Medicaid state-assistance programs.¹⁴ In addition, about 2.4 million people in 2000, including many seniors, received medicines through pharmaceutical company patient-assistance programs.

In 1997, Congress created the National Bipartisan Commission on the Future of Medicare to develop recommendations to ensure the long-term solvency of the program, whose growth is expected to outpace the resources needed to finance it during the next 10 years. The Commission spent more than a year studying ways to modernize the program. This bipartisan Commission, comprised of members of Congress and experts in the health-care field, released its majority recommendation in March 1999. The majority recommendation was in three parts: (1) the design of a premium-support system, (2) improvements to the current Medicare program, and (3) financing and solvency issues. The plan, offered by Sen. John Breaux (D-La.) and Rep. Bill Thomas (R-Calif.), received 10 of the super-majority 11 votes (out of 17) needed for the Commission to make recommendations to the President and Congress. The Commission has since disbanded, but its recommendations continue to be heeded on Capitol Hill and parts have been incorporated in legislation introduced in both the House and the Senate.

In 2000, the House passed a bipartisan prescription-drug bill, the Medicare Rx Drug Act of 2000. The bill offered seniors and the disabled the choice of at least two private drug-insurance plans, no matter where the beneficiary lived. The bill also created a new agency in the Department of Health and Human Services called the

Medicare

Medicare is a nationwide federal program of health insurance for the elderly and certain disabled persons.

In 1998, the program covered an estimated 39 million people, about 87 percent of whom were 65 or older. Nearly all individuals 65 and older are automatically eligible for Medicare Part A, which provides inpatient hospital services, home-health services, limited skilled nursing-facility care, and hospice care.

All but about 2 million of the 39 million individuals eligible for Medicare voluntarily enrolled in Part B, which provides coverage for physicians' services, laboratory services, durable-medical equipment, outpatient hospital services, and other medical services. Part B provides limited outpatient drug coverage—primarily for immunosuppression, blood-clotting factors for hemophilia, erythropoietin for dialysis patients, and certain oral anti-cancer and anti-emetic drugs.

Two trust funds are used to finance the program: the Medicare Hospital Insurance Trust Fund for Part A, and the Supplementary Medical Insurance Trust Fund for Part B. The hospital fund is primarily funded through equal payroll tax deductions by employees and employers. Part B is financed through beneficiary premiums and general tax revenues. Total program outlays were estimated to be \$237 billion in fiscal year 2000.¹

But that's expected to change soon—and dramatically. The Congressional

Budget Office projects that, during the next 10 years, spending will more than double—reaching \$491 billion by fiscal year 2011.² The hospital insurance program is expected to run out of money by 2029.³

In addition to its financial troubles, Medicare has other serious problems and shortcomings. It does not cover healthcare products and services that many elderly and disabled Americans desperately need. It does not cover long-term care, such as the very high costs of nursing-home care. Nor does Medicare provide for the treatment of mental illnesses on the same terms as for physical illnesses. And it does not generally help beneficiaries pay for prescription medicines, the most effective and cost-effective treatment for many diseases.

Need for Change: There is wide agreement that the Medicare program needs to be restructured. When the program was established in 1965, about 20 million Americans were 65 or older—about half the number today. Like the private-sector health-care system of the day, Medicare was created as a “fee-for-service” program. Doctors, hospitals, and other providers were reimbursed for “reasonable and customary” charges.

Outpatient prescription drugs were a relatively minor component of health care. The breakthrough drugs now available for heart disease, cancer, and stroke—the three leading causes of death for those 65 and older—and for Alzheimer's disease, osteoporosis, diabetes, Parkinson's disease,

ulcers, depression, and many other diseases had not yet been discovered. Much more than today, surgery and hospitalization were first-line treatments.

Since 1965, health care has undergone a sea change. In part because of the increasing effectiveness of modern medicines, the number of Americans 65 and older has continued to rise in the past three decades—and will rise even faster in the years ahead. The number of seniors—now 35 million, one in eight—is expected to double during the next 35 years.⁴

While most Medicare beneficiaries still have fee-for-service arrangements, about 80 percent of younger, employed Americans and their families are enrolled in managed-care programs. And about 95 percent of the people in managed-care programs have some sort of coverage for outpatient drugs. Because there are so many innovative and cost-effective medicines available, they now play an indispensable role in health care.

The challenge is to provide today's seniors—and tomorrow's—with high-quality, cost-effective health care in a creative way that does not produce unintended adverse consequences, such as slowing medical innovation just when scientific and technological advances are paving the way for unprecedented progress against disease.

In 1997, Congress created the National Bipartisan Commission on

the Future of Medicare to develop recommendations to modernize the program and ensure its long-term solvency. In March 1999, a majority of the Commission recommended comprehensive modernization of Medicare to provide high-quality, integrated health care for seniors and the disabled with cost-containment based on competition, not government price controls and regulations.

A number of proposals have been made to provide an outpatient prescription-drug benefit under Medicare and make other changes in the program, including to carry out the recommendations of the Bipartisan Commission.

PhRMA supports pharmaceutical coverage for Medicare beneficiaries. The industry believes that the best way to provide drug coverage to Medicare beneficiaries is through comprehensive modernization of the program to provide beneficiaries a choice of health plans that provide drug coverage. If such modernization does not occur this year, PhRMA would support federal legislation that would provide all seniors with access to pharmaceutical insurance coverage, wherever they live and no matter how sick they are.

Such a proposal would have the following elements:

- All beneficiaries would have the ability to enroll in any qualified pharmaceutical coverage plan of their choosing.
- Federal government subsidies would help low-income beneficiaries afford coverage.

- Each beneficiary would be offered a choice of multiple competing, private insurance plans that rely on marketplace competition to control costs and improve quality.
- Plans would provide coverage for beneficiaries with high pharmaceutical expenditures.
- Beneficiaries would have access to all medicines.
- Plans would be overseen by a new, independent government entity.
- This new program would be consistent with, and a step toward, needed comprehensive modernization of the Medicare program.

Several existing proposals embody these elements in whole or part. PhRMA offers its assistance and support in advancing the goal of enhanced pharmaceutical coverage this year.

Last year, one of these proposals, The Medicare Rx Drug Act of 2000, a bipartisan prescription-drug bill, passed the U.S. House of Representatives but was not voted on in the Senate.

The industry strongly opposes government-mandated price controls as part of a new Medicare drug benefit. Such controls would subject a huge part of the U.S. pharmaceutical market to government price regulation. Thirteen percent of the market already is subject to price controls under Medicaid and other government programs (including those of the DoD, DVA, PHS, and state pharmaceutical assistance programs).⁵ That number would increase to over

40 percent because seniors comprise about one-third of the entire U.S. prescription-medicine market.

The U.S. research-based pharmaceutical industry has long been the leader in discovering and developing important new medicines because this country has the freest and most competitive market in the world.

Government-mandated price controls on Medicare drugs would undermine the ability of U.S. firms to continue their high level of innovation. Such a penny-wise, pound-foolish approach would limit the amount spent on each prescription, but it would also discourage private investment in the highly risky, time-consuming, and expensive business of drug discovery and development.

Price Controls Have Never Worked: Price controls have been tried many times in the past in many countries on many products—and they have never worked. Instead, they produce shortages and black markets. Price controls on oil and natural gas in the 1970s led to widespread artificial shortages and long lines at the gasoline pumps. Price controls on rental property produced housing shortages and the deterioration and neglect of existing housing.

In an open letter to President Clinton on his massive health-care plan published in *The New York Times* on January 13, 1994, 565 economists wrote:

In countries that have imposed these types of [price] regulations, patients face delays of months and years for surgery, government bureaucrats decide treatment options instead of doctors and patients, and innovations in medical techniques and pharmaceuticals are drastically reduced.

More recently, in an op-ed article in *The New York Times* on January 26, 2000, Stephen Pollard, a columnist for *The Express* in London, wrote that experience under the National Health Service in Great Britain demonstrates that government control of prescription drugs is a disaster:

The first casualties are consumer choice and medical progress. Four words are ingrained in all N.H.S. managers' brains: "Sorry can't afford it".... With overwhelming evidence of a system that can't cope, there are increasing calls for greater private involvement.

Price controls harm private research by restricting investors' opportunity for a return on their investment, without reducing the risk involved. If private investment in pharmaceutical and biotechnological research declines, companies will have less funds for research. They would continue as best they could because that is their business—finding new cures and treatments. But they could only do what they could finance.

Government price controls would hit the more than 1,200 small, entrepreneurial biotechnology companies in the U.S. the hardest because most of them are funded by venture capital.⁶

The vast majority of these companies do not yet have a product on the market and thus have not made any profits. Venture capital is their sole life support because their high-risk nature makes it impossible for them to borrow money from other sources. Price controls on Medicare drugs would encourage venture capitalists to invest in other businesses

that are not so stringently regulated by the federal government.

Endnotes

1. Testimony before the House Ways and Means Committee, Subcommittee on Health, 107th Cong., 1st Sess. (March 27, 2001) (Statement of Dan L. Crippen, Director, Congressional Budget Office).
2. *Ibid.*
3. Medicare Trustees Report, 2001.
4. U.S. Administration on Aging, www.aoa.gov.
5. IMS America, March 1999; U.S. Medicine Web Site, FY 1998; NPC Pharmaceutical Benefits Under State Medical Assistance Programs, December 1998.
6. 1998-1999 Bio's Guide to Biotechnology.

Medicare Benefits Administration, to manage Medicare+Choice programs, along with the new prescription-drug plans. The bill also provided protection against high out-of-pocket drug costs beyond which Medicare would pay all expenses. The bill was not voted on in the Senate.

AIDS Drug Assistance Programs

In 1987, Congress established the AIDS Drug Assistance Program (ADAP) to help uninsured or underinsured patients with AIDS who do not qualify for Medicaid gain access to medicines. In 1999, these programs served an estimated 61,822 patients.

ADAPs are funded through Title II of the Ryan White Care Act. States may contribute additional funding to these programs, but are not required to do so. Overall ADAP budgets, including federal and state expenditures, have tripled between fiscal year 1996 and fiscal year 1999, from \$208 million to \$666 million.¹⁵ These expenditures have been driven by the dramatic success of combination drug therapy for HIV and AIDS.

In purchasing drugs, ADAPs may take advantage of a provision of the Veterans Health Care Act that mandates substantial discounts, equal to the rebate manufacturers are required to pay state Medicaid programs. Some ADAPs prefer to contract with a pharmacy network, a mail-order pharmacy, or a PBM to purchase drugs, also at significant discounts.

Vaccines for Children Program

The Vaccines for Children (VFC) program, enacted in 1994, expanded the federal government's already substantial role in purchasing childhood vaccines. Federal purchasing of childhood vaccines began with enactment of Section 317 of the Public Health Services Act of 1962. That provision initiated distribution, free of charge, of federally contracted vaccines to children at public-health clinics. Also, prior to the VFC program, 12 states had combined funds from Medicaid and the Section 317 program with state funds to offer free vaccines to all physicians to be distributed to all patients in their practices, including the fully insured. Through the VFC program,

the federal government purchases vaccines to be distributed at participating physicians' offices to Medicaid-eligible children, Native Americans, uninsured children, and children whose insurance coverage does not include vaccines.

The VFC program also encourages additional government purchases by giving states the right to buy vaccines for non-VFC-eligible children at the Public Health Service's below-market VFC contract prices. The effect of these programs has been to significantly increase government purchases at discounted prices. The Centers for Disease Control estimates that the government's share of the childhood vaccine market has increased from less than 50 percent prior to the VFC program to over 70 percent today.¹⁶

The Pharmaceutical Industry: Committed to Philanthropy

The mission of the research-based pharmaceutical industry is to save lives, cure disease, and improve the quality of life. The industry does this both through its business operations—by discovering, developing, and marketing life-saving, life-enhancing medicines—and through its extensive philanthropic endeavors—which make it a U.S. and world leader in charitable contributions.

Each year since 1991, according to the Conference Board, a New York-based corporate research organization, the pharmaceutical industry has been the largest corporate supporter of philanthropic causes. The most recent data, based on the Conference Board survey for 1997, showed that the six pharmaceutical companies that responded to the survey contributed \$426 million to charitable organizations. The median level of the pharmaceutical companies' contributions was 2.2 percent of consolidated pretax income, compared to a median level of .8 percent for all companies responding to the survey.

The most recent edition of the Taft Corporate Giving Directory lists five pharmaceutical companies (Merck & Co., Inc., Johnson & Johnson, Pfizer Inc., Eli Lilly and Company, and Bristol-Myers Squibb Company) among the top 10 corporate givers in the U.S.

Patient-Assistance Programs

Patient-assistance programs represent one of the industry's most important philanthropic efforts.

Drug companies have a long-standing tradition of providing prescription medicines free of charge to physicians whose patients might not otherwise have access to these products. Some companies also allow hospitals, community pharmacies, home health companies, and others to obtain drugs for indigent patients. A number of companies have pledged that no patient in need of their medicines will do without them.

PhRMA maintains a directory of the member-company programs on its web site at www.phrma.org. The directory describes how to request assistance and what medicines are covered. The application process and eligibility vary for each company.

Last year, the General Accounting Office (GAO), the investigative arm of the U.S. Congress, released a report on the pharmaceutical industry's patient-assistance programs. In its report, the GAO found that patient-assistance programs provide valuable assistance to many individuals who lack health-insurance coverage. The number of patients receiving assistance through these programs increased more than 50 percent from 1997 to 2000. Company patient-assistance programs provided \$934 million worth of prescription drugs to 2.4 million patients in 2000 alone—almost double what was provided in 1998. The GAO's report concluded that voluntary company patient-assistance programs provide valuable assistance to a significant number of uninsured patients.

Disasters: Kosovo and Hurricane Georges

The response to the Kosovar disaster typifies the way in which pharmaceutical companies assist the victims of war and natural disasters such as Hurricane Georges.

Twenty-two pharmaceutical companies contributed more than \$9.5 million in medicines and money in the spring of 1999 to help the Kosovar Albanians who were driven from their homes and land by Serbian forces. The donated medicines included a variety of antibiotics and analgesics.

The contributions were distributed through such charitable organizations as the Red Cross, Project HOPE,

AmeriCares, the Catholic Medical Mission Board, Heart to Heart International, the International Rescue Committee, Catholic Relief Services, and Map International.

Following the devastation caused by Hurricane Georges in September 1998, employees of Lilly's plant in Mayaguez, Puerto Rico—many of whom suffered damage to their own homes and property—took extraordinary steps along with the company to help their neighbors. They donated medicines to local shelters; set up health clinics operated by Lilly doctors and nurses; supplied water to more than 1,000 families; turned a flatbed truck into a mobile laundromat for needy families; and distributed plastic liners to use as temporary roof coverings. The company also contributed \$150,000 to local relief efforts.

AIDS Efforts

The industry has also taken a leadership role in combating the world AIDS epidemic. The following are just a handful of the numerous programs designed to help AIDS patients in the U.S. and developing countries:

- Boehringer-Ingelheim has begun a program to donate nevirapine for the prevention of mother-to-child transmission of HIV infection for the next five years.
- Merck sells Crixivan and Stocrin, two antiretroviral medicines for the treatment of HIV infection, for, respectively, \$600 and \$500 per patient per year, announcing it "will make no profit on these medicines in the developing world."
- Johnson & Johnson helps to fund the Pediatric AIDS Foundation, the Names Quilt Project, the National AIDS Fund, and other national and community-based efforts.
- Pfizer recently established the Academic Alliance for AIDS Care and Prevention in Africa, a union of African and Western infectious disease experts that will build the first large-scale HIV/AIDS clinic in Africa for training medical personnel on treatment options. The Pfizer Foundation will fund the clinic, and the Alliance will operate it in partnership with Makerere University.

- DuPont Pharmaceuticals recently donated a specially equipped van to the Delaware HIV Consortium to help provide early intervention and treatment for the disease.
- GlaxoSmithKline offers discounted HIV/AIDS and anti-malarial drugs to 63 developing nations, including all of sub-Saharan Africa. The preferential pricing policy is expanded to include additional AIDS-fighting drugs and the malaria medications malarone and halfan. The company extends its offer to least-developed countries identified by the U.N.
- Abbott Laboratories, with Abbott Laboratories Fund, created Step Forward ... for the world's children, a program that offers aid to orphans with AIDS and vulnerable children around the world.
- Bristol-Myers Squibb, GlaxoSmithKline, Merck, Boehringer-Ingelheim and Roche establish the Accelerating Access Initiative to sell HIV/AIDS medicines at a discounted price to developing nations. By May 2001, ten African nations—including Rwanda, Uganda, Senegal, Cote d'Ivoire, Cameroon, Mali and Burundi—are receiving discounted drugs under the program.
- Novartis, a member of the Global Alliance to Eliminate Leprosy, is donating treatment for all leprosy patients in the world until 2005. Its Foundation also supports country-level efforts to dispel the stigma surrounding leprosy and improve patient access to leprosy services.
- Schering-Plough donates medical products in Central and South America, India, Egypt, Philippines, Romania, Russia and other countries. It supports a prison conditions program in South Africa, hepatitis institutions in India and rectal cancer screening in the Philippines.
- Bayer, with the German Pharma Health Fund, supports development and use of a portable, tropics-compatible mini-lab in developing countries to detect counterfeit and substandard drugs.
- Pfizer is working with the Edna McConnell Clark Foundation to fight trachoma, a leading cause of preventable blindness. The company will spend an estimated \$62 million over two years to treat about 3 million patients in Morocco, Ghana, Mali, Tanzania, and Vietnam with a long-acting antibiotic that is effective against the disease.

Projects in Developing Countries

PhRMA companies also fund or conduct a number of other philanthropic programs in developing countries. Many of which are particularly crucial. In some African countries, donated drugs and medical services provide 30-70 percent of the available health care. For example:

- Merck has been providing free supplies of a drug to fight river blindness in Africa and Latin America for more than a decade. An estimated 25 million patients are being treated on an annual basis.

Other Causes

Pharmaceutical companies support a variety of other charitable causes including, diabetes camps for children, a home-away-from-home for patients and families on the campus of the National Institutes of Health, community-based health centers throughout the U.S., and a program to provide health care and other services for children under six.

Through its diverse charitable efforts, the pharmaceutical industry has demonstrated its commitment to helping relieve the pain and suffering of patients in need all around the world.

Endnotes

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