Tough Questions, Straight Answers

A Discussion of Today's Pharmaceutical Issues

PhRMA

contents

Over the past century, Americans have witnessed astonishing scientific advances, including cures for some of the world's most contagious and deadly diseases. Many of these advances—such as the triumph over polio, smallpox, and measles, and more recently dramatic improvements in the treatment of diabetes, arthritis, high blood pressure, and high cholesterol—have been due to pharmaceuticals.

At the same time that remarkable progress has been made, health care costs have risen. Though few would be willing to give up the benefits of the past century's medical breakthroughs, Americans are apprehensive as they see health care costs continue to climb.

Policymakers, health care providers, and consumers alike have wondered if the cost of pharmaceuticals could be responsible for the overall increase in the cost of health care. And they have wondered how to control drug costs, with various theories being put forward.

introduction

The member companies of the Pharmaceutical Research and Manufacturers of America (PhRMA) welcome exploration of health care costs. Only through careful analysis, a firm grasp of the facts, and healthy debate can sound policies be developed.

In this brochure we highlight some tough questions that have been asked about pharmaceutical spending, and we present answers rooted in research, analysis, and facts.

We hope the information provided will further Americans' understanding of today's health care environment, and help them make the best possible decisions about their health care now and into the future.

Q: "What is today's pharmaceutical industry doing to find new cures?"

A: America's pharmaceutical research companies are investing more than ever in the creation and development of new medicines.

The key to pharmaceutical innovation is research and development (R&D). Member companies of the Pharmaceutical Research and Manufacturers of America (PhRMA) invested an estimated $33.2 billion on R&D in 2003, up from $1.3 billion in 1977.[1] These increasing expenditures played a key role in driving numerous important advances over the past 25 years.

Advances in new medicines have come even as the length, complexity, risk, and costs involved in the R&D process continue to grow. New scientific discoveries are enabling a better understanding of the nature of many diseases and conditions. Potential drug candidates for more complex diseases require more time to study, and they are often more difficult to evaluate. Companies also face a regulatory process that has emphasized the need for more clinical data. All of these factors have driven the average cost of developing a single medicine to over $800 million, from $138 million in 1975.[2]

KEY FACT

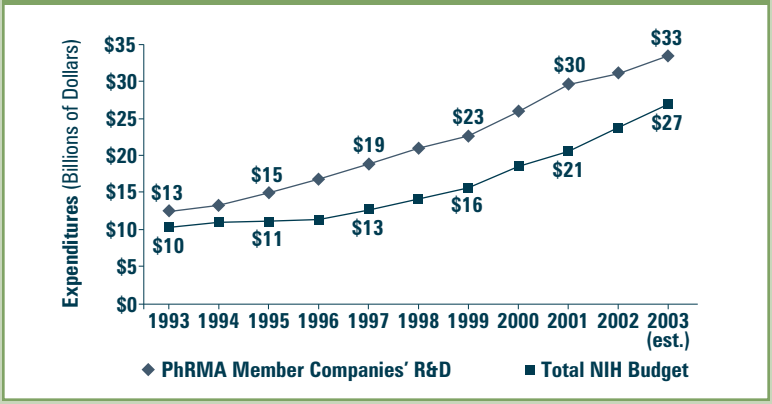
In 2003, pharmaceutical research companies spent 11 times more money on R&D (an estimated $33 billion) than on direct-to-consumer advertising ($3.3 billion).[4,5]

Pharmaceutical Research and Manufacturers of America, *Pharmaceutical Industry Profile 2004;*
IMS Health, *Integrated Promotional Services*™ and CMR, 6/2004

research & development

Nevertheless, over the past decade more than 350 new drugs, biologics, and vaccines that prevent and treat more than 150 diseases and conditions were approved for use by the Food and Drug Administration (FDA). That work continues today, with the aggressive pursuit of over 1,000 medicines in the development pipeline.[3]

Figure 1: PhRMA Member Companies' R&D Expenditures Exceed Total NIH Operations Budget: 1993–2003



Sources: Pharmaceutical Research and Manufacturers of America, *PhRMA Annual Membership Survey, 2004,* and National Institutes of Health, *"Summary of the FY2004 President's Budget,"* 3 February 2003, http://www.nih.gov/news/budgetfy2004/fy2004presidentsbudget.pdf (accessed 9 January 2004).

Q: "How does investment in pharmaceutical research and development benefit patients?"

A: The products of scientific discoveries and innovations allow millions of patients to live longer, better, and more productive lives.

The pharmaceutical research industry continues to invent important new classes of medicines that dramatically advance the treatment of diseases and conditions such as rheumatoid arthritis, HIV/AIDS, Parkinson's disease, Alzheimer's disease, schizophrenia, diabetes, high blood pressure, and high blood cholesterol. Patients who just a few years ago faced decline and disability now have new treatment options that help them live healthier, more productive lives. For instance, in the past 10 years:

- Four new classes of oral antidiabetic medicines and two new types of insulin have been developed that allow patients with diabetes to better control their blood sugar levels and help prevent the disease's devastating complications.
- The introduction of new atypical antipsychotics caused an expert panel of physicians to rewrite their treatment guidelines for schizophrenia in 1999. Atypical antipsychotics are now considered first-line therapy for treating this condition.

KEY FACT

Between 1993 and 2003 alone, FDA approved 350 new medicines, biologics, and vaccines to prevent or treat more than 150 diseases and conditions. FDA also approved new indications and new formulations for many medicines.[8]

Pharmaceutical Research and Manufacturers of America, *A Decade of Innovation*

- Three new classes of medicines have been introduced that dramatically improve treatment of rheumatoid arthritis.

Many new medicines are not only improving health but also lengthening life. "'In the old days you had a heart attack and you died,' said Dr. Claude Lenfant, who has monitored the changes as the [National Heart, Lung, and Blood Institute's] director for the last 21 years. 'You were almost signing the death certificate in advance. Now you know you can get another 20 or maybe 25 years.'"[6] Similarly, life expectancy for patients with cancer has increased because of pharmaceuticals that are available today.[7]

In addition to the development of new classes of medicine, the pharmaceutical industry also produces new medicines within existing therapeutic classes. These new medicines provide better treatment choices for individual patients, lower the risk of complications, improve patient compliance with treatment, and create the competitive market that payors use to drive hard bargains.

> "The FDA would like to offer patients a choice of drugs within the same class, since not every patient responds to every drug in the same manner."[9]
> —Janet Woodcock, M.D., Director of the FDA Center for Drug Evaluation and Research

Q: "Does direct-to-consumer advertising benefit patients?"

A: Yes! By better informing patients about treatment options without increasing drug prices.

Direct-to-consumer (DTC) advertisements, which are regulated by the FDA, encourage patients to seek treatment for previously untreated conditions. Since 1997, approximately 30 million consumers talked to their doctor about a medical condition for the first time after seeing a DTC advertisement.[10] This is particularly important, since studies show that many conditions for which medicines are DTC-advertised are undertreated and underdiagnosed.

In addition to getting patients to their doctors for care of previously untreated conditions, DTC ads help with the problem of patient compliance. A recent patient compliance study reports that patients who have seen a DTC ad are 75 percent more likely to stay on their arthritis medications, twice as likely to stay on their allergy medications, and 37 percent more likely to stay on their antidepressant medications.[11]

Rather than undermining the physician's role, many physicians report that DTC advertising can play a positive role in health care, prompting patients to become more involved in their own health

KEY FACT

"One-quarter of adult patients who visited their physician after seeing a DTC ad were diagnosed with a new condition, including high cholesterol, high blood pressure, diabetes, and depression."[16]

J. Weissman et al., "Consumers' Report on the Health Effects of Direct-to-Consumer Advertising"

care.[12] In addition, FDA survey data show that when patients ask for a DTC-advertised medicine, doctors often prescribe a different medicine or a non-pharmaceutical alternative.[13]

While DTC advertising plays an important role in the health care system, it is not driving up the prices of prescription drugs. According to December 2003 Federal Trade Commission comments to the FDA, "[DTC advertising] can empower consumers to manage their own health care by providing information that will help them, with the assistance of their doctors, to make better-informed decisions about their treatment options.... Consumers receive these benefits from DTC advertising with little, if any, evidence that such advertising increases prescription drug prices."[14]

Likewise, a recent study conducted by Harvard University and the Massachusetts Institute of Technology found that DTC advertising accounts for less than 2 percent of the total U.S. spending for prescription medicines.[15]

What Others Say About the Value of DTC Ads...

"DTC advertising provides important information to consumers and patients, which is beneficial to their health" [17]
—National Health Council

"...the majority of drugs advertised can treat the diseases that disproportionately affect the African-American community.... These ads can increase disease awareness that may be a beneficial tool to decrease the rampant disparities in the health of the community." [18]
—National Medical Association, April 2002

Q: "Aren't Americans using far too many prescription drugs?"

A: No. In fact, according to a number of recent studies there is considerable underuse of prescription drugs for many serious health conditions that could be effectively treated.

On June 26, 2003, *The New England Journal of Medicine* published "The Quality of Health Care Delivered to Adults in the United States." The study, which was conducted by RAND Health and funded by The Robert Wood Johnson Foundation, found that nearly half of all adults in the United States fail to receive recommended health care.[19]

According to researchers on the RAND study, "the deficiencies in care...pose serious threats to the health of the American public that could contribute to thousands of preventable deaths in the United States each year."

In assessing underuse and overuse of health care services, the RAND study included an examination of nine health conditions

KEY FACT

A May/June 2003 study published in *The Journal of Managed Care Pharmacy* found that "effective medication appears to be underused." The researchers concluded that "the results are particularly surprising and disturbing when we take into account the fact that three of the conditions studied (asthma, CHF, and depression) are known to produce high costs to the healthcare system."[22]

K. Gilberg et al., "Analysis of Medication Use Patterns: Apparent Overuse of Antibiotics and Underuse of Prescription Drugs for Asthma, Depression, and CHF"

that require treatment with prescription medicines. RAND determined that there was underuse of prescription medications in seven of the nine conditions. Conditions where underuse was found include asthma, cerebrovascular disease, congestive heart failure, diabetes, hip fracture, high cholesterol, and high blood pressure. Asthma, diabetes, high cholesterol, and high blood pressure are considered "high priority" conditions by the Agency for Healthcare Research and Quality and the Institute of Medicine.[20]

According to the National Committee for Quality Assurance (NCQA) *Quality Compass® 2003,* there is significant undertreatment of asthma and depression patients in managed care plans. According to NCQA, in 2002, nearly one-third of commercially insured patients with asthma had not been prescribed medicines that the National Heart, Lung, and Blood Institute guidelines deem acceptable for the long-term treatment of asthma; and only 42 percent of patients with depression "received effective continuation phase treatment by remaining on antidepressant medication continuously in the six months after the initial diagnosis and treatment."[21]

> "Even people who had health insurance and access to health care services failed to receive some elements of good care. This suggests that just being able to get in the door to see a doctor is no guarantee that you'll receive the care you need."[23]
> —Elizabeth A. McGlynn, Ph.D.,
> Associate Director of RAND Health

Q: "If we continue to spend more on drugs, won't health care costs spin out of control?"

A: No. Prescription medicines, including the cost of brand and generic medicines and the cost of pharmacies, account for only 10.5 cents of every dollar spent on health care in 2002. In addition, medicines can help control overall health spending by helping patients stay healthier and avoid costly hospitalizations.

While the cost of health care is rising, only a fraction of the increase is attributable to increased spending on prescription medicines. For instance, from 1998 to 2003, while health plans' total premiums increased by an average of $104.62 per person, outpatient prescription drug costs increased by only $22.48. Thus, over the most recent five-year period, total brand and generic prescription drug spending accounted for just 21.5 percent, or less than one-quarter, of the total increase in premiums. HMOs' monthly spending on prescription medicines averaged $35.43—out of the total monthly expenditure of $238.70 per person.[24]

KEY FACT

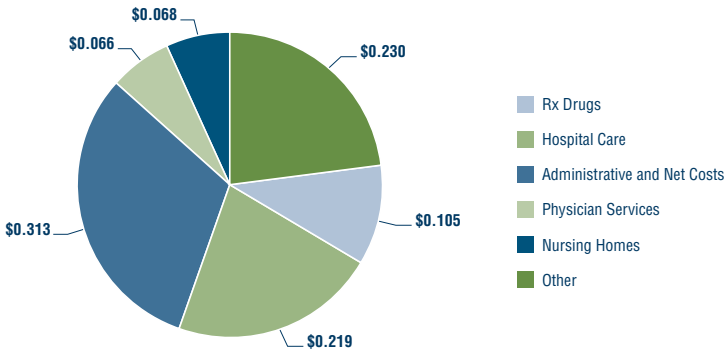
The 2002 *Economic Report of the President* cites a "growing body of evidence" that increased spending, up front, for treating many diseases pays off. This spending is more than offset by savings in direct and indirect costs of the illnesses, including lost productivity and poor health.[27]

G. W. Bush, *Economic Report of the President*

Likewise, prescription medications are not responsible for Medicaid's cost problem. In 2002, Medicaid spending for prescription drugs accounted for 11.4 percent of total expenditures, and from 1997 to 2002 Medicaid prescription drug increases accounted for less than one-fifth of the total increase in Medicaid spending.[25]

Prescription medicine spending should be put in the context of overall health care spending, including the avoided costs of surgery, visits to emergency rooms, or lengthy stays in hospitals or nursing homes. For instance, in a disease management program for patients with congestive heart failure, spending on medicines increased by 29 percent but overall health costs dropped by 14 percent, as patients avoided hospitalizations.[26]

Figure 2: Where the Health Care Dollar Goes: 2002



Source: Centers for Medicare & Medicaid Services, *National Health Expenditures,* 8 January 2004, http://www.cms.gov/statistics/nhe (accessed 9 January 2004).

Q: "Why not apply government price controls as a way to lower drug costs?"

A: Government price controls restrict patient access and discourage development of new medicines. Instead, the United States contains costs through use of a competitive market.

In the United States, powerful purchasers, several of whom buy on behalf of tens of millions of persons, use strategies such as brand-to-brand competition and generic substitution in order to contain costs. For example, nearly half of all prescriptions in the United States are for generic copies of medicines,[28] much more than in many countries that use brand-name price controls and other price containment mechanisms to control costs.

These "alternative forces" keep the U.S. system competitive. This approach promotes cost containment without burdening American patients with price control schemes that restrict patient access to new medicines or compromise investment in R&D, which jeopardizes the creation of new cures.

KEY FACT

"Government controls may reduce or delay access to specific drugs for seniors. Even when a drug is available, government controls often increase the likelihood that older, lower cost products will be prescribed rather than newer, more innovative products, which may have fewer side effects or other features that improve patient compliance and hence, the effectiveness of medical treatment."[32]

U.S. Department of Health and Human Services,
Securing the Benefits of Medical Innovation for Seniors

price controls

Price controls have had a negative impact on R&D in countries that have employed them. According to a 2004 report by Bain & Company, because of "onerous regulations on drugmakers that keep prices and utilization artificially low," the pharmaceutical industry is "reallocating R&D investment from Europe to the US."[29]

While it is clear that price controls and other forms of cost containment have had a negative impact on R&D in Europe, it is also important to understand that price controls would have had a negative impact on R&D in the United States. According to economist John A. Vernon, a new policy regulating pharmaceutical prices in the United States will lead to a decline in industry R&D by between 23.4 and 32.7 percent.[30] Furthermore, between 330 and 365 fewer new drugs would have been brought to market had price controls been in effect from 1952 to 2001.[31]

Q: "Is there competition in the prescription drug market?"

A: Yes! In addition to competing with generic drugs, branded medicines also vigorously compete against each other. Further, large purchasers representing millions of patients use this competition when negotiating with manufacturers to get the best deal for patients.

Innovators do compete—and the competition has increased, with the period of time a typical medicine is on the market prior to having competition from another brand-name medicine within the same therapeutic class steadily shrinking.

Competing medicines give patients needed choices, since not every patient responds the same way to each type of medicine. Competing medicines also give patients economic benefits. Purchasers, some representing tens of millions of Americans, use the availability of multiple medicines to drive hard bargains with manufacturers. These purchasers benefit from the vigorous competition among different drugs within a class.

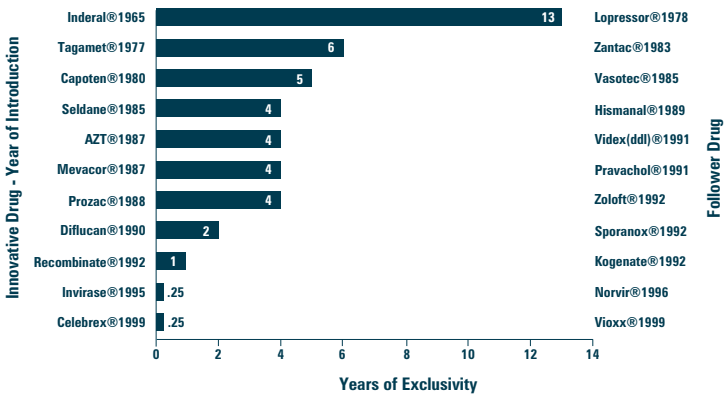
KEY FACT

Competition between innovator medicines is as significant as competition between an innovator and a substitutable generic drug.[34]

F. R. Lichtenberg and T. J. Philipson,
The Dual Effects of Intellectual Property Regulations: Within- and Between-Patent Competition in the US Pharmaceuticals Industry

According to a study by Dr. Joseph A. DiMasi of Tufts University for the U.S. Department of Health and Human Services, new drugs in a class are often priced lower than existing drugs in the class. Specifically, the study found that of the 20 drugs examined, 13 were priced at discounts; five were introduced in line with existing prices; and two entered the market above the average in the class but at a discount relative to the price leader in the class.[33] This suggests that multiple medicines yield savings for Americans, along with better treatment choices.

Figure 3: Shrinking Period of Market Exclusivity Between Introduction of Breakthrough Medicine and Competing Innovators



Inderal® (beta blocker for cardiovascular disease); Tagamet® (H_2 antagonist for ulcers); Capoten® (ACE inhibitor for cardiovascular disease); Seldane® (antihistamine for allergies); AZT® (antiviral for HIV/AIDS); Mevacor® (HMG-CoA reductase inhibitor for high cholesterol); Prozac® (selective serotonin reuptake inhibitor for depression); Diflucan® (antifungal); Recombinate® (antihemophilic blood factor); Invirase® (protease inhibitor for HIV/AIDS); Celebrex® (cox 2 inhibitor for arthritis).

Sources: Pharmaceutical Research and Manufacturers of America, 2000; The Wilkerson Group, 1995.

Q: "How can patients get better access to prescription medicines?"

A: Pharmaceutical research company patient assistance programs and drug discount cards provide help to millions of patients, and the addition of a prescription drug benefit to Medicare will offer much-needed help to America's seniors and disabled persons.

The key to good access to medicines is good insurance coverage. Health care services, such as hospital care, that account for much more spending than medicines also are much better insured. That's why nearly all of the debate about health costs is focused on the 10.5 percent of spending accounted for by prescription medicines. Many Medicare patients with insurance coverage for doctors and hospitals have not had prescription drug coverage. And private insurance pays for a lower share of drug costs than of other health care costs.[35]

In 2003, one of the biggest gaps in prescription drug coverage was addressed by passage of the Medicare Modernization Act. The Act provides a discount program for Medicare beneficiaries and cash assistance for low-income beneficiaries which began in June 2004, and insurance coverage for medicines beginning in January 2006. This prescription drug benefit will offer seniors and disabled persons access to the newest breakthroughs in medicine, while con-

KEY FACT

In 2003, an estimated 6.2 million patients received 17.8 million prescriptions free of charge through PhRMA member companies' patient assistance programs.[37]

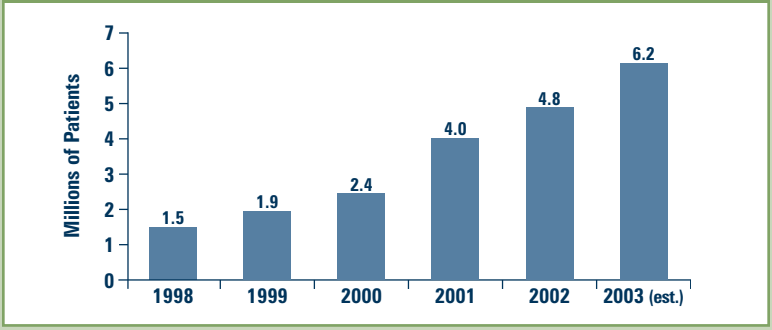
Pharmaceutical Research and Manufacturers of America, *Member Company Patient Assistance Programs Survey 2003*

trolling costs through market competition and maintaining incentives for future innovation.

America's pharmaceutical research companies continue to voluntarily address the access issue with patient assistance programs that provide prescription drugs free of charge to patients who might otherwise not have access to necessary medicines. In 2003, an estimated 6.2 million patients received free medications through these voluntary patient assistance programs.[36] For more information about patient assistance programs, visit www.helpingpatients.org.

PhRMA's member companies have also voluntarily provided Medicare beneficiaries without prescription drug coverage free enrollment in their discount card programs. By presenting these cards at the counters of their pharmacies, cash-paying patients receive a discount of as much as 40 percent off their prescriptions. Several companies have announced that they will adapt their patient assistance or discount programs to work in coordination with the new Medicare-endorsed discount cards.

Figure 4: Patients Receiving Medicines Through PhRMA Member Patient Assistance Programs: 1998–2003



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