Abstract: Drug cost projections for 2001 and factors that are likely to influence drug costs are discussed. The year 2000 introduced many new factors into the decision-making process for drug pricing and raised new considerations regarding drug therapy, distribution, and costs. It is anticipated that drug costs will continue to increase at a rate of 11–15% in 2001. Research and development expenditures for new drugs continue to grow and are estimated to be $26.4 billion in 2000, but the number of new drug approvals, especially for new entities, has not increased significantly. The generic drug industry has been expanding, and sales of generics are expected to increase to $20 billion by 2005. Drug costs also keep rising, and sales may reach $243 billion by 2008; this amounts to 12.6% of total health care spending, compared with 8.1% in 1999. There is a trend toward increasing the rate of conversion of prescription drugs to nonprescription status; this may reduce drug budgets somewhat. 2001 will see new systems of drug distribution and pricing, a federal prospective pricing system for ambulatory care patients covered by Medicare, drug imports from foreign manufacturers, and states taking legal action to reduce prescription drug costs. Drug costs in 2001 are expected to continue to increase at double-digit rates. The increase in costs is due to increased utilization, to new products replacing older products, and to price increases for drugs currently on the market.

Index terms: Costs; Drug distribution; Drugs; Drug use; Economics; Health care; Prescriptions; Pricing; Product development; Regulations; Sales

Am J Health-Syst Pharm. 2001; 58:125-33
According to IMS Health, a company that conducts market research on the pharmaceutical industry,5 chain drugstores accounted for 30% of all prescription drug purchases, while hospitals accounted for 12.4%, representing a decrease of 1% compared with 1998. Clinics accounted for 6.7% of total drug purchases and had the highest percent increase of any group, 27%, compared with the previous year. Long-term care maintained 4% of total market purchases. Domestic sales of drugs are expected to be over $105.6 billion in 2000, up 11.2% from 1999; and total sales will increase to $149.8 billion in 2000, up 11.2% from 1999; sales abroad are estimated at $43.6 billion, up 3% from 1999; and total sales will increase to $149.8 billion in 2000, up 11.2%. For hospitals, outpatient visits increased to $149.8 billion in 2000, up 12.4%, representing the largest increase in the past seven years.7

Hospital operating profits continued to decrease in 1999, falling 27%.8 This follows a decrease of 28% in 1998. In the two-year period from 1997 to 1999, the average hospital’s operating profit decreased 50%, from 6.1% to 3.2%. This has occurred while expenses are keeping pace with inflation but operating revenues are not experiencing any growth. The Northeast experienced operating profits of 0% in 1999, down from 3.7% in 1997. The South Atlantic and North Central regions had the highest operating profits, 4.42% and 4.16% for the year, respectively, while the South Central and West regions were intermediate, at 2.15% and 3.75%, respectively. Hospitals with less than 150 beds had the best profit margins, 4.19%, while those with over 300 beds had the worst, 2.69%; hospitals with 150–300 beds were intermediate, at 3.07%. At the same time, retail prices at the nation’s hospitals rose 5.1% in 1999, compared with a 2.7% inflation rate for all goods and services.9 In view of the above findings, it is not difficult to understand why hospitals, among other health care providers, are under great financial pressures. These changes have been occurring at the same time that health care spending has increased to over $1.1 trillion for 1999.10

During 1999 and the first quarter of 2000, the merger movement among hospitals slowed and some of the most notable planned mergers, such as those involving Penn State, Geisinger Health System, Optima Health, and Stanford Health System, have broken up or are in the final stages of breaking up. Among the stated causes are that financial goals were not met, that cultures clashed, and that there were ethical problems.11

In 1999 PricewaterhouseCoopers predicted that pharmaceutical companies must generate blockbuster drugs, enter restructured markets, or merge to remain viable and that the number of top firms would be reduced to 13 by 2005.12 The prediction may be accurate, but the time element in which it would occur appears to have been shortened by the mergers that took place in 1999 and 2000.

2000 began with pharmaceutical industry consolidations further decreasing the number of independent, major pharmaceutical companies. Glaxo Wellcome and SmithKline Beecham joined to form GlaxoSmithKline. Thus the names “Wellcome” and “Beecham,” both so well-known, disappeared, and the largest pharmaceutical company in the world was formed. Pfizer merged with Warner-Lambert, which became a division of Pfizer Inc. This merger formed a company with a $4.7 billion investment in research and development (R&D), the largest expenditure for R&D in the industry. Pharmacia & Upjohn merged with Monsanto and became known as the Pharmacia Corporation. The name of Upjohn is no longer listed on the pharmaceutical landscape. G. D. Searle, a division of Monsanto, also joined the Pharmacia group as a subsidiary. Pharmacia thus became a member of the top-10 pharmaceutical company club and has set as its goal becoming the best-managed company in the industry.13

American Home Products, which lost out to Pfizer in the bidding for Warner-Lambert, is said to be looking for a partner in order to survive as a major player in the field. The same concern for survival holds for other major pharmaceutical companies, such as Bristol-Myers Squibb. The reasons for all this activity are to produce new, effective medications and to enter the consumer market quickly. The mergers of Glaxo Wellcome and SmithKline Beecham, Pfizer and Warner-Lambert, and Pharmacia & Upjohn and Monsanto add to those that produced Aventis, Novartis, and AstraZeneca. It must be asked whether the industry will now introduce exciting new drugs faster and whether drug prices will rise as a result of decreasing competition. Government control of drug prices could hinge on the answers to these questions.

Among the significant transformations taking place in the pharmaceutical market is a change in the marketplace itself. PACE Alliance, a 220-member independent pharmacy buying group, has agreed to purchase pharmaceutical products through the business-to-business Web site Rxmarketplace.com.14 Bergen Brunswig is shipping 25,000 direct-to-customer orders per week through its new Internet fulfillment center.15 Drugstore.com, through its partnership with Amazon.com, has increased traffic to its site 20–30%.16 Drugstore.com added 295,000 new customers during the first quarter of 2000, a 42% increase over the preceding quarter. The Web site now has a total of 990,000 customers.

These changes are reflective of a market undergoing major changes. The issues facing pharmacy and the pharmaceutical industry are how the market should operate and how it will function in the future. Is the
wholesaler as we know it a business of the past, and what further changes can be expected? Is a direct-to-patient relationship with a provider through a Web site going to be the usual means of providing medical care? How will this affect hospitals and other health care facilities in reference to patient care?

This article projects drug costs for the second half of 2000 and for 2001 and discusses the factors influencing drug utilization and costs. It is hoped that, with this information, health care professionals may determine how future changes in drug expenditures will affect their areas of practice. Some data in this article may be inaccurate because of events that have occurred since September 2000, when the information was finalized for publication.

New drug pipelines

Table 1 shows expenditures on R&D by the pharmaceutical companies considered to have the 10 best new drug pipelines. Previous publications of this special feature can be compared with the table to determine past and current findings in reference to spending. Each listed company spent more than $1 billion on R&D in 1998 and 1999. The estimated spending in 1999 varied from a high of $3 billion (Aventis) to a low of $1.7 billion (Schering-Plough). Spending on R&D as a percentage of sales was lowest for Merck, at 6.3%, despite the fact that Merck ranked sixth in overall R&D spending. In contrast, Pharmacia & Upjohn ranked number 10 but spent 23.6% of all sales dollars on R&D.

Four of the companies listed merged within the past two years, but the table does not indicate mergers occurring in 2000. There were major mergers in 2000, including the merger of Pfizer and Warner-Lambert (the combined company has an estimated expenditure for R&D of $4.7 billion), Glaxo Wellcome and SmithKline Beecham, and Pharmacia & Upjohn and Monsanto. It was announced that Pfizer expected to reduce by about 6% the $4.7 billion allocated for research. The cuts will come from eliminating duplications and overlaps in administration and research. Since all three of these mergers include companies already on this list, the total dollars spent by the top 10 for R&D will increase significantly in 2000. Of further interest, only four companies on the list have not merged as of this writing: Merck, Eli Lilly, Schering-Plough, and American Home Products.

With respect to total nationwide spending on R&D, aside from approximately $24 billion spent by the pharmaceutical industry, FDA spent $1.3 billion and the National Institutes of Health spent an additional $15.6 billion on R&D. These additional expenditures dramatically increased the dollar investment on R&D in the United States in 1999.

There are predictions that in the future fewer blockbuster drugs will be released because of the shift from treating patients to attempting to keep people healthy. Included in the definition of keeping people healthy is the modification of new-drug pipelines to incorporate more life-enhancing drugs. Pfizer’s Viagra (sildenafil) is one of the first of these drugs to be a major success. Other examples include Merck’s Propecia (finasteride) for hair loss and a drug being developed for acne, while Pharmacia is working to allow for once-daily administration of some of its drugs. New opportunities also exist in such areas as genome research that will further change the direction of R&D and drug therapy and may lead to new, better-directed therapeutic agents.

A study by the University of Maryland for the Health Insurance Association of America predicts that “pipeline” pharmaceuticals will be responsible for 40% of the annual increase in drug expenditures over the next five years. Drugs currently in development will account for $42.8 billion of a $107 billion increase in pharmaceutical spending. The remaining $62.2 billion will be due to price increases and greater utilization of currently marketed drugs. The yearly increase in spending for pharmaceuticals will be 15-18% over the next five years. Should this prediction prove accurate, it will reemphasize the importance of managers to proactively (1) track drugs in the pipeline that are likely to be used in their practice setting and (2) track the changes in utilization and expanded use of currently marketed products to better assess the effect of price increases.

Table 1. Spending on Research and Development (R&D) by Companies with Best New-Drug Pipelines

<table>
<thead>
<tr>
<th>Company</th>
<th>1999 (Estimated)</th>
<th>1998 (Actual)</th>
<th>% Change from 1998</th>
<th>R&amp;D as % of Sales</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aventis</td>
<td>3.00</td>
<td>NA</td>
<td>NA</td>
<td>14.8</td>
</tr>
<tr>
<td>Pfizer</td>
<td>2.81</td>
<td>2.28</td>
<td>23.2</td>
<td>17.1</td>
</tr>
<tr>
<td>AstraZeneca</td>
<td>2.75</td>
<td>2.47</td>
<td>11.3</td>
<td>14.6</td>
</tr>
<tr>
<td>Novartis AG</td>
<td>2.71</td>
<td>2.50</td>
<td>8.3</td>
<td>12.6</td>
</tr>
<tr>
<td>Glaxo Wellcome</td>
<td>2.15</td>
<td>1.93</td>
<td>12.1</td>
<td>14.9</td>
</tr>
<tr>
<td>Merck</td>
<td>2.20</td>
<td>1.82</td>
<td>15.4</td>
<td>6.3</td>
</tr>
<tr>
<td>Eli Lilly</td>
<td>1.92</td>
<td>1.74</td>
<td>10.3</td>
<td>18.9</td>
</tr>
<tr>
<td>American Home Products</td>
<td>1.78</td>
<td>1.66</td>
<td>7.2</td>
<td>12.8</td>
</tr>
<tr>
<td>Pharmacia &amp; Upjohn</td>
<td>1.34</td>
<td>1.20</td>
<td>6.3</td>
<td>23.6</td>
</tr>
<tr>
<td>Schering-Plough</td>
<td>1.17</td>
<td>1.01</td>
<td>15.8</td>
<td>12.8</td>
</tr>
</tbody>
</table>

*Group expenditures are represented. Foreign currencies were converted at constant average rates for November 1999 provided by the Federal Reserve. Data were obtained from the January 2000 issue of R&D Directions.*
are highlighted by FDA’s withdrawal of troglitazone, which was introduced in 1997 as a new treatment for type 2 diabetes mellitus. In March 2000, FDA withdrew the drug from the market because of reports of sudden liver failure in 90 patients, 63 of whom died. With the introduction of rosiglitazone and pioglitazone, FDA convened a meeting to discuss the withdrawal of troglitazone and to warn of a similar potential adverse reaction to the two newly released drugs. What is unusual is that FDA withdrew troglitazone without consulting its advisory panel, which had recommended keeping the drug on the market with restrictions, and held a meeting to discuss the withdrawal after the fact. Is FDA changing its approach to the problem of drug recalls? Was FDA successful in acting quickly, or did it fail because patients died? FDA is very concerned that adverse-effect warnings on product packages and labeling are not enough to ensure patient safety. Therefore, FDA is beginning to agree with manufacturers that restricted-distribution mechanisms are needed to minimize serious adverse effects for selected high-risk drugs (e.g., dofetilide). If such mechanisms result in far fewer adverse effects, pharmacists should expect that these types of arrangements will be repeated for other newly marketed high-risk drugs.

On May 23, 2000, the Clinton administration announced that the Department of Health and Human Services would be taking new steps to strengthen federal oversight over and increase the accountability of researchers conducting clinical trials with human subjects. Among the actions proposed were (1) requiring researchers to undergo training in standard ethics and human subjects research before funds are granted, (2) requiring institutional review boards to conduct audits to determine if informed consent has been obtained, (3) providing for widespread review of the informed-consent process, and (4) imposing civil penalties of up to $250,000 for individual researchers and $1 million for institutions for repeated violations of current regulations. The intent is to safeguard patients in clinical trials and place additional responsibility on investigators and hospitals.

On January 1, 2000, FDA began to release information to the public that had been submitted by drug manufacturers for review by advisory committees. The information submitted for consideration includes statistical summaries of safety, names of principal investigators, proposed indications, dosages, and routes of administration. As of January 1, FDA began posting this information on its Web site (www.fda.gov). Before this change, the information was not available until after the drug was approved.

The Public Citizen Health Research Group sued FDA in 1999 to make the information available to the public. The Pharmaceutical Research and Manufacturers of America (PhRMA) seeks to limit the amount of information FDA releases. It is concerned that the current draft guidelines may result in publicizing of manufacturers’ trade secrets. However, it should be noted that commercial confidential information, including product formulation and manufacturing information, is exempt from public disclosure under the current draft guidelines.

**New drug approvals**

By the end of July 2000, the number of new drug approvals in 2000 was 37, compared with 77 in all of 1999 and 79 in 1998. In 1999 FDA approved 77 new products, including 35 new chemical entities and 5 new biological agents. For the 35 new chemical entities approved in 1999, FDA approval required an average of 12.6 months, while the 5 biologicals took an average of 17.1 months. The Food and Drug Administration Modernization Act of 1997, which allows for companies that sponsor new drug applications to pay user fees to FDA, has been instrumental in speeding the approval time of new drugs in 1999; in 1997, the average time to approval was 16.2 months. FDA must try to review “priority” drugs—drugs that are significant therapeutic agents—within a six-month period. Approval times among the drugs that were classified as such in 1999 were 5.9 months for rofecoxib, 6 months for oseltamivir, 6 months for rosiglitazone, and 7.8 months for quinupristin-dalfopristin. In the 10-year period 1990–1999, 370 new prescription pharmaceuticals were brought to market, compared with 239 in the previous decade. To bring new products to market, the industry spent approximately $24 billion in 1999, versus $8.4 billion in 1990 and $2.0 billion in 1980. The drugs approved in 1999 were targeted at 35 diseases affecting 545 million patients worldwide and had an annual cost of $600 billion. Among the important products introduced in 2000 were a new class of antimicrobials, a new breast cancer treatment, a new class of drugs for preventing organ transplant rejection, and a new product for Parkinson’s disease. The 35 new entities approved represented the third largest number of approvals from 1990 to 1999. FDA approved 53 new entities in 1996 and 39 in 1997.

At the start of 2000 there were 200 agents in Phase III trials and approximately 200 more awaiting final FDA review; some with high sales potential are shown in Table 2. Drugs being considered for approval include products for depression, irritable-bowel syndrome, Alzheimer’s disease, colorectal cancer, and migraine headache. The possibilities for future drug approvals include individually tailored gene therapies, products to correct DNA problems, and cures for several diseases thought to be incurable. The therapeutic category with the largest number of drugs awaiting approval in 2000 is cancer drugs, followed by central-nervous-system drugs and anti-infective drugs.
Generic drugs

The generic drug industry is an important factor in the pricing and cost of prescription drugs, but the future of the industry is unclear. It is anticipated that many blockbuster drugs will be coming off patent within the next few years. By 2005, drugs that will have lost their patent protection include Prilosec (omeprazole), Zocor (simvastatin), Vasotec (enalapril), Pravachol (pravastatin), and Glucophage (metformin). These drugs are among the major medications for chronic diseases; their total sales value is estimated to be $40 billion. One projection has indicated that the generic industry’s sales may be over $20 billion by the year 2005, up from an estimated $13 billion in 2000.

It is believed that the Baby Boomers will be a more budget-conscious and computer-savvy group of drug purchasers than were their parents. In a recent survey by Merck-Medco, 87% of respondents said they would buy a generic drug over a brand-name drug. In another recent study, the percentage of patients who believed that generic drugs were riskier than brand-name drugs varied from 14.2% to 53.8%. The perceived risk of generic versus brand-name products varied with the condition being treated. Generics were most frequently seen as risky by heart disease patients (53.8%), while only 14.2% of patients using generic drugs for cough saw them as risky. Although this study had limitations (e.g., a sample from one small area of one state), there appeared to be a relationship between cost and risk.

The Federal Trade Commission (FTC) is taking action to determine if unfair competition in generic drug marketing continued into 2000. FTC has warned that it is prepared to seize the profits of companies illegally delaying generic drugs from coming to market. During 2000, FTC filed civil charges against Aventis, Abbott Laboratories, Andrx Corp., and Geneva Pharmaceuticals. It stated that contracts between companies “can raise serious antitrust issues.” Charges against Abbott and Geneva concerning Hytrin (terazosin) were settled. At this writing, a suit against Aventis and Andrx concerning Cardizem CD (diltiazem) was pending, and a federal judge declared the Cardizem CD agreement an illegal restraint of trade. FTC alleged that Aventis’s quarterly payments of $10 million to Andrx not to market the generic version of Cardizem CD were illegal.

In another case, pending since late 1988, Mylan Laboratories agreed to...
In 2000, compared with 242 in 1999—a 30% increase. The limited approvals during 1999 may have resulted from mergers between generic companies. FDA’s intent is to have most applications reviewed within a 180-day time frame, according to the acting director of the OGD, Gary Buehler. With the availability of generic brands of important pharmaceuticals, as demonstrated by the approval of generic brands of midazolam and propofol in 2000, one can expect significant price decreases for both the generic and brand-name drugs. The generic industry is growing in importance and size and will continue to do so. If drug coverage for the elderly and Medicare patients becomes a reality, one can expect greater growth than in the past.

**Increasing drug costs**

The increasing cost of drugs can be traced to a number of factors causing a higher level of spending for pharmaceuticals. Among the factors are new and expensive drugs, broader health-insurance coverage, the availability of drugs for which no therapy was available in the past, a shift from other therapeutic modalities to drug therapy, and increased consumer demand driven by direct-to-consumer advertising. Data indicate that drug companies spent $5.7 billion on detailing in 1998, a 15% increase over 1997. In addition, after the introduction of some major new drug classes (e.g., lipid-lowering drugs and low-molecular-weight heparins), drugs have been found to be effective for conditions other than the approved indications and may be recommended for patients in the same diagnostic categories who were thought not to be candidates when the drugs were introduced.

Spending on prescription drugs was estimated to be over $112 billion in 1999 and to account for more than 8% of total national health expenditures. It is anticipated that by 2008 expenditures will increase to $243 billion and will consume 12.6% of total health care spending. Spending on prescription drugs is increasing at a rate of 12% per year and is predicted to increase 10% annually for the next eight years. IMS Health has projected an average global sales growth of 8.1% per year to 2004, expanding the global market to $506 billion. North America was the world’s largest market in 1999, with sales of $138.8 billion, a growth rate of 18%, and projected average yearly increases in growth of 11% until 2004. It should be noted that projections of sales and expenditures vary, depending on the period of estimation during a given year.

A study by Express Scripts found that prescription drug spending increased by a record 17.4% in 1999. The overall average cost per prescription increased by 9.6%. The average cost per prescription increased by 14% for people 70 to 79 years of age and 16.4% for those 80 or older. Approximately 50% of the increase was due to higher costs for the typical prescription, and 50% was due to increased use of prescription drugs and the introduction of new drugs. This study raises important questions concerning the pharmaceutical industry’s pricing practices.

According to the Lazarus report, containing information from 45 well-known hospitals, drugs accounted for 80.5% of pharmacy costs in 1999, compared with 75.1% in 1998. Drug expenditures were up 18.1% on average, versus 14.4% in 1998, while the average cost per patient-day was $98.62. The cost was $65.50 per patient-day for the lowest quartile and $111 for the highest. Hospitals with outpatient prescription departments had an average increase of 22.6% in ambulatory care drug costs in 1999.

All the forecasts being made may be considered to be bullish in anticipation of expensive new drugs coming onto the market. Should health care reform be introduced and include a drug coverage program, sales may not reach the levels anticipated. In addition, patent expirations over the next few years may reduce sales growth.

Another view is one that predicts the introduction of more blockbuster drugs, offsetting lost revenue from patent expirations. In addition, drugs developed through pharmacogenetics research and other scientific breakthroughs will provide innovative new therapies. Anderson Consulting has predicted that the pharmaceutical industry will quadruple the number of drug launches each year by 2008. This will be accomplished by reducing to 10% from 30% the number of experimental drugs that never reach the market.

**Pharmacists’ responsibility**

What responsibility do pharmacists have regarding drug costs? It is obvious to legislators, the public at large, and health care providers that the cost of drugs is continuing to increase. The cost in some instances is beyond what patients can afford and yet continues to increase.

Various attempts have been made by pharmacists, or are being introduced, that may limit—but probably not decrease—drug costs. The formulary system was one of the first methods of controlling costs, followed by clinical pharmacy involvement, drug rounds, switching from i.v. to oral dosage forms, restricting the use of selected drugs, and using generic products. Trying a less expensive drug first (e.g., prescribing a histamine H2-receptor blocker before using a proton-pump inhibitor), requiring copayments, and not covering “lifestyle drugs,” such as sildena-
fil, are other methods in place to control costs, but the fact remains that costs continue to escalate.

Some additional alternatives include reducing R&D spending, using only generic drugs when available, restricting company advertising and detailing, imposing price controls, pricing drugs on the basis of ability to pay, and equalizing drug costs throughout the world. Although there may be more alternatives, no one good alternative has been presented that would not have a detrimental effect on the patient or the industry's ability to introduce important new pharmaceuticals.

Perhaps we have reached the point where a national formulary tied to firm, nationwide standards is required. Unprejudiced reviews of large-scale drug use may need to be undertaken to determine how effective agents are and whether in fact drugs reduce other health care costs (e.g., length of stay for hospital inpatients). Whether FDA needs to approve another “me-too” drug might be questioned. How many nonsteroidal anti-inflammatory or lipid-lowering drugs are required? Have we reached the point where decisions must be made as to which duplicate products should or should not remain on the market? What does appear to be necessary is that a national program be established that will not discourage innovation by the pharmaceutical industry and that will at the same time provide the drugs necessary for treating people at an affordable cost.

**Prescription versus nonprescription status**

Among the important changes that will continue to affect health care during 2001 are direct-to-consumer advertising, the growing use of herbal products, and the greater availability of medical information to patients. These changes have led to more patients managing their own treatment.

In May 2000, FDA announced it would begin reviewing drugs for chronic conditions that should be available without a prescription. The agency was interested in determining new candidates for nonprescription status. FDA requires that nonprescription drugs treat conditions that a consumer can diagnose without a physician’s involvement and that labeling be understandable and correct. PhRMA is not in favor of any changes in the current system, probably because nonprescription drugs are less profitable than prescription drugs. From the viewpoint of hospitals, managed care companies, and other systems that dispense drugs, such a change could provide a significant reduction in drug costs to many drug dispensers.

For the first time since 1972, when 600 drugs were switched from prescription to nonprescription status, FDA is reviewing nonprescription drug regulations with an eye to creating a new system for approving nonprescription status for prescription drugs. An agency official leading the review recognized patients’ growing interest in self-care. However, concern about patient harm must be raised when defining minor conditions. Among the drug classes being reviewed are cholesterol-lowering drugs, antibiotics, and birth-control products. Sidney Wolfe of the Public Citizen Health Research Group has stated his objection to some of the classes suggested for change. Others have suggested that the agency follow Canada’s system of “under-the-counter” drugs—drugs that do not require a prescription but that require pharmacist involvement before those that are potentially dangerous may be sold. Thus, action taken by FDA may be favorable by lowering the cost of drugs to many pharmacy facilities or by having pharmacists control a third class of drugs.

In June 2000, health plans, large employers, unions, and consumer advocates formed a coalition, Rx Health Value, consisting of 83 million members, designed to slow the increase in spending for prescription drugs. Plans for the coalition to cut drug costs include sharing information obtained from independent studies to identify the most effective agents and to increase consumers’ political influence on drug matters. The coalition pointed out that the pharmaceutical industry spent $13.9 billion to market drugs in 1999, 50% more than in 1996, when direct-to-consumer advertising was approved. An organization, Rx Intelligence, sponsored by Blue Cross, will undertake clinical studies to determine which new drugs are an improvement over existing drugs. The goal of the coalition is to have “enough heft so it can speak with a voice equal to the pharmaceutical industry’s,” said John Golenski, executive director of the new group.

**Gene therapy**

In June 2000 it was announced that sequencing of the human genome had been completed. It was recognized that the first practical impact of this finding would be in the health care field; medicine as we know it will dramatically change.

Directing cells to repair damaged tissue and interact with foreign bodies and tailoring medications to treat and prevent medical problems in individual patients may become everyday events. It can be anticipated that there will be a great deal of activity to produce new therapeutic agents that will be expensive and at times unaffordable by many patients. In the near future, such agents will have limited use and will probably not be a major factor in the overall cost of drug therapy. However, should the R&D cost of these new agents exceed what the pharmaceutical industry anticipates, their introduction may increase the cost of agents currently on the market.

**What lies ahead**

Concerns about drug prices have escalated to a point beyond what we have ever witnessed before. Several responses of the pharmaceutical mar-
marketplace may be anticipated or have already begun.

A variety of new companies are starting to offer below-market prices on prescription drugs and on services such as physician, dental, and eye care and medical tests. People sign up as if joining a discount club like Costco or Sam’s Club, pay a small annual membership fee, and purchase drugs and services from pharmacies and other sources that have agreed to charge lower prices.

Medicare’s new prospective pricing system for hospital outpatients uses an ambulatory payment classification (APC) system to divide services into 451 groups. Payment is adjusted on the basis of geographic location. Reimbursement is based on J codes (revenue codes) for each drug covered by the program. With the exception of J-coded drugs, drugs are bundled into the cost of major procedures.

As of this writing, the U.S. House of Representatives and the U.S. Senate have passed amendments to the Agriculture, Rural Development, FDA, and Related Agencies Appropriation Bill (H.R. 4461). The Senate version is slightly more restrictive than the House version and would allow pharmacists and drug wholesalers to import FDA-approved prescription drugs from other countries. Under the Senate amendment, consumers would still be restricted from importing prescription drugs into the United States.

Maine’s drug-pricing law is being considered by an alliance of 21 states that support the Prescription Drug Fair Pricing Act. Florida is now in the earliest stages of the legislative process and hopes to introduce a bill in the next legislative session. PhRMA has called the law unconstitutional and has filed a lawsuit in U.S. District Court in Bangor, Maine. PhRMA said that the state is reaching outside its borders to require discounts from out-of-state manufacturers.

The Clinton administration plans to cut payments for anticancer drugs administered to patients in physicians’ offices. Secretary of Health and Human Services Donna Shalala has justified this action on the basis of frequent overcharging for drugs, mainly for Medicare patients. It has been suggested that patients would be sent to hospitals for treatment.

Drug cost coverage for the elderly or for Medicare patients is a hotly debated public policy issue. Passage of legislation approving such coverage by any drug plan would significantly alter the landscape of drug utilization and costs.

Conclusion
The last months of 2000 and the year 2001 will bring many changes within the pharmaceutical industry and thus increased changes in the purchasing and utilization of drugs within the United States.

There are about 530 new products and new indications awaiting approval for marketing, and an additional 970 new products and new indications are in Phase III trials. It is expected that the 1500 new products and indications will be approved within the next three years. The U.S. pharmaceutical industry will spend $27.4 billion for R&D in 2000, and sales are expected to be $149.1 billion, an 11.2% increase over the 1999 figure. Although there has been a decrease in productivity due to increased clinical development costs, it is forecast that declines in productivity will not continue.

Drug benefit costs for large employers are expected to increase 23.4% over the next year for retirees, and new drugs will have increased utilization, leading to higher prescription costs. Americans over age 65 have seen the average cost of a prescription increase from $28.50 in 1992 to $42.30 in July 2000. It is predicted that the average cost per prescription will increase to $72.94 by 2010.

Spending on prescription drugs averaged $387.09 per person in 1999, an increase of 17.4%. The major reasons for the 1999 increase and the continuing increase in 2000 were higher prices and greater utilization. New drugs introduced since 1992 accounted for 40.8% of 1999 costs but only 25.4% of prescription drug use. Although the increase in drug prices affected all drug classes, the largest cost increases were due to increased utilization. Antihyperlipidemics ranked first, followed by antidepressants, GI drugs, and antihistamines.

PhRMA has determined that, of the total increase in the cost of drugs in 1999, 10.8% was due to increased use of existing drugs, 4.2% to increased prices of existing drugs, and only 3.8% to new drugs. Since 1990 there has been a change in the cause of increased drug costs. Price increases for existing drugs accounted for 4.8% of the total drug cost increase and new drugs for 1.4%. However, the main cause of increased costs since 1994 has been the increased use of existing drugs. In budgeting for 2001, it would be prudent to consider the increased use of existing drugs to be the major factor in spiraling costs.

The 1999 Lazarus report, a survey of 42 hospitals from across the country, found that drug expenditures accounted for 80.5% of pharmacy expenditures, compared with 75% in 1998. Drug costs had increased 18.1% and the cost per case 3.2%. The projection of an annual increase of 11.2% into 2001 by IMS Health indicates that we can anticipate increased drug costs in 2001.

We project that drug cost increases in 2001 will range from 11% to 15%, depending on the area of practice. Increased drug utilization will probably have a more significant effect on total drug costs than new, more expensive drugs. The major unknown is what actions federal and state governments will take to control prescription drug prices.

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