PRICING

THE COST OF DOING BUSINESS

BY DENISE MYSHKO

Distinguishing between value and price is central to the debate surrounding prescription-drug costs

DR. DAVID WEBSTER

PICK UP A NEWSPAPER, TURN ON THE TELEVISION, OR LOG ONTO THE INTERNET and almost every week, a politician, agency, or consumer group can be found criticizing the pharmaceutical industry's pricing, promotional, or marketing practices.

Central to the controversy, more often than not, is the cost of pharmaceutical products and the impact this cost has on healthcare expenditures and on consumers' wallets.

"Drug companies have products to sell and they want to maximize their value within each segment of the market," says Jim Czaban, an attorney in the Washington, D.C., office of Heller Ehrman White & McAuliffe. "Criticisms of the industry's drug-pricing policies often are politically motivated. When people say drug pricing is not rational, it's often a code for their political references."

According to some industry analysts because there is an overlay of strict regulatory requirements, which includes adhering to stringent R&D guidelines, and an amortization of product value (the patent life of pharmaceutical products), the formula is not cut-and-dry.

The debate surrounding pharmaceutical pricing intensified in November when the Tufts Center for the Study of Drug Development released its latest estimate on the cost to develop a new drug — $802 million. The pharmaceutical industry has traditionally used the Tufts' research as a way to benchmark one of its primary expenses — research and development. An expense that, according to Pharmaceutical Research and Manufacturers of America (PhRMA), is integral in setting industry pricing.

The November figure of $802 million is triple Tuft's 1987 estimate of $231 million. (The $802 million is based on 2000 dollars and the earlier estimate was done a decade ago and is based on 1987 dollars.)

Dr. Joseph A. DiMasi, director of economic analysis at the Tufts Center and the principal investigator for the latest study, attributes much of the increase in the total cost of new drug development beyond inflation to rising clinical-trial costs. "The difficulty in recruiting patients into clinical trials in an era when drug development programs are expanding, and the increased focus on developing drugs to treat chronic and degenerative diseases, has added significantly to clinical costs," Dr. DiMasi says.

Included in the drug cost analysis are expenses of project failures and the impact that long development times have on investment costs. The estimate also accounts for out-of-pocket clinical costs, out-of-pocket discovery and pre-clinical development costs, clinical success and phase attrition rates, as well as the cost of capital.

"Bringing new drugs to market has always been an expensive, high-risk proposition, and our latest analysis indicates that costs have continued to skyrocket," says Tufts Center Director Dr. Kenneth I. Kaitin. "The single largest challenge facing drug developers — both pharmaceutical and biotechnology companies — is to contain R&D costs and reduce development times without compromising clinical test design. It's a tall order."

Critics of the study claim that the pharma-


DR. THOMAS NAGLE

IT'S NOT THAT PRICES are high because R&D is high, but rather because prices are high, companies are more willing to do R&D to develop therapies for indications that are hard to crack.

PRESCRIPTION DRUG PRICES ON THE RISE

THE AVERAGE PRICE OF A PRESCRIPTION CONTINUES TO INCREASE, FUELED BY INCREASES IN MANUFACTURER PRICES FOR EXISTING DRUGS AND BY PROPORTIONATELY HIGHER PRICES FOR NEWER, BRAND-NAME DRUGS. MANUFACTURER PRICE INCREASES IN RECENT YEARS HAVE BEEN HIGHER THAN IN THE MID-1990S.

- The overall average retail prescription price was $45.79 in 2000, more than double the average price in 1990 ($22.06). Increases in average retail prices reflect both price increases for existing drugs and shifts in use to newer, more expensive medicines.
- The average retail price of a prescription for a brand-name drug was more than 3 times that of a generic drug in 2000 ($65.29 compared to $19.33). This price differential between average brand and generic prescription prices has increased over time, from just less than 2.9 times in 1996 to 3.4 times in 2000.
- The average retail prescription price increased more than 3 times the rate of general inflation (CPI-all items) and more than twice the CPI for medical care from 1998 to 2000 (9.2% compared with 2.8% and 3.8%, respectively). The average annual percent increase in retail prescription prices from 1998 to 2000 was 30% higher than the increase from 1991 to 1998.
- Price inflation in the form of manufacturer price increases for existing drugs decreased in the mid-1990s, but recently increased from 1.6% in 1996 to 3.9% in 2000. However, since 1993, manufacturer price inflation for existing drugs has remained low relative to increases in prescription expenditures overall (17.4% in 2000) or average retail prescription prices (7.9% in 2000), which reflects shifts in use to newer, more expensive drugs.
- Prescription use continues to show steady growth. A variety of factors influence this growth, including increased availability of and dependence on medications for treatments, increases in promotion of prescription drugs by pharma manufacturers, improved access to drugs through insurance coverage for prescriptions, and an aging population.
- The number of prescriptions dispensed in retail pharmacies has grown at an average annual rate of 6.0% since 1992, reaching almost 3.0 billion prescriptions in 2000. This compares to only a 1.4% growth in the population for the same time period.
- Prescriptions dispensed per capita have increased by almost half in the past 8 years, from 7.3 prescriptions per capita in 1992 to 10.8 in 2000.

Source: The Henry J. Kaiser Family Foundation, an independent, national health philanthropy dedicated to providing information on health issues; Prescription Drug Trends – A Chartbook Update Kaiser Family Foundation November 2001.

ceutical industry overestimates its R&D costs by as much as 75%. The updated Tufts study used the same methodology as the 1991 study, which also was prepared by Dr. DiMasi. In July 2001, Public Citizen published a detailed report, Rx R&D Myths, critiquing Dr. DiMasi's original study. It demonstrated that the actual after-tax cash outlay for developing a new drug, including failures, was $110 million – about 75% less than PhRMA's 1991 $500 million estimate. (See box on this page, for more details.)

The pharmaceutical industry has long used the Tufts' research in its discussions about pricing. Statements and brochures put out by PhRMA consistently defend the industry's

The single largest challenge is to contain R&D costs and reduce development times without compromising design.

The Rising Cost of Drug Development

Two major industry constituents have very different points of view relating to the actual cost of research and development. On one side is The Tufts Center for the Study of Drug Development, which has long been recognized as the leading resource for evaluating R&D cost metrics. On the other, is the national consumer advocacy group Public Citizen, which refutes the Tufts' study, claiming the research overstates the actual costs associated with pharmaceutical R&D.

POINT: In November 2001, The Tufts Center for the Study of Drug Development announced that the average cost to develop a new prescription drug is $802 million. That figure is the major conclusion of a recently completed in-depth study conducted by the Tufts Center based on information obtained directly from research-based drug companies. These data update a similar study done by the Tufts Center a decade ago, when the average cost to develop a new drug was estimated to be $231 million, in 1987 dollars.

AMONG THE STUDY'S KEY FINDINGS WERE THE FOLLOWING:

- The full capitalized resource cost of new drug development was estimated to be $802 million (2000 dollars). This estimate accounts for the cost of failures, including research on compounds abandoned during development, as well as opportunity costs of incurring R&D expenditures before earning any returns.
- When compared to the results for previous studies, the R&D cost per approved new drug increased 2.5 times in inflation-adjusted terms.
- After adjusting for inflation, the out-of-pocket cost per approved new drug increased at a rate of 7.6% per year between the 1991 study and the current study. The annual rate of growth in capitalized cost between the two studies was 7.4% in inflation-adjusted terms.
- While costs have increased in inflation-adjusted terms for all R&D phases, the increases were particularly acute for the clinical period. The inflation-adjusted annual growth rate for capitalized clinical costs (11.8%) was more than five times greater than that for pre-clinical R&D.

The Tufts Center for the Study of Drug Development based its conclusions on detailed survey data on 68 drugs obtained directly from 10 drug companies. Because drug development is a complex process involving long lead times and substantial technical risks, a reliable estimate of the cost of development accounts for the expense of project failures and the impact that long development times have on investment costs. For more information about the study and its methodology, please log onto: www.tufts.edu/med/

POINT

ACCORDING TO THE TUFTS CENTER FOR THE STUDY OF DRUG DEVELOPMENT:

- The full capitalized resource cost of new drug development is estimated to be $802 million.
- This estimate accounts for the cost of failures, including research on compounds abandoned during development.

COUNTERPOINT: According to Public Citizen, the Tufts Center for the Study of Drug Development once again significantly overstates real research and development costs. In a July 2001 report titled, Rx R&D Myths: The Case Against The Drug Industry's R&D "Scare Card," Public Citizen states that major U.S. drug companies and their Washington, D.C., lobby group, the Pharmaceutical Research and Manufacturers of America (PhRMA), have carried out a misleading campaign to scare policy makers and the public. PhRMA's central claim is that the industry needs extraordinary profits to fund expensive, risky and innovative R&D for new drugs. According to Public Citizen, the R&D scare card – or canard – is built on myths, falsehoods and misunderstandings, all of which are made possible by the drug industry's staunch refusal to open its R&D records to congressional investigators or other independent auditors.

ACCORDING TO PUBLIC CITIZEN, THE TUFTS CENTER STUDY HAS TWO DRAMATIC FLAWS.

- First, the study is not representative of real drug industry R&D because none of the 68 drugs used in the Tufts study received any government sup-

pricing policies, stating pharmaceutical prices are justified in light of the risk, high cost, and time involved in drug development; the need to cover costs for those products that don't come to market; the eventual loss of patent protection and competition from generics; the need to fund future research; and the intrinsic value pharmaceuticals provide.

"Research and development is an important factor in pricing," says Irwin Lerner, CEO of Reliant Pharmaceuticals LLC. "The costs, the risks, and the time to get a reasonable return on that investment — these all play some role in the pricing of a product. It isn't necessarily the determinant role, but it certainly is a major factor in calculating or coming up with the ultimate price for the product."

Mr. Lerner stresses that several factors determine a pharmaceutical product's price, but R&D costs cannot be ignored, especially when the average company spends somewhere between 18% to 25% of revenue from sales on R&D. "That is a ratio of research to sales unmatched by any other industry," he says.

In 2001, PhRMA member companies invested an estimated $30.3 billion in R&D – a 16.6% increase from the 2000 level. In 2001, pharmaceutical and biotechnology companies added 32 new treatments to the nation's medicine chest — 24 drugs and 8 biologics.

According to PhRMA, the increase in R&D spending, which was estimated at $2 billion in 1980, can be attributed to inflation, and an increase in investments in biotechnology and genomic research, which have resulted in better medicines, says Jeff Trewhitt, a spokesman for PhRMA. "Anytime an industry increases R&D spending that much, it will be reflected in the price," he says.

Others disagree to the extent R&D costs affect pharmaceutical pricing. "Research costs are sunk costs and really do not have much influence on the final price of the drug," says Stuart Schweitzer, Ph.D., professor, health services, and director, Ph.D. and M.S. programs, at the UCLA School of Public Health.

"Drug prices are determined by the value of the drug not by R&D costs," he says. "Even if a drug costs more to research, the company doesn't stand a chance of recouping those costs

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port – a fact admitted by the study's author, Dr. Joseph A. DiMasi, at a Nov. 30, 2001, briefing on the report. Many, if not most, drugs brought to market receive financial support from the government at some stage in their discovery and development. Therefore, the Tufts study focuses on a skewed sample of drugs and inflates the actual cost of R&D for the average drug.

A National Institutes of Health (NIH) internal document, dated February 2000 and obtained by Public Citizen last year, showed that all the top five selling drugs in 1995 received significant taxpayer backing in the discovery and development phases.

• Second, the Tufts Center study exaggerates the actual R&D expenditures for its sample of drugs. Specifically, the new Tufts Center estimate of $802 million includes significant expenses that are tax deductible and theoretical costs that drug companies don't actually incur. For example, roughly half of Dr. DiMasi's estimate ($399 million) is the "opportunity cost of capital" – a theoretical calculation of what R&D expenditures might be worth if they were invested elsewhere. Dr. DiMasi calculated actual out-of-pocket R&D costs for drugs in the study at $403 million per new drug.

Those out-of-pocket expenditures are pre-tax costs, however. Drug companies can and do deduct 34% of their R&D expenses under federal tax law. Therefore, the actual after-tax cash outlay for each drug in the new Tufts study is about $240 million, according to Public Citizen. But it must be stressed that the average R&D cost for each new drug brought to market is significantly less than $240 million because that figure applies only to the drugs used in the Tufts study.

According to Public Citizen, the drug industry's own data show how Dr. DiMasi's sample of drugs is skewed toward the most expensive new products. Dr. DiMasi puts clinical-trial outlays at $282 million per drug, which accounts for 70% of his $403 million in total out-of-pocket expenditures.

But according PhRMA, clinical trials accounted for only 29% of all industry R&D expenses in 1999 (the latest year for which such data is available).

According to Public Citizen, The Tufts Center figure is important because it is used by the drug industry to defend its extraordinary profits and rising prices. In its last study on the cost of developing a new drug, completed in 1991, the Tufts Center – which receives 65% of its funding from drug companies – pegged the figure at $231 million. PhRMA used that in its calculations to conclude that the cost of developing a new medicine, including successes and failures, had grown to $500 million. PhRMA then claimed that any attempt by federal or state governments to moderate drug prices would harm R&D innovation.

The updated Tufts study used the same methodology as the 1991 study, which also was prepared by Dr. DiMasi. In July 2001, Public Citizen published a detailed critique, Rx R&D Myths, of the original Dr. DiMasi study. It demonstrated that the actual after-tax cash outlay for developing a new drug, including failures, was $110 million — about 75% less than PhRMA's $500 million estimate. Public Citizen's analysis was based on a major study analyzing Dr. DiMasi's report prepared by the congressional Office of Technology Assessment (OTA).

PhRMA commissioned the accounting firm Ernst & Young to respond to the Public Citizen report. Ernst & Young failed to rebut Public Citizen's separate findings that were based on PhRMA data, which showed R&D costs for all new drugs brought to market (including failures) to range between $71 million and $150 million. This analysis (contained in Section II of Rx R&D Myths) was not based on Dr. DiMasi's methodology but on PhRMA's own claims about how much the industry spends on R&D compared with the number of new drugs approved by the Food and Drug Administration.

Public Citizen, a national, nonprofit consumer advocacy organization founded in 1971, represents consumer interests in Congress. For more information on Public Citizen's findings log onto: www.citizen.org.

THERE IS ONLY ONE FACTOR — what will the market bear. It makes no sense to suggest that companies price their products according to the cost of R&D.

through higher prices if there is no real value to their product."

In the long run, Dr. Schweitzer says, "Companies that come up with mediocre drugs that were expensive to produce will eventually go out of business. The companies that stay in business are the companies that are able to cover all of their costs. But that doesn't determine the price at which drugs are set. It's the other way around."

Others agree. "Research costs do not drive pharmaceutical prices," says Thomas Nagle, Ph.D., chairman of Strategic Pricing Group Inc., a marketing consulting firm that specializes in pricing and value-based strategy. "That is just a silly idea. It's actually the other way around: Pharmaceutical prices drive the amount of research and how much the company is willing to spend to develop new drug therapies. It's not that prices are high because R&D is high, but rather because prices are high, companies are more willing to do R&D to develop therapies for indications that are hard to crack."

"Tufts has very good researchers, but they aren't economists," Dr. Nagle says. "They don't understand how prices are set. They've done a good job of tracking R&D costs, they just don't understand the implications. Most researchers, most politicians, or people in general don't understand what drives prices."

Advocacy groups, especially Public Citizen, have criticized Tufts' estimates, particularly the inclusion of opportunity costs, which it says are theoretical.

For example, according to Public Citizen, roughly half of Dr. DiMasi's estimate is the "opportunity cost of capital" – a theoretical calculation of what R&D expenditures might be worth if they were invested elsewhere.

Critics have pointed out that the Tufts' estimate includes expenses that are tax deductible. PhRMA, however, points to a study by Ernst & Young, which says the cost of capital in pharmaceuticals is especially important given the risks the industry takes.

"The methodology used by Tufts has withstood the test of time," Mr. Trewhitt says. "Tufts developed this methodology 15 to 20 years ago. Since then, a number of academics, business groups, and even a congressional agency have embraced the methodology and use the data to update (estimated R&D costs)."

ECONOMICS 101

Some industry experts say, however, that pricing is simply a matter of what people are willing to pay.

"There is only one factor — what will the market bear," says Edward M. Feaver, Pharm.D., president and CEO of Prescription Solutions, a pharmacy benefit manager. "Pharmaceutical manufacturers have moved away from trying to price a product based on return, or investment or risk/reward, and instead they price a product based on what the consumer is willing to pay.

"I used to buy into the argument that researching new drugs is a risky venture," Dr. Feaver says. "But looking at the returns those drugs have brought companies over the past 10 to 15 years, that argument appears irrational. It makes no sense to suggest that companies price their products according to the cost of R&D."

Mr. Trewhitt attributes part of determining a product's price to the issue of patent expiration. Shareholders, he says, want a large return on their investment not only because of the risks associated with drug development, but also to make up for the drop in sales that occurs once a patent expires.

"Within two years of patent expiration, 75% of a product's market is lost to generic competition," he says. "Between 2002 and 2005, many brand-name drugs with annual sales of up to $40 billion a year will lose patent protection. This is a regular part of doing business, but companies have to sustain the R&D engine."

The biggest factor in determining the price of a drug, consultants say, is its value in the marketplace. But some maintain that the industry has been deficient in its efforts to communicate to the public the value of medications.

"When the industry has defended itself, companies all too consistently have pointed to high R&D costs," Dr. Nagle says. "But there isn't a lot of sympathy for companies that complain about costs. What companies need to do is flip the equation around and focus on value. They need to remind the public that before drug companies invested in AIDS therapies, for example, people were dying. The industry has given life back to these people."

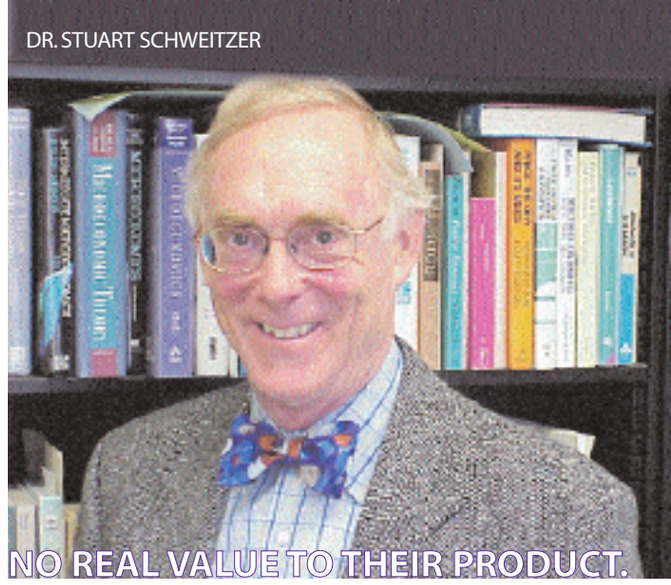
PhRMA consistently tries to educate the public about the cost-effectiveness of drug therapy versus other alternatives, but too many people choose not to listen.

"Pharmaceuticals are cheaper than other healthcare alternatives," Mr. Trewhitt says. "For example, the average operation to correct an ulcer costs about $28,000. The average antiulcer drug costs about $900 a year. Increasingly, as drugs become more effective, patients are being stabilized and sustained on medicine alone, eliminating surgery and nursing-home confinement."

The pharmaceutical industry hasn't been as effective as it could be in addressing criticism, says David L. Webster, Ph.D., founder and president of The Webster Consulting Group Inc. "The industry has set up an argument that puts itself in a very small box. Prices are high because of R&D — but that's not the only reason. By sticking to that argument, companies expose themselves to a lot of criticism. It's easy to point out that the industry also spent a lot of money on things other than R&D."

A study by Families USA in July 2001 refutes the claim that high drug prices are needed to sustain research and development. This study says companies spend more than twice as much on marketing, advertising, and administration as they do on research and development. The study also is critical of the large compensation packages for senior industry executives and of the industry's high profits.

The Henry J. Kaiser Family Foundation released a study in November 2001 that concluded that pharmaceutical industry profits exceeded R&D spending (24% of revenue compared with 14% on R&D spending). This study indicated that profits as a percentage of revenue have been more than four times the


DR. STUART SCHWEITZER

Drug prices are determined by the **value** of the drug not by **R&D** costs. Even if a drug costs more to **research**, the company doesn't stand a chance of **recouping** those **costs** through higher prices if there is **NO REAL VALUE TO THEIR PRODUCT.**

median rate for all Fortune 500 companies in the late 1990s. Conversely, PhRMA points to a study that cites that three of 10 products are not profitable (this study was performed in 1994 based on products in the 1980 to 1984 time frame).

"The No. 1 issue with respect to pricing is the industry's image with the public," Dr. Webster says. "It's an issue of credibility and trust. And every time the pharmaceutical industry puts out public relations related to pricing that are not credible, the industry's image is taken down one more notch. It makes people much more willing to seriously consider price regulations. At the core, the industry's arguments are accurate. But it's also not credible to say if pricing were cut R&D would evaporate. That is not the complete truth. It would certainly decline somewhat, but R&D would not evaporate. Companies would have to reduce everything: marketing budgets, manufacturing budgets, lobbying budgets, etc."

Companies need to be up front about the fact that they are in a competitive business, Dr. Webster says.

"We operate in a competitive free-market environment and I think companies have made the point very well that we're all better off because of that," he says. "But companies face many challenges in a profit-maximizing environment. Companies have to compete for CEO talent, for example."

WHO PAYS?

The debate surrounding pharmaceutical prices persists even though the cost of drugs accounts for about 10% of total spending on healthcare in the U.S., which was $1.3 trillion in 2000, according to the Centers for Medicare & Medicaid Services, or CMS, (formerly the Health Care Financing Administration) in Baltimore.

Although drugs are just a small piece of total healthcare spending, they are a fast-growing portion. In 2000, prescription drug spending rose by 17.3%, the sixth year in a row of double-digit increases, according to CMS.

As prescription spending increases, the cost of purchasing drugs is being passed along to patients and employers.

In 2001, prescription drug costs for employers increased by 16.8%, according to consultant William M. Mercer. In 2002, employers expect a 15% increase, a sign that while prices are still rising for employers the rate of increase is slowing.

"We're used to a system in which the benefit of drugs far outweighs how much they cost," Dr. Schweitzer says. "Drug companies never used to charge for the full value of products. Now they do. Pharmaceutical companies have gotten smarter and they've hired economists to calculate the benefits of their products. And they are using those calculations as guides to determine prices."

Many employers pass on the higher drug costs to their employees through increased payroll deductions, higher co-payments, and changes in benefit design. Growing in popularity is a three-tier drug plan, where the employee pays the least for a generic drug, a little more for a brand-name drug, and the highest co-pay for a brand-name product not on formulary. The use of such programs has increased from 6% in 1998 to 35% in 2000, according to a study conducted by the Pharmacy Benefit Management Institute Inc.

Managed-care companies and PBMs play the primary role in influencing a product's price.

"The best price often is established at the managed-care or PBM level," Dr. Feaver says. "These intermediaries mandate where a product's price falls within a therapeutic class. This best price often becomes the benchmark."

Patients, today, for the most part have been sheltered from the true cost of pharmaceuticals, Dr. Feaver says. Even though employers are shifting more of the cost onto employees, this shift hasn't been drastic enough for consumers to accept controls.

"Our hands are tied in trying to negotiate a better price, especially when there is such a premium placed on access," Dr. Feaver says.

"Times have changed," Dr. Webster says. "Managed care and for-profit hospitals now dominate, the American consumer is now much more comfortable with the fact that healthcare is a for-profit enterprise."

The Kaiser Family Foundation study reports that the proportion of prescription drug expenditures paid out of pocket by consumers declined during the 1990s from nearly two-thirds (59%) in 1990 to a projected one-third (34%) of all prescription spending for 2000.

The decline in out-of-pocket spending represents a shift primarily to private insurance, which grew from 25% of expenditures in 1990 to a projected 44% of expenditures in 2000. For uninsured patients, there can be catastrophic healthcare costs associated with certain drugs.

"For example, a transplant patient faces several thousands of dollars of maintenance costs a year just for medication," Dr. Schweitzer says. "Patients can really become impoverished because of drugs. That never used to be the case."

A study released in November by Harris Interactive, a market research and consulting firm, found that one in five adults (22%) had not filled at least one prescription in the past year because of the cost. One in seven adults (14%) said during the past year, they had taken smaller doses than prescribed because of the cost. And 16% said they had taken a medication less frequently than prescribed to save money.

Some within the industry say while pharmaceutical spending is increasing, this is not necessarily because of higher prices.

According to Richard Manning, Ph.D., and Alison Keith, Ph.D., both of Pfizer Inc., growth in pharmaceutical spending is being driven by an aging population, advances in science that bring to market new and better treatments, and changes in treatment protocols and clinical-practice standards.

Mr. Trewhitt says the industry faces tremendous internal and external challenges in terms of its pricing practices.

"Investors and shareholders want a decisive

return on investment to justify the gamble they have taken," he says. "And make no mistake: it is a gamble. There is a very high-failure rate in biomedical research and pharmaceutical companies can lose millions of dollars on a single project. And investors and stockholders know that."

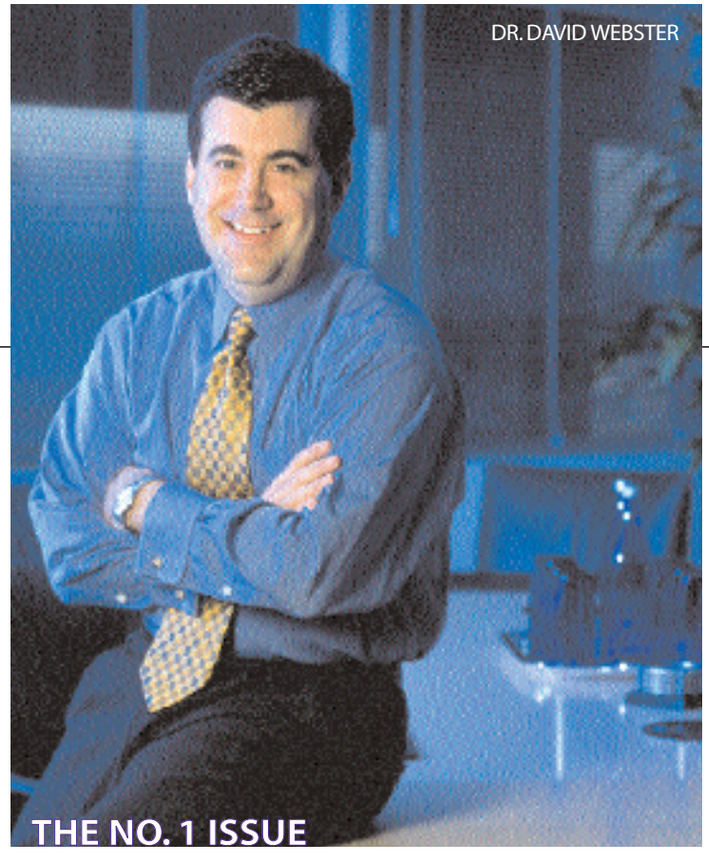
A SHIFTING MARKET

The "market" for pharmaceuticals is complex — often shaped by shifting influences and a consortium of various constituents.

"The market is really determined by the nature of the disease, the prevalence and incidence of the disease, and in assessing that, there are all the constituents who are involved in trying to ameliorate the condition," Mr. Lerner says. "There is the consumer, who suffers from the problem. There are the learned intermediaries — the physician and the pharmacist. And then there are the managed-care organizations and hospitals."

Dr. Nagle says the definition of the market changes depending on who benefits most from the product.

"In the case of a sepsis drug in a hospital setting, it is the hospital that receives the most


DR. DAVID WEBSTER

THE NO. 1 ISSUE with respect to pricing is the industry's image with the public. It's an issue of credibility and trust.

industry transitions from a doctor-directed system to a patient-directed one," Dr. Matthews says. "DTC advertising isn't the cause of this transition, it's a result of it. Anyone who understands the Wal-Mart model knows that advertising in a competitive market lowers prices, not raises them."

Irwin Lerner, CEO of Reliant Pharmaceuticals LLC, agrees: "DTC does not raise prices. The economic function of advertising is to increase competition and increase awareness of products to potential consumers. But awareness and usage are not synonymous, there still must be a learned intermediary."

In a recent article, Economic Realities in Health Care Policy, written by Richard Manning, Ph.D., and Alison Keith, Ph.D., both of Pfizer Inc., it is argued that the cost of advertising is recouped through increased sales volume rather than through higher prices.

"What advertising and marketing do are make people aware of the value of a therapy," says Thomas Nagle, Ph.D., chairman of Strategic Pricing

DTC Promotion: A Handy Scapegoat

Proponents of direct-to-consumer advertising say these ads empower consumers to work with doctors to chart a path toward proper care. Opponents, however, maintain that the ads only confuse consumers and drive up healthcare costs. Since 1997, when the FDA issued new guidelines for DTC, consumer advertising of prescription drugs has grown significantly and is now a visible part of healthcare. Pharmaceutical companies spent $2.4 billion on DTC advertising from January 2001 through October 2001, according to Scott-Levin Associates and Competitive Media Reporting.

A Henry J. Kaiser Family Foundation study, estimated that pharma companies spent $15.7 billion on all promotion of drugs in 2000, or 14% of revenue. The study compared the pharmaceutical industry's promotional spend against that of consumer-related industries. The study found that the percentage of sales revenue spent on promotion by the game and toy industry was 12%; soap and detergent, 10.7%; tobacco, 3.9%; and department stores, 3.7%.

INCREASED SPENDING ON DTC HAS BEEN CRITICIZED FOR DRIVING UP PRESCRIPTION DRUG PRICES. But many within the industry say there is no clear connection between higher levels of advertising and increased product prices. DTC advertising, they say, isn't a factor in product pricing and they argue that the main objective of DTC is to increase awareness of and help educate consumers about prescription drugs, as well as help facilitate communication between the physician and the patient. Critics maintain that DTC advertising increases costs, misinforms consumers, and encourages overconsumption.

According to Dr. Merrill Matthews Jr., in a report written for the Institute for Policy Innovation (IPI), it is not advertising that increases the costs of drugs, it is the lack of it. "DTC advertising creates a competitive market, which forces drug companies to keep prices lower than they otherwise would in order to gain market share."

According to Dr. Matthews, the annual growth in marketing dollars for the pharmaceutical industry has remained relatively consistent, despite the recent influx of DTC ads. "What's changing is the focus of marketing dollars: from doctors to patients, as the healthcare

value from that product, since the hospital gets paid for its services on a fixed basis, and is looking for ways to cut costs," Dr. Nagle says. "By cutting the incidence of sepsis, hospitals can keep down their expenses.

"But in the case of an antiemetic drug for those under chemotherapy, the value is not to the hospital but to the patient," he says. "From a financial perspective, the hospital doesn't care if the patient goes home and throws up or has a wonderful afternoon. It is the patient who cares." ✦

PharmaVoice welcomes comments about this article. E-mail us at feedback@pharmalinx.com.

Group Inc."In Europe, there is no DTC advertising. (The U.S. and New Zealand are the only Westernized nations that permit DTC advertising.) The effect of that keeps the value of a new innovative product down because consumers are kept from finding out about it."

"We can eliminate advertising tomorrow and patients still are going to get a considerable amount of information from newspapers, television programs, public television, books, nutrition shops, the Internet; DTC is everyone's scapegoat," says Stuart Schweitzer, Ph.D., professor, health services, and director, Ph.D. and M.S. programs, at the UCLA School of Public Health.

He says DTC is important to drug development."Drugs come out every month that treat new diseases, eliminate side effects, or improve convenience, which patients tend to value," Dr. Schweitzer says."Pharma companies would be reluctant to innovate if they couldn't market and convince people that their product is a better product."

David L. Webster, Ph.D., president and founder of The Webster Consulting Group Inc., says the industry needs to be credible when defending its promotional activities. "The industry touts the educational advantage of DTC and the empowerment of individual consumers, which is credible. But there are other reasons companies advertise; companies have competitive motives for advertising to the consumer, they are trying to get market share."

Experts on this topic

JAMES N. CZABAN. Attorney, Heller Ehrman White & McAuliffe LLP, Washington, D.C.; Heller Ehrman is a law firm

JOSEPH A. DIMASI, PH.D. Director of Economic Analysis, Tufts Center for the Study of Drug Development, Boston; the Tufts Center for the Study of Drug Development is an independent, academic, nonprofit, research group affiliated with Tufts University

FAMILIES USA. Washington, D.C.; Families USA is a national nonprofit, non-partisan organization dedicated to the achievement of high-quality, affordable health and long-term care for all Americans

EDWARD M. FEAVER, PHARM.D. President and CEO, Prescription Solutions, Costa Mesa, Calif.; Prescription Solutions, a wholly owned subsidiary of PacifiCare Health Systems Inc., is a pharmacy and medical management company that manages the prescription drug benefit of commercial, Medicare, and governmental health plans, as well as those of employers and unions representing 5 million members nationwide and $1.9 billion in pharmaceutical purchases

HARRIS INTERACTIVE INC. Rochester, N.Y.; Harris Interactive is a worldwide market research and consulting firm

KENNETH I KAITIN, PH.D. Director, Tufts Center for the Study of Drug Development, Boston, and assistant professor of pharmacology and experimental therapeutics at Tufts University School of Medicine; the Tufts Center for the Study of Drug Development is an independent, academic, nonprofit, research group affiliated with Tufts University

THE HENRY J. KAISER FAMILY FOUNDATION. Washington, D.C.; the Kaiser Family Foundation is an independent, national health philanthropy dedicated to providing information and analysis on health issues to policy makers, the media, and the general public

IRWIN LERNER. CEO, Reliant Pharmaceuticals LLC, Liberty Corner, N.J.; Reliant is a privately held pharmaceutical company

DR. MERRILL MATTHEWS. Visiting Scholar, Institute for Policy Innovation, Lewisville, Texas; IPI is a non-profit, non-partisan public policy "think tank" founded in 1987 to research, develop, and promote innovative and non-partisan solutions to today's public policy problems

THOMAS NAGLE, PH.D. Chairman, Strategic Pricing Group Inc., Waltham, Mass.; Strategic Pricing Group provides value-based pricing and marketing strategy development for business-to-business and business-to-consumer markets

PHARMACY BENEFIT MANAGEMENT INSTITUTE INC. Tempe, Ariz.; PBMI provides information and educational services focused on the pharmacy benefit management industry

PUBLIC CITIZEN. Washington, D.C.; Public Citizen is a national, nonprofit consumer advocacy organization founded by Ralph Nader in 1971 to represent consumer interests in Congress, the executive branch, and the courts

STUART SCHWEITZER, PH.D. Professor, Health Services, Director, Ph.D. and M.S. Programs, UCLA School of Public Health, Los Angeles, Calif.; the learning objectives of the Department of Health Services are to teach concepts to advance the health of populations by improving the effectiveness and efficiency of personal and other health services in private and public health organizations

JEFF TREWHITT. Pharmaceutical Research and Manufacturers of America, Washington, D.C.; PhRMA represents the country's leading research-based pharmaceutical and biotechnology companies

DAVID L. WEBSTER, PH.D. President, Founder, The Webster Consulting Group Inc., Bethlehem, Pa.; the Webster Consulting Group provides management consulting services to the pharmaceutical, biotechnology, and medical industries