



NEW DRUG COMMERCIALIZATION COSTS Lead to Blockbuster Model's End



Ashish Singh

"With fewer resources to drive primary-care products and to invest in the 'arms race' in R&D and sales and marketing, most pharmaceutical companies must take steps to proactively replace their blockbuster strategies," says Ashish Singh, director of Bain's global healthcare practice.

The high cost of commercialization is leading to the demise of the pharma industry's blockbuster approach to developing new drugs, according to a study from Bain & Company. When the costs of failed prospective drugs are factored in, the actual cost for discovering, developing, and launching a single new drug has risen to almost \$1.7 billion, a 55% increase over the average commercialization cost from 1995 to 2000.

The rising costs associated with commercializing a new drug also are expected to substantially drive down investment returns. Based on recent investment levels, success rates, and forecasts of commercial performance, Bain analysts expect the current blockbuster drug model to deliver just a 5% return on investment, significantly lower than the industry's risk-adjusted cost of capital. This suggests that only one of six new drug prospects will likely deliver returns above their cost of capital, an unattractive prospect for investors.

Factors contributing to lower returns from the blockbuster model include declining R&D productivity, rising costs of commercialization, increasing payer influence, and shorter exclusivity periods.

The study concludes that the industry needs a

new, integrated model that effectively brings together planned experimentation, aggressive use of partnerships, and eventually, a far-reaching transformation in the way most pharmaceutical companies are organized to compete.

Bain analysts believe that companies will need to experiment to create a new model, managing the inherent risks through a sound strategy and a thoughtful approach to execution. Companies should craft a tailored model constructed from four interrelated building blocks: a shift from opportunism to focus, the use of partnerships to manage risk and return, the development of a customer-driven approach, and the development of an integrated business model. Bain analysts say these strategies already are being used by niche companies to compete successfully among the giants of the industry.

PHARMACEUTICAL WHOLESALE GROWTH EXPECTED TO SLOW, Yet be Above Industry Average

The pharmaceutical wholesale distribution sector is expected to experience revenue growth of 5.9% in 2004, according to Facing the Forces of Change, a



Dr. Adam Fein

Healthcare distributors are challenged by the fact that they have almost reached the maximum market share in the channels in which they compete.

report by The National Association of Wholesaler-Distributors' (NAW), the Distribution Research and Education Foundation (DREF), and Pembroke Consulting, which will be released in March. While this anticipated growth is above the overall wholesale distribution industry average, analysts say the percent increase is lower than in previous years because of three factors: the shift from branded to generic drugs, an expected slowdown in price increases for pharmaceutical products during the next few years, and maximization of market share.

But, according to Adam J. Fein, Ph.D., president of Pembroke Consulting and a NAW/DREF fellow, these downward trends in the pharmaceutical sector will be countered by positive factors, including an increase in overall consumption, as well as an increase related to the Medicare bill. Four areas that Dr. Fein expects to impact wholesale distributors across all industries in 2004 are customer self service, strategic sourcing, fee-based services, and logistics and fulfillment.

"One area that is particularly relevant to the pharmaceutical industry right now is fee-based services," Dr. Fein says. "There has been dramatic growth in the

FORECAST FOR REVENUE GROWTH IN WHOLESALE DISTRIBUTIONS

INDUSTRY	REVENUE % CHANGE FROM 2003
Agricultural Products Wholesalers	6.1
Apparel Wholesalers	6.4
Beer, Wine, and Liquor Wholesaler-Distributors	5.0
Building Material Wholesalers and Distributors	4.9
Chemicals and Plastics Distributors	6.1
Computer, Commercial, and Medical Equipment Wholesalers and Distributors	6.2
Electrical Wholesalers	6.2
Furniture and Home Furnishings Wholesalers	5.5
Grocery and Food-Service Wholesaler Distributors	5.3
Industrial Distributors	5.1
Metal Service Centers	5.6
Motor Vehicle Aftermarket Parts and Supplies Wholesalers	4.9
Office Product Wholesalers and Paper Merchants	5.5
Oil and Gas Products Wholesalers	5.9
Other Consumer Products (periodicals, tobacco, florist) Wholesalers	6.0
Pharmaceutical Wholesalers	5.9
Plumbing and HVAC Wholesalers	4.7
Sporting Goods, Toys/Hobby, and Jewelry Wholesaler-Distributors	5.5
Overall Wholesale Distribution Industry Average	5.6

Source: Pembroke Consulting Inc., Philadelphia. For more information, visit pembrokeconsulting.com.

use of fee-for-service pricing models by pharmaceutical wholesalers."

Another area that he expects to impact pharmaceutical wholesale distributors in 2004 is strategic sourcing, specifically the growth of alternative routes to market.

"The growth of third-party logistics companies and fulfillment companies that provide some of the same core functionality and distribution delivery functions of traditional channels provide manufacturers with viable alternatives," he says. "The hospital or institutional customer is not going to move away from its traditional channel, but more of the retail demand will continue to shift away from the wholesale business."

Pharma-Sponsored CME OPPORTUNITIES VIEWED POSITIVELY by Physicians

More than 70% of primary-care physicians participating in a national survey by The Pri-Med Institute believe that pharmaceutical industry support has a positive impact on continuing medical-education (CME) opportunities, and only 8% say they are less likely to attend a CME program if it is funded by industry grants.



Anne Goodrich

Industry support through educational grants is viewed as enriching the spectrum of CME programs available to clinicians.

While one in 10 respondents viewed industry involvement as a "negative," 86% said industry involvement is not a factor in their decision to participate in a CME program.

"These findings confirm that a large majority of doctors are satisfied that educational providers are adhering rigorously to standards mandating that product promotion be separate from education," says Anne Goodrich, research director at Pri-Med Institute.

One in two survey respondents prefer continuing medical education through live conferences, and more than one-third of all CME credits were earned by attending these forums. While Web-based CME opportunities continue to expand, only one physician in 10 say these are his or her first choice.

Participants rated relevance of clinical topics, schedule and dates, and caliber of speakers as the three most important factors in choosing a CME activity. Cost, travel time, and time away from practice also weighed in as significant determinants of attendance.

Accessibility also was found to be a key factor in choosing CME activities. Two of three physicians surveyed prefer local and regional conferences — within 200 miles of their practice — to national meetings. Minimizing time away from practice through weekend and evening programs also is a key concern.

Survey Finds Physician RELIANCE ON PDAS INCREASING

More than half of the doctors in the United States use PDAs, and among residents and students the percentage is even greater.

Skyscape Inc.'s Skyscape PDA Usage Survey, released in December 2003, reveals physicians' increasing reliance on PDAs and the impact the devices have on daily activities.

Skyscape surveyed more than 900 doctors who use handheld computers. More than 85% of the respondents indicated that PDA use helps to reduce the number of medical errors, with more than 50% indicating PDA use reduces their medical errors by 4% to 5%.

"The survey results reinforced what we already knew about the benefits that PDA use brings to medical professionals, but the impact PDAs have when it comes to reducing medical errors and improving efficiencies exceeded our expectations," says RJ Mathew, VP of marketing and business development at Skyscape. "The survey clearly shows physicians have moved into a mainstream reliance on PDAs and medical software for PDAs."

Even as the adoption of PDAs increases, less than 20% of medical professionals have their PDA software integrated with a larger hospital IT enterprise. Additionally, less than 10% of medical professionals reported that their PDA software is integrated with prescription, billing, charge capture, or patient records.

RISE IN COPAYS Leads Patients to Quit Drug Therapy

Dramatic jumps in prescription drug copayments may cause some patients to stop taking necessary medications, potentially jeopardizing quality care, according to a study conducted by Medco Health Solutions Inc. and Harvard Medical School, with funding from the Robert Wood Johnson Foundation. The study found that a significant number of patients stopped taking their medicine when their health plan enacted a four-fold increase in their drug copayment, while members of a plan that made modest increases in copayments experienced virtually no impact on medication compliance.

"Many employers and health plans are shifting larger portions of the cost of prescription medications to enrollees," says Haiden Huskamp, Ph.D., assistant professor of health economics at Harvard Medical School and the study's lead investigator. "We discovered that although incentive formularies are effective in helping to control rising drug costs for payers, large increases in copayments can cause patients to stop taking their medicine, which could have implications for quality of care."

The study followed two employers as they changed their prescription coverage plans in 2000 to incentive formulary plans. Employer A switched from a one-tier to a three-tier plan and increased copayments across all tiers. Employer B's employees switched from a two-tier to a three-tier formulary and increased copayments for the third tier only. The study also identified two comparison groups, employers that had similar plans to Employer A and B, which allowed researchers to evaluate what would have happened if no changes had occurred.

Employer A's workers, who experienced substantial copayment increases, had a marked reaction to the changes in that some enrollees stopped taking necessary medications. For example, 16% of patients using tier-three ACE inhibitors stopped taking their medication (only 6% stopped in the comparison group); 21% of patients using tier-three cholesterol-lowering statins stopped taking their medication (only 11% stopped in the comparison group); and 32% of patients using tier-three proton pump inhibitors (PPIs) stopped using their medica-

RJ Mathew



Results show that just like the stethoscope, the PDA increasingly is becoming an integral tool in doctors' daily practice.

PDAS ARE ENABLING DOCTORS TO PROVIDE BETTER CARE AND TREAT ADDITIONAL PATIENTS

- ▶ More than **88%** of doctors use their PDAs at least four times a day, with 15% using their PDAs more than 25 times a day.
- ▶ When asked how they use their PDAs, **72%** of doctors reported they rely on their PDA for treatment purposes, primarily for drug references, clinical references, drug interaction guides, or hospital-treatment guidelines.
- ▶ Almost **90%** of doctors say PDAs help them provide better care.
- ▶ More than **85%** of physician respondents agreed that by using a PDA they had decreased the number of potential medical errors. More than **50%** of physicians said by using a PDA they were able to eliminate more than **4%** of medical errors.
- ▶ When asked to quantify the specific benefits PDAs bring to their daily practice, almost **20%** of respondents concluded that PDA use enables them to treat at least three more patients a day, with another **20%** of respondents concluding that they can treat one to two additional patients per day.
- ▶ Doctors do not just rely on one reference for their PDA. More than **70%** of doctors have at least three medical references on their PDA and **22%** have more than eight references.

Source: Skyscape Inc., Hudson, Mass. For more information, visit skyscape.com.

tions (only 19% stopped using their medication in the comparison group).

Many of Employer A's enrollees who faced the largest copayment increases, switched from the drug they currently took to a drug in a lower tier. Relative to patients in the comparison group, patients in Employer A's plan paid 142% more for ACE inhibitors, 148% more for PPIs, and 118% more for statins.

Conversely, Employer B did not see a significant impact in compliance or spending among its members based on its modest plan design change. But Employer B's members were more likely to switch from a nonpreferred brand-name medication to a less expensive brand-name or generic medication. Almost 41% of patients taking ACE inhibitors switched to a lower-tier drug (15% switched in the comparison group); 18% of patients using a PPI switched to a lower-tier drug (2% switched in the comparison group); and 48% of patients using a tier-three statin switched to a lower-tier statin (8% switched in the comparison group).

Survey Finds **AMERICANS UNCOMFORTABLE WITH PROFIT MOTIVE**

A majority of Americans surveyed do not view

healthcare as a business that should be driven by a profit motive, according to a Harris Interactive poll conducted for The Wall Street Journal Online's Health Industry Edition. The online study polled a cross section of 2,587 adults, 18 years old and older to gauge their perception on the roles that for-profit and nonprofit organizations should play in delivering healthcare services, including manufacturing and medical research.

"Most people do not think of healthcare as a business and would prefer healthcare services to be provided by nonprofits or government," says Humphrey Taylor, chairman of The Harris Poll at Harris Interactive. "The nearest exception being pharmaceutical manufacturing, with a plurality — but only a 37% plurality — thinking this should be run mainly by for-profit business. There is little appetite for businesses to run home care, health insurance, nursing homes, hospitals, or medical research."

The survey revealed that 31% of the U.S. public thinks that the government should provide most health insurance; 25% say nonprofit organizations should do so; and 22% would prefer for-

profit insurance. In addition, 42% believe that universities should conduct most medical research, followed by 16% who believe for-profit companies should do so.

THE PREFERRED ROLES OF COMPANIES, GOVERNMENT, AND NONPROFIT ORGANIZATIONS IN HEALTHCARE

An online U.S. survey conducted between November 3 and 17, 2003, polled a nationwide cross section of 2,587 adults, ages 18 years old and older to gauge their perception as to who should own, provide, or run most healthcare products and services: for-profit companies; federal, state, and local governments; universities; or other nonprofit organizations.

WHO SHOULD RUN

	For-Profit Companies	Government	Universities	Other Nonprofits	Not Sure
Pharmaceutical manufacturing	37%	17%	6%	18%	22%
In-home care	25	14	1	37	23
Health insurance	22	31	1	25	21
Nursing homes	21	19	2	36	22
Hospitals	19	17	11	35	19
Medical research	16	11	42	15	16

Source: Harris Interactive, Rochester, N.Y., The Wall Street Journal Online, New York. For more information, visit harrisinteractive.com or wsj.com.



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Contract Research Boom Continues

AS PHARMA OUTSOURCING SPENDING GROWS AT DOUBLE-DIGIT PACE

The amount of pharmaceutical R&D spending headed out-of-house to research suppliers engaged in drug-development work is expected to increase almost 15% annually for the next five years, according to a new study released by Kalorama Information. The increases forecasted for outsourced spending in the coming years is nearly double the anticipated increase in R&D spending generally.

Kalorama estimates that by 2004 almost 42% of all pharmaceutical drug-development expenditures will be committed to outsourcing, as compared with 4% in the early 1990s. The study, Outsourcing in Drug Development: The Contract Research Market from Preclinical to Phase III, has found that although established contract service organizations (CSOs) stand to gain the most from the spending increases, smaller organizations, such as site management organizations, central laboratories, and niche players such as data-handling and recruitment companies, also stand to increase their revenue if not their share.

SUMMARY OF TOTAL AND OUTSOURCED GLOBAL RESEARCH AND DEVELOPMENT EXPENDITURES				
Year	R&D Spending (in billions)	Growth Rate	Outsourcing Spending (in billions)	Portion of R&D Outsourced
1999	\$39.0	—	\$8.9	22%
2003	52.3	8%	13.6	26
2008	77.4	8	27.9	36

COMPOUND ANNUAL GROWTH RATE		
Period	R&D Spending	Outsourcing Spending
1999-2003	8%	11%
1999-2008	8	14

Source: Kalorama Information, New York.
For more information visit kaloramainformation.com.

(AAGR) of 13.2%, this market is expected to exceed \$1 billion in 2007.

DNA microarrays have their roots in the chemical methods for gene analysis that developed during the past four decades. The microarray materials market, which can be broken down into substrates, probe molecules, and marker molecules, is currently estimated at \$126 million and is expected to grow at an AAGR of 16.8% through 2007.

The BCC report, RB-197 DNA Microarrays and Their Materials, finds that DNA microarrays are widely used in two markets: academic research and industrial research, with a major focus on drug development. Quantification of gene expression remains challenging for microarrays, thus most microarrays are used for expression profiling. Other applications such as diagnostics await more robust microarray technology.

Data stemming from the Human Genome Project are now far more usable than when the project originally was declared finished. The convergence of these technologies has led to an explosion of interest in gene-based biology, leading to new tools, such as the DNA microarrays now in commercial production, which are an indispensable part of a biology program.

Pharmaceutical scientists have been using microarrays in large numbers to determine mechanisms of toxicity, as well as for drug development. Cost is the only major drawback of microarrays, which have become the most expensive disposable product in a laboratory.

U.S. Market for DNA Microarrays and Materials TO SURPASS \$1 BILLION BY 2007

According to Business Communications Company Inc. (BCC), the U.S. market for DNA microarrays and microarray materials in 2002 was valued at \$544.4 million. Based on an average annual growth rate

Follow up

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