



GENERICs SECTOR

Expected to Double
by 2007

According to Datamonitor, by 2007 the generics market is expected to be valued at \$57 billion, more than twice its estimated value of \$27 billion in 2001. Researchers at the company conclude that the generic market will continue to be highly fragmented with many of today's leading companies expected to lose market share during the next five years; in 2001 the leading company held just 5.5% of the market.

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Datamonitor research suggests that success in the generics market will be driven by several key strategies: a focus on high-value R&D within the generics business; targeting specialty generics, supragenerics, and biogenerics; an international expansion strategy; boosting revenue potential by new market penetration; and a move toward proprietary R&D.

Solid Growth Predicted for **STRUCTURAL AND FUNCTIONAL GENOMICS MARKET**

The new and emerging technological process of structural genomics is changing researchers' understanding of biological systems. The process involves the determination, analysis, and dissemination of three-dimensional structures of macromolecules,

including proteins and RNA molecules. Worldwide structural genomics growth is substantial and forecasters at Front Line Strategic Consulting Inc. expect a 32% compound annual growth rate for the market during the next five years.

The structural view of macromolecules have the capacity to increase comprehension of molecular functions and interactions. Structural genomics technologies are divided into four categories: nuclear magnetic resonance, X-ray crystallography hardware, computational approaches, and discovery platforms.

One important application for structural genomics is in drug discovery and development where the pharmaceutical industry is pursuing human proteins as targets and the ability to access three-dimensional macromolecular structures that can accelerate drug discovery. These factors are expected to contribute to the growth of this market, with U.S. sales expected to reach 70%, Europe at 20%, and Japan at 5% in total revenue during the next five years.

Internet is **NO LONGER CONSIDERED "ALTERNATIVE MEDICINE"** for Americans

According to a study released by Manhattan Research, Americans have embraced the Internet as a source of healthcare information. The study results build on eight years of trend data and illustrate the continued evolution of the Internet and how it is being integrated into the healthcare delivery system.

Among the study's findings is that the impact of the Internet in health extends well beyond the individual Internet user accessing online health information and resources into their "zone of influence," which often includes their children, spouses, and elderly parents. Current data show that 63.3 million Americans actively use online health resources, and 124.7 million are directly, or indirectly, influenced by e-health in total.

In addition, the population of consumers seeking drug information online surged ahead in 2002, with 24.7 million consumers stating they have searched for drug information online during the past three months. This increase is driven in part by the growing number of online resources, and by general consumer advertising (i.e., television, print) driving consumers to the Web for more information.

Consumers also were found to rely primarily on search engines to start their online journey when seeking health information, as opposed to going directly to the targeted Website. Although the use of leading health portals, such as WebMD, increases each year, consumers are placing a high level of

importance on search engines, such as Yahoo! and Google.

In addition to their increased tendency to search for additional information after seeing an offline advertisement for a prescription medication, e-health consumers are much more likely to take action offline, such as visiting a physician, consulting with a pharmacist, or calling an 800 number. The latest data show that e-health consumers are 2.3 times more likely than offline consumers to request a prescription drug by name from their physician.

"Last year, the focus was on the evolution of e-health," says Mark Bard, president of Manhattan Research. "This year, the mantra is integrating e-health back into healthcare. From the point of view of the consumer, the Internet has already become a critical resource when researching health information, making decisions about treatment options, and interacting with health professionals and organizations. However, many health and life-sciences organizations, pharmaceutical companies included, have yet to realize the full potential of marketing to this disproportionately valuable segment of the population, and the competitive advantage of integrating the online component back into the overall business."

Blockbuster Drugs **NEED FINANCIAL AND STAFFING INVESTMENTS,** Study Notes

According to a study by Cutting Edge Information, starving potential blockbusters is one of the worst mistakes a pharmaceutical company can make, and most companies are not spending enough on marketing. The study shows that top companies increase marketing spending by 400% to 500% during Phase III. Staff headcounts alone increase by 150%. Pharmaceutical brand teams spend 80% of their commercialization marketing budgets in Phase IIIa and product launch activities.

In addition to increased spending to support marketing, the study found that the market planning function receives the greatest percentage of team members — 42% of the total staffing by function. This core area, which houses the brand team and central components of brand leadership, requires headcounts and employees up to the task of coordinating and executing brand strategy.

The market research function occupies the second slot with 21% of total functional staffing. Market research, whether operating during early stages or

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setting the scene for affiliate launches, arms pharmaceutical marketers with critical information to direct brand strategy.

"Starving potential blockbusters is one of the worst mistakes a pharmaceutical company can make — and most pharma companies aren't spending enough," says Jason Richardson, Cutting Edge Information's CEO. "Companies must double or triple their pipeline success to keep up with the competition."

BIG SIX CATEGORIES IN DTC

During the first half of 2002, six therapeutic categories accounted for 55% of the industry's total DTC investment.

Allergy — **\$260 MILLION**

Gastrointestinal disorders — **\$124 MILLION**

High cholesterol — **\$109 MILLION**

Depression — **\$101 MILLION**

Arthritis — **\$82 MILLION**

Asthma — **\$80 MILLION**

Direct-to-Consumer Awareness Up, SPENDING DOWN

According to a Market Measures/Cozint study, despite the slowdown in direct-to-consumer advertising spending, DTC awareness across all disease states has increased, with 75% of sufferers recalling having seen an advertisement for their condition.

According to Market Measures/Cozint's 2002 DTC Monitor report, about 90% of sufferers in eight categories are aware of advertising for their condition. These high-awareness categories include erectile dysfunction, allergy, arthritis, estrogen replacement therapy, gastrointestinal disorders, high cholesterol, osteoporosis, and HIV/AIDS.

In addition, the report found that for the first time in 2002, 20 pharmaceutical brands achieved awareness levels exceeding 50%, compared with 14 in 2001 and six in 2000.

DTC is realizing these significant awareness gains at the same time DTC spending is slowing. DTC spending increased by only 8% in 2001 — a significant decline from the 77% growth recorded between 1998 and 2000. For the first half of 2002, companies spent \$1.3 billion on DTC — slightly below the \$1.4 billion invested in DTC during the same period last year.

If spending continues at the same rate, total DTC spending for 2002 is expected to reach \$2.6 billion — a slight increase compared with the 2001 total of \$2.5 billion. DTC spend is not only slowing, it also has been found to become more concentrated in specific categories (see chart).

Market Measures/Cozint researchers also found that heavy spending does not necessarily translate into high contact rates. Although doctor contacts as a result of direct-to-consumer promotion are on the rise, two of the categories with the highest DTC spend — allergy and high cholesterol — show the lowest contact rates.

Allergy, with a contact rate of 12%, and high cholesterol, with a contact rate of 8%, are far below the 22% average, despite heavy DTC spending in these classes. These findings are consistent with the DTC Monitor's historical trend data, which show that categories with asymptomatic conditions, as well as those with strong over-the-counter competition, generate low contact rates.

The study also revealed that although television advertising attracts the most DTC dollars, magazines generate the highest response. Between January and June 2002, pharmaceutical companies spent \$855 million on TV commercials, representing 67% of total DTC expenditures. Magazines were the second-choice medium for DTC advertisers, with a spend of \$369 million — or 29% of the total — in the first half of 2002. Although TV ads attract the bulk of the dollars, magazine ads generate higher contact rates. In the first half of 2002, the contact rate associated with magazine ads was 25%, compared with a contact rate of 20% for TV.

Additional study results include the finding that 41% of patients who engage in DTC-driven discussions with their doctors request a prescription for the advertised product, a decline from the 2001 rate of 47%.

DTC Monitor consistently shows that patients are much more likely to receive a prescription for a brand when they explicitly request it.

In 2002, 71% of patients who asked for a specific brand they saw advertised received a prescription for that product.

SNP GENOTYPING Expected to Play KEY ROLE in Life Sciences

According to a recent survey by Bioinformatics LLC, single nucleotide polymorphisms (SNP) genotyping is expected to be a fast-growing segment of the life-science market, as more than half of the respondents expect to increase their level of SNP genotyping during the next 12 months.

Applied Biosystems, Affymetrix, Illumina, Orchid Biosciences, Sequenom, and Qiagen are the companies most closely associated with the fast-growing market for products and services related to SNP genotyping.

More than 540 researchers currently studying SNPs were surveyed for The Market for SNP Products and Services: Enabling Pharmacogenomics report.

"SNPs are the focus of so much attention in the pharmaceutical industry because they provide a powerful approach to understanding the connec-

tion between genetic variation and its physical manifestation," says Dr. Tamara Zemlo, senior science advisor for Bioinformatics. "Understanding the role of genetic variation is expected to profoundly change our understanding of human disease and the practice of medicine in the years to come."

The enormous number of SNPs currently being discovered as a result of whole genome association studies is prompting industry to develop new technologies emphasizing ever-higher throughput and cost effectiveness. At the same time, however, the report demonstrates that the products a scientist chooses to detect mutations will vary greatly depending on the scale and scientific question he or she is trying to answer.

SNP GENOTYPING TO INCREASE

More than 540 researchers currently studying SNPs were surveyed for The Market for SNP Products and Services: Enabling Pharmacogenomics report:

► **ACCURACY** is the most important feature sought by **87%** of scientists currently performing SNP genotyping in their own lab. Of the SNP genotyping methods available, **62%** employ **SEQUENCING** — a technique that offers researchers the highest degree of specificity and selectivity.

► **27%** of respondents cited **EXPERTISE PROVIDED BY THE SERVICE PROVIDER** as the principal reason for outsourcing SNP genotyping.

► Cost per reaction (**73%**), sample preparation (**38%**), and probe/primer design (**36%**), are the **MOST SIGNIFICANT LIMITATIONS** or problems that lab/groups experience when genotyping SNPs.

► More than half (**55%**) of respondents expect **TO INCREASE THEIR LEVEL OF SNP GENOTYPING** in the next 12 months.

GAO Report Finds Pharmaceutical Company SPENDING ON R&D OUTPACES PROMOTIONAL SPENDING

A U.S. General Accounting Office report titled FDA Oversight of Direct-to-Consumer Advertising Has Limitations, has determined that pharmaceuti-

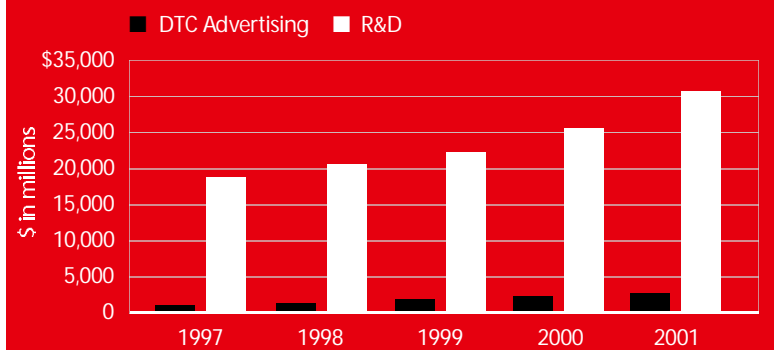
cal companies spend billions more on research for new cures and medicines than they do on their advertising and promotional activities.

The study found that pharmaceutical companies spend more on R&D initiatives than on all drug promotional activities, including direct-to-consumer advertising. According to industry estimates, in 2001 pharmaceutical companies spent \$30.3 billion on research and development and \$19.1 billion on all promotional activities, which includes \$2.7 billion on DTC advertising.

Pharmaceutical companies, however, have increased spending on DTC advertising more rapidly than they have increased spending on research and development. Between 1997 and 2001, DTC advertising spending increased 145%, while research and development spending increased 59%. In 2001, promotion to physicians accounted for more than 80% of all promotional spending by pharmaceutical companies. In 2001, total promotional spending was equivalent to 12% of drug sales in the U.S.

The report also noted that DTC advertising appears to increase prescription drug spending and use. Pharmaceuticals that are promoted directly to consumers often are among the best-selling drugs, and sales for DTC-advertised drugs have increased

R&D SPENDING OUTPACES SPENDING ON DTC ADVERTISING



Source: U.S. General Accounting Office, FDA Oversight of Direct-to-Consumer Advertising Has Limitations

faster than sales for drugs that are not heavily advertised to consumers. The study notes that most of the spending increase for heavily advertised drugs is the result of increased use, not price increases. Between 1999 and 2000, the number of prescriptions dispensed for the most heavily advertised drugs rose 25%, but increased only 4% for drugs that were not heavily advertised. During the same period, prices rose 6% for the most heavily advertised drugs and 9% for the others.

According to GAO researchers, while generally effective at halting the dissemination of advertisements it reviews and identifies as misleading, the FDA's oversight of DTC advertising has limitations. The report noted, however, that the FDA's oversight has not pre-

vented some companies from repeatedly disseminating new misleading advertisements for the same drug, and some pharmaceutical companies have failed to submit in a timely manner all newly disseminated ads to the FDA for review.

Furthermore, the study reports that the FDA's oversight has been adversely affected by a January 2002 change in its procedures for reviewing draft regulatory letters that was directed by the Department of Health and Human Services. This change has significantly increased the time between DDMAC's identification of a mis-

leading ad and the FDA's request to remove it from dissemination, with the result that some regulatory letters may not be issued until after the campaign has run its course.

In light of the delay caused by the change in policy for review of draft DTC regulatory letters, the report recommends that the HHS expedite the review of these letters to ensure that misleading DTC ads are withdrawn as soon as possible once identified. The findings were supported by the Pharmaceutical Research and Manufacturers of America, which supports the FDA plan to speed government action on drug company ads. The FDA announced its plan in response to the sole recommendation of the GAO report.

Follow up

BIOINFORMATICS LLC, Arlington, Va., is a market research firm that supports marketing, sales, and R&D executives in the life-science, medical-device, and pharmaceutical industries through published research reports, custom research, and consulting. For more information, visit gene2drug.com.

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THE GENERAL ACCOUNTING OFFICE, Washington, D.C., is the investigative arm of Congress, which exists to support the Congress in meeting its Constitutional responsibilities and to help improve the performance and ensure the accountability of the federal government for the American people. For more information, visit gao.gov.

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