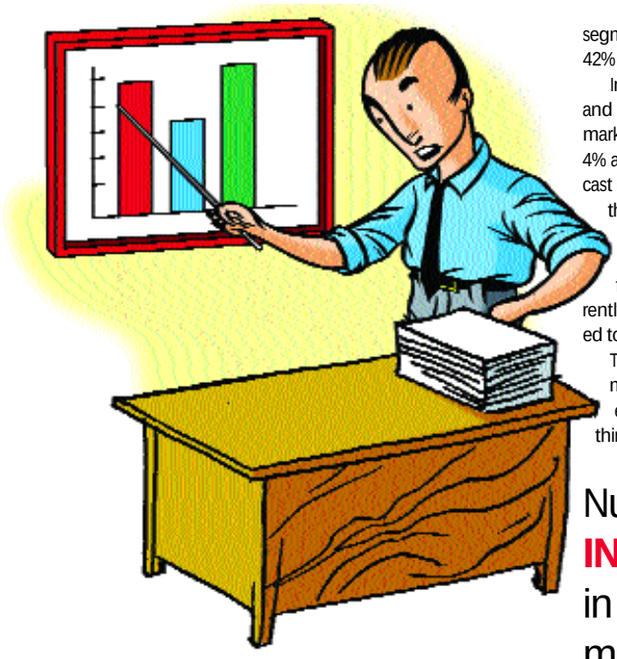

Worldwide **PULMONARY** drug delivery market **FORECAST TO DOUBLE** by 2005

The worldwide pulmonary drug-delivery market is expected to double in the next four years to $15.2 billion in 2005 from $8.4 billion in 2001, according to a report from Front Line Strategic Management Consulting.

Growth through 2010 is expected to be moderate but steady, says the report. Contributing to growth are new technologies such as dry-powder inhalers, displacing injectable therapies and phased-out CFC-based systems.

COMBINED THESE BRANDS ACCOUNTED FOR $4.7 BILLION (63% OF THE MARKET) IN 2000

- Advair/Seretide
- Atrovent
- Combivent
- Flovent
- Pulmicort
- Serevent
- Ventolin

Leading pharmaceutical pulmonary brands include Flovent, Serevent, Pulmicort, Atrovent, Ventolin, Combivent, and Advair/Seretide. Combined, these brands accounted for $4.7 billion, or 63% of the market, in 2000. According to analysts, generics, however, are expected to continue to increase their share of the bronchodilator and anti-inflammatory markets.

New combination asthma therapies are rapidly gaining adoption and contributing to strong growth. Currently, bronchodilators and anti-inflammatories represent the largest segments, respectively commanding a 48% and 42% market share.

In addition, inhaled proteins such as pulmozyme, and other small molecules represent the greatest market growth opportunities with current shares of 4% and 2% each. The protein segment share is forecast to grow from $293 million in 2000 to just more than $1.2 billion by 2005. Driving this growth will be several product launches including Exubera, a dry-powder inhaled insulin treatment from Aventis Pharmaceuticals Inc. that is currently in late-stage development. Exubera is expected to lead its category.

The U.S. represents about 44% of the worldwide market due to a large number of asthma sufferers and a favorable reimbursement policy from third-party payers.

Nutritional awareness **INCREASES DEMAND** in **NUTRACEUTICALS** market

Demand for products that claim health and medicinal benefits is expected to expand rapidly as awareness of the link between nutrition and health grows.

A new report by Frost & Sullivan, Strategic Analysis of the U.S. Nutraceuticals Market, indicates the total market for functional ingredients, functional foods, functional beverages, dietary supplements, and foods for special dietary use is about $50 billion at present.

"Realizing the potential of this industry segment will greatly depend on government regulations, which currently do not offer the necessary framework to ensure the future success of the nutraceuticals market," says Carlos Ayala, an analyst at Frost & Sullivan.

Nutraceuticals and functional foods currently do not have official definitions from the government. Large pharmaceutical and food companies recognize the promise of these products, but are reluctant to commit significant resources until there are regulatory assurances that their investments will be rewarded.

Mergers have become key strategies for market participants. While some companies continue to use mergers to gain dominance in a particular segment, others hope to acquire complementary technologies. For small companies, alliances will allow access to established distribution channels and necessary research resources.

"The middle and lower-tier companies will benefit most from strategic partnering," says Aninditta Savitry, a Frost & Sullivan analyst. "Rapid growth rates in key demographics, including health-conscious consumers, should provide the small and mid-size acquisitions of niche food companies with more long-term profitability than many of the recent mega-mergers."

Aging female population presents **NEW CHALLENGES** in **HRT MARKET**

The growing number of postmenopausal women translates into new challenges for clinicians and is leading to increased focus on the hormone replacement therapy market.

Hormone Replacement Therapy, a study from Decision Resources Inc., identifies opportunities for products competing in the HRT market. For example, companies are trying to expand the number of combination products available in transdermal form and, in some cases, provide them in once-weekly doses. Single-agent patches will offer transdermal formulations of several molecules, such as norethisterone and testosterone, previously available only in pill form. Companies are looking to combine estrogen with a host of progestational agents that have not yet been made available for the management of HRT. These agents are expected to have fewer progestogen-related side effects than some currently available agents.

TWO NOVEL SERMs ARE IN LATE-STAGE DEVELOPMENT

- **Wyeth-Ayerst/ Ligand's** TSE-424
- **Pfizer/ Ligand's** lasofoxifene

The most exciting area of HRT development involves selective estrogen receptor modulators, also known as SERMs. Continued development of these agents may lead to a product that can alleviate vasomotor symptoms, or at least will not exacerbate these symptoms.

Research focuses on SERMs' ability to prevent osteoporosis and Alzheimer's disease, as well as on its cardio-protective properties, and its effect on breast and endometrial tissues.

Two novel SERMs are in late-stage development:

- Wyeth-Ayerst/Ligand's TSE-424
- Pfizer/Ligand's lasofoxifene

Promising evidence has emerged from preliminary trials with these agents, as measured in terms of bone-density markers, cholesterol levels, and lack of vasomotor side effects.

Wyeth-Ayerst's conjugated equine estrogen products — Premarin, Prempro, and Premphase — are expected to continue to lead the market through 2010.

New SERMs, novel combination HRT products, and synthetic steroidal hormones, however, will make some inroads in the next decade. The most promising oral combinations under development include Aventis/Wyeth-Ayerst's estradiol-trimegestone and CEE-trimegestone combinations. Trimegestone promises to have more benign side effects than other progestogens currently on the market.

Once released, the drugs are expected to boost sales of oral combination products from $850 million in 2000 to almost $1.5 billion in 2010.

ACTIVE BABY BOOMERS propel first-aid and sports-medicine market

Active baby boomers could be the source of a multibillion-dollar market in the first-aid and sports-medicine arena,according to the latest publication from Packaged Facts.

According to the report, the U.S. Market for First Aid and Sports Medicine Products, the needs of baby boomers have driven demand for first-aid and sports-medicine products to new highs, and will, along with several other factors, propel the market to $2.6 billion in annual sales by 2005.

Rising healthcare costs also are identified by the report as a factor in the increase of home-care product use.

"People are taking medical matters into their own hands," says Meg Hargreaves, VP of Research Publishing for MarketResearch.com, which owns Packaged Facts."Consumers are opting to purchase first-aid supplies and sports-medicine products for use in the home rather than extending hospital stays or even visiting medical facilities at all."

The report outlines the country's youth as a considerable force in the market."Children are demanding fun alternatives to plain taupe bandages," Ms. Hargreaves says. "Marketers have been quick to understand the influence children have in the purchasing habits of their parents and have begun creating products that appeal specifically to children."

The U.S. Market for First Aid and Sports Medicine Products provides detailed information about consumer demographics, as well as distribution and marketing trends, product development, and emerging retail campaigns.

Largest OTC MARKET SEGMENT on the verge of BIG CHANGE

Big changes could be in store for the over-the-counter (OTC) allergy and asthma product market in the near future, according to a new study from Kalorama Information and available through MarketResearch.com. Allergy and asthma products, the largest OTC segment in the U.S. with sales surpassing $1.7 billion last year, could be getting some company on the already crowded drugstore shelves.

The new study, The U.S. Market for Over-the-Counter Allergy and Asthma Products, identifies at least 10 likely candidates for Rx-to-OTC switches in this area in the next few years. The most important category — nonsedating antihistamines such as Claritin, Allegra, and Zyrtec — will most likely be available OTC by 2003, according to the study. These allergy medications could grab upwards of 25% of the total market almost immediately after their introduction.

Although the study found modest growth to be the norm in most of the areas covered, remedies for ocular allergies generated respectable growth (about 10%) recently, and the potential OTC candidates likely to reach the market by 2003 are forecast to generate healthy growth rates, more than 12%, in subsequent years.

"Modeling OTC markets is notoriously difficult," says Steven Heffner, acquisitions editor at Kalorama. "There are many more unpredictable variables to take into account than in prescription markets: consumer behavior and brand loyalty, fierce pricing competition especially in the robust generic area, and uncertain reimbursement policies from pharmacy benefits companies. Our analysts looked at consumer and regulatory trends and compiled excellent market information from both the retail unit sales side to the manufacturers' dollar volume to analyze this complex market."

LIKELY NONSEDATING ANTIHISTIMINE CANDIDATES FOR RX-TO-OTC SWITCH BY 2003

THESE ALLERGY MEDICATIONS COULD GRAB UPWARDS OF 25% OF THE TOTAL MARKET ALMOST IMMEDIATELY.

- Claritin
- Allegra
- Zyrtec

Source: MarketResearch.com

NEW NCEP GUIDELINES will lead to significant changes in treating HIGH CHOLESTEROL

Physicians will significantly change the way they treat high-blood cholesterol, as a result of new guidelines issued in May by the National Cholesterol Education Program (NCEP) Expert Panel on Detection, Evaluation and Treatment of High Blood Cholesterol in Adults. According to a Market Measures Interactive study on the impact of the revamped NCEP guidelines, 87% of doctors say they will now place more patients on pharmacologic therapy, with 42% planning to skip experimenting with diet and exercise alone, moving more of their patients directly to drug treatments.

In addition, 87% of physicians indicate they will become more aggressive in treating diabetics with

PHARMA FACTS

Discovery and Development of New Medicines

The U.S. pharmaceutical industry leads the world in the discovery and development of new medicines. New treatments are being discovered at a faster rate than ever before, with more than 370 new medicines added to the medicine chest in the last 10 years alone and more than 400 medicines in development to treat cancer.

- The pharmaceutical industry is profitable, which enables it to attract the investment needed to research and develop new medicines in a high-risk environment.
- Drug price increases are in line with inflation. Total prescription drug expenditures are going up because more people are getting more and better medicines. This is good news because prescription medicines are often the least invasive, most effective, and most cost-effective form of healthcare.
- The National Institutes of Health (NIH) leads the way in basic research,but this research can't help patients unless pharmaceutical companies translate this knowledge into medicines. The industry outspends NIH on biomedical research. To put it in perspective, this year the industry is expected to spend more than $30 billion on R&D, that's more than the entire budget of the NIH.
- According to PriceWaterhouseCoopers,"the pharmaceutical industry pays more tax than 97% of all industries." And the Congressional Research Service warned that raising taxes on the pharmaceutical industry would mean that drug companies would be able to undertake fewer research projects.
- IMS Health reports that the pharmaceutical industry spends far more on R&D than on marketing — $25.7 billion on R&D in 2000 compared with $15.7 billion on marketing. And more than half the marketing expenditures went to providing doctors with free samples to give patients.
- Thanks to a 1984 law, generic drugs can enter the market as soon as an innovator's patent expires. Today, generic drugs make up about 50% of the pharmaceutical market. Without patents there would be no breakthrough drugs — and no generic copies.

Source: Pharmaceutical Research and Manufacturers of America (PhRMA), Washington, D.C.

JOURNALS CITED AS THE MOST USEFUL INFORMATION SOURCE

THE MMI STUDY SHOWS THAT THE VAST MAJORITY OF PHYSICIANS — 76% — ARE AWARE OF THE EXECUTIVE SUMMARY, HIGHLIGHTING THE NEW NCEP GUIDELINES.

- 74% of physicians cite journals as the resource that has been most useful in alerting them to the revised NCEP standards
- 43% of physicians cite pharmaceutical reps as being a valuable information source
- 42% of physicians cite peers
- 29% of physicians cite the Internet
- 24% of physicians cite medical symposia
- 22% of physicians cite news broadcasts

normal lipids; 81% will use higher doses of statin therapies, such as an 80-mg dose of Zocor; and 75% will use more combination therapies in a wider range of patient types.

The new MMI study also shows that the revised guidelines have doctors looking for new treatment options, with almost half of responding physicians reporting that they are eagerly awaiting the next group of super statins to be approved for marketing by the Food and Drug Administration.

Fielded in June via the Internet, the MMI study provided physicians' real-time responses to questions exploring how the new NCEP report would affect their approach to treating dyslipidemia. The study gathered feedback from 294 physicians, including primary-care physicians, endocrinologists, and cardiologists.

"Our new Internet study on Lipids demonstrates the power of the Web in helping the industry quickly evaluate the impact of new developments, fully understand their implications and swiftly take the right actions to seize opportunities," says Chris Naegle, managing director of MMI's Product and Market Assessment Group.

Study **QUANTIFIES RISK** to patients participating in **CLINICAL TRIALS**

A recent CenterWatch study finds that the incidence of deaths attributed to investigational treatments, during both government and industry-sponsored clinical trials, is rare. The study also finds that one adverse event per research subject is typically reported on new drug applications approved by the Food and Drug Administration.

"To our knowledge, no information about the general risks associated with clinical trial participation has ever been assessed," says Ken Getz, CEO of CenterWatch. "Yet, communicating this information to potential study volunteers should be an important part of health consumer education and of the informed consent process. Our primary goal in publishing this information is to stimulate discussion among industry professionals, regulators, and the general public."

In September 2001, CenterWatch gathered data from 130 randomly selected new drug applications (NDAs) that had received approval since 1987. This represented about one-third of all new molecular entities approved by the FDA during this period.

In total, more than 122,000 patients participated in the clinical drug trials evaluated. About 3,500 serious adverse events (SAEs) were reported. According to the study, the industry reported a total of 13 deaths to study drug effects.

According to Mary Jo Lamberti, Ph.D., manager of CenterWatch Research, the findings present metrics on general risks but these metrics are averages that fail to convey the wide variability in risk between clinical studies.

According to analysts, there are numerous variables that will impact research risk, including the type of disease, the type of drug being researched, and the study duration.

"Our analysis is also based on FDA data from approved NDAs," Dr. Lamberti says. "We have not yet evaluated the many industry-sponsored trials that are terminated before an NDA is filed."

INDUSTRY SNAPSHOT

Meet Them on the Web

In the last decade, meetings and events have become a key part of pharmaceutical product promotion. More recently, the Internet has become a hot meeting place for drug companies and their prescription-writing customers, according to the Physician Meeting & Event Audit (PMEA) from Scott-Levin Associates Inc., Newtown, Pa., a Quintiles Transnational company.

From February 2001 through April 2001, Scott-Levin surveyed its PMEA panel every month to determine the extent of "e-event" activity. More than 3,100 physicians participated in the study.

WHAT'S UP DOCS

- 39% of physicians indicate that they had been invited to an event conducted via the Internet
- 30% have positive attitude
- 64% will participate in future e-events

Follow up

CENTERWATCH is a Boston-based information services company that focuses on the clinical trials industry. CenterWatch offers a variety of publications and services for clinical research and health professionals, patients and health consumers. For more information, please visit centerwatch.com.

DECISION RESOURCES INC., a provider of pharmaceutical research and advisory services, is based in Waltham, Mass. For more information visit dresources.com.

FRONT LINE STRATEGIC MANAGEMENT CONSULTING INC., offers strategic business consulting and is based in Foster City, Calif. For more information visit frontlinesmc.com.

FROST & SULLIVAN is an international strategic marketing consulting and training company based in San Antonio, Texas. For more information visit food.frost.com.

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MARKET MEASURES INTERACTIVE L.P., Livingston, N.J., is an NOP World Health company, and a supplier of primary research to the global healthcare community. For more information on the Lipids TCS.net, please contact Chris Naegle, managing director of MMI's Product and Market Assessment Group, by calling 800-456-4405, ext. 420 or e-mailing cnaegle@mmi.nopworld.com. For more information or additional press releases on MMI, please visit mmi-research.com.

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