BY DENISE MYSHKO

The Asthma Market

The approach to treating asthma continues to evolve. Rescue bronchodilator therapies are giving way, both in medical practice and in the market, to prophylactic strategies, which include inhaled corticosteroids, long-acting beta2 agonists, and leukotriene antagonists. Sales of combination therapies, leukotriene antagonists, and the introduction of more expensive novel agents are expected to BREATHE NEW LIFE INTO THE MARKET.

BREATHES EASIER

The asthma market has undergone a significant revision over the past five years, with a host of therapeutic options becoming available and more being investigated worldwide. The need for innovative treatments is evident. As a chronic and multifaceted inflammatory disorder, asthma causes significant morbidity in affected individuals, including permanent structural damage to the airways and long-term reductions in lung function, according to Decision Resources.

Despite a greater number of good treatments coming to the market, there are still unmet needs. In its March 2004 report on the asthma market, Decision Resources identifies those needs as being safe and effective prophylactic therapies, convenient treatments that improve patient compliance, agents for refractory severe persistent asthma, improved diagnostic tests, and physician education and adherence to treatment guidelines.

"There has been a fair amount of activity in this therapeutic category in recent years, including the approval of the first biologic to treat serious asthma, a continued uptake of combination products, and an increased emphasis in medical practice," says Tom Luginbill, senior practice executive of the brand management practice at Campbell Alliance. "The question then is, why are people still ending up in emergency rooms? The answer is that even with the innovation that has occurred, there is still room for further improvement in this market."

Cynthia Mundy, Ph.D., an analyst with Decision Resources, says one of the challenges inherent in the asthma market is that patients and doctors are comfortable with the drugs being used and may be reluctant to switch.

"Physicians believe their patients' needs are very well met," she says. "That presents a challenge for drug developers because they're trying to displace agents that doctors are very happy with in terms of efficacy."

Still, industry experts expect the market for asthma therapies to increase. Driving that growth will be corticosteroid/bronchodilator combination products. The focus on prevention will likely lead to increasing use of inhaled corticosteroids, long-acting beta2 agonists, and leukotriene antagonists.

"Despite great products and a lot of public-

Tom **LUGINBILL**

Clearly, FDA's willingness to tolerate risk appears to be evolving and for therapy areas such as asthma **THAT PRESENTS SPECIAL CHALLENGES BECAUSE OF THE NATURE OF THE DISEASE.**

Alek **BITUIN**

THE LEADERS IN ASTHMA ARE SO HEAVILY ENTRENCHED IN THE MARKETPLACE that it would be difficult for new and upcoming drugs to make a dent.

health awareness and a community-based approach to manage symptoms and address behavioral issues to prevent episodes, the industry doesn't seem to be winning the asthma-management battle, particularly with kids," says Rose Higgins, senior VP and head of sales and marketing at iMetrikus Inc. "Pharmaceutical companies have done a good job in delivering these types of messages because they know how to do massive data engagements, based on their clinical-trials experience."

The **ASTHMA** Market

The prevalence of asthma has been increasing since the early 1980s among all age and racial groups and in both sexes. According to the Centers for Disease Control and Prevention, in 2002, 30.8 million people (111 people per 1,000) had been diagnosed with asthma during their lifetime. Among adults, 106 per 1,000 had a lifetime asthma diagnosis (21.9 million) compared with 122 per 1,000 children 0 to 17 years (8.9 million).

Around 300 million people are estimated to have asthma, according to the Global Initiative for Asthma, which estimates there may be an additional 100 million persons with asthma by 2025. As the number of patients afflicted with this chronic and sometimes deadly disease continues to increase, the patient population is becoming more fragmented. People with asthma may have different triggers, which requires different medications, behavior changes, and treatment plans. Many factors can trigger an asthma attack, including allergens, infections, exercise, abrupt changes in the weather, or exposure to airway irritants, such as tobacco. (See box on page 33 for more information.)

According to a Decision Resources' study, which evaluated the sales of asthma therapies from 2002 to 2012 in seven major pharmaceutical markets (United States, France, Germany, Italy, Spain, United Kingdom, and Japan), the market is expected to increase to $12.9 billion in 2012 from $7.0 billion in 2002. Growth will be driven by sales of combination therapies, leukotriene antagonists, and the introduction of more expensive novel agents.

Currently, industry experts say the asthma market is dominated by three products: GlaxoSmithKline's Advair, Merck's Singulair, and AstraZeneca's Symbicort.

Advair (salmeterol, fluticasone propionate) has been available in the United States since April 2001 to treat asthma in patients 12 years of age and older. In April 2004, GlaxoSmithKline received approval for Advair (the product is known as Seretide outside the United States) for use in children 4 to 11 years of age with asthma who are symptomatic on inhaled corticosteroid therapy alone.

Advair contains an inhaled corticosteroid and a long-acting beta2 agonist. In 2003, glob-

An Asthma **BREAKDOWN**

IN 2002, 30.8 MILLION PEOPLE HAD BEEN DIAGNOSED WITH ASTHMA DURING THEIR LIFETIME, according to the Centers for Disease Control and Prevention.

Asthma is a life-threatening lung disease in which airways become inflamed, leading to breathing difficulties. It is a chronic respiratory disease characterized by episodes or attacks of inflammation and narrowing of small airways in response to asthma triggers.

Asthma attacks can vary from mild to life-threatening and involve shortness of breath, cough, wheezing, chest pain or tightness, or a combination of these symptoms.

Many factors can trigger an asthma attack, including allergens, infections, exercise, abrupt changes in the weather, or exposure to airway irritants, such as tobacco smoke. Although several theories exist about why asthma rates have risen during the last two decades, there probably is no simple answer.

Officials from the National Institute of Allergy and Infectious Diseases, a part of the National Institutes of Health, say one theory is that people today, especially in developed countries, are spending more time indoors, increasing their exposure to more indoor allergens, such as dust mite allergen, which can cause asthma.

Another reason may be that people today live in cleaner, more sanitary conditions, which affects the immune system.

Other theories point to increased levels of air pollutants, a decline in the amount of exercise people get, and a rising obesity rate as factors in the increase of asthma.

Incidence Rates

Asthma prevalence has been increasing since the early 1980s among all age and racial groups and in both sexes. According to the Centers for Disease Control and Prevention, in 2002, 30.8 million people (111 people per 1,000) had been diagnosed with asthma during their lifetime.

Among adults, 106 per 1,000 had a lifetime asthma diagnosis (21.9 million) compared with 122 per 1,000 children 0 to 17 years of age (8.9 million).

Among all racial and ethnic groups, Puerto Ricans have the highest rate of lifetime asthma (196 per 1,000) and Mexicans the lowest (61 per 1,000). Puerto Ricans were almost 80% more likely, and non-Hispanic blacks and American Indians were about 25% more likely, to have been diagnosed with asthma than non-Hispanic whites.

Females were about 7% more likely than males to have been diagnosed with asthma. Among children 0 to 17 years of age, males were more likely to have an asthma diagnosis than females.

In 2002, 4,261 people died from asthma, or 1.5 per 100,000 people. Among children, asthma deaths are rare. In 2002, 187 children ages 0 to 17 years of age died from asthma, or 0.3 deaths per 100,000 children compared with 1.9 deaths per 100,000 adults 18 years of age and over. Non-Hispanic blacks were the most likely to die from asthma and had an asthma death rate more than 200% higher than non-Hispanic whites and 160% higher than Hispanics.

Related Costs

According to the National Heart, Lung, and Blood Institute, direct and indirect financial costs for all forms of asthma total $14 billion, including $9.4 billion in direct costs and $4.6 billion in indirect costs (missed school and work days).

People with difficult-to-control asthma comprise the majority of asthma-associated costs, with 80% of asthma-associated costs driven by 20% of the asthma population.

According to analyses from the American Lung Association and the Centers for Disease Control and Prevention, asthma-related mortality increased 50% from 1980 to the mid-1990s.

Quick **FACTS**

Number of noninstitutionalized adults who were ever diagnosed with asthma: **21.9 MILLION**

Percentage of noninstitutionalized adults who were ever diagnosed with asthma: **10.6%**

Number of noninstitutionalized children who were ever diagnosed with asthma: **8.9 MILLION**

Percentage of noninstitutionalized children who were ever diagnosed with asthma: **12.2%**

Number of children who had attack in past year: **4.2 MILLION**

Percentage of children who had attack in past year: **5.8%**

Number of visits to office-based physicians: **12.7 MILLION**

Number of hospital outpatient department visits: **1.2 MILLION**

Number of hospital emergency department visits: **1.9 MILLION**

Number of deaths: **4,261**

Deaths per 100,000: **1.5**

Source: Centers for Disease Control and Prevention, National Center for Health Statistics, Hyattsville, Md. For more information, visit cdc.gov/nchs.
Source: United States National Library of Medicine, National Institutes of Health, Bethesda, Md. For more information, visit nlm.nih.gov.
Source: Genentech Inc., South San Francisco, Calif. For more information, visit gene.com.

DIRECT AND INDIRECT FINANCIAL COSTS FOR ALL FORMS OF ASTHMA TOTAL $14 BILLION, INCLUDING $9.4 BILLION IN DIRECT COSTS AND $4.6 BILLION IN INDIRECT COSTS (MISSED SCHOOL AND WORK DAYS), according to the National Heart, Lung, and Blood Institute.

al sales for Advair were $3.6 billion; U.S. sales were $2.03 billion. Global sales from January through September 2004 for Advair were $3.26 billion; U.S. sales for the same time period were $1.75 billion.

Datamonitor analysts predict that by 2009, Advair will have sales of $5.6 billion. Success will be heavily dependent on future performance in the U.S. market, which already accounts for 70% of total sales.

GlaxoSmithKline also markets Serevent Diskus, an inhaled corticosteroid, indicated for the long-term, twice-daily (morning and evening) administration in the maintenance treatment of asthma in patients 4 years of age and older; the prevention of exercise-induced bronchospasm in patients 4 years of age and older; and for the maintenance treatment of bronchospasm associated with chronic obstructive pulmonary disease (COPD), including emphysema and chronic bronchitis.

In 2003, global sales for Serevent were $710 million; U.S. sales were $321 million. Global sales for Serevent from January through September 2004 were $481 million; U.S. sales for the same period were $186 million.

Singulair (montelukast), a leukotriene receptor antagonist, is indicated for the prophylaxis and chronic treatment of asthma in patients 12 months old and older. Worldwide sales of Singulair were reaching $731 million in the fourth quarter of 2004 and $2.6 billion for 2004, representing an increase of 44% and 30% compared with the respective periods of 2003.

Symbicort, which is approved for the treatment of asthma and COPD, provides the anti-inflammatory corticosteroid budesonide and the rapid and long-lasting bronchodilator formoterol in a single inhaler.

According to AstraZeneca, Symbicort sales were $797 million for full year 2004, an increase of 32% from 2003.

Datamonitor analysts predict the market for asthma and COPD will grow to $19 billion by 2009.

For asthma alone, the total worldwide market will be about $13 billion in 2005, increasing to around $22 billion by 2010, say analysts from Navigant Consulting Inc.

"The market is growing because of an expanding patient population and the increased use of the different combination products such as Advair and Symbicort," says Alek Bituin, a senior consultant with Navigant Consulting. "The combination products address the compliance issue because now instead of patients having to administer two different inhaled formulations, they only have to use one."

Researchers from Decision Resources agree and say it appears that the use of long-acting beta2 agonists in combination with low to medium doses of inhaled corticosteroids is more effective and safer than using high doses of inhaled corticosteroids as monotherapy.

"We see the asthma market expanding," Dr. Mundy says. "We expect continued uptake of combination long-acting beta2 b and inhaled corticosteriods inhalers. Physicians like them because they believe they improve compliance among patients who require inhaled corticosteroid therapy and because they are steroid sparing."

In addition, treatment guidelines issued in 2002 by the National Heart, Lung and Blood Institute (NHLBI) recommend inhaled corti-

Sound Bites from the Field

PHARMAVOICE ASKED INDUSTRY EXPERTS TO IDENTIFY THE BIGGEST ISSUES IN THE ASTHMA MARKET.

MARIA ELENA ALIOTO, Associate Clinical Coordinator, University of California, San Francisco, Asthma Research/School of Nursing, San Francisco; The School of Nursing provides education and research training in the social, behavioral, and biological sciences focused on health, illness, and healthcare. For more information, visit nurseweb.ucsf.edu.

"Patients need more education. There are a lot of medicines out there. We have great doctors and great institutions. But patients need a roadmap to be able to navigate the maze because two people can have asthma but their condition may not be triggered by the same things nor will they respond the same to some medicines. Environmental controls may work for one but not another. Asthma is a very complex and multifaceted disease. Treatments need to be individualized."

PATRICK ANGELASTRO, VP, Strategic Development, Impact Rx Inc., Mount Laurel, N.J.; Impact Rx is a provider of market insight to the pharmaceutical industry. For more information visit impactrx.com.

"The industry traditionally defines markets and evaluates share based on a simple grouping of products that have similar indications. That approach works for most markets, but it's not good enough for a respiratory market that consists of products with multiple and overlapping indications. So when companies are trying to accurately define a market for products such as Advair and Singulair, it's important that they look at share within a specific diagnosis or indication to get an accurate read on brand performance."

PAUL J. ATKINS, PH.D. CEO, Oriel Therapeutics Inc., Durham, N.C.; Oriel Therapeutics is an emerging inhaled drug-delivery company based on innovative technology for aerosolizing powders using the application of powder-specific electrical frequencies. For more information, visit orieltherapeutics.com.

"Albuterol is the only generic metered-dose inhaler. The difficulty for generics in this area is that they have to minimally match *in-vitro* performance (in the laboratory), and this is technically challenging. The approval of generic albuterol was a long and public process. At this moment, there are no other guidelines for getting generic products approved in the United States. I don't think we will see more truly generic inhalers in the asthma arena for awhile."

costeroids as first-line therapy for adult and pediatric patients with persistent asthma.

The First BIOLOGIC

The emergence of Xolair (omalizumab) marketed by Genentech, Novartis/Sankyo, and Tanox Biosystems, offers a new treatment for asthma. Approved in the United States in June 2003, Xolair is the first humanized therapeutic antibody for the treatment of asthma and the first approved therapy designed to target the antibody IgE, a key underlying cause of the symptoms of allergy-related asthma.

In many people, asthma appears to be an allergic reaction to substances commonly breathed in through the air, such as animal dander, pollen, or dust mite and cockroach waste products. Some people have a genetic predisposition to react to certain allergens.

When these people breathe in the allergen, the immune system goes into high gear and produces IgE, the antibody central to the allergic reaction. For example, it causes mast cells, a type of specialized defensive cell, to release chemical "weapons" into the airways. The airways then become inflamed and constricted, leading to coughing, wheezing, and difficulty breathing — an asthma attack.

Xolair is indicated for adults and adolescents (12 years of age and older) with moderate-to-severe persistent asthma who have a positive skin test or *in vitro* reactivity to a perennial aeroallergen and whose symptoms are inadequately controlled with inhaled corticosteroids.

Xolair was jointly developed under an agreement among Novartis Pharma AG, Genentech, and Tanox, and is comarketed in the United States by Genentech and Novartis Pharmaceuticals. Xolair also received marketing license from health authorities in Australia.

Decision Resources researchers say various factors, such as cost and administration as an injection, will limit its uptake. But they say because of its high price, it will be one of the products that will drive growth of this market.

Dr. Mundy says peak sales for Xolair will probably be about $500 million to $750 million worldwide, which is a change from the previous year's forecast. Based on more recent market evaluations, Decision Resources has lowered its projection for this product.

In 1997, the National Institutes of Health (NIH) came out with its first set of guidelines for the management of asthma. The guidelines recommend that many patients who have at least persistent asthma should be tested for their allergen sensitivity.

"We know that between 70% and 90% of children, depending on which group of studies you want to believe, have allergic asthma," says Dennis Kane, VP, U.S. sales and marketing at Pharmacia Diagnostics. "In adults, that number is around 50%. Interestingly, less than 5% of asthmatics have been tested for allergen sensitivity."

Mr. Kane says 85% of all asthmatics are managed at the primary-care level and 15% are managed at the specialist level. Of that 15%, 10% are managed by pulmonologists and 5% by allergist specialists.

"An allergist specialist is the only person who's aware, trained, prepared to do allergen sensitivity testing, and he or she does that through skin testing," he says. "An alternative is serologic testing for IgE. We are embarking on an important campaign to educate pulmonologists, family physicians, internal medicine doctors, and pediatricians about the role of allergen sensitivity in asthma."

He says while a patient may have an allergic sensitivity to dust mites or cockroaches and that may be a contributing factor, there may be other triggers such as molds, animal dander, and even some pollens that contribute to the total allergic load.

"When that load exceeds an individual's threshold, he or she becomes symptomatic," Mr. Kane says. "That's when a patient needs a rescue inhaler, or he or she may end up in the hospital. The understanding of what causes those symptoms is what is missing."

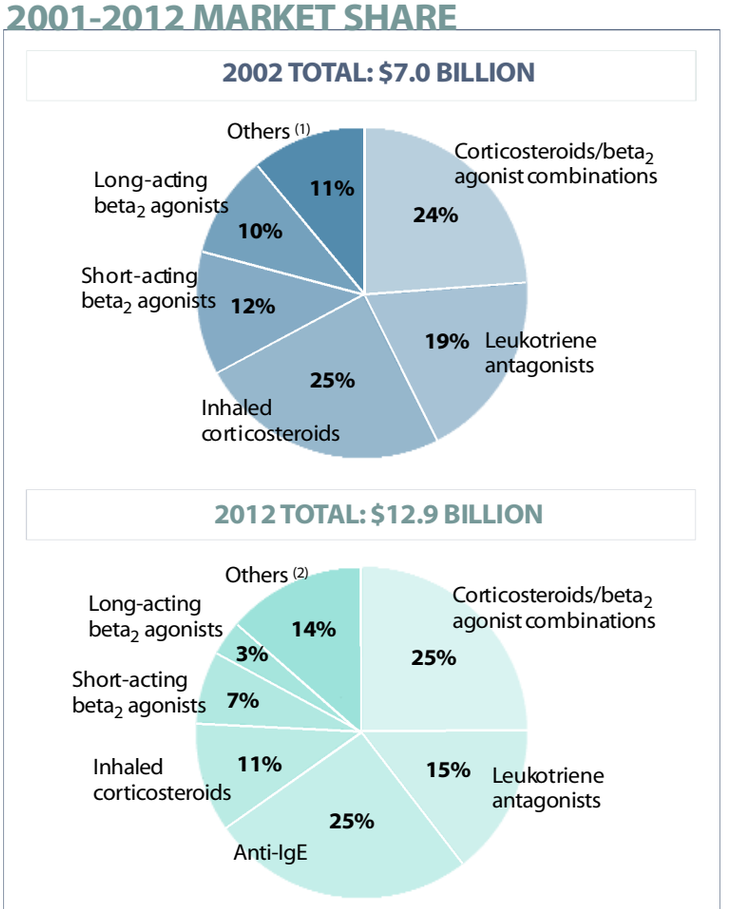
Products TO WATCH

Although many asthmatics respond well to currently available treatments, significant unmet needs remain, especially among patients with severe forms of the disease. A number of companies are seeking to fulfill these needs with new drugs.

According to Decision Resources, novel corticosteroids are in various stages of development worldwide. The most commercially promising agents are those that elicit fewer side effects.

Novartis and Schering-Plough are jointly

Asthma Therapies
2001-2012 MARKET SHARE



Source: Decision Resources Inc., Waltham, Mass. For more information, visit decisionresources.com.

Note: (1) Other drug classes included in the 2002 analysis include: oral and injectable corticosteroids, cromolyns, anticholinergics, phosphodiesterase inhibitors, and H1 receptor antagonists. (2) Other drug classes included in the 2012 analysis include: oral and injectable corticosteroids, cromolyns, anticholinergics, phosphodiesterase inhibitors, H1 receptor antagonists, anticytokine agents, cell adhesion inhibitors, and platelet-activating factor inhibitors.

Note: Percentages may not add to 100 because of rounding.

Note: Based on recent market projections, researchers at Decision Resources now anticipate that the market share of anti-IgE products will be about 5%.

developing a fixed inhaled combination product. The product combines Novartis' Foradil (formoterol fumarate) a selective, long-active beta2 agonist, and Schering-Plough's Asmanex (mometasone furoate), an inhaled corticosteroid. Based on physicians' views, Decision Resources forecasts peak year sales of $250 million to $500 million for the product.

Another promising product in the pipeline is Alvesco (ciclesonide), a corticosteroid inhaler for treating asthma, which is being jointly developed by Altana Pharma, Sanofi-Aventis, and Teijin. Altana Pharma and Sanofi-Aventis have joint marketing rights to the product.

Altana Pharma has been granted market approval for Alvesco in Australia, Brazil, Mexico, and the United Kingdom, the reference state for the mutual recognition process for approvals in other European countries. The first European market launch of Alvesco took place in January 2005.

In October 2004, Altana's U.S. partner, Sanofi-Aventis, received an approvable letter from the FDA for Alvesco. In Japan, Teijin filed for approval in January 2004.

A Phase II study of ciclesonide in fixed combination with formoterol, a long-acting beta agonist, is due to start in the near future.

Dr. Mundy says peak sales of Alvesco could be between $750 million and $1 billion in the seven major markets covered by the company.

Altana Pharma also is developing Daxas (roflumilast), which belongs to the class of selective phosphodiesterase-4 (PDE4) inhibitors. The active agent is under development for the treatment of asthma and COPD. Roflumilast is once-daily oral tablet.

In 2002, Altana Pharma signed collaboration agreements to codevelop and copromote roflumilast with Pfizer worldwide, except for Japan. Altana Pharma has partnered with Tanabe Seiyaku in Japan.

Daxas is expected to generate sales of more than $1 billion by 2010 after launching in the European Union in 2005 and in the United States in 2006, says Wade Sunada, Ph.D., an analyst at Navigant Consulting.

"Daxas could end up holding between 7% and 8% of the market by 2010," he says. "Physicians say they are looking for a systemic drug with the safety profile of the leukotriene inhibitors but with better efficacy. Oral formulations are especially important for the elderly and for children who can't use the inhaled formulations that well."

Pfizer, along with Boehringer Ingelheim, also markets Spiriva HandiHaler (tiotropium bromide inhalation powder), which has been approved by the FDA for the long-term, once-daily, maintenance treatment of bronchospasm associated with COPD.

According to Datamonitor, expected sales of Spiriva and the launch of Daxas will propel Pfizer as a major player in COPD, which is the fastest growing segment of the asthma market.

Even as combination products are expected to dominate the asthma market, they are sometimes more difficult to study in clinical trials, says Alek Safarian, CEO of Novotech.

"Sponsors need patients who have never been on a steroid before to test efficacy," he says. "As high as the incidences of asthma are in

Children and **ASTHMA**

Findings from a recent survey about children and asthma, Children and Asthma in America, reveal that more than half **(54%)** of all children with asthma had a severe asthma attack in the past year and more than one quarter **(27%)** had an asthma attack so bad they thought their life was in danger.

The survey, conducted on behalf of Asthma Action America and released in December 2004, found that the majority of children with asthma do not have it under control. This places children at potential risk for a variety of consequences, including frequent symptoms, missed school, restrictions on activities, emotional distress, hospitalization, and even life-threatening asthma attacks.

Asthma Action America is a national asthma education program supported by 21 leading organizations, including the Respiratory Institute established by GlaxoSmithKline, which is working to improve the understanding and management of asthma in the United States.

Asthma is one of the most common chronic illnesses among children, with an estimated **5.8** million American children 4 to 18 years of age currently diagnosed with the condition.

In a survey, four out of five respondents reported that their child's asthma was well controlled **(43%)** or completely controlled **(35%)**, yet children missed the mark on nearly every treatment goal established by the National Heart, Lung, and Blood Institute (NHLBI), part of the National Institutes of Health.

The survey reveals widespread misunderstanding about the causes of and treatments for asthma symptoms. The majority of respondents **(90%)** admitted that they never heard of bronchoconstriction — tightening of the muscles surrounding the airways — and **(93%)** said they were unfamiliar with inflammation — airway-swelling and irritation — which are the two underlying causes of asthma symptoms.

Only **53%** of those surveyed classified their children as having severe asthma and **63%** of those with moderate asthma reported they or their children took prescription medication, such as an inhaled corticosteroid for daily maintenance therapy during the past four weeks. Additionally, **30%** of respondents incorrectly named a short-acting beta-agonist (an inhaler used for treating sudden asthma symptoms) as a long-term asthma control medicine. National treatment guidelines recommend daily use of an inhaled corticosteroid as the preferred therapy for people with persistent asthma.

Source: Asthma Action America and GlaxoSmithKline, Philadelphia. For more information, visit asthmaactionamerica.org

Dennis **KANE**

In the future, in the treatment for asthma and other conditions, there is going to be a greater inter-relationship between the diagnostic test and the treatment.

MEDICINE IS HEADED TOWARD BETTER MARKERS AND BETTER DIAGNOSTIC TOOLS.

some parts of the world, that can be difficult. Proving the efficacy of combination products is always a little more difficult because it is not always clear which active ingredient is doing what. There can be a successful trial in terms of reaching endpoints for patients, but there are regulatory challenges in terms of proving that the combination was really needed as opposed to only one of the ingredients or the dose mix that was used by the sponsor."

Additionally, there is much concern about drug safety, and the FDA likely will require very closely monitored postmarketing studies for new combination asthma products, says Lawrence Sher, M.D., medical director at Criterium Inc.

"If we look at the problems pharmaceutical companies have had recently, adverse events have developed after 1 million to 2 million people were on a medication for one to two years," he says "Studies can't be designed for such high numbers of patients nor for that length of time."

PharmaVOICE welcomes comments about this article. E-mail us at feedback@pharmavoice.com.

Dr. Wade **SUNADA**

THE TOTAL WORLDWIDE MARKET FOR ASTHMA, which includes the top five European countries, Japan, and the United States, **WILL BE ABOUT $13 BILLION IN 2005; IT WILL EXPAND TO ABOUT $22 BILLION BY 2010.**

Experts on this topic

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