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Emphysema Takes Your Breath Away

November 2007

BEING A LITTLE HEAVY MAY HAVE SOME BENEFITS Study: Those up to 25 pounds overweight may better survive some illnesses

Being 25 pounds overweight doesn't appear to raise your risk of dying from cancer or heart disease, says a new government study that seems to vindicate Grandma's claim that a few extra pounds won't kill you.

Released just a few weeks before Thanksgiving, the findings might comfort some who can't seem to lose those last 15 pounds. And they hearten proponents of a theory that it's possible to be "fit and fat."

The news isn't all good: Overweight people do have a higher chance of dying from diabetes and kidney disease. And people who are obese — generally those more than 30 pounds overweight for their height — have a higher risk of death from a variety of ills, including some cancers and heart disease.

'A conundrum'

However, having a little extra weight actually seemed to help people survive some illnesses — results that baffled several leading health researchers. "This is a very puzzling disconnect," said Dr. JoAnn Manson, chief of preventive medicine at Harvard's Brigham and Women's Hospital. "That is a conundrum."

It was the second study by the same government scientists who two years ago first suggested that deaths from being too fat were overstated. The new report further analyzed the same data, this time looking at specific causes of death along with new mortality figures from 2004 for 2.3 million U.S. adults. "Excess weight does not uniformly increase the risk of mortality from any and every cause, but only from certain causes," said the study's lead author Katherine Flegal, of the U.S. Centers for Disease Control and Prevention.

The study, which appears in the *Journal of the American Medical Association*, analyzed the body-mass index of people who died from various diseases. In many cases, the risks of death were substantial for obese people — those with a body-mass index, or BMI, of at least 30.

Specifically, obesity raised the risk of death from heart disease, diabetes and kidney disease, and several cancers previously linked with excess weight, including breast, colon and pancreatic cancer.

Less likely to die of pneumonia

But being merely overweight — having a BMI between 25 and 30 — did not increase the risk of dying from heart disease or any kind of cancer.

Also surprising was that overweight people were up to about 40 percent less likely than normal-weight people to die from several other causes including emphysema, pneumonia, injuries and various infections. The age group that seemed to benefit most from a little extra padding were people aged 25 to 59; older overweight people had reduced risks for these diseases, too.

Why extra fat isn't always deadly and might even help people survive some illnesses is unclear and in fact disputed by many health experts. But University of South Carolina obesity researcher Steven Blair, who says people can be fat and fit, is a believer. He called the report a careful and plausible analysis, and said Americans have been whipped into a "near hysteria" by hype over the nation's obesity epidemic.

While the epidemic is real, the number of deaths attributed to it and to being overweight has been exaggerated, Blair said. People should focus instead on healthful eating and exercise, and stop obsessing about carrying a few extra pounds or becoming supermodel thin, Blair said. He says his hefty grandmother used to justify her extra padding, saying, "That way I have protection in case I get sick." Maybe there is something to that.

A little extra weight might provide "additional nutritional reserves" that could help people battle certain diseases, Flegal said.

Misleading results?

Dr. Robert Eckel, a spokesman for the American Heart Association, argued that the results may be misleading. For example, diabetes and heart disease often occur together and both often afflict overweight people. So when diabetes is listed as a cause of death, heart disease could have contributed, he said. Eckel also said the study results might reflect aggressive efforts to treat high blood pressure and cholesterol or other conditions that can lead to fatal heart attacks. Those conditions often occur in overweight people and can be costly and debilitating even if they aren't always deadly, he said.

Obesity researcher Barry Popkin of the University of North Carolina in Chapel Hill, agreed, noting that the study "is about death. This is not about health and sickness." It doesn't address whether cancer and heart disease occur more often in overweight people — something that has been suggested by other research.

Dr. Michael Thun of the American Cancer Society noted that staying slim tops a recent list of recommendations for preventing cancer in a report from the World Cancer Research Fund and American Institute for Cancer Research. The report was based on a review of more than 7,000 studies. The CDC report "definitely won't be the last word," Thun said.

Manson, the Harvard researcher, cautioned that extra pounds can lead to obesity so people shouldn't be complacent about being overweight.

Laurie Slocum, who went from a size 20 to a size 12 after joining Weight Watchers two years ago, says the study won't turn her into a slacker. A 47-year-old banker from Durand, Ill., she lost more than 60 pounds and still has a few to go. Thanks to dieting and exercise, her blood pressure has dropped from "the stroke zone" to normal. She said she feels too good now to use the new findings as an excuse to indulge. "It's not going to change anything I'm doing," Slocum said. "The number on the scale isn't my goal ... it's a healthy lifestyle."

Source: .msnbc.msn.com

ASTHMA UK ADVICE FOR A FLU-FREE WINTER

'People with asthma are at a greater risk from flu than others because asthma symptoms are often triggered by respiratory infections, so having a flu jab is the sensible option.' That's the advice from Erica Evans, Asthma Care Development Manager at Asthma UK as we gear up for winter 2007.

Over 5 million people in the UK have asthma and for 90% of them, colds and flu trigger their asthma symptoms, meaning that having the flu is a major concern. While it is almost impossible to avoid catching the common cold, having a flu jab can help to prevent the virus taking hold. Erica says: 'Each year we receive a lot of calls to the Asthma UK Adviceline from people with asthma who find that their symptoms are worse in the winter months. Flu is always a worry and prevention is key. We would recommend that anyone with asthma discusses the possibility of having a flu jab with their GP this autumn, before the virus begins to circulate.'

Flu is highly infectious: according to the Department of Health, 100,000 flu particles can be projected into the air with just one sneeze. Given that a sneeze travels at 80 miles per hour and can reach distances of 30 feet away, it's hardly surprising that at least 10% of the population develops flu each year. The flu vaccination offers protection from the virus for a year and is free to people who are most susceptible, including those with asthma.

Autumn is the best time to have a jab and it is also important to have a vaccination every year to protect you against the latest strains of the virus, which is constantly mutating. 'The flu vaccine has been widely used for many years and is both safe and effective with very few side effects,' assures Erica. 'Apart from having the flu vaccine there are other measures that people can take to reduce the effects of colds and viruses on their asthma. Following a written personal asthma action plan so that they know when and how to adjust their treatment if their asthma worsens, is

just one such way.

Erica advises: 'People with asthma should contact their doctor or practice nurse and ask for a personal asthma action to ensure that your asthma is kept under control':

- Keep taking your regular medication as prescribed by your doctor
- If you know that cold air triggers your asthma, take a couple of puffs of your reliever inhaler before going outside. Wrap up well and wear a scarf over your nose and mouth - this will help to warm up the air before you breathe it in
- Take extra care when exercising in cold weather. Warm up for 10 - 15 minutes and take a couple of puffs of your reliever inhaler before you start
- Be sensible - if cold air triggers your asthma, it's probably best not to try that cross country run when it's chilly outside.

Source: .asthma.org.uk.

ASTHMA/COPD INNOVATION SCARCE AMONG TOP PHARMACEUTICAL COMPANIES

Many asthma and chronic obstructive pulmonary disease patients are now being treated with inhaled corticosteroid/long-acting beta2-agonist fixed-dose combinations, a lifecycle management strategy generating high sales from a relatively low investment. However, the lack of truly novel drug targets means that other unmet needs in asthma and COPD are being overlooked by the leading players.

Patients suffering from respiratory diseases like asthma and chronic obstructive pulmonary disease (COPD) are increasingly being treated with fixed-dose combination inhalers. Since GlaxoSmithKline (GSK) launched the first inhaled corticosteroid/long-acting beta2-agonist (ICS/LABA) combination in 1998, this drug class has been the leading class in terms of sales in the seven major markets. Advantages for combination drugs

Indeed, ICS/LABA products accounted for 33% of the asthma/COPD market at about \$5.7 billion in 2006 and are set to remain the leading class, with sales of \$6.1 billion in 2016. The combination products are popular for several reasons, including improved patient compliance, simplified disease management and the assurance of bronchodilator and steroid co-administration. Non-adherence to treatment is a significant problem in asthma and COPD, especially in the later stages of disease, when patients have a multitude of drugs to deal with and treatment regimes can become confusing.

Patients show a specifically low compliance when it comes to their ICS medication because, unlike a bronchodilator, it does not give them immediate relief. However, the regular use of steroids is key to treating the underlying inflammatory process of asthma and COPD. The automatic intake of the ICS alongside the bronchodilator, improving disease management for both patients and physicians, is a major advantage of combination drugs.

Another benefit of these combination products is that patients always inhale their LABAs in combination with an ICS. Concerns regarding the dangers of LABA monotherapy in the

treatment of asthma led to the 1996 Salmeterol Multicenter Asthma Research Trial (SMART), which investigated salmeterol (a type of LABA) in the treatment of asthma. A possibly increased mortality rate in certain subgroups of asthma patients using this drug was found, leading to safety warnings on LABA drug labels. Very few physicians now prescribe LABAs as monotherapy and non-compliance among patients using LABAs without ICS's is the main reason.

Combination products ensure revenue stream

The case of GSK's ICS/LABA combination Advair/Seretide (fluticasone/salmeterol) is a prime example of a life-cycle management strategy resulting in a first-to-market position being optimally used. For companies with a product facing the loss of patent protection, lifecycle management strategies are essential to prevent erosion of market share by generic competitors. Frequently this involves securing an extension of exclusivity through reformulation and launching a second-generation product or introducing a combination therapy.

Additionally, products that are first to market have a distinct advantage with regards to capturing market share. GSK's Advair/Seretide was launched several years before the patent expiry of either of its components Flixotide/Flovent and Serevent, allowing the company enough time to drive switching to the combination product. Indeed, Advair/Seretide became the highest-selling product in the asthma/COPD market with sales of just over \$5 billion in 2006.

Unmet needs remain

Although the introduction of fixed dose ICS/LABA combination products has meant an improvement in the standard of treatment for the majority of asthma and COPD patients, there still remains a high level of unmet need, especially in the treatment of COPD. Key examples include the lack of efficacious anti-inflammatories for COPD (current therapies neither arrest nor reverse inflammation and the resulting decline in lung function), finding better ways to prevent and control asthma and COPD exacerbations, and developing therapies for the 10% of refractory asthma patients whose symptoms cannot be controlled with currently available drugs.

At the same time, the leading pharmaceutical companies' in-house R&D is having trouble finding new ways to treat asthma and COPD, despite significant investment. Part of the problem has been the lack of novel validated targets after significant delays and failures in developing classes such as PDE4 inhibitors. Key players in the asthma and COPD market therefore had to rely on a more conservative approach, investing into the lifecycle management of currently marketed drugs. However, this does not help those patients who need novel drugs to help the control their disease and stop the decrease of lung function.

As a result of R&D setbacks and the bias towards lifecycle management, genuinely novel pipeline drugs for asthma/COPD are scarce among such companies. Instead, innovation primarily comes from smaller biotech companies

who often do not have the means to drive the development of new compounds as larger companies would have. This means that while increasingly more ICS/LABA combination products enter the market, the unmet needs in certain asthma and COPD patient groups are still not being addressed.

Source: Mdlinks

CLINICAL SCENARIO: MEASURING EXERCISE CAPACITY IN COPD

A 55-year-old man with an unremarkable medical history was referred to the emergency department due to acute onset of dyspnea, cough, yellowish sputa and wheezing. The patient had a smoking history of 45 pack-years. On admission, ECG demonstrated a sinus tachycardia with no signs of ischemia. Troponins and D-dimers were within the normal limits but C reactive protein (CRP) was moderately increased (40 mg/l). X-ray of the chest suggested thoracic hyperinflation but excluded underlying pneumonia. The tentative diagnosis of a chronic obstructive pulmonary disease (COPD) exacerbation was established and treatment with systemic steroids, antibiotics and short-acting bronchodilators was initiated. Under this treatment our patient significantly improved over the next 48 hours and was able to be discharged from hospital 4 days after admission. Four weeks later, the patient presented at the outpatient clinic with persistent fatigue and complaints of dyspnea when walking up stairs although he had been taking a tempering regimen of systemic steroids until this time and been using salbutamol 4 times daily.

Source: Resp. Rehab. and Resp. Div., Univ. Hospitals, Leuven, Belgium

COPD AND EXERCISE- BREATHING AND EXERCISE PROGRAMS FOR COPD

If you have trouble breathing, exercise may be the last thing you feel like doing. But exercises for COPD can help your breathing, allowing you to stay as active as possible and improving your quality of life. Before beginning with a COPD exercise program, be sure to talk with your doctor or other health care provider.

How Exercises for COPD Can Help You

Exercise -- especially exercise that works your lungs and heart -- has many benefits for those with chronic obstructive pulmonary disease (COPD).

Exercise can:

Improve how well your body uses oxygen, which is important since people with COPD use more energy to breathe than other people do.

- Decrease your symptoms and improve your breathing.
- Strengthen your heart, lower your blood pressure, and improve your circulation.
- Improve your energy, making it possible to stay more active.
- Improve your sleep and make you feel more relaxed.
- Help you maintain a healthy weight.
- Enhance your mental and emotional outlook.
- Reduce your social isolation, if you exercise with others.

- Strengthen your bones.

4 Types of Exercises for COPD

These four types of exercises can help you if you have COPD. How much you focus on each type of exercise may depend upon the COPD exercise program your health care providers suggests for you. Before starting these programs speak with your health care provider.

- Stretching exercises lengthen your muscles, increasing your flexibility.
- Stretching can also help prepare your muscles for other types of exercise, decreasing your chance of injury.
- Aerobic exercises use large muscle groups to move at a steady, rhythmic pace. This type of exercise works your heart and lungs, improving their endurance by working your respiratory muscles. This helps your body use oxygen more efficiently and, with time, can improve your breathing. Walking and using a stationary bike are two good choices of aerobic exercise if you have COPD.
- Strengthening exercises involve tightening muscles repeatedly to the point of fatigue. When you do this for the upper body, it can help increase the strength of your breathing muscles.
- Breathing exercises for COPD help you strengthen breathing muscles, get more oxygen, and breathe with less effort.

Here are two examples of breathing exercises you can begin doing for five to 10 minutes, three to four times a day.

Pursed lip breathing:

- Relax your neck and shoulder muscles.
- Breathe in for two seconds through your nose, keeping your mouth closed. Breathe out for four seconds through pursed lips. If this is too long for you, simply breathe out twice as long as you breathe in.

Use pursed-lip breathing while exercising. If you experience shortness of breath, first try slowing your rate of breathing and focus on breathing out through pursed lips.

Diaphragmatic breathing:

- Lie on your back with knees bent. You can put a pillow under your knees for support.
- Place one hand on your belly below your rib cage. Place the other hand on your chest.
- Inhale deeply through your nose for a count of 3. (Your belly and lower ribs should rise, but your chest should remain still.)
- Tighten your stomach muscles and exhale for a count of 6 through slightly puckered lips.

COPD and Exercise Guidelines

You may find that it helps to exercise at the same time each day; late morning or early afternoon may be a time when you have more energy.

Source: Ann in UK via WebMd.com

COPING WITH COPD

It's a deadly disease claiming one life every four minutes.

Even scarier, 24 million Americans have it, but only half of them know they're sick. COPD (chronic obstructive pulmonary disease) is the fourth leading cause of death in the U.S. That's why doctors want to warn you about something very life threatening and also very treatable.

"Most people don't know the symptoms, so they don't know what to tell their doctor," said Dr. Anthony Keele of Cape Family Practice. "It can be tricky to diagnose, but we can do it with a machine we call the Body Box." Not only can it check for COPD, but also asthma and other breathing disorders.

Warning signs include a chronic cough, excessive fatigue, and trouble sleeping.

Source: Mdlinx

ENCOURAGING RESULTS REPORTED ON AIRWAY BYPASS PROCEDURE

Broncus Technologies, Inc., a medical device company investigating the airway bypass procedure for the treatment of emphysema, announced that the results of its open-label ExhaleR Drug-Eluting Stent feasibility study have been published in the October issue of the Journal of Thoracic and Cardiovascular Surgery. Positive results include a statistically significant reduction in the amount of air trapped in the lungs and an improvement in breathing for patients at six months after the airway bypass procedure.

Airway bypass is a catheter-based bronchoscopic procedure designed to reduce lung hyperinflation and improve breathlessness (the clinical hallmarks of emphysema/COPD) by making new pathways for trapped air to exit the lungs. During the minimally invasive procedure, new openings are created in the airway wall connecting the damaged lung tissue to the natural airway. These pathways are supported and kept open by Exhale Drug-Eluting Stents. The hope is to improve quality of life by relieving severe symptoms including shortness of breath and hyperinflation of the chest.

Emphysema, a component of COPD, is a chronic, progressive, and irreversible lung disease characterized by the destruction of lung tissue. The loss of the lungs' natural elasticity and the collapse of airways in the lung combine to make exhalation ineffective, leaving emphysema sufferers with hyperinflation because they are unable to get air out of their lungs. Breathing becomes inefficient and patients have to work very hard just to breathe - making normal activities, like walking, eating or even bathing, difficult. Treatment options for most patients with emphysema are currently limited and generally result in anguished patients and frustrated physicians.

The prospectively-defined primary endpoint of this feasibility study was a reduction in residual volume (RV, the amount of air remaining in the lungs after full exhalation) at 6 months. The goal was for a 300mL reduction in RV. Overall the trial surpassed that goal with a 400mL improvement in RV over baseline at 6 months (p=0.04). Patients also showed a statistically significant improvement in the modified Medical Research Council Dyspnea Scale (mMRC), a breathlessness test, of -0.5 points (p= 0.025). Retrospective analysis revealed that patients with the most severe hyperinflation of their lungs (as determined by a residual volume to total lung capacity ratio above the median) derived the greatest benefit from airway

bypass. At 6 months after the procedure, these patients showed a mean improvement in RV of 870mL (p=0.022).

"The management of emphysema poses a difficult challenge for the medical community as the disease progressively deprives patients of their ability to perform daily activities. These findings are encouraging because there are so few options for the millions of patients who suffer from this disease," states Paulo F.G. Cardoso, M.D., Ph.D, Division of Thoracic Surgery, Santa Casa de Porto Alegre-Pavilhao Pereira Filho Hospital, Brazil and lead author of the paper. "These results reveal significant improvements in pulmonary function and reduction in breathing difficulties out to six months and indicate that airway bypass is a potentially viable therapeutic option for patients with marked severe pulmonary destruction, whose only current option may be to wait for a lung transplant."

"The data from this study are very exciting, as they help build the case that airway bypass might reduce hyperinflation and have long-term benefit," states Cary Cole, CEO of Broncus. "We hope to continue this success with the current, pivotal EASE Trial, our largest clinical study to date." The EASE Trial

Airway bypass is currently being investigated in the pivotal IDE Exhale Airway Stents for Emphysema (EASE) Trial. Over 50 patients have been randomized in the trial, underway at over 20 leading research institutions around the world.

Leading pulmonologists and thoracic surgeons are studying the safety and effectiveness of airway bypass in people struggling with severe homogenous (or diffuse) emphysema in a prospective, randomized, sham-controlled, double-blind study. At least 225 patients will be enrolled at approximately 45 sites in North America, Europe, Australia and South America during the next 12 to 18 months. Involvement in the study will last from approximately 15 months up to 5 years (depending on if the patient is randomized to the control or the treatment group) and include 8 to 16 physician appointments. All study-related medical procedures will be carried out at no charge to the patient and patients will be closely monitored throughout the trial. Participants will also receive at least 14 weeks of pulmonary rehabilitation therapy.

If you or someone you know over the age of 35 have been diagnosed with advanced widespread emphysema and no longer smokes (or would be willing to stop smoking two months prior to the study), you may qualify to participate in this study. For more information please call 866-431-3273 or visit <http://www.EASEtrialUS.com>.

Researchers are careful to point out that there is no expectation that this new investigational procedure will cure emphysema. However, it is hoped that the procedure will prove useful in reducing the severity of symptoms, by improving pulmonary function and the quality of life for patients with the disease. Source: medicalnewstoday.com

FIRST PATIENTS ENROLLED IN IBV VALVE TRIAL

Spiration, Inc announced that the first patients have been

enrolled in the company's IBV Valve Trial in the United States. The purpose of the trial is to generate safety and effectiveness data for submission to the U.S. Food and Drug Administration (FDA) for approval to market the company's IBV Valve System in the United States for the treatment of patients with severe emphysema.

The first patients were enrolled in the pivotal trial by Daniel Nader, DO, FCCP, clinical assistant professor of internal medicine and director of the Oklahoma State University Center for Respiratory Medicine in Tulsa, Oklahoma. "There are currently few treatment options for people with severe emphysema, who struggle with each breath and therefore cannot do very simple things that most people take for granted, such as simultaneously walking and talking," said Dr. Nader. "Spiration's valve therapy -- which is much less invasive than lung surgery -- may one day offer a new treatment option to improve quality of life for these patients."

The IBV Valve Trial is a prospective, randomized, blinded clinical trial that will enroll up to 500 patients at up to 40 sites in the United States. The objective of the study is to demonstrate the safety and effectiveness of the IBV Valve treatment. The primary endpoints of the study will be measured at six months. Patients enrolled in the control arm of the study will be eligible to receive treatment with the IBV Valve System after completion of the six-month study period.

For the treatment of emphysema, the IBV Valve System is designed to redirect airflow from diseased portions of the lung to healthier areas. During the minimally invasive procedure, a catheter is passed through a bronchoscope (a flexible tube passed into the bronchial tubes through the mouth or nose) to deploy the small umbrella-shaped valves into the airways of the upper lobes of the lungs. Although the valves are intended to be permanent, they are designed to be removed via a minimally invasive procedure if necessary.

The IBV Valve Trial design is based on results of a pilot study. "Findings of the pilot study are encouraging, and suggest that the IBV Valve may provide improvements in quality of life for many patients. We hope to confirm these results in the pivotal trial," said Daniel Sterman, M.D., director of Interventional Pulmonology of the University of Pennsylvania Medical Center in Philadelphia, who presented further results from the pilot study last week at the European Respiratory Society's Annual Congress in Stockholm, Sweden.

Study investigators are actively recruiting patients for the IBV Valve Trial. The study is open to men and women age 40 to 74 who have been diagnosed with predominantly upper lobe emphysema and shortness of breath with exertion. Eligible patients are able to participate in pulmonary function and standardized exercise tests, have not smoked for four months and are willing to not smoke during the trial. Additional criteria must be met for participation in the study. For more information, including trial site locations, please visit www.emphysematrial.com or call (877) 547-8839.

Source: genengnews.com

DO ASTHMA/COPD COMBINATION DRUGS STAND IN THE WAY OF INNOVATION?

An increasing number of asthma and chronic obstructive pulmonary disease (COPD) patients are being treated with inhaled corticosteroid/long-acting beta2-agonist (ICS/LABA) fixed-dose combinations. These combination products have advantages for both patients and physicians alike, as compliance can be improved and disease management can be simplified. By combining two existing drugs into fixed dose combinations, the pharmaceutical industry serves to protect their franchises and generate high sales from relatively low investment. However, the convenience and relative ease of this lifecycle management strategy and the lack of truly novel drug targets means that other unmet needs in asthma and COPD are being overlooked by big pharma, according to a new report by independent market analyst Datamonitor. Combination drugs have major advantages for both patients and physicians

Patients suffering from respiratory diseases like asthma and chronic obstructive pulmonary disease (COPD) are increasingly being treated with fixed-dose combination inhalers. Since GlaxoSmithKline (GSK) launched the first inhaled corticosteroid/long-acting beta2-agonist (ICS/LABA) combination in 1998, this drug class has been the leading class in terms of sales in the seven major markets**. Indeed, ICS/LABA products accounted for 33% of the asthma/COPD market at about \$5.7 billion in 2006 and are set to remain the leading class with sales of \$6.1 billion in 2016. The combination products are popular for several reasons, including improved patient compliance, simplified disease management and the assurance of bronchodilator and steroid co-administration.

Non-adherence to treatment is a significant problem in asthma and COPD, says Datamonitor respiratory analyst Lisette Oversteegen. "Especially in the later stages of disease, when patients have a multitude of drugs to deal with and treatment regimes can become confusing".

Patients show a specifically low compliance when it comes to their ICS medication because, unlike a bronchodilator, it does not give them immediate relief. However, the regular use of steroids is key to treating the underlying inflammatory process of asthma and COPD. The automatic intake of the ICS alongside the bronchodilator, improving disease management for both patients and physicians, is a major advantage of combination drugs.

Another benefit of these combination products is that patients always inhale their LABAs in combination with an ICS. Concerns regarding the dangers of LABA monotherapy in the treatment of asthma led to the 1996 Salmeterol Multicenter Asthma Research Trial (SMART), which investigated salmeterol (a type of LABA) in the treatment of asthma. A possibly increased mortality rate in certain subgroups of asthma patients using this drug was found (1), leading to safety warnings on LABA drug labels. Datamonitor believes that very few physicians prescribe LABAs as monotherapy and that non-compliance among patients using LABAs without ICS's is the main reason, Oversteegen says. "The combination of these two drug classes in a fixed dose combination goes a long way in dealing with

this issue."

Companies continue to develop combination products to ensure revenue stream

The case of GSK's ICS/LABA combination Advair/Seretide (fluticasone/salmeterol) is a prime example of a life-cycle management strategy resulting in a first-to-market position being optimally used. For companies with a product facing the loss of patent protection, lifecycle management strategies are essential to prevent erosion of market share by generic competitors. Frequently this involves securing an extension of exclusivity through reformulation and launching a second-generation product or introducing a combination therapy. Additionally, products that are first to market have a distinct advantage with regards to capturing market share, Oversteegen says. "GSK wanted to capitalize on the standard of care that dual ICS and LABA therapy brings to most asthma patients and at the same time ensure a revenue stream beyond the lifespan of either of the component products.

"Advair/Seretide was launched several years before the patent expiry of either of its components Flixotide/Flovent and Serevent, allowing the company enough time to drive switching to the combination product. Indeed, Advair/Seretide became the highest-selling product in the asthma/COPD market with sales of just over \$5 billion in 2006," she says.

However, does Big Pharma still invest in the remaining unmet needs?

Although the introduction of fixed dose ICS/LABA combination products has meant an improvement in the standard of treatment for the majority of asthma and COPD patients, there still remains a high level of unmet need, especially in the treatment of COPD. Key examples include the lack of efficacious anti-inflammatories for COPD (current therapies neither arrest nor reverse inflammation and the resulting decline in lung function), finding better ways to prevent and control asthma and COPD exacerbations, and developing therapies for the 10% of refractory asthma patients whose symptoms cannot be controlled with currently available drugs.

At the same time, big pharma's in-house R&D is having trouble finding new ways to treat asthma and COPD, despite significant investment. Part of the problem has been the lack of novel validated targets after significant delays and failures in developing classes such as PDE4 inhibitors, Oversteegen says. "Key players in the asthma and COPD market therefore had to rely on a more conservative approach, investing into the lifecycle management of currently marketed drugs. "However, this does not help those patients who need novel drugs to help them control their disease and stop the decrease of lung function," she says.

As a result of R&D setbacks and big pharma's bias towards lifecycle management, genuinely novel pipeline drugs for asthma/COPD are scarce among such companies. "Instead, innovation primarily comes from smaller biotech companies who often do not have the means to drive the development of new compounds as larger companies would have", Oversteegen says. "This means that while increasingly more ICS/LABA combination products enter the market, the unmet needs in certain asthma and COPD patient groups are still not being

addressed."

Source: Pharmaceutical Media Group

GETTING HEALTHIER: IT'S PARTLY IN YOUR HEAD

This has got to be the easiest way to boost the benefits of your workout: Just think about them.

Sounds crazy, right? But it was true in a study of hotel workers. Just 4 weeks after the room cleaners were educated on how their duties counted toward their exercise needs, they saw a drop in weight and blood pressure -- despite no changes in overall activity levels.

Placebo Effect at Work

Changing bed linens, vacuuming, dusting, scrubbing the bathroom floor -- it's not spin class, but it is physical activity. And if you do physically active things with the right mind-set (namely, think "This is good for me."), it could translate into greater health gains. Just chalk it up to that mind-body connection to which so many other health benefits (like the placebo effect) have been traced. (Read this article on how the mind-body connection can ease pain.)

Think About It

You need only about 30 minutes of exercise daily to meet the surgeon general's physical activity recommendations. And keep in mind that things like pulling weeds, painting the garage door, and folding laundry count toward that total. And we mean literally keep it in mind. Couldn't hurt, right?

Source: RealAge

HEALTH CARE QUALITY, COST INCREASE

More patients getting recommended treatments, but notable gaps exist

The quality of health care in the United States is steadily improving, with more patients getting recommended treatments, but there are a few notable gaps — and costs are skyrocketing, according to a report released on September 25. Treatment for conditions such as heart attack are exemplary, the National Committee for Quality Assurance found. But fewer than 20 percent of patients with heart disease have their cholesterol down to recommended levels, the group found in its annual report card on health care quality. "Since 2000, improvement in just four areas of care — beta-blocker treatment for heart attack patients, cholesterol management, controlling high blood pressure and improving blood sugar control among diabetics — has saved the lives of almost 125,000 Americans," the independent, nonprofit group said in its report.

The committee rated 767 different health plans, including Medicare, private insurers and health maintenance organizations, on a variety of measures from heart disease care to immunization. The best-performing plans did an excellent job, said NCQA President Margaret O'Kane. "When a plan is reminding physicians to do things, they will do it across the board," O'Kane told a news conference.

For instance, experts agree that anyone who has had a heart attack should get a beta-blocker drug. "When NCQA began measuring this life-saving treatment in 1996, fewer

than 2 in 3 patients were receiving the right care," the report reads. "But in 2006, more than 97 percent of heart attack patients received beta-blockers and nearly every plan that reported on its performance had beta-blocker treatment rates of 90 percent or higher. This single improvement has saved between 4,400 and 5,600 lives over the last six years, and improved the health of tens of thousands of people."

The group also found that close to 80 percent of children in commercial health plans received all recommended vaccines and 73.4 percent of children in Medicaid plans were fully immunized. But only 1 in 4 children had a recommended follow-up visit with a primary care doctor after being prescribed an attention deficit/hyperactivity disorder drug, even though such follow up is considered key.

The report said that if the entire health care system were to perform as well as the top 10 percent of plans surveyed, every year between 35,000 and 75,000 deaths, 45 million sick days and \$7.4 billion in lost productivity could be prevented.

Peter Orszag, Director of the U.S. Congressional Budget Office, said costs are skyrocketing. "If we stay on the same path, the (U.S. federal) budget will become dominated by Medicare and Medicaid," he told the news conference. He looks at the report's findings on which regions of the country had higher health care spending. "The higher-spending regions do not generate better outcomes than lower-spending regions," Orszag said. Health insurers, both private and public, need to study which health care treatments work, which do not, and stick to the most cost-effective approaches, the report said. Source: MSNBC.com

USE YOUR COMPUTER TO FIGHT FLAB

Clearly, too many hours sitting at the computer can be a recipe for jiggy hips and thighs.

But here's a computer pastime that fights desk-chair flab: interactive exercise programs. In a study, people who enrolled in a personalized Internet-based exercise program reported a significant bump in their activity levels at the end of a year.

Fitness at Your Fingertips

There are lots of free online options for exercise tracking, so get Googling! Here's what you want in an online exercise program: educational and motivational materials (think fitness how-to's and success stories), goal-setting options, a physical activity log where you can track your workouts, and an occasional e-mail that prompts you to use the program. People who joined an online group with these elements reported 90 minutes of physical activity per week at the 1-year mark. (Use this online tool to tailor your calorie-burning needs.)

Get Together

Need more motivation? Find an online buddy. Reporting to your buddy every day on what exercises you tackled is a surprisingly motivational way to keep yourself focused on your goal. If you can't figure out what to do, start with walking. 30 minutes a day could save your life; exercising regularly, expending at least 3,500 calories of energy a week, can make your RealAge 3.4 years younger.

Source: Real Age



Information in this newsletter is for educational purposes only. Always consult with your doctor first about your specific condition, treatment options and other health concerns you may have.



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