Second Wind
NEWSLETTER

APRIL 2004

PERF, The Pulmonary Education and Research Foundation, is a small but vigorous non-profit foundation. We are dedicated to providing help, and general information for those with chronic respiratory disease through education, research, and information. This publication is one of the ways we do that. The Second Wind is not intended to be used for, or relied upon, as specific advice in any given case. Prior to initiating or changing any course of treatment based on the information you find here, it is essential that you consult with your physician. We hope you find this newsletter of interest and of help

KEY WORDS: COPD Caucus, e-mail Washington, Herb on Herbals Part II-Manufacturing Herbal Remedies, Gold Stage 2, Ambulatory vs. stationary oxygen, NHLEP & Snowdrift by Dr. Petty.

We are pleased and excited to finally be able to announce the following important news.

SENATOR CRAPO FOUNDS CONGRESSIONAL COPD CAUCUS

Senator calls pulmonary problems a national concern

Washington, DC (April 1, 2004) – During a speech today before a national physician's group in Washington D.C., Idaho Senator Mike Crapo announced the founding of the Congressional Chronic Obstructive Pulmonary Disease (COPD) Caucus. The group will be dedicated to furthering aware-ness of COPD risks and promoting policies that improve the lives of COPD patients. The Caucus, which Crapo will chair, will partner with a broad coalition of physician, patient, and homecare organizations to educate members of Congress on COPD and advocate

policies to encourage prevention and early detection. During his speech, given before the American College of Chest Physicians (ACCP), Crapo pointed out the effects of the disease on individuals and society.

"COPD is a major national health problem that significantly impacts the lives of those diagnosed with the disease, and carries large societal costs," Crapo said. "Those with COPD say it affects every part of their lives, including limiting their ability to work, sleep, and participate in social and physical activities. **It is estimated that over 13 million people in the U.S. have been diagnosed with some form of COPD, with millions more undiagnosed.** The disease accounts for 8 million office visits and more than 1.5 million emergency room visits every year, and costs over $32 billion dollars in medical expenditures and lost work hours. The Congressional COPD Caucus is a necessary first step to address an important problem."

COPD is an umbrella term used to describe the airflow obstruction that is associated primarily with emphysema and chronic bronchitis. It is the fourth leading cause of death and disability in the U.S. Deaths from COPD have increased steadily in the past ten years, with the death rate for women surpassing the death rate for men.

Senator Crapo is joined by Senator Blanche Lincoln (D-Arkansas), and Representatives John Lewis (D-Georgia) and Cliff Stearns (R-Florida) as Co-Chairs of the Caucus. Caucus partner organizations include: ACCP (American College of Chest Physicians), American Association for Homecare, Alpha-1 Association, American Thoracic Society, American Lung Association, and the American Association for Respiratory Care.

The President of the ACCP, Richard S. Irwin, MD, FCCP, said: "For years, the ACCP has recognized the severe impact COPD has on the lives of our adult patients, their families, and the national health system; however, to the general public, it is nearly an unrecognized disease. The ACCP commends Senator Crapo for establishing this much needed COPD Caucus, where members of Congress and medical societies such as the ACCP can work together to address this serious respiratory condition."

Kay Cox, CEO of the American Association for Homecare, commented: "The American Association for Home-care and its members join Senator Crapo in taking every necessary step to ensure that COPD patients are receiving the best of care."

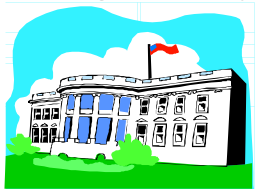
John W. Walsh, President & CEO of the Alpha-1 Foundation, added: "The creation of the Congressional COPD Caucus marks a significant victory in the campaign to expand awareness of a quiet killer. The fourth-leading cause of death in the United States, COPD is a debilitating, costly disease. However, early detection and the development of new therapies can improve health outcomes, save the healthcare system money and help millions of people with COPD live longer,

healthier lives. The Congressional COPD Caucus will also help to increase awareness and early detection of Alpha-1 Antitrypsin Deficiency, the most significant genetic risk factor for COPD. On behalf of the Alpha-1 Foundation, we congratulate Senator Crapo for his leadership, vision and commitment in helping fight these two little-known but deadly diseases."

"On behalf of the American Thoracic Society, I congratulate Senator Crapo, Senator Lincoln, and Representatives John Lewis and Cliff Stearns for starting the Congressional COPD Caucus," said Homer A. Boushey, Jr., MD, President of the American Thoracic Society. "**Despite being the fourth leading cause of death in the United States, Chronic Obstructive Pulmonary Disease or COPD remains largely under diagnosed, under treated, under researched and under appreciated by the America public.** The Congressional COPD Caucus will play a valuable role in bringing research, resources and solutions to the devastation caused by COPD."

Crapo proposed the development of a COPD Caucus during the National COPD Conference in November 2003. In September 2003, he introduced a Senate resolution designating November 2003 as COPD Awareness Month. Crapo has become an activist in health awareness issues since he was diagnosed and successfully treated for prostate cancer in January 2000. He has sponsored the Mike Crapo Health Awareness Booths at four regional fairs in Idaho for the last three years. The booths provide early detection tests for prostate and breast cancer along with cholesterol and blood pressure screenings and health promotion information. Crapo is planning another year of the booths in 2004. Crapo also co-chairs the Congressional Heart and Stroke Coalition.

The COPD Caucus is a tremendously important step towards finally giving some recognition to those with pulmonary disease. ***So far, only Senator Blanche Lincoln (D-Arkansas), and Representatives John Lewis (D-Georgia) and Cliff Stearns (R-Florida), have joined Senator Crapo.*** We urge all of our readers to e-mail a letter to *your* Senators and Congressmen. (Written letters take a long time and go through security checks.) It was recommended that our letters not be too long, but it is hard to be informative and brief at the same time! Make them aware of the term **COPD** and urge them to join this **COPD Caucus**! If you get a successful response, let us know. We will print the names of those legislators who join this effort.



Ask your friends, neighbors, and acquaintances if they know what COPD stands for. Educate them! Ask them to join in this campaign to make COPD a household word, and to convince our national representatives to join

this COPD Caucus initiated by Senator Crapo. Bring your patient clubs and support groups on board in this effort!

If you don't want to write a letter just e-mail your representatives, **"Make COPD a household word. Join the COPD Caucus."** Only by making Washington aware of this serious problem will we get the legislation, the research, and the funding we need to help us win this battle. Act today!

Greetings to the Better Breathers Club of Wm. Beaumont Hospital in Royal Oak, MI and thanks to W.R. Sponsler.

***The Jerry Donatoni family** has been overwhelmed by the response to their request for donations to PERF in memory of their beloved husband and father. They wrote to tell us that PERF has been a great support to their family and that they shared the newsletters with Jerry's "Breathing Buddies" support group.*

His wife Stella continued, "We are grateful for the research that enabled Jerry to benefit from home oxygen therapy and the newest medications. We are also painfully aware that while patients are surviving longer, it is often at a significantly reduced quality of life. We are therefore pleased to send this additional sum for COPD research in Jerry's name from his family Stella, Giannina, Paul, Giuliana and Margherita as well as those from our relatives, friends and colleagues." Additional donations this month came from Lisa &Marcello Menga, Anita Comeau, Jay & Sam Manders, Tony & Fay Soesanto, Lim Hoe & Reny Tan, Lim Hok & Agnes Tan, Lim Pwe & Cisca Tan, Burt & Isabelle Wilkins, The Brotman Hospital Rehabilitation Department, the Los Angeles County (DHS) Sexually Transmitted Disease Program and the USC Kenneth Norris Pharmacy. We can promise all of you that your donations will be earmarked for research into advancing the fight against COPD.

Enclosed in their letter was an advertisement for a "safe" cigarette, which was published in the April 1, 2004 issue of Woman's Day. They hoped that we would print an official response from PERF in our newsletter. As long time supporters of smoking restrictions, we will be pleased to do that in an upcoming edition of the Second Wind.

HERB on HERBALS

Manufacturing Herbal Remedies

Part two of a five part series

By Herbert Webb, MD, pulmonologist Medical Director San Pedro Peninsula Pulmonary Medicine Department

Let me start by saying that I am definitely not an expert on herbals. My perspective is that of a skeptical, professional, conservative, mainstream pulmonary physician, and my watchwords are "Prove it to me, that it is safe and effective, before I put it into my body or recommend it for

you." I approach this task hoping to accommodate an attitude that herbals can be complimentary rather than an alternative to conventional medications.

I think it's quite clear herbs are potentially therapeutic, as well as potentially dangerous. So, as I said last month, I think you should think of herbals and nutritional supplements as drugs. Herbs, just like FDA-approved pharmaceuticals, have side effects, toxicities and drug interactions. Last month, I discussed the aspects of a solid, scientifically useful study and the frustrating lack of research on herbs. Let's talk now about the significant differences in manufacturing between FDA approved medications, dietary supplements and herbal remedies.

The United States has a wide variety of government commissions that regulate every topic under the sun, so it seems strange to report that U.S. citizens are getting less government protection with herbs than folks in other countries. For example, in Germany, production of herbal medications and the claims made by their manufacturers are tightly controlled. The Germans require absolute proof of safety, as well as reasonable proof that an herb actually works, for the seal of approval from the German equivalent of our FDA. Compare this to the United States. In 1994, the **Dietary Supplements Health and Education Act (DSHEA)** *deregulated* the supplement industry so that the FDA has *NO* control over it at all. **Herbal remedies are sold over the counter as dietary supplements, and there are no manufacturing standards**. And, in my opinion, for medication to be effective, safe, and predictable, there should be.

Much research regarding herbals has been done in Germany, and is recently being translated into English, making it easier for U.S. physicians to access. That's the good news. Herbal remedies are considered much more legitimate in Germany than in the United States, and there is some incentive to at least perform limited research on German herbal remedies. *It costs about 3 to 5 million U.S. dollars for a German manufacturer to get a botanical product tested and approved for use there.* In contrast, *to get an herbal OK'd by the FDA, it would have to pass the careful scrutiny given to all prescription medications, which would take roughly 350 million dollars.* This is bad news for the manufacturers, who would much rather take the easy route and market their products as dietary supplements, rather than drugs. The further bad news? **Even if an herb has an outstanding German scientific study, you can't be sure that anything you buy in the U.S. has anything in common with German herbals. Our manufacturing standards just aren't there.** It's very frustrating for both consumers and health care providers.

When you consider putting any medication in your body, you should always ask, is it safe and does it work? You can't answer the first question for herbals and supplements in this country currently with our deregulated supplement industry.

The lack of standards for controlling active ingredients and eliminating contaminants has led to a great deal of concern. Consumer Reports tested a dozen brands of gingko biloba and echinacea for a March 1999 report and found *extreme* variations in the amount of herb present in different brands and even in different bottles of the same brand! The brand-to-brand variation was also found for ginseng. Some congressmen are trying to establish controls of the supplement industry, but in the meantime, we have big problems. The FDA has started highlighting some of these, and recently put out an alert that echinacea can impair the effectiveness of birth control pills --- a warning that came just a tad tardy for one surprised young woman I know! The FDA also reported that weight loss and energy supplements containing ephedra (ma-huang) can lead to heart attacks, strokes, convulsions, and fatalities in otherwise healthy adults. In addition, *many foreign produced herbals contain poisons, including hemlock, strychnine, even heroin and cocaine, as well as heavy metals including lead, mercury and arsenic. Unfortunately, there are pesticide residues in many foreign herbals as well. Herbals have been contaminated with dangerous bacteria and fungi, for example, in alfalfa tablets.* For medication to be effective, safe, and predictable, it should pass careful scientific scrutiny and testing.

Herbal medication, however, is regulated under the same laws as the oregano in your spaghetti sauce. Herbs can come in a variety of containers, including unmarked zip lock Baggies. (A bottle marked with "N.F." however, indicates some quality control and a higher level of confidence in the product.) The container may, or may not be, marked with contents and instructions. If dosing directions are vague or instructions are incomplete, then doses will vary widely. Brewing a tea? How much herb in how much hot water? And how long do you let it steep, remembering that the longer it steeps, the stronger it gets? Remember, anything taken in large doses can be dangerous; mega-doses of nutmeg cause hallucinations. Many herbals are directly toxic to your organs. Liver toxicity has been documented to occur with chaparral, gentian, germander and shark cartilage. Unfortunately, intentional adulteration of dietary supplements has been also documented. The Chinese herbal remedy tung shueh recently caused acute kidney failure; it was found to be adulterated with nonsteroidal anti-inflammatory agents as well as Valium. One Chinese ginseng preparation purchased by the Texas Department of Health listed ginseng as the only ingredient, but chemical analysis showed large amounts of caffeine and ephedrine (which quickens heartbeat, acts as a diuretic and bronchodilates) also present.

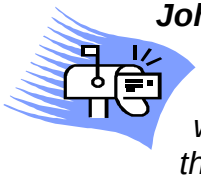
If the quality is so unpredictable, why doesn't the FDA stop the selling of herbals? For the FDA to halt manufacture of sale of an herbal supplement, the FDA must prove that it can be expected to harm most people who consume it, rather than just a subset of the population. So although they aren't regulating them, the FDA has made several general

recommendations about herbal medications. The list goes like this: don't take herbals when you're pregnant, nursing, or attempting to conceive. Don't give herbals to children. Don't expect herbals to be effective in treating serious disease but do expect them to interact with prescription medications.

The bottom line is that the consumer must be aware. There are no manufacturing standards for herbal remedies and supplements. And, I think, for medication to be effective, safe, and predictable, there should be.

Thanks Dr. Webb! We look forward to Part 3, "*Misguided Logic*", next month.

We get mail….(lots of it!)



John *says he has been told that he is in stage 2 of lung disease and wants to know what that means.*

Dear John,

We think you are referring to **GOLD stage 2**, which is a pretty wide middle ground between 50 and 80% of predicted FEV1. The GOLD Website is at http://www.goldcopd.com if you would like more information. The summary document has the tables you may want. You can also look up pocket guides and spirometry.

This stage is a wake up call to take care of yourself. You should get a consultation with a pulmonologist about the right inhalers, a pneumonia shot, annual flu shots and, very importantly, start an exercise regime. Needless to say, stop smoking if you haven't already done so!

Fred *notes that in a 2nd Wind Newsletter dated February 2004 Dr. Thomas Petty refers to 'ambulatory oxygen' and 'stationary oxygen'. He wants us to tell him the difference.*

Dear Fred,

A stationary system would be an oxygen concentrator or a large container of liquid oxygen used for refill purposes. The term "ambulatory" varies according to who is using it. Some providers consider a 22-pound E-cylinder lasting 4 hours at 2 liters per minute ambulatory. We don't. More accurately, the E-cylinder is something that can be moved. An Oxygen Consensus Conference *several years ago* stated that the container should weigh *less* than 10 pounds with 8 hours of oxygen use at 2 liters per minute. Current improvements have resulted in systems weighing less than 5 pounds (some only 3.5), which last 8 hours. Those of us who work with respiratory patients are struggling to make that kind of system available to all patients.

Dr. Thomas L. Petty

A system that small is truly portable. Walking and exercising with oxygen then becomes possible. Hope that helps.

Have you noticed that Dr. Petty is now using different stationery? When we asked why he was using ***Snowdrift*** stationery rather than ***NLHEP*** (National Lung Health Program) this was his reply.

I am president of **Snowdrift** and also of **NLHEP**, which I am transferring to the **AARC** (American Association of Respiratory Care). I feel that with the infrastructure of a society to promote our programs on COPD (Chronic Obstructive Pulmonary Disease), we can be even more effective than in the past. The AARC is the official organization of the respiratory therapists that numbers approximately 130,000. These professionals are in virtually every hospital in the USA and can be the grass roots "foot soldiers," who can carry out the *mission* of the NLHEP. We are now turning over the NLHEP to the AARC including the foundation. We will keep Snowdrift as the home for what ever we want to write about COPD and related topics including lung cancer that closely relates to COPD. Everything on Snowdrift can be found on http://www.lungcancerfrontiers.org/

Briefly, **The Snowdrift Pulmonary Conference** is a not for profit corporation founded by me and a few others about 9 years ago for the purpose of writing monographs and other publications for primary care physicians. This is where, and how, we publish the **Frontline Treatment** series of monographs, which so far, have been supported and distributed by Boehringer Ingelheim. Our first one was **Frontline Treatment of COPD**, which has been revised and is now in the second edition, published in 2000. We also wrote an excellent monograph on **Dyspnea**. These are the ones that we have written at Great Slave Lake in Canada. Nine pulmonologists with broad experiences in both academic medicine and private practice write these consensus documents on an annual basis. Boehringer distributes them, but some of them have had little visibility. Our most popular one was written for patients, entitled **Frontline Advice for COPD Patients**, and is also distributed by Boehringer. The one in press and soon to be published is **Frontline Update in COPD**. AARC will publish this one. Some of these can be found on the web site http://www.nlhep.org/.

Snowdrift also publishes a quarterly newsletter on the early diagnosis and treatment of lung cancer. This one goes to all board certified pulmonologists in the USA and Canada.
It has a web site:
http://www.lungcancerfrontiers.org/.
Some of our NLHEP monographs are there too. Snowdrift has had a variety of pharmaceutical sponsors but presently has none. I am still printing the next issue on a grant that I have about lung cancer. Both foundations are 501-(c)3 not for profit corporations under the IRS.

Thanks, Dr. Petty! *Now* we understand. Your letter of the month is one of the first things we read in each new edition. Dr. Tom tells us that he appreciates the letters that you send, so keep them coming

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DROWNING IN SALT (Part I)

This and the next installments will explain the importance of salt in health and disease, and how diet affects salt. These concepts are extremely important IN health AND IN THE PREVENTION AND TREATMENT OF ILLNESS.

The body requires salt to maintain what is known as its "internal environment." Chemically, salt is sodium plus chloride. It is the sodium referred to as the major particle, known as "cation" that control where water is distributed within the cells and the fluids of the body. A minimum amount of salt intake is critical to good health. Excess salt may cause fluid retention, congestion, or drowning of organs including the lungs.

As humans evolved, it became necessary to conserve salt in periods of short supply or heat with perspiration. Salt is lost through perspiration. The human body developed active mechanisms for the kidneys to reduce salt excretion for conservation of the "internal environment". The evolution of various hormones over time was adaptive to the problems of salt depravation or loss. The problem is that the same adaptations may now pose impediments to cardiac and kidney function in older age and in states of disease.

Where excessive salt and water retention occurs, edema forms. It usually starts with the swelling of the legs. Edema can become generalized throughout the body. It is particularly troublesome when it fills the lungs. Here you are literally "drowning" in your own salt and water.

Edema is managed by the use of diuretic drugs, i.e. "water pills". Diuretic drugs cause increased elimination of salt by the kidneys. But the excessive use of diuretics can reduce the circulating blood volume and thus lower blood pressure to a harmful level. Thus, the overly aggressive use of "diuretics" is unwise.

How to maintain a salt balance through diet and the judicious use of diuretic drugs is extremely important in health and disease. Subsequent newsletters will elaborate on these important concepts.

I'll be in touch next month.

Your friend,

Thomas L. Petty MD
Professor of Medicine, University of Colorado Health Sciences Center
President, Snowdrift Pulmonary Conference