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THE PRI BULLETIN

A NEWSLETTER OF SCIENTIFIC RESEARCH FOR QUALITY MEDICAL CARE

*In dealing
with depressive
relapse we're
closer to finding
the cure than
ever before!*

Why Aren't I Feeling Better?

Alan L. Schneider, M.D., F.A.P.A.

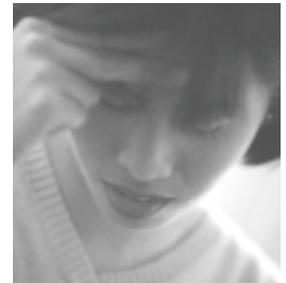
The main goal of the treatment of depressed patients is the complete elimination of all depressive symptoms. We as clinicians are no longer satisfied with just "partial" improvement.

It is recognized that there is a substantial subgroup of patients that are partial responders or non-responders. That is, they are treated with antidepressant medication with either partial improvement, or receive treatment with multiple trials of medications with no discernible improvement. Studies to date suggest that 30-46% of patients on antidepressants fall into one of these two categories. Of equal concern is the fact that almost 20% of depressed patients proceed onto a chronic course with symptoms that may last for years.

Before a patient is identified as a non-responder, several key questions must be

addressed. First, was the diagnosis correct? Second, did the patient receive an adequate antidepressant trial (e.g. a high enough dose for at least 12 weeks)? Lastly, was the right medication or combination of medications utilized? While these are by far not the only three questions to pose, they tend to be the most important ones when dealing with patients who seem not to respond to treatment.

Studies conducted on depressed patients suggest that about 10-20% of patients on antidepressants will relapse during their treatment. These patients are faithfully taking their medications, yet become depressed once again. Once referred to as "antidepressant



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Get Help with Quitting Smoking

Robert D. Linden, M.D.

Cigarette smoking is an issue for both the individual and for public health. The Centers for Disease Control (CDC) estimates that in 1999 there were over 46 million adult smokers in the U.S. During the years of 1995-1999, the CDC estimates that there were approximately 440,000 premature deaths each year in the U.S. from smoking.

While the serious health consequences of smoking have been widely known for years, smoking cessation remains an unrealized goal for many. It is estimated that, while 80% of smokers want to stop and each year 35% of smokers make an attempt to quit, only 5% are successful in unaided attempts to stop smoking.

Particularly troublesome is the rate of relapse in those who stop smoking. As Mark Twain is credited with saying "Smoking is easy to quit – I've done it a thousand times." Besides the cravings for tobacco, another bothersome aspect of smoking cessation is the propensity for weight gain.

At PRI, we have been selected to participate in an international study of a potential new medication, "Rimonabant," being investigated as an aid to smoking cessation. We will be investigating its ability to prevent relapse and prevent the weight gain associated with smoking cessation.

The study medication, Rimonabant, is the

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Alzheimer's Disease, PRI and Hollywood

Charles S. Wilcox, Ph.D.

"If you see a little less spring in my step, if your name fails to leap to my lips, you'll know why."

Charlton Heston

Ever since the disclosure that former President Ronald Reagan has Alzheimer's Disease (AD), the public awareness of and attention toward the battle against Alzheimer's has intensified. Through the work of the Alzheimer's Association thousands of people, including a substantial number of Hollywood celebrities, volunteer time, effort and money to assist both patients and caregivers. Several members of our research team are volunteers with the Los Angeles and/or Orange County Chapters of the Alzheimer's Association.

As members of the PRI research team, we are increasingly encouraged by the breadth and promise of new clinical research which is now underway. Indeed, since conducting our first anti-Alzheimer's research medication study in the 1970's, significant progress has been made in both the diagnosis and treatment of Alzheimer's Disease. Nonetheless, as family members with relatives and friends who have been faced with the challenges associated with Alzheimer's Disease, we are personally saddened by each and every newly diagnosed patient – while our professional resolve is only further strengthened.

Clearly, those feelings of sadness and resolve were felt by millions of people as Charlton Heston disclosed [in August of this year] that he too has now been diagnosed with AD. Political supporters and opponents of Mr. Heston were touched by his disclosure.

His *open letter to the world* was so consistent with the feelings that patients and their families share with us, we have decided to include an edited version here:

"For an actor," he said, "there's no greater loss than the loss of his audience. I can part the Red Sea, but I can't part with you, which is why I won't exclude you from this stage in my life."

"If you see a little less spring in my step, if your name fails to leap to my lips, you'll know why. And if I tell you a funny story for the second time, please laugh anyway."

"I'm neither giving up nor giving in but [this is] a fight I must someday call a draw. I must reconcile courage and surrender in equal measure. Please feel no sympathy for me. I don't."

"I want you to know that I'm grateful beyond measure. My life has been blessed with good fortune. I'm grateful that I was born in America..."

"I'm confident about the future of America [because] our country, our culture and our children are in good hands. I know you will continue to meet adversity with strength and resilience and come through with flying colors – the ones in Old Glory."

{For a complete reprint of Mr. Heston's *open letter to the world*, please do not hesitate to call our nearest office at 888.PRI.HOPE (774-4673).}

Continued from page 1. **Get help with quitting smoking**

first of a new class of medicines under development for possible treatment of obesity, nicotine and alcohol dependency. It acts to block a newly discovered receptor in the brain known as the cannabinoid (CB1) receptor. Additional evidence indicates that the CB1 receptors may play a role in nicotine and alcohol dependency.



Rimonabant is being studied as an aid to decrease nicotine cravings, help with smoking cessation, as well as prevent the weight gain that usually occurs when people stop smoking. A very important benefit of this new study at PRI is the inclusion of a counseling program developed at The Mayo Clinic to help with smoking cessation. The program, called "Smoke-Free and Living It," acknowledges the fact that becoming a non-smoker is a *process* rather than an act or simply a decision. It is a process in which people make new choices resulting in new changes that positively affect their lifestyle. At each visit a trained PRI member will spend time with the participant to help him/her develop a new habit – not smoking!

New and Improved PRI Website

Charles S. Wilcox, Ph.D.

For PRI Bulletin readers that refer friends and family members to PRI, we are pleased to inform you that our website was recently rebuilt to provide much more easily accessible information about who we are, what we do and how we do it here at PRI!

Briefly, here are some of the features and information that one can quickly and easily find at www.priresearch.com. As part of the “Company Profile” we provide information on the education, training and board certifications of our physicians [see *Key Personnel*], we have included a brief *Company History* and we have posted our *Privacy Policy*. If you click on “Experience” you will find a comprehensive list of PRI’s National and International grant *Sponsors*, as well as a chronological listing of nearly 200 scientific *Publications [1st]* and *Presentations [2nd]*. We have also included a very brief sampling of some of the *Testimonials* that prior study participants and/or their caregivers have submitted to us. Within the “Program Information” module one will find very quick and easy-to-use pre-screening checklists, a detailed *Patient*

Process and a brief description of just how easily the *No Cost Clinical Evaluations* can be arranged. We also have a section for “Newsletters” dating back to PRI’s Silver Anniversary Edition in 2000.

The “Locations/Contact Us” section provides people with easy-to-follow directions and a photo of each office so you’ll recognize our locations immediately upon your arrival. The “FAQs (Frequently Asked Questions)” section provides one with both background information on the Clinical Trial process, as well as definitions of the most commonly used Clinical Trial terms. Lastly, our revised “Home Page” now includes information about PRI’s *After Care* program as well as a *Free Offer*, which provides all prospective study participants – at PRI or anywhere else – with some key insights as to “How to Research a Research Site.”

Our goal has been to have a new website that is both easier to navigate and deeper in substance. As always, we look forward to hearing from you, whether it’s via the Internet, telephone, facsimile or, best of all, in person!

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The Professionals at PRI

Natalie N. Tran, R.N., M.S.N., N.P. is a member of our clinical research team at the Riverside office. She brings to the position fourteen years of clinical experience in both inpatient and outpatient settings. She completed her bachelor’s degree in nursing at Emory University in Georgia and came out to the West Coast to pursue her master’s degree in nursing at the University of California, Los Angeles (UCLA). Natalie greatly appreciates the uniqueness of working at PRI and using the primary-nursing as well as the team-nursing approaches to provide the best care for her patients. She also takes pride in being part of a clinical research team investigating new medicines, medicines that are not available today but will be in the near future. On a personal note, she is also a working mother of three children, ages nine, seven and three. She feels very blessed to have the family support to balance both her family life and her career as a research nurse.



Continued from page 1. Why aren't I feeling better?

poop-out syndrome,” the physiological underpinnings of this condition remain a mystery.

Whether there is no response, partial response, or relapse, all of these conditions warrant aggressive therapy. Typically the current antidepressant is discontinued and another substituted in its place. There are however a variety of other strategies employed such as combining two or sometimes three antidepressants, or at times utilizing “catalyst” style drugs to get the antidepressant working more effectively. These catalysts come from many categories, including medications to control blood pressure, Parkinson’s disease, thyroid problems, and certain types of stimulants. In dealing with depressive relapse we’re closer to finding the cure than ever before!

The PRI Bulletin is an official publication of the Pharmacology Research Institute and is intended for patients and friends of the Institute. PRI does not rent, sell or trade its mailing list with any other organization or company. Your personal information is kept completely confidential. Inquiries and changes of address may be directed to any one of the sites below.

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What's New at PRI?

Stop Smoking!

PRI has been selected to help conduct a 4,000 patient international study with a new truly novel smoking cessation research medicine. For persons smoking at least ten cigarettes per day [on average], who are really motivated to quit, this new program is an outstanding opportunity. Plus, to assist folks in their efforts to successfully stop – permanently, this program includes a “Smoke-Free and Living It” counseling component, specially designed by The Mayo Clinic. We’re conducting this study at our Newport Beach and Los Alamitos offices.



Senior Sadness/Depression

Do your “golden years” feel blue rather than golden? PRI has been awarded two studies for people who are at least 65 years of age and experiencing symptoms of depression for at least one month. Studies have shown, the longer one waits to seek treatment for depression the longer it can take to feel good again – if you feel sad, blue or depressed call us.

Migraine Headaches?

The progress that has been made in the diagnosis and treatment of migraine headaches is remarkable! PRI has been awarded several new grants for migraine headache treatment and/or prevention. For information on our newest anti-migraine studies please contact the office nearest to you!

Are You Stressed Out?

Almost 25% of the adult population in the United States will suffer from an anxiety disorder at some time in their lives. Why wait until developing the physical symptoms associated with anxiety [such as stomach problems and/or tension headaches] before taking action to correct the problem? We have new anti-anxiety research programs at all four locations. Don't wait and wear out from anxiety before you reach out and ask for help – call PRI today!

Depressed? How Long Will You Wait?

Do you suffer from mild or moderate depression? Have you had a loss of interest or pleasure in usually rewarding activities? Changes in your sleep or appetite? If yes, please call an office near you.

For a confidential and supportive [no cost] evaluation or information on any of these programs, please call the nearest office.

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