

Since 1975: There's more than hope, there's PRI!



THE PRI BULLETIN



A NEWSLETTER OF SCIENTIFIC RESEARCH FOR QUALITY MEDICAL CARE

PRI Celebrates 30 Years of Clinical Research!

by Charles S. Wilcox, Ph.D.

As a recipient of this newsletter you are quite likely someone who has participated in one of our research studies here at PRI and we want to begin by saying thank you! We truly appreciate your time and trust. As a direct result of your participation in one of PRI's studies, some remarkably beneficial new medicines have become available to literally millions of people all around the world!

Over these past 30 years we have completed nearly 600 scientific research programs involving thousands and thousands of study participants. While this newsletter lists most of the commercially available medications which you have helped us to evaluate, it is clearly an understatement of the sense of accomplishment we feel when we think of the markedly improved quality of life which has resulted from the availability of safer and/or more effective new treatments. Whether it was as a direct result of your

participation in a study, or perhaps as a result of our complimentary aftercare, we hope that you found the research experience to be positive for you.

When we conducted our first projects back in 1975 consent forms were one page in length and studies were extremely simplistic, both for participants and research teams as well! Today everything is more complex; however, the net results are an enhanced breadth of comprehensive evaluations with more personalized inquiry aimed at even better outcomes. While the overall research and approval process

continues to necessarily require many years [before new medicines are commercially available], the increased speed with which potential new medicines are being discovered is very exciting!

In parallel with the ever-quicken pace of new drug discovery, the rapidly widening research on genetics [or pharmacogenomics] encompasses tremendous promise for millions of people. Whether we are evaluating a



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Anxiety – Past and Future

by Robert D. Linden, M.D.

As PRI observes its 30th anniversary year, it is interesting to look back at some of the changes and progress made during this time in the treatment of anxiety. It is also of value to take stock in what may lie ahead, and what areas could benefit from new and better treatment options.

In reviewing a list of the nearly 600 clinical trials PRI has participated in, among the very first studies in 1975 and 1976, were clinical trials of anti-anxiety

medicines. These medications were then under development such as Xanax, Valium and Librium. Over the years, PRI has been involved in the study of many other medicines, which have been successful in offering new help in the treatment of anxiety. Among these medications are some more familiar names such as Paxil®, Zoloft®, Celexa®, BuSpar® and Prozac® — and in fact most of the medications are now available for the treatment of anxiety.

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Our Patients' Contribution

by Francine C. Echtenkamp, M.A.

Over the course of the past thirty years, PRI has been instrumental in the approval of numerous medications by the Food and Drug Administration (FDA). These medications are used to treat diseases, ranging from high blood pressure to dementia, depression to migraines, arthritis to indigestion and diabetes to anxiety. Below is a list of some of the approved medications that PRI has evaluated.



This list wouldn't be possible without PRI's patients. We would like to thank you, our current and past patients, their families, and their health care providers, for helping us to get to our 30th Anniversary and making it such a successful one.

Medications That YOU Helped Us to Evaluate

Abilify® (aripiprazole)
Acompli™ (rimonabant)
Ambien® (zolpidem)
Ansaid® (flurbiprofen)
Aricept® (donepezil)
Ativan® (lorazepam)
Axert™ (almotriptan)
Betoptic® (betaxolol)
Bextra® (valdecoxib)
BuSpar® (buspirone)
Capoten® (captopril)
Cardizem-SR® (diltiazem)
Celexa® (citalopram)
Clinoril® (sulindac)
Coreg® (carvedilol)
Cymbalta® (duloxetine)
DDA VP® (vasopressin)
Desyrel® (trazodone)
Diapid® (lypressin)
Effexor® (venlafaxine)
Effexor-XR® (venlafaxine)
Eldepryl® (selegiline)
Exelon™ (SDZ ENA 713)

Frova® (frovatriptan)
Gabitril® (tiagabine)
Halcion® (triazolam)
Haldol® (haloperidol)
Imitrex® (sumatriptan)
Lamictal® (lamotrigine)
Lexapro® (escitalopram)
Luvox® (fluvoxamine)
Maxalt® (rizatriptan)
Meridia® (sibutramine)
Mirapex® (pramipexole)
Motrin® (ibuprofen)
Namenda® (memantine)
Nimotop® (nimodipine)
Parlodel® (bromocriptine)
Paxil® (paroxetine)
ProSom® (estazolam)
Provigil® (modafinil)
Prozac® (fluoxetine)
Relpax™ (eletriptan)
Remeron® (mirtazapine)
Reminyl® (galantamine)

RevEyes® (dapiprazole)
Seromycin® (cycloserine)
Serzone® (nefazadone)
Slinequan® (doxepin)
Sonata® (zaleplon)
Stadol® (butorphanol)
Surmontil® (trimipramine)
Trental® (pentoxifylline)
Triavil® (perphenazine/amitriptyline)
Vasodilan® (isoxsuprine)
Vestra™ (reboxetine)
Vioxx® (rofecoxib)
Wellbutrin® (bupropion)
Wellbutrin-SR® (bupropion)
Xanax® (alprazolam)
Zantac® (ranitidine)
Zofran® (ondansetron)
Zoloft® (sertraline)
Zomig® (zolmitriptan)
Zyban® (bupropion)
Zyflo® (zileuton)
Zyprexa® (olanzapine)

Continued from page 1. **Anxiety – Past and Future**

During the past 30 years, the whole concept of “anxiety” has changed. Rather than there being one type of “anxiety” we now recognize a group of distinct disorders, which includes panic disorders, social anxiety disorder, Post-Traumatic Stress Disorders (PTSD), obsessive-compulsive disorders (OCD) and generalized anxiety disorders. Each of these anxiety disorders has its own set of symptoms, natural history/course, and

treatment options. For some of the anxiety disorders, such as panic disorders, excellent treatment options already exist, including the use of many antidepressant medications that can also help specific types of anxieties. For other anxiety disorders, such as generalized anxiety disorder, we are involved in studying new and potentially better medicines than those that are presently available.

potential new treatment for Alzheimer's Disease, ADHD, anxiety, depression, migraine headaches or smoking cessation, we here at PRI enthusiastically embrace the foreseeable importance and benefits of pharmacogenomics, including a potential role in the treatment of these and roughly 30% of all diseases. Furthermore, over these last five years we have appreciatively witnessed more than 95% of all study participants [here at PRI] voluntarily agree to participate in [confidential/anonymous] genetic testing. Together, we have made some very significant contributions to the medical arena since 1975. The reduced pain and suffering cannot be accurately measured, individual-by-individual...

As we look forward to these next few years our sense of prior achievement is immediately overshadowed by the hope and promise for what lies just ahead on the scientific horizon. In 2005 we already see very novel and completely new research medications for a wide array of problems, affecting both young adults and seniors as well [please see "What's New At PRI" on the last page of this newsletter]. Whether you are a prior

study participant, the health care provider for one or more of our study participants or perhaps a caregiver for someone previously involved in a study at PRI, we hope you know how much we appreciate your involvement. Indeed, whether large or small, every step forward over these past 30 years has been a combined effort involving you, our dedicated team members and, of course, our study sponsors. We remain committed to our premise of treating all study participants in the same manner as we would wish to be treated and we thank you – each of you – for your trust in us. Both personally and professionally, it has been an extremely gratifying experience for all of us to have been involved in so many important, successful and beneficial studies spanning over the past three decades; however, we honestly believe that the best is yet to come!



The Illness of Depression

by Ronald L. Warnell, M.D.



Most of us have felt sad or blue for a brief period of time. These feelings are often triggered by a stressful event. Fortunately, normal feelings and function return quickly. In contrast, people who develop a Major Depressive Illness find that the sad or blue feelings don't disappear but continue despite the person's efforts to return to a normal

routine or in spite of the admonitions of well-meaning people to not give in to the symptoms. As the symptoms continue beyond two weeks, the threshold for marking the beginning of a major depressive episode, additional symptoms are also present. These include lack of energy, decreased ability to concentrate, sleep disturbances, a change in appetite, decreased ability to enjoy everyday activities, an increase in negative thinking, and some times suicidal thoughts.

Major depression is common in the general population. In a 12-month time period, about 10% of adults will experience an episode of major depression. And approximately 17% of adults will have an episode of

major depression during their lifetime. If left untreated, depression can lead to considerable dysfunction in one's life. In fact, worldwide, major depression is the 4th leading cause of disability and it is estimated to become the 2nd leading cause of disability by 2020. Clearly, identifying depression and adequately treating it is vital.

While a brief bout of depressed feelings may respond to support from a friend or a professional, major depression requires more specific treatment. This includes various psychotherapies, which may be stressful, and/or antidepressant medications. Antidepressants are, as a whole, quite effective in reducing the symptoms of depression but not everyone responds to the medications that are currently available.

When a person suffers from major depression, research shows that brain functioning changes in many ways. These changes in brain functioning have opened the door to studying many different medications, which affect different brain systems. The ultimate goal of these studies is to produce effective antidepressants which, because they work on different systems, will help people who do not now respond to antidepressants. Another goal is to produce antidepressants with fewer side effects so that more people will be able to remain on them and receive adequate treatment.

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What's New at PRI?

Alzheimer's Disease

PRI has been positioned on the leading edge of Alzheimer's Research since the 1970s. Study participants here have gained the benefits of access to medications like Aricept, Exelon and Namenda years before they were available to the general public. We have several exciting new studies for 2005 and all of these projects allow study participants to continue taking their current anti-Alzheimer's medications, whilst [also] being able to become involved in these new programs.

Stressed Out? Anxious? Nervous?

Remember what it was like to feel calm or relaxed? All of us feel "stressed out" sometimes; if you feel tense, irritable, anxious or nervous most of the days of the week, most weeks, "toughing-it-out" may result in "wearing-you-out"! Effective treatment can remove the barriers which may be preventing you from enjoying life as much as you should or could... Life should be enjoyed not endured. If you suffer from these symptoms we invite you to call us for a no-cost, no-obligation, consultation at the PRI office nearest you.

Adult ADHD

For the millions of adults who suffered from ADD or ADHD as a child, being misunderstood and/or misdiagnosed was not uncommon. The advancements in both the diagnosis and treatment over these past fifteen years have been quite good. PRI Northridge has been awarded a new grant to evaluate a potential new medication for ADHD, with a new formulation developed specifically for adults with ADHD.

Smoking Cessation

Would you be surprised to learn that here in California, where good weather and "healthy living" are the hallmarks, we have the lowest per capita rate of smoking out of all 50 states? Nonetheless, millions of Californians continue to smoke cigarettes and most have tried to quit, repeatedly. PRI's Los Alamitos office has been selected to conduct a new smoking cessation study with a new class of potential anti-smoking medication. Plus, this new study includes an important smoking cessation counseling component to assist all study participants with their efforts to *stop smoking!*

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

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