



**Pharmacology  
Research  
Institute**

# The PRI Bulletin

**A Newsletter of Scientific Research  
for Quality Medical Care**

Since 1975: Convenient, Personal and Professional!

Silver Anniversary Issue

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## PRI Celebrates 25 Years in Research

### A Letter from the Executive Director

By Charles S. Wilcox, Ph.D.

All of us here at Pharmacology Research Institute (PRI) are pleased to commemorate twenty-five years of involvement in the field of clinical research. We have seen some remarkable advancements since 1975 and we are truly excited about the promise for even better medicines in the near future!

Over the past 25 years, we have completed well over 400 scientific programs involving more than 13,000 study participants. We never envisioned that our team would grow to the extent where we are now providing services at four sites, to people from Ojai to Indio. Our masters level nurses and board-certified physicians have extraordinary competence, experience and empathy.

We feel most fortunate to be able to improve the quality of life for so many people, by providing all of our services to participants in a caring and confidential manner, and always "at no charge."

The results of PRI's research programs have been cited in more than 200 scientific publications and presented at scientific meetings in Asia, Australia, Canada, the Caribbean, Europe, Mexico and, of course, throughout the United States. It is gratifying to be entrusted (by patients, grant sponsors and various government agencies) with some of the newest and most promising potential new treatments years before they are

available as marketed products. PRI has internationally recognized expertise in the research arena consistently positioning the Institute on the leading edge.

We are indebted to **you**, the thousands of study participants, caregivers, referring medical professionals, family members and friends who have so strongly supported our research programs. We pledge to continue directing our professional energies toward medical advancements, which translate into meaningful improvements in one's quality of life. Thank you for your trust and involvement. We are very optimistic that this new millennium will introduce many of the most beneficial medications ever envisioned—and soon!

### Just How Good Are PRI's Physicians?

The Washington, D.C.-based Center for the Study of Services [CSS]--- a non-profit consumer-research organization that specializes in providing information to help people make informed health care decisions for themselves, recently addressed a similar question. The results of the CSS survey have been categorized as, "A compendium of OC [Orange County] physicians who are most respected by their peers." CSS contacted more than 20,000 physicians in both Orange and

Los Angeles Counties as part of their research efforts. Based upon this research, the January 2000 edition of *Orange Coast Magazine* ran a feature article entitled "TOP OC DOCS: The Physicians your Doctor Respects." All of us here at PRI were very pleased to see Don F. DeFrancisco, M.D., Ph.D. listed as one of only three psychiatrists within the article.

A member of the PRI research team since 1975, Dr. DeFrancisco is board-certified in both adult and geriatric psychiatry. The patients and staff here at PRI have always had the utmost respect for Dr. DeFrancisco's education, experience and clinical acumen; it's not surprising to read that

he is so highly regarded by his peers in the medical community as well. We rely heavily upon his expertise and we are proud to work with him.

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## PRI Would Like To Thank You!

By Alicia A. Puppione, R.N., M.S.N., C.S.

Over the course of the last twenty-five years, PRI has been instrumental in the Food and Drug Administration (FDA) approval of many medications.

These medications are used to treat

diseases, ranging from high blood pressure to dementia, depression to migraines, arthritis to indigestion and diabetes to anxiety. For your information, below is a list of some of the approved medications with which PRI has been involved.

We would like to take this opportunity to thank you, our current and past patients, their families, and their health care providers, for allowing us to have such a successful Twenty-fifth Anniversary.

### Medications That You Helped Get Approved

Ambien® (zolpidem)

Ansaid® (flurbiprofen)

Aricept® (donepezil)

Ativan® (lorazepam)

Axert™ (almotriptan)

Betoptic® (betaxolol)

BuSpar® (buspirone)

Capoten® (captopril)

Cardizem-SR® (diltiazem)

Celexa® (citalopram)

Clinoril® (sulindac)

Coreg® (carvedilol)

DDAVP® (vasopressin)

Desyrel® (trazadone)

Diapid® (lypressin)

Effexor® (venlafaxine)

Effexor-XR® (venlafaxine)

Eldepryl® (selegiline)

Relpax™ (eletriptan)

Exelon™ (SDZ ENA 713)

Halcion® (triazolam)

Haldol® (haloperidol)

Lamictal® (lamotrigine)

Luvox® (fluvoxamine)

Maxalt® (rizatriptan)

Meridia® (sibutramine)

Motrin® (ibuprofen)

Nimotop® (nimodipine)

Parlodel® (bromocriptine)

Paxil® (paroxetine)

Prosom® (estazolam)

Prozac® (fluoxetine)

Remeron® (mirtazapine)

RevEyes® (dapiprazole)

Seromycin® (cycloserine)

Serzone® (nafazadone)

Sinequan® (doxepin)

Sonata® (zaleplon)

Stadol® (butorphanol)

Surmontil® (trimipramine)

Trental® (pentoxifylline)

Triavil® (perphenazine/amitriptyline)

Vasodilan® (isoxsuprine)

Wellbutrin® (bupropion)

Wellbutrin-SR® (bupropion)

Xanax® (alprazolam)

Zantac® (ranitidine)

Zofran® (ondansetron)

Zoloft® (sertraline)

Zomig® (zolmitriptan)

Zyflo® (zileuton)

Zyprexa® (olanzapine)

Vestra™ (reboxetine)

## Social Anxiety Disorder: aka Disabling Shyness

By Robert D. Linden, M.D.

While everyone experiences shyness up to a point, a surprisingly large number of people experience disabling anxiety in social situations. When people suffer with extreme shyness, they might have Social Anxiety Disorder, previously called Social Phobia. This anxiety about being scrutinized or judged critically by others, can lead to avoidance of social situations, or situations where one may be “in the spot light.”

A person with Social Anxiety Disorder might:

1. Avoid work promotions, if it involves speaking in front of others.
2. Be unable to go to restaurants, church, or be in public places.
3. Significantly limit their social activities,

or endure social contacts only with great anxiety.

In a recent survey, Social Anxiety Disorder was found in almost 15% of the general population. Social Anxiety Disorder typically is a condition that begins in childhood and persists for years. Because it is so common, and has major impact on quality of life, there is a major research effort going on looking for new treatments.

The typical medicines for anxiety, such as Valium®, Xanax®, Ativan®, are sometimes used short-term. Over a longer period of time, people can become “tolerant” of this type of medicine and need more and more to have the same relief of anxiety. Recently the FDA approved an

antidepressant medication, Paxil®, for longer-term treatment of Social Anxiety Disorder. Ongoing research is evaluating additional medicines that can safely be used over longer periods of time.

As part of this new research, PRI is currently studying medicines that are already available by prescription for the treatment of Depression. We are also researching promising new medicines under development, which involve unique new approaches to treating Social Anxiety Disorder. New and better treatments for this common and significant disorder are needed. We hope to continue to be a part of this advance in medicine with the clinical research studies being pursued at PRI.

## Preventing Recurrent Depression — So Feeling Bad Doesn't Get Worse

By Jon F. Heiser, M.D.

Until recently, healthcare professionals believed that major depression was a completely reversible illness. Like the common cold, you recovered from a major depression completely and were no different than before. Furthermore, healthcare providers believed people had only one major depressive episode in their lifetime.

According to recent research, we now know lifetime recovery from depression is rare. Rather than resembling the common cold, major depression seems more like other chronic illnesses such as arthritis, with acute “flare-ups” followed by a period of dormancy with residual symptoms. Subsequent flare-ups may result in a greater number of residual symptoms. Residual defects, such as a loss of enthusiasm for life or a subtle change in personality, may remain after the acute depression subsides. These residual defects tend to be resistive to treatment and increase in both number and severity after each acute depression.

The good news is that health care providers can often prevent recurring depression by maintenance antidepressant therapy - the continued use of antidepressant medication and psychosocial therapy after the resolution of all depressive symptoms. Until recently, it was standard to advise a person to take antidepressant medication only as long as their symptoms persisted or a few weeks more “for good measure.” We now know that when a person's first depression responds well to an antidepressant medication and appears cured, they have a 50 percent chance of relapsing if the medication is discontinued in less than a year. Treatment for depression now focuses on prevention of acute episodes and maintenance of a person's quality of life.

Research suggests that a year of treatment is sufficient to prevent immediate relapses. If the person does not continue therapy for a year, they are more likely to relapse. If you have been depressed, you are likely to have a second

major depression. After three episodes of depression, it is almost certain more depressions will follow. Each succeeding depression tends to last longer; be harder to treat; and have more symptoms associated with it. With each reoccurrence of depression, the length of preventative treatment increases. People who have had three or more bouts of depression should remain on maintenance antidepressant medication or in psychotherapy for their lifetime.

With the antidepressants and mood stabilizing medications now available, lifetime treatment is safe, effective and well tolerated. Most importantly, by preventing future depressions, “down time” is diminished and the development of residual defects, which may significantly impair the quality of life of the person and those around them, may be minimized or totally prevented.

## What's New at PRI?

### Social Anxiety Disorder

In the summer of 1999, the cover story in U.S. News & World Report was *How Shy Is Too Shy?: One out of eight Americans suffers from Social Anxiety. Now there's help.* The article described a condition which affects millions of Americans—people who are so shy or timid that encounters with others are viewed as a source of overwhelming dread. Sometimes referred to as Social Phobia, studies have demonstrated that medications can be very beneficial for people of all ages who suffer from Social Anxiety Disorder. PRI has studies for Social Anxiety Disorder at each of its offices; for more details please call the office nearest to you.

### Depression

PRI has received funding to conduct several exciting new research studies in Y2K, with some of the most unique and potentially promising antidepressants ever developed. We have programs forthcoming for children and adolescents, as well as adults ranging in age from 18 to 99. We have projects for people with recurrent depression and “mixed depression with anxiety symptoms.” Effective treatment for depression makes a substantial difference in one's life—personally and professionally—as well as for those around them.

### Migraine Headaches

The year 2000 will include at least two very unique migraine studies for PRI: one for the prevention of migraine headaches, also known as migraine

prophylaxis, and one for children and adolescents suffering from acute migraine headaches. To learn more about either of these projects, please call us.

### Anxiety or Nervousness?

The lifetime prevalence of Generalized Anxiety Disorder (GAD) is somewhere between ten and eighteen million people... in the United States alone! A GAD patient often utilizes health care professionals—especially for stomach complaints—more often than the average person. The ability to really enjoy life to its fullest can be markedly enhanced when GAD has been treated successfully. PRI has been awarded a grant to evaluate a novel new potential anti-anxiety medication and patients may participate at any one of our offices.

For more information on PRI's programs for Depression, Migraine Headaches, Anxiety or Social Anxiety, please call the nearest office.

*The PRI Bulletin is an official publication of the Pharmacology Research Institute and is intended for patients and friends of the Institute. Inquiries and changes of address may be directed to one of the site coordinators (listed below).*

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