

## What's in the Parkinson's Pipeline?

By David G. Standaert, M.D., Ph.D.

If you are a person living with Parkinson's disease (PD), you may be wondering if new and better medications will be available in the near future and how they may help you.

It is difficult to predict which treatments in trials will be approved for the market, but we can assess the possibilities by looking at the "pipeline" — the process by which we find new treatments for Parkinson's. Currently, there are two categories of therapies, symptomatic and neuroprotective, which are making their way through the PD pipeline.

The first category, symptomatic drugs, treats both the motor and nonmotor effects of Parkinson's. There are already several treatments for Parkinson's symptoms and these have made a tremendous difference in the lives of many who live with PD. However, these medications have side effects and do not address certain symptoms — for example, none of them help with the

common problems of fatigue, constipation or balance. So, one goal is to find better symptomatic drugs.

Second, there is excitement about the possibility of developing neuroprotective treatments, those that would slow or prevent the progression of Parkinson's disease. So far,

no therapies have been proven to be neuroprotective and most of the candidates are in the early stages of the development process, years away from approval.

### The Drug Development Process

Scientists find new medications in one of two ways. One way is to test the efficacy of compounds that have already

been approved by the US Food and Drug Administration (FDA) for other diseases. The other is to theorize a new pathway that may affect PD, and then to find a new compound to target it. Under both approaches, the therapy must travel through a multi-step process before it can be approved for the market.

The first phase of this process is



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## NEWS IN BRIEF

### Dopamine Agonists Linked to Impulse Control Disorders in PD

People with Parkinson's disease (PD) who take dopamine agonists are about three times more likely than those who do not to develop certain compulsive behaviors, according to a study in the May issue of *Archives of Neurology*.

In the largest study to date of impulse control disorders (ICD) in PD, researchers led by Daniel Weintraub, M.D., at the University of Pennsylvania School of Medicine, interviewed more than 3,000 people with Parkinson's being treated at 46 centers in the United States (US) and Canada. Nearly all of the participants were taking levodopa and/or a dopamine agonist. Dopamine agonists are a class of Parkinson's medications that include pramipexole (Mirapex®) and ropinirole (Requip®).

Using standardized assessment tools, the researchers identified impulse control disorders in 13.6 percent of participants. Earlier studies on dopamine agonists and ICD had focused primarily on pathological gambling. The new report; however, found that four impulse control disorders occurred at similar rates: problem gambling (5 percent),

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## PDF Announces Research Awards Totaling \$1.2 Million

See page 3 for full story

## Thank You for Participating in Parkinson's Awareness Month 2010!

Your efforts during the month of April helped to raise awareness around the country and around the world.

- **PDF**, because of your support, **raised over \$60,000** through the Parkinson's Awareness Month Challenge. \$50,000 of this total was matched by PDF's board for a total of \$110,000. Proceeds will fund a PD researcher in 2011.
- Over **1,400** of you browsed through the **Parkinson's Awareness Month Toolkit** to find tips for raising awareness in your neighborhoods.
- **30 of 50 states**, 27 counties and 28 cities around the US, and the US Senate **officially proclaimed April** as **Parkinson's Awareness Month**, because of your advocacy efforts.
- Over **1,600** of you wore the **Fight to Win T-Shirt**, designed by the winner of the 2010 T-Shirt Contest.
- **200** of you decided to **Quilt for Parkinson's**, joining 400 others whose quilt panels will be displayed at the World Parkinson Congress in Scotland this September to show the world the impact of Parkinson's.
- **1,000** of you became **new fans of PDF on Facebook** — sharing your stories with the PD community.

We can't forget the countless others of you, **in communities around the US**, who have hosted events, displayed posters in your local community centers and more. Thank you for your efforts in raising the visibility of Parkinson's around the US and around the world!

### Arizona Mom Wins PDF's Parkinson's Awareness Month T-Shirt Contest



Heather Hinrichsen's *Fight to Win* design for Parkinson's Awareness Month was featured on a t-shirt that has now been worn by hundreds of people throughout the US. She received over 800 of 1,900 votes in the PDF T-Shirt Contest, beating out four other finalists. Ms. Hinrichsen, who lives with young-onset Parkinson's disease (PD), says "I hope that by sharing my story, people will realize that Parkinson's is not just an older person's disease. It can strike younger people. Through the t-shirt, I want to spread the message to everyone to fight PD. I plan to fight until I win — I have PD, but it doesn't have me."

### PR Veteran Lobbies for Parkinson's Awareness Month in Two Cities



After being diagnosed with Parkinson's less than two years ago, California resident and former public relations professional Terry Shapiro found new meaning in April. So this year, she and friend Steven Kimbrough planned a night of comedy for Parkinson's which took place on April 3 at Bluebird Café in Culver City, CA. It gathered family and friends, and garnered media coverage. Ms. Shapiro also lobbied Whittier Mayor Bob Henderson and Culver City Governor Andrew Weissman to recognize Parkinson's Awareness Month in their cities. She says, "The more that the public understands the challenges of Parkinson's and the more that individuals raise awareness, the easier it will be for researchers to make progress in finding the causes of Parkinson's."

### Artist Brings Passion for Martinis and Music to Parkinson's Quilt Project



Larry Schneider Jr., used his talents during April to contribute to PDF's Parkinson's Quilt Project. Mr. Schneider, 40, has lived with PD since the age of 27. He has been an artist for his entire life, working in college as a free-hand illustrator and now as a computer graphic artist. He put his skills to use by creating two quilt panels. The first, entitled, "Park N Sons Martini Bar and Lounge (Always Shaken, Never Stirred)," is a light-hearted take on his PD. The second, a tribute to music, features an image of him playing bass guitar. He says, "Although Parkinson's has affected my life, I am still a husband, a father and an artist. I feel positive about anything I can do to help raise awareness about Parkinson's." Mr. Schneider's quilt and those of 600 other individuals will be displayed at the World Parkinson Congress in Scotland in September.

At PDF, we now recommit ourselves to working every month of the year to not only raise awareness of Parkinson's, but **to fund the best research to understand, treat and one day ... cure it.**

## 2011 Research Awards Total \$1.2 Million

The Parkinson's Disease Foundation (PDF) is pleased to announce awards totaling \$1.2 million through its external grants program — \$700,000 to support first-year studies of eight research scientists, and \$500,000 to support a second year of funding for 2010 grantees who have demonstrated a successful first year of research. The eight newly-selected grant recipients were chosen from a group of 150 applicants by a review committee that was chaired by Robert Burke, M.D., and included Stanley Fahn, M.D., PDF's Scientific Director.

The awards are given through two key research programs — the International Grants Program, which awards grants for up to two years at \$75,000 a year and the Research Fellowship Grants Program, which awards one-year grants of up to \$55,000. The programs seek to fund “high-risk/high-reward” research that may have a significant impact upon Parkinson's science; and, in the case of the fellowship program — to support scientists early in their careers.

### Grantee Profiles

These concepts are evident in the work of this year's awardees, including Leo Pallanck, Ph.D., of the University of Washington and James Maas, M.D., Ph.D., of the University of California.

Dr. Pallanck will be using his research grant to investigate the potentially protective effects of tobacco on Parkinson's. Dr. Pallanck says that while earlier studies have been promising, we still do not know which of the many chemicals within tobacco account for its suggested capacity to protect against PD — not to mention that PD cannot be treated with tobacco directly because of dangers associated with its use. In his previous work, Dr. Pallanck has found two important clues: first, tobacco extract

protects neurons in fruit fly models of Parkinson's, and second, it appears that nicotine is not the protective factor. Now, he will dig deeper to find the exact chemical component of tobacco that may save neurons in PD, which he says “in turn, may one day lead to the identification of a potential treatment for Parkinson's.”

While Dr. Pallanck focuses on a potential therapeutic pathway for PD, Dr. Maas will be conducting research into one of the most basic elements of Parkinson's: the role of dopamine. He notes that this neurotransmitter — the one whose loss leads to Parkinson's symptoms — is poorly understood to this day.

When dopamine is released from a neuron, it typically travels in one direction to its target destination. Dr. Maas will explore dendritic dopamine release, a process in which dopamine is released in the opposite direction. This unconventional mechanism may affect how much dopamine is released in the brain. A better understanding of this fundamental aspect of the basic biology of neurons may shed light on how the brain controls muscle movement — and how the loss of that control develops in the course of Parkinson's.

### Conclusions

Dr. Fahn comments as follows, “The work of Drs. Pallanck and Maas and this year's other grantees is replete with original ideas for improving our understanding of Parkinson's at the most basic levels, and finding new approaches to treating it. We need to be sure that the best talent is attracted to the challenge of solving Parkinson's and helping those who live with it. Funding fellows and young scientists, an area in which PDF leads, is the best way to make this happen.”

*In FY2010, PDF contributed more than \$5.5 million to support Parkinson's research.*

## PDF 2011 External Grant Recipients

### International Research Grants

Tobias Kurth, M.D., Sc.D.,  
and Robert Y. L. Zee, Ph.D., M.P.H.  
*Brigham and Women's Hospital*

Leo J. Pallanck, Ph.D.  
*University of Washington*

David Park, Ph.D.\*  
*University of Ottawa*

Hardy Rideout, Ph.D.\*  
*Biomedical Research Foundation  
of the Academy of Athens*

Antonio Strafella, M.D., Ph.D.,  
F.R.C.P.C.\*  
*Centre for Addiction and Mental Health*

Christian Wider, M.D.,\* and Matthew  
J. Farrer, Ph.D.  
*CHUV Lausanne and Mayo Clinic  
Florida*

Cyrus Zabetian, M.D., M.S.\*  
*University of Washington*

### Research Fellowship Grants

Thomas Durcan, Ph.D.  
*McGill University*

Sonia George, Ph.D.  
*University of Minnesota*

James Maas, M.D., Ph.D.  
*University of California at San  
Francisco*

Khurshida Shahidullah, Ph.D.  
*Weill Cornell Medical College*

Ryan Walsh, M.D., Ph.D.  
*University of Alabama at Birmingham*

Maria Xilouri, Ph.D.  
*Biomedical Research Foundation  
of the Academy of Athens*

*\*Denotes second year of funding.*

Learn more at:

[www.pdf.org/en/results\\_funded](http://www.pdf.org/en/results_funded)

## Legal Issues and Parkinson's: Planning for Long-Term Health Care

By Janna Dutton, J.D.

Everyone benefits from planning ahead for legal issues and health care. Planning ensures that your needs and preferences will be met in the case of an unexpected illness, disability or chronic disease like Parkinson's disease (PD). If you or a loved one is already living with Parkinson's, the process is especially important to your lifestyle and peace of mind.



Janna Dutton, J.D.

There are several elements to contemplate when planning for your future with Parkinson's. Among the most important are making provisions for long-term care (including Social Security and Medicare); designating an agent for your health care; and appointing someone to execute power of attorney for your finances and a living trust. This article begins a four-part series covering each of these issues, beginning with long-term care.

### What is Long-Term Care?

When most people think of long-term care, they think of a nursing home (now called a skilled nursing facility). But the concept also encompasses such support systems as assisted-living communities and the in-home aides whom you may bring in to help with personal needs such as dressing, shopping, eating and cooking. It can also include community services, such as Meals-on-Wheels. You may need one or more of these services, depending upon when you were diagnosed, the rate at which your Parkinson's disease is progressing, and your preferences. Some people are happy in an assisted-living community; others prefer to stay home and bring in home health aides.

Once you have decided upon your preferred plan for long-term and other medical care, you can estimate how much it will cost and assess how to pay for it (see examples below).

### How Can You Pay for Long-Term Care?

#### Medicare

Medicare — whether it is the general policy, or supplemental policies and/or the drug benefit — is one of the most important resources that a person with Parkinson's has for his or her health care. A federal insurance benefit, it is not tied to assets and income,

**“Looking into long-term care now ... can help you to take control of your Parkinson's care and your life in the future.”**

but requires that you be 65 or older or determined disabled under the rules of the Social Security Administration (see section on page 7) and have worked a sufficient number of quarters paying into the social security system. If you are under age 65 and seeking Medicare due to disability, you must undergo a two-year waiting period from the date of eligibility prior to receiving free hospital insurance coverage (Medicare Part A). Once the two-year wait period is complete, you are then eligible to enroll in Medicare Medical Insurance (Part B) by paying a monthly premium.

Medicare A and B cover doctor's

visits, lab tests, hospital stays, physical, occupational and speech therapy and more. Note that there are usually deductibles associated with such services. Typically you can purchase supplemental insurance to cover these costs.

The biggest gap in Medicare coverage is the cost of custodial long-term care, meaning nursing home care or in-home assistance with activities of daily living. It does cover, on a short-term basis (typically up to 100 days) skilled care in a nursing facility, when the need for such care follows hospitalization.

Parkinson's medications can be costly. If you are enrolled in Medicare A and B, you can also join a Medicare Advantage Plan (Part C) and a Medicare Prescription Drug Plan (Part D). Part C plans provide additional coverage but may also require an additional premium. The drug plan has also a large gap known as the “donut hole.” What this means is that once you have reached an annual spending limit — typically around \$2,700 — coverage stops, and you are responsible for the cost of prescription drugs for the rest of the year until you meet your plan's designated cap. Then, Medicare begins paying again. In some cases, the plan will cover generic drugs, but not brand-name drugs.

#### Private Health Insurance

The next step is to review your options for health insurance coverage. These may include insurance through your employer, if you are still working. If you have insurance, find out whether your policy covers the services you may need. Pay attention to gaps — for example, does your policy cover in-home or nursing care? If you are not working or are not enrolled in a group policy, what are your choices? One possibility may be to continue your employer's health care plan at your own expense. This option is referred to as COBRA, named for the Consolidated Omnibus Budget Reconciliation Act. It may allow you to extend your insur-

ance for up to 36 months after you leave your place of employment.

#### Private Funds

Next, review your assets. Do you have income to help pay for your health care? What about assets such as savings accounts, stocks, bonds and pensions? Do you have family members with whom you can live or who will be able to help you pay for care?

If you have the resources, you may want to look into purchasing Long-Term Care Insurance, which is designed to cover many expenses, including nursing home care. Many of these policies are not currently available for people living with PD, but there may soon be a new program available under the health care reform law for anyone who is employed. Learn more at [www.kff.org/healthreform/upload/8069.pdf](http://www.kff.org/healthreform/upload/8069.pdf).

#### Medicaid

If you have very few resources, you may be eligible for Medicaid. Medicaid will always cover skilled nursing facilities and, depending upon your state's program, may cover assisted-living facilities and in-home programs. If it is likely that you will need long-term care, and you have no source of paying for it other than Medicaid, start planning right now. Medicaid is complex. You will need to research what it covers in your state and take steps that will protect your assets. We will discuss this subject in detail in the fourth article in this series.

#### Social Security Disability

Another resource that can help some people with PD to pay for long-term care and health care insurance is Social Security Disability Insurance (SSDI). To be eligible, you must: 1) have paid into Social Security for a requisite number of quarters (usually 40, but this number is reduced for younger individuals); 2) demonstrate that you are unable to engage in substantial gainful employment because you are medically impaired; and 3) show that your impairment is expected to last at

least 12 months.

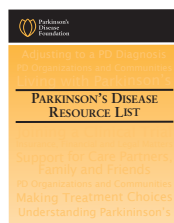
If you meet these requirements, you should qualify. The Social Security Administration uses what is called the Listing of Impairments for Parkinson's and other diseases. It determines the level of Parkinson's symptoms that a person has to prove to be considered disabled enough in order to be prevented from doing any gainful activity. In brief, you must have: "significant rigidity, bradykinesia (slow movement), or tremor in two extremities, which, singly or in combination, result in sustained disturbance of gross and dexterous movements, or gait and station." The benefit you can receive is based on your earnings record. Once you have been determined disabled for SSDI purposes for 24 months, you can then begin receiving Medicare benefits.

#### Making Your Plan

Looking into long-term care now will help to ensure that your wishes are met. It can help you to take control of your Parkinson's care and your life in the future. In the Fall issue of *News & Review*, look for part two of this series, which will cover tips for designating a health care agent.

*Ms. Dutton is an Eldercare Attorney with Janna Dutton & Associates. She recently presented this topic at one of PDF's PD Expert Briefings. View it online by visiting [www.pdf.org/en/parkinson\\_briefing\\_legal](http://www.pdf.org/en/parkinson_briefing_legal).*

## FIND LEGAL RESOURCES



To find organizations and websites that can help you learn more about long-term care and other important issues, browse the online *Parkinson's Disease Resource List* or order your free print copy today.

[info@pdf.org](mailto:info@pdf.org) | [www.pdf.org/en/resourcelist](http://www.pdf.org/en/resourcelist)

#### News In Brief

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compulsive sexual behavior (3.5 percent), compulsive shopping (5.7 percent), and binge eating (4.3 percent). The researchers identified two or more disorders in 3.9 percent of participants.

People taking both levodopa and a dopamine agonist had the highest rate of impulse control disorders, 17.7 percent. These disorders were identified in 14 percent of people treated only with a dopamine agonist, and in 7.2 percent of those taking levodopa alone. There was no difference in rates between people who took pramipexole and those who took ropinirole.

Patterns of impulse control disorders among study participants mirrored those in the general population. Those who developed the disorders tended to be younger than those who did not. They also were less likely to be married, and more likely to smoke cigarettes and to have a family history of gambling problems. Men were more likely to develop compulsive sexual behavior, whereas women were more likely to be diagnosed with compulsive buying and binge-eating disorders. The researchers also found that participants living in the US developed problem gambling and compulsive buying behaviors more often than those living in Canada.

Compulsive behaviors among people with PD who are treated with dopamine drugs are distressful and potentially harmful. Researchers increasingly recognize the high prevalence of these behaviors in people with PD. If you or your loved one with Parkinson's experiences compulsive behaviors, such as gambling, over-eating, shopping, or excessive Internet use, it is important to discuss these issues with your treating physician.

#### Deep Brain Stimulation Provides Added Benefit to Medication

Treating advanced Parkinson's disease (PD) with both deep brain stimulation (DBS) and drug therapies improves quality of life more than drug therapies alone for eligible individuals, according to a report in the online April issue of *The Lancet Neurology*.

Researchers led by Adrian Williams,

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**PD Pipeline**

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called preclinical research. During this stage, a new compound is discovered and tested on model systems (meaning systems other than humans) that replicate some aspect of PD — from simple systems, using a Petri dish or test tube; to more complex models, like yeast and fruit flies; and eventually to very complex systems, such as mice and nonhuman primates.

Once a potential new drug has been “validated” through animal testing, it may move to the phase where it needs to be tested on humans, called clinical trials. Clinical trials typically proceed through four phases. In a Phase I trial, a drug is tested for safety only, among a small group of 20 to 80 people. A Phase II trial enrolls between 100 and 300 people and while continuing to assess the safety of a medication, now tries to get some idea of whether it is likely to be effective in treating Parkinson’s. A Phase III trial typically enrolls between 300 to 3,000 participants at multiple sites. Phase III is the definitive study in which a potential drug is proven safe *and* effective — and therefore eligible for approval by the FDA — or it falls by the wayside. After a drug is approved and is used by people with PD, a Phase IV “post market” trial may be conducted to find out more about how it works in large populations, how it interacts with other drugs, or if it has additional uses.

**The Current Pipeline**

The following is an assessment of the state of the current Parkinson’s pipeline. It includes potential treatments, beginning at the end of the pipeline (Phase IV), and traveling back to the earliest studies (preclinical). Most of the information is drawn from [www.PDtrials.org](http://www.PDtrials.org). Please note that each PD medication listed below may be referred to by one or more of its three names. When a drug is in the early stages of development, it has only

a chemical name, consisting of letters and numbers. Later on, the medication will be given a generic name. And once it is approved, it will acquire a brand name. For example, a current Parkinson’s medication was first referred to by its chemical name, TVP-1012. It then developed the generic name rasagiline, and is now known primarily by its brand name, Azilect®.

**Phase IV: Post Market Studies**

Some drugs that have already been approved by the FDA, either for use in Parkinson’s or for another condition, are now being studied to see if they might work for additional Parkinson’s symptoms. For example, the drug **rasagiline** was originally approved to treat Parkinson’s — both in the early stages (used alone) and in the later stages (as an adjunct to levodopa and other therapies). Today, it is being studied for its effects when given in combination with dopamine agonists.

Then there is **naltrexone** (brand names ReVia®, Vivitrol™ and Depade®), which is currently used to treat addictions, but which scientists suspect may be useful for treating impulse-control disorders in PD, such as compulsive gambling or shopping. **Rivastigmine** (Exelon®), a drug approved for the treatment of PD dementia, is being studied for treatment of additional cognitive symptoms. **Lubiprostone** (Amitiza®), a gastrointestinal medication, is being evaluated for its efficacy in alleviating constipation. Finally, **donepezil** (Aricept®), originally indicated for the treatment of Alzheimer’s,

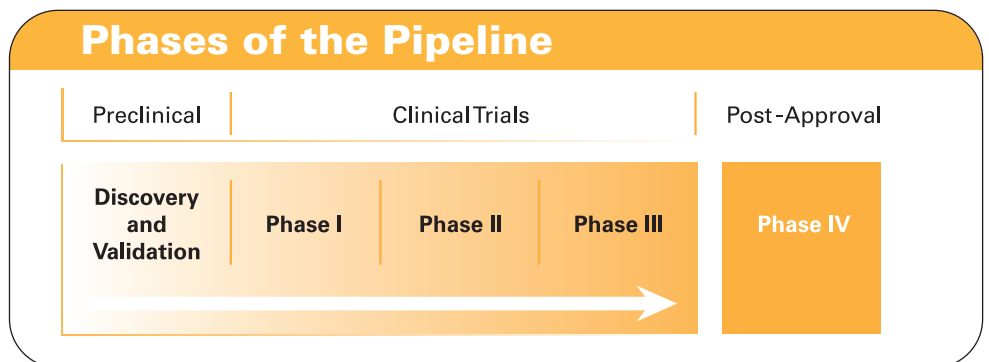
is under investigation for the treatment of dementia in Parkinson’s.

**Phase III: “Pivotal” Studies**

In Phase III trials, the “make-or-break” stage of the clinical research process, most of the candidate treatments are symptomatic. Few of the neuroprotective therapies have made it this far. The symptomatic therapies being studied include several reformulations of levodopa, which aim to address problems associated with current formulations, such as wearing-off — that is, when the time during which the drug is effective becomes shorter. The newer medications are designed to provide more “on-time” for people with PD and simplify a person’s medication schedule by requiring less frequent dosages throughout the day.

One example is **IPX066**, which comes in pill formulation. It is an extended-release medication — that is, it has a mechanism that releases the compound slowly in the bloodstream throughout the day rather than all at one time, thus requiring a person to take fewer pills. Another therapy under study is **intraduodenal levodopa** (Duodopa®), which is a gel form of levodopa that is pumped directly into the intestines. Its goal is to provide continuous amounts of levodopa to avoid wearing-off. A third medication, **safinamide**, which is in the class of medications called MAO inhibitors, is also designed to increase “on-time” and decrease “off-time” associated with levodopa in the middle

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# SPOTLIGHT

## on Research

### Supported by PDF

Amie L. Peterson, M.D.

Can something as basic as taking your vitamins ease some of the effects of Parkinson's disease (PD)? This is



Dr. Amie L. Peterson

the question behind the research of Amie L. Peterson, M.D., a movement disorders fellow at Oregon Health Sciences University in Portland, OR. She is looking at vitamin

D — found as a nutrient in foods such as fish and milk, in dietary supplements, and most importantly, created by the skin with sun exposure — as a potential therapy to improve the quality of life for people with Parkinson's.

Dr. Peterson's research is funded under the Parkinson's Disease Foundation (PDF)-Parkinson Study Group (PSG) Mentored Research Award, which expects its recipients to focus on "patient-centered research." Dr. Peterson emphasizes that addressing falls and balance is vital to the safety and well-being of people with PD. These problems are not just bothersome, but also dangerous; in fact, they are a major cause of injuries and mortality in later-stage PD. Yet there is no medication available that a person with Par-

kinson's can take to ease balance issues and reduce his or her risk for falls.

Could vitamin D be the answer? Studies show that people with PD have lower vitamin D levels than do healthy individuals. Furthermore, research among people who have balance issues — but are not living with PD — has suggested that vitamin D supplements may lead to a decrease in falls.

To see if the same finding holds true for people living with PD, Dr. Peterson is conducting a pilot study among 40 such individuals. She will benefit from the knowledge of her mentors, Jay Nutt, M.D., a well-known movement disorder specialist and Fay Horak, Ph.D., an expert on gait and balance. Dr. Peterson will compare vitamin D levels and balance performance among people with Parkinson's disease to see if there is any correlation between the two. She is planning a larger study to investigate more thoroughly whether people who take a vitamin D supplement versus a placebo find an improvement in balance and strength, and a decrease in their falls.

As Dr. Peterson puts it, "Down the road, if the vitamin D approach works, it could demonstrate a simple way for people with PD to improve daily life and avoid potential injuries. And if it turns out that vitamin D is not the answer, the research will still have improved our understanding of gait, balance and strength, which are sorely under-addressed issues in Parkinson's."

*The Mentored Research Award is funded by PDF's Advancing Parkinson's Therapies Innovations Grant, which, in FY2010, totaled \$175,000.*

#### News In Brief

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M.D., of Queen Elizabeth Hospital in Birmingham, England, studied 366 people whose PD symptoms were not adequately controlled by medical therapy. In this randomized, multi-center study, half of the participants were assigned to undergo deep brain stimulation — a surgical treatment available for PD that used the now-standard techniques of electrode implantation — and receive state-of-the-art medication treatment. A second group, matched for age, duration and severity of Parkinson's, received "best medical therapy" alone.

Participants were treated at medical centers in the United Kingdom. Many of them received continuous infusion of apomorphine, a Parkinson's medication not widely used in the US.

The primary goal of the study was to determine the effect of DBS surgery on the quality of life experienced by each participant. One year after entering the study, all participants answered the 39-item Parkinson's disease quality of life questionnaire. The main result was that people in the surgically treated group experienced important improvements in their quality of life, as compared to those in the medication-only group. These improvements in the surgical group were associated with improvements in mobility, independence in performing activities of daily living and physical discomfort.

As reported in many previous studies, DBS was associated with improvements in many other areas, including rating scale measurements of Parkinson's symptoms and signs, dyskinesias, and reduction in medication usage. The surgery was also associated with higher risks than medical treatment alone: nearly 20 percent of the participants receiving DBS had a serious adverse event related to the surgery, including hemorrhage (2 percent), post-operative confusion (3 percent), and infection (9 percent).

As researchers noted, the primary flaw in the study is that it was not blinded: both the participants and the investigators were aware of who had the surgery. This type of "open label" trial can lead to a biased result in favor of surgery due to the placebo effect, especially when the primary study outcome is the person's own measure of

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## PD Pipeline

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and late stages of PD. This drug is being studied as an adjunct treatment, meaning it would be taken in addition to levodopa and other existing PD medications. Also in Phase III is a medication called **istradefylline** (KW-6002), an adenosine (A<sub>2A</sub>) agonist. Investigators hope that this drug will suppress dyskinesia, the involuntary movements caused by PD medications, as well as ease the motor symptoms of Parkinson's itself.

Finally, there are two symptomatic drugs under study in Phase III trials that address nonmotor PD issues:

**pimavanserin** (ACP-103), which may suppress psychosis and hallucinations, and **pitolisant** (BF2.649) which addresses the excessive sleepiness that is experienced by many people with PD.

In the neuroprotective category, two medications have reached Phase III, both of them sponsored by the National Institutes of Health. One is **Coenzyme Q10** (CoQ10), and the other is **creatine**. Both are substances that occur naturally in the body. They are being given in much higher amounts than are normally present.

### Phases II and I: Safety and Efficacy Studies

Earlier in the pipeline, we find four symptomatic therapies and four neuroprotective drugs under study. Three of the symptomatic therapies — **AFQ056**, **pardoprunox** (SLV-308) and **fipamezole** (JP-1730) — target particular kinds of receptors in the brain with the hope of easing the movement symptoms of PD. They are all taken as pills. The fourth, **Prosavin**<sup>®</sup>, is a gene therapy that is administered surgically into the brain. It consists of a genetically engineered virus that expresses enzymes in the brain that help levodopa to be converted into dopamine. The hope is that boosting dopamine will alleviate the symptoms of PD.

Also in the neuroprotective category is a second gene therapy ap-

proach called **CERE-120** (AAV-neurturin), which uses a growth factor that makes the protein neurturin. The hope is that neurturin will help regenerate the dopaminergic system and turn the clock back on PD.

Another interesting neuroprotective candidate being studied in Phase I and II clinical trials is **isradipine** (DynaCirc<sup>®</sup> CR). Isradipine is one in a class of medications called calcium channel blockers that is already used to treat high blood pressure. An additional trial, called SURE-PD, is studying **urate**, a normal constituent in blood. Several studies have shown

*“While we can't know exactly what's next, we can be optimistic at the level and type of research ongoing for Parkinson's.”*

that people with high natural levels of urate seem to be protected from PD. Last among the neuroprotective agents in early phase trials is **PYM50028** (Cogane<sup>®</sup>), which is derived from the extract of the sasparilla plant.

### Preclinical: Discovery and Validation

In earlier preclinical discovery phase, much of the excitement surrounds neuroprotective strategies, some of them using recent discoveries about the genetic causes of PD. Drugs under investigation target the proteins produced by the genes known as alpha-synuclein and LRRK2. Another approach in this phase is reducing in-

flammation in the brain. A third approach is studying the use of growth factors and neuroregenerative approaches as an attempt to not only *stop* the progress of Parkinson's disease, but also to *reverse* it.

### Looking Forward

It is always difficult to predict which potential therapies will work and which will not. At each step along this pipeline, research becomes much more expensive. And for every potential therapy that enters the process, perhaps one in a thousand will end up being approved for use.

That said, we can “forecast” that the drugs most likely to emerge soon from the pipeline are symptomatic treatments that have been studied the longest (in Phase II and Phase III trials). These treatments include those that are finding new ways to use levodopa and dopamine agonists as well as those that aim to address fatigue, constipation and memory loss.

Neuroprotective and restorative treatments are being studied at earlier phases in the pipeline. Within about three years, the hope is that modestly effective neuroprotective therapies — perhaps CoQ10, creatine or isradipine — will be approved.

While we can't know exactly what's next, we can be optimistic at the level and type of research ongoing for Parkinson's, all of which aims to improve and perhaps more importantly, reverse the course of Parkinson's for all of those living with the disease.

*Dr. Standaert is John and Juanelle Strain Professor and Vice Chair of Neurology at the University of Alabama at Birmingham. He recently presented this topic at one of PDF's PD ExpertBriefings. View his entire presentation at, [www.pdf.org/en/par\\_kinson\\_briefing\\_pipeline](http://www.pdf.org/en/par_kinson_briefing_pipeline).*

*In the last year, Dr. Standaert has served as a consultant to Solvay Pharmaceuticals, manufacturer of Duodopa<sup>®</sup>, and Teva Neuroscience, manufacturer of Azilect<sup>®</sup>.*


**The Advocate Report: ILLINOIS**

It is because of individuals who have stepped forward to take part in clinical research studies that any Parkinson's disease (PD) medications are available today. This is the sentiment of the graduates of the Parkinson's Disease Foundation (PDF) Clinical Research Learning Institute, including Frances Waldynski, a former special education teacher who hails from the suburbs of Chicago, IL. So, this past April, a group of Learning Institute graduates, including Ms. Waldynski decided to recognize "partners in progress" — individuals from the Chicago area who have participated in trials.

The graduates joined forces with local doctors, clinical trial coordinators and PDF staff, to organize an educational forum entitled, *Partners in Progress: The Essential Role that People with Parkinson's Play in Clinical Research*. In addition to honoring research participants, the event was designed to increase participation by people with Parkinson's in the cutting-edge studies taking place in the area. As the graduates note, a shortage of clinical research participants is a key factor in the delay of testing and approval of new Parkinson's medications.

The first session featured research teams from three nearby medical centers, including Rush University Medical Center (a PDF-

funded research program), represented by Christopher G. Goetz, M.D.; Northwestern University, represented by Tanya Simuni, M.D.; and University of Chicago Medical Center, represented by Un Jung Kang, M.D. Each team spoke about recent findings and opportunities for people with PD to get involved. Next, a panel of people with PD spoke about their personal experiences volunteering for trials.

Ms. Waldynski, who has participated in over 13 trials herself, said, "I think this event raised awareness of the breadth of clinical trials available. Many people think that participating in a clinical trial means taking an experimental medication for a terminal illness, not for a chronic disease like Parkinson's. But there are so many trials to test important new Parkinson's drugs and study its symptoms."

As the event came to a close, clinical trial participants were singled out with a gift of tulips. As one Learning Institute graduate noted, "I stood by the door and observed the 200 or more people in the room — those living at all stages of Parkinson's, and their family members. It reminded me of why we planned this program — to help to minimize disability and improve quality of life for people with Parkinson's, so they can be with their families and friends."

### Apply to PDF's Third Annual Clinical Research Learning Institute

**Thursday, October 21 –  
Saturday, October 23, 2010**

Florham Park, NJ

#### Learning Institute Graduates:

- Educate their communities about clinical study participation
- Work with industry and academia to ensure the voices of people living with Parkinson's are heard
- Make a difference in Parkinson's disease research

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*Applications are available during July.*



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## AROUND & ABOUT THE COMMUNITY

### **Bal du Printemps Pays Tribute to Philanthropists and the Power of Music**

On May 12, nearly 300 guests gathered for PDF's annual gala, *Bal du Printemps*, at New York City's Pierre Hotel, to support Parkinson's disease (PD) research. The evening honored two long-time friends of PDF and was a festive tribute to the special significance of music as a healing and creative force for people living with Parkinson's disease.

John and Margo Catsimatidis and their children, John Jr., and Andrea, were presented with the Page and



The Catsimatidis family — John, Andrea, Margo and John, Jr. — is presented with the Page and Black Family Philanthropy Award by TV personalities Nick Gregory (far left) and Ernie Anastos (far right).

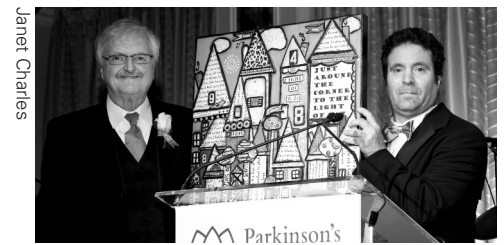
William Black Family Philanthropy Award, in recognition of their years of generosity and leadership at PDF —

including Mrs. Catsimatidis' work on PDF's Board of Directors and instrumental role in *Bal du Printemps*. They were introduced, via video, by their close friend, former President William Jefferson Clinton, who spoke about the family's commitment to bettering their community.

Later in the evening, Robert "Bob" Benjamin and The Light of Day Foundation were awarded with the Page and William Black Humanitarian Award. Mr. Benjamin was diagnosed with Parkinson's in 1996 at the age of 38, and shortly thereafter, founded Light of Day. In the past ten years, Light of Day has held concerts in eleven countries, welcoming special guests such as Bruce Springsteen, and raising \$1 million for Parkinson's organizations, including PDF.

Musical performances included those by Willie Nile, Jesse Malin and Dawne Allyne. A special display of panels from the Parkinson's Quilt Project highlighted personal reflections from people with Parkinson's about the meaning of music in their lives.

As PDF Executive Director Robin



PDF Executive Director Robin Elliott presents Bob Benjamin with a personalized award, a painting created for him by Cindy DeLuz, a person living with PD who is a participant in PDF's Creativity and Parkinson's Project.

Elliott noted, "Both the Catsimatidis family and Bob Benjamin have been long-time partners in the cause and have provided inspiration to others in the community through their philanthropic efforts. We are proud to say that this year we honor not just generous supporters, but also true friends."

PDF thanks this year's gala leadership for making this event possible: Honorary Co-Chairs Page Morton Black, Amy Goldman and Judith Sulzberger, M.D.; Gala Co-Chairs Jill Taub Drury, Stephanie Goldman-Pittel, Stevi Gurkoff, Karen Burke Goulardris, M.D., Ph.D., Isobel Robins Konecky, and Arlene Levine; Corporate Co-Chairs John K. Castle, Stephen M.

### **News In Brief**

*Continued from page 7*

quality of life. To address the potential for a placebo-effect explanation for the DBS benefits, and to evaluate the long-term benefit of surgery, the researchers plan to monitor study participants for up to nine years.

Deep brain stimulation surgery is now a standard treatment for people with Parkinson's who experience disabling tremors, wearing-off fluctuations and dyskinesias. This study has confirmed the results of DBS reported in previous studies and is significant because it is the largest randomized study to date, and has focused on quality of life as the main outcome.

For further information, consult PDF's booklet, *Deep Brain Stimulation for Parkinson's Disease, Third Edition*.



### **FDA Reviews Safety of Parkinson's Drug**

The US Food and Drug Administration (FDA) announced on March 31 that it is evaluating a possible link between entacapone/carbidopa/levodopa, or Stalevo®, and increased risk for prostate cancer. The medication is currently indicated for people living with Parkinson's who experience end-of-dose "wearing-off."

The FDA is conducting the investigation due to data that emerged from a clinical trial called, "Stalevo Reduction in Dyskinesia Evaluation — Parkinson's Disease (STRIDE-PD)." STRIDE-PD evaluated the onset of dyskinesia (twisting and writhing movements) in people with Parkinson's who took Stalevo compared to those who took carbidopa/levodopa only. The trial resulted in an unexpected finding: a greater number of people taking Stalevo were ob-

served to develop prostate cancer than those taking carbidopa/levodopa alone.

The FDA notes that prostate cancer is commonly diagnosed in men of the same age as those included in the trial. Additionally, earlier trials of Stalevo did not yield increased rates of prostate cancer, and neither did trials of entacapone (Comtan®), a key ingredient of Stalevo. More study is needed to determine whether there is any relationship between the use of Stalevo and the development of prostate cancer.

In the meantime, men taking Stalevo are advised to discuss their use of the medication with their treating neurologist, and to continue to follow the normal guidelines for annual prostate screening with their internists. For updates on this topic, visit [www.pdf.org](http://www.pdf.org) or [www.fda.gov](http://www.fda.gov).

## AROUND &amp; ABOUT THE COMMUNITY

Ackerman, Alan C. Greenberg and Howard Dewitt Morgan; and Master of Ceremonies, Ernie Anastos, news anchor for *Fox 5 News*.

### **Celebrate Spring Engages Young New Yorkers in the Cause**

On April 29, nearly 300 guests joined PDF and the Young New Yorkers for the Fight Against Parkinson's committee for *Celebrate Spring* at Slate, in New York City.

For the third year, co-chairs G. Pennington Egbert III, Missy Egbert Sheehan and Georgina B. Schaeffer, whose fathers both lived with Parkinson's disease, led the event. They did so with the help of a group of nearly 100 New Yorkers also dedicated to advancing a cure for Parkinson's.

The co-chairs, now well-seasoned event leaders, emphasized the importance of *Celebrate Spring* in engaging people of all ages in the Parkinson's cause. As Mr. Egbert said, "It is imperative to hold events like *Celebrate Spring*, to reach out to a younger generation and let them know there are ways that they too, can help in the fight against PD."



**Celebrate Spring Co-Chairs, Missy Egbert Sheehan, G. Pennington Egbert III and Georgina Schaeffer, led the charge to involve young New Yorkers in PDF's work.**

The event raised funds for a research program identified by Lucien Côté, M.D., a Parkinson's specialist at Columbia University.

PDF thanks its co-chairs and the Young New Yorkers for the Fight Against Parkinson's committee for their continued support of this event.

### **PDF Pacers Participate in Annual Walk**

On April 24, members of the Parkinson's community gathered for the 16th Annual Parkinson's Unity Walk in New York City's Central Park, raising over \$1.4 million for research.

By early morning, the Park was filled with thousands of people with



**Members of PPAC — Team Captain Joanna Steichen, David Eger, Carey Christensen, Ann Wasson and Rhona Johnson — greeted walkers at the PDF booth.**

Parkinson's, their families and friends. The crowd strolled through "Find a Cure Boulevard," stopping by PDF's booth for visors, educational materials and information on the Parkinson's Quilt Project, before making their way to the two-mile walk. Many walkers carried festive signs in honor of loved ones and wore the award-winning, *Fight to Win* t-shirt, designed by Heather Hinrichsen (see page 2).

This year, PDF's team, the "PDF Pacers," made up of staff members, board members and members of the People with Parkinson's Advisory Council (PPAC), was led by PPAC member Joanna Steichen. The PDF Pacers raised more than \$4,000. Ms. Steichen said the team, "represented the kind of cooperation and unity of purpose that the Parkinson's Unity Walk encourages."

Proceeds from the Walk are directed to the research programs of seven PD organizations, including PDF.

*The PDF Pacers would like to thank former team captain Bruce Talbot, for the support and inspiration he provided to the team.*

### **Brain Imaging Scientist Honored**

On April 14, at the American Academy of Neurology (AAN) annual meeting in Toronto, David Eidelberg, M.D., became the 10th recipient of the PDF-AAN Movement Disorder Research Award. This award is presented to a scientist who represents the ideals of involvement in research, clinical care and training of younger colleagues.

Best known for his work with neuroimaging, Dr. Eidelberg has been hailed as an innovative thinker who has advanced our understanding of Parkinson's. In his most recent study, using a neuroimaging method called the FDG-PET scan, he and his colleagues were able to accurately differentiate people living with classic PD from those living with related disorders, such as progressive supranuclear palsy (PSP) and multiple system atrophy (MSA). This finding sheds light on potential tools for properly assessing difficult diagnoses of Parkinson's.



**Dr. Eidelberg (second from left) receives his award from AAN Meeting Subcommittee Chair, Cynthia Comella, M.D. They are joined by PDF Executive Director Robin Elliott and James Beck, Ph.D.**

Dr. Eidelberg is currently a Professor of Neurology at New York University School of Medicine and Director of the Center of Neurosciences at the Feinstein Institute for Medical Research and of the Movement Disorders and Functional Neuroimaging Center at North Shore LIJ Health Systems.

Would you like to learn more about Dr. Eidelberg's work? Read the transcript of Dr. Beck's interview with him in Toronto, now available on PDF's blog at [www.pdf.org/en/blog](http://www.pdf.org/en/blog).

# Calendar of Events



## Seattle to Portland Bicycle Classic

**Date:** Saturday, July 17 – Sunday, July 18

**Place:** Seattle, WA, to Portland, OR

The Northwest Parkinson's Foundation (NWPf) is seeking riders and volunteers for the 31st Annual Seattle to Portland Bicycle Classic. Riders raise funds for NWPf's quality of life programs and services for people living with PD. For more information, call (877) 980-7500, email [alecha@nwpf.org](mailto:alecha@nwpf.org) or visit [www.nwpf.org](http://www.nwpf.org).



## 17th Annual Morris K. Udall Awards Dinner

**Date:** Wednesday, October 6

**Place:** Capital Hilton Hotel Washington, DC

The Parkinson's Action Network (PAN) invites you to its annual fundraiser and awards ceremony. This year's leadership includes Dinner Co-Chairs, Diane and John Rehm, Honorary Chairman, Michael J. Fox, and Special Program Guest, Lonnie Ali. Honorees include a former member of PDF's People with Parkinson's Advisory Council, James Trussell, US Senator Gordon Smith and US Representative John Spratt. For more information, call (202) 638-4101, email [udalldinner@parkinsonsaction.org](mailto:udalldinner@parkinsonsaction.org) or visit [www.parkinsonsaction.org](http://www.parkinsonsaction.org).

## Clinical Research Learning Institute

**Date:** Thursday, October 21 – Saturday, October 23

**Place:** Hamilton Park Hotel and Conference Center Florham Park, NJ

You are invited to apply to PDF's annual multi-day training, which educates participants about the ways in which people living with PD can contribute to the development of new treatments and a cure for Parkinson's. Enrollment is limited. An eligible applicant must be a person with Parkinson's, living in either the US or Puerto Rico. For those who are selected, all expenses will be covered by PDF. For more information, contact PDF at (800) 457-6676 or [info@pdf.org](mailto:info@pdf.org) or visit [www.pdf.org/en/crli](http://www.pdf.org/en/crli).

## Night of a Thousand Stars

**Date:** Saturday, November 13

**Place:** Steinway Piano Gallery of Detroit Commerce, MI

The Michigan Parkinson Foundation (MPF) hosts its annual benefit, featuring live entertainment, dinner, dancing and a silent auction. For more information, call (800) 852-9781, email [info@parkinsonsmi.org](mailto:info@parkinsonsmi.org) or visit [www.parkinsonsmi.org](http://www.parkinsonsmi.org).



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## 2<sup>nd</sup> WORLD PARKINSON CONGRESS

September 28 – October 1, 2010  
Glasgow, Scotland

Learn about the latest in Parkinson's research and care, and hear from people with Parkinson's and voluntary organizations around the world about their efforts to further the cause.

To learn more or register, visit [www.worldPDcongress.org](http://www.worldPDcongress.org) or call (800) 457-6676. PDF is a leading supporter, joining 152 organizational partners from 45 countries.

The Parkinson's Disease Foundation® (PDF®) is a leading national presence in Parkinson's disease research, education and public advocacy. We are working for the nearly one million people in the US who live with Parkinson's by funding promising scientific research and supporting people with Parkinson's, their families and caregivers through educational programs and support services. Since its founding in 1957, PDF has funded over \$85 million worth of scientific research in Parkinson's disease, supporting the work of leading scientists throughout the world.

If you have or believe you have Parkinson's disease, then promptly consult a physician and follow your physician's advice. This publication is not a substitute for a physician's diagnosis of Parkinson's disease or for a physician's prescription of drugs, treatment or operations for Parkinson's disease.

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