

## Trial of New PD Treatment Halted: Some Patients and Advocates Protest

**Robin Elliott**

On Friday, February 12, Amgen Inc. announced that, after much internal hand wringing, it was denying a request by participants in trials of a molecule known as GDNF, an experimental Parkinson's treatment, to continue receiving the treatment following termination of the trials.

California-based Amgen, the world's largest biotechnology company, had abruptly concluded its own double-blind trial almost six months earlier, saying that the treatment had not been shown to be effective and citing safety concerns in two areas. In one of these, several subjects were found to have developed antibodies that could potentially attack the body's own GDNF, a naturally occurring product that is essential for the production of dopamine, the chemical messenger that is deficient in Parkinson's.

The other safety concern came out of a separate trial involving monkeys. It turned out that a few of the animals were found to have evidence of lesions in the area of the brain known as the cerebellum.

### Several leading scientists and advocacy groups take issue with Amgen's decision

Several of the scientists who had served as investigators in the Amgen tri-

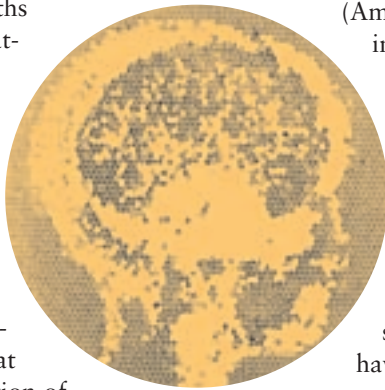
als, including Drs. Michael Hutchinson of New York University, Don Gash and Greg Gerhardt of the University of Kentucky, Richard Penn of the University of Chicago and Steven Gill at the University of Bristol, England, have challenged Amgen's interpretation of both the efficacy and the safety data. As to efficacy, some have argued that the wrong statistical test was used, and that an alternative test would have showed GDNF to be effective.

(Amgen, supported by several investigators including Drs. Jay Nutt of the Parkinson Center of Oregon and Anthony Lang of the University of Toronto, has held to its original opinion that the trials failed to show efficacy.)

As to the safety issues, some of the doctors have argued that Amgen has overreacted on both counts. The

antibody issue, they say, is frequently seen in such studies and does not necessarily have any adverse effects on the health of the patient. (Indeed, they note that when the antibody findings first surfaced in the spring of 2004, Amgen seemed unconcerned by the data and would have continued with preparations for a larger-scale Phase III trial of GDNF, had the second wave of monkey data not come along.)

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### NEWS IN BRIEF

#### Study Suggests that Levodopa Does Not Hasten — and May Even Slow — Progression of PD

A study led by Columbia University scientists and published in the December 9 issue of *The New England Journal of Medicine* suggests that the commonly-used Parkinson's drug levodopa does not hasten the progression of Parkinson's disease — as some scientists had feared — and may actually slow it down.

Columbia University is a beneficiary of PDF's largest research grant.

The trial enrolled 361 early-stage Parkinson's patients and randomly divided them into four study groups. Three of the groups received levodopa in different doses and one received a placebo. After 40 weeks, the medication was withdrawn, and two weeks later, investigators used the Unified Parkinson's Disease Rating Scale (UPDRS) to assess disease progression. The results showed that participants from the levodopa groups experienced less decline overall than the placebo group, suggesting that levodopa does not speed disease progression and may even slow it.

"We still haven't found all of the answers we're looking for, but this is an important step in determining how levodopa affects Parkinson's disease

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**GDNF**

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As for the monkey data, some of these doctors point to evidence that suggests that the cerebellar damage was caused, not by the toxicity of the intervention, but by its precipitate withdrawal (six months into the trial). They also point out that the dose used for the monkeys was many times the doses used in the human trials.

**Michael J. Fox Foundation stages “Scientific Summit” on GDNF**

At a meeting in Chicago in early August 2004, where the efficacy data on GDNF were announced, Debi Brooks, President and CEO of the Michael J. Fox Foundation for Parkinson’s Research, offered to host a scientific summit on the subject. The summit, which was held in November, drew some 30 scientists from North American and European centers for Parkinson’s research and concluded with a broad consensus that while GDNF remained a promising potential treatment, more animal studies should be done to assess the health concerns before any new human trials should be undertaken.

What this discussion did not address was what should be done about the 48 people in the U.S. and the United Kingdom who have participated in one of the Amgen-sponsored trials, several of whom have indicated that they wish to continue receiving the treatment. Most observers believe that the “risk-benefit” calculus for these people is different from what it would be for a new patient because all of them have already undergone the surgery necessary to participate in the trial, and several of them have been on GDNF for as long as three years. Representatives of this group have set up a website — [www.GDNF4Parkinsons.org](http://www.GDNF4Parkinsons.org) — which has become a rallying-point for the Parkinson’s community.

Not surprisingly, Amgen’s February announcement was especially galling to this group — many of whom had written personal letters to Amgen pleading for reinstatement of GDNF. They were backed by several of the community’s advocacy groups, including the Parkinson’s Disease Foundation, the Parkinson’s Action Network and the Parkinson Pipeline Project.

To understand how GDNF got to this point, we need to look at the scientific history of the molecule.

**GDNF — The trials and tribulations of a promising Parkinson’s treatment**

Glial-cell line-derived neurotrophic factor, or GDNF, is one of the most powerful naturally-occurring human factors known to nourish and foster the growth of dopamine-generating neurons. Soon after GDNF was identified in 1993, Dr. Gash and colleagues at the University of Rochester and later at the University of Kentucky showed that the injection of GDNF protein into both rat and monkey models of parkinsonism showed therapeutic promise.

Dr. Gash’s work was soon followed by the first gene therapy trial of GDNF, conducted in a rat model by Dr. Martha C. Bohn and her colleagues at the University of Rochester. This seminal study, which was published in the journal *Science* in 1997, showed that continuous delivery of GDNF at low levels using a so-called “viral vector” was able to protect dopaminergic neurons from neurotoxin-induced cell death.

Drs. Jeffrey H. Kordower and Marina E. Emborg, along with their colleagues at Rush University Medical Center in Chicago and the University of Lausanne in Switzerland, picked up the ball by conducting the first study of GDNF gene therapy in a monkey model. Their studies showed improved motor performance in the animals which received the GDNF gene (compared with animals that received no treatment). In the treated animals, parkinsonian symptoms were reduced, and, after the animals were sacrificed, the numbers of healthy dopamine neurons were found to be significantly enhanced. A summary of the findings was published in *Science* in 2000.

**The investigation in humans**

While the animal studies were continuing, scientists began to examine how GDNF might work in humans. Based on the preliminary results of Dr. Gash’s studies in rat and monkey models, Amgen initiated a human, randomized, double-blind trial of GDNF, led by Dr. Nutt. The results, published in a 2003 edition of the journal *Neurology*, were disappointing; the treatment showed little benefit and several side-effects, confirming that benefit in animals does not necessarily translate to benefit in humans.

Some two years later, a British team conducted a follow-up study that greatly raised world interest in the promise of GDNF. In this study, led by Dr. Gill

and his colleagues at Frenchay Hospital in Bristol, scientists implanted catheters in the brains and pumps in the abdominal walls of five people with moderate Parkinson’s. The pumps continuously fed GDNF into specific areas of the brain via the catheters at a precise rate of infusion. All five patients showed improvements in “off” states comparable to their “on” states within two months of the onset of the trial. Their motor skills continued to show improvement and even gait difficulties were eased. Brain scans documented the patients’ progress while the dosage of anti-Parkinson’s medications was steadily reduced. The results showed significant improvement in the functioning of the dopaminergic system.

**The Amgen “double-blind” trial**

Impressive as the new data appeared to be, the Bristol trial did not provide an answer as to whether GDNF works. The reason is that it was of the so-called “open-label” variety, in which every participant received the treatment and some of them — human nature being what it is — may have imagined that they felt better than they really were. To correct for this factor, known as the “placebo effect,” scientists try to confirm early data by conducting what is known as a “double-blind” trial, in which some patients are randomly placed on the treatment and the others are given a sugar pill. To test the validity of the British data, Amgen initiated such a trial for GDNF in 2003 with 34 patients.

As reported by Dr. Lang at a meeting of the American Neurological Association in October, 2004, the study did not prove the efficacy of GDNF. The investigators judged the patients’ “off” periods to be somewhat improved, but saw no improvement in “on” periods.

**The uncertain future of GDNF**

Dr. Clive N. Svendsen of the University of Wisconsin (co-investigator in the Bristol study), as well as other investigators involved in GDNF research, has suggested that the studies’ dissimilar results may have been a consequence of the different dosages used, as well as by the different sizes of the catheters used to infuse the treatment.

Dr. Bohn says she is encouraged by

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# SPOTLIGHT

on Research  
Supported by PDF

**Christopher G. Goetz, M.D., Professor and Associate Chairman of the Department of Neurological Sciences, Rush University Medical Center, Chicago, IL**

By 7 AM almost every morning, Dr. Christopher Goetz may be found at his desk at Rush University Medical Center in Chicago, where he presides over one of the nation's largest and most respected movement disorders centers. For the rest of the day, with crisp, authoritative style and clockwork timing, Dr. Goetz sees a full patient roster; serves on multiple advisory boards; acts as a reviewer and editor for various journals; supervises an impressive team of seven neurologists, two neuropsychologists and one psychiatrist, along with nurses, a physician assistant and support staff and conducts and publishes important research aimed at increasing knowledge about Parkinson's disease.

Dr. Goetz focuses his PD research these days on three major topics: hallucina-



**Dr. Christopher Goetz**

tions and other behavioral aspects of the disease; the effect of placebo treatment on the dopamine system in Parkinson's disease and the development of rating scales for monitoring disease-related impairments and disabilities.

He is one of the few nationally-recognized scientists to focus on hallucinations, which affect one-third of people with Parkinson's. Working with his colleagues in neuroimaging, Dr. Goetz has used new brain-scan techniques to establish a mechanism for defining the regions of the brain that are over- or under-active in patients who hallucinate. Using this method, he has found that these people register visual information poorly in visual regions of the brain, and instead use frontal regions in the brain that normally remain inactive when a person is processing this information. He will continue this research to learn more about the anatomical layout of hallucinations in people with Parkinson's.

In addition to his research on hallucinations, Dr. Goetz is working with a grant from the National Institutes of Health to analyze how the so-called "placebo effect" (the frequent reaction among patients to the inert substance that is given to members of the control group in a clinical trial) works in Parkinson's. More than any other neurological disease group, Parkinson's patients seem to respond positively to treatment with placebo in both surgical and pharmacological clinical trials. The findings from this study will have important implications for the design of future Parkinson's clinical trials.

Dr. Goetz's other major current research focus comes with his role as Chair of a Movement Disorder Society Task Force that is working on developing a more comprehensive version of the Unified Parkinson's Disease Rating Scale (UPDRS), the standard test for measuring the severity and progression of Parkinson's. The task force expects to present some of its findings and recommendations at professional neurological meetings in 2005.

Natural counterparts to his research are Dr. Goetz's myriad activities as a community leader and educator. He has published and co-authored 14 books and monographs, and has authored more than 300 peer-reviewed papers and another 300 invited articles and book chapters. He has served on the editorial boards of several respected journals, and is currently the co-Editor-in-Chief of *Movement Disorder*, the official journal of the Movement Disorder Society.

Dr. Goetz is also known as an outstanding teacher, with content grounded in learning and experience and delivered in a clear, arresting manner. As the head of his group in Chicago, he is also the administrator of Rush's research center, which is funded in part by the Parkinson's Disease Foundation.

As an active complement to PDF's major center at Columbia University in New York, Rush has carved out an international reputation in clinical research on Parkinson's and other movement disorders. For more information on Dr. Goetz's work and research or the Movement Disorders Center at Rush University Medical Center, please call (312) 563-2030 or email [movement\\_disorders@rush.edu](mailto:movement_disorders@rush.edu).

## GDNF

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the Bristol results but believes that a delivery system utilizing gene therapy rather than infusion via catheter may ultimately be safer (since it does not require the administration of live virus to the brain) and may offer a better long-term outcome for patients. Dr. Svendsen agrees, and suggests that another potential delivery technique might be the implantation of genetically-engineered stem cells that could in turn release GDNF.

Dr. Svendsen also reports that he and

other study participants are meeting with Amgen to analyze the differing results of the studies to date and to seek consensus on whether and when there will be further studies of GDNF. Meanwhile, additional animal studies are being pursued.

### The reinstatement issue continues

While discussions continue concerning the long-term future of GDNF, the short-term issue of the patients who were in the trials to date remains unresolved. Some have indicated that they would like to go back on GDNF if the opportunity were to be offered, but several have now had their pumps and cath-

eters removed. Voluntary organizations such as PAN and PDF are continuing to explore options of persuading Amgen to reconsider its position. In the words of a recent open letter from leaders of the Parkinson Pipeline Project, a group of patient advocates: "[Reinstatement] is important not only to today's patients but to our prospects of being able to recruit sufficient numbers of people for future trials...[without people to participate] all of us — companies as well as patients — will be the losers."

*Robin Elliott is the Executive Director of the Parkinson's Disease Foundation.*

## Pain in Parkinson's Disease

**Blair Ford, M.D.**

Center for Parkinson's Disease  
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For most people with Parkinson's disease (PD), the most serious concern is with the motor system: stiffness, slowness of



Dr. Blair Ford

movement, impaired handwriting and coordination, poor mobility and balance.

Descriptions of PD do not generally include the mention of pain. And yet, when carefully questioned,

more than half of all

people with Parkinson's disease say that they have experienced painful symptoms and various forms of physical discomfort. Most people experience aching, stiffness, numbness and tingling at some point in the course of the illness. For a few of them, pain and discomfort are so severe that they overshadow the other problems caused by the disease. This article will address these overlooked painful symptoms of PD, and describe an approach to diagnosing and treating the various pain syndromes that may occur.

Pain is described in textbooks as an unpleasant experience associated with physical injury or tissue damage. Pain can arise from anywhere in the body, of course. It goes without saying that people with Parkinson's are subject to all of the painful conditions — cardiac, gastroenterological, rheumatological, among others — that can affect people without PD. This discussion will focus on pain that is directly related to PD itself.

Pain syndromes and discomfort in Parkinson's usually arise from one of five causes: (1) a musculoskeletal problem related to poor posture, awkward mechanical function or physical wear and tear; (2) nerve or root pain, often related to neck or back arthritis; (3) pain from dystonia, the sustained twisting or posturing of a muscle group or body part; (4) discomfort due to extreme restlessness and (5) a rare pain syndrome known as "primary" or

"central" pain, arising from the brain.

It takes diagnostic skill and clinical experience to determine the cause of pain in someone with PD. The most important diagnostic tool is the patient's history. Where is the pain? What does it feel like? Does it radiate? When does it occur during the day? Does it occur in relation to any particular activity or medication? Perhaps the most important task for people with Parkinson's who experience pain is to describe as accurately as they can whether their medications induce, aggravate or relieve their pain. To help your physician in diagnosing pain, refer to the questions listed on page 5.

### Musculoskeletal pain

Aching muscles and joints are especially common in PD. Rigidity, lack of spontaneous movement, abnormalities of posture

*Perhaps the most important task for people with Parkinson's who experience pain is to describe as accurately as they can how their medications seem to induce, aggravate or relieve their pain.*

and awkward mechanical stresses all contribute to musculoskeletal pain in PD. One of the most common musculoskeletal complaints is shoulder stiffness, sometimes called a frozen shoulder (this may in fact be the first sign of PD). Hip pain, back pain and neck pain are all common painful complaints in PD. With prolonged immobility of a limb, band-like tendons, termed contractures, may occasionally develop, usually in the hands or feet; one example is the clenched fist contracture that may occur with prolonged flexion of a hand.

An accurate diagnosis of musculoskeletal pain is based on a careful history

and a physical examination that takes into account posture, limb and trunk rigidity and gait. It can occasionally be challenging to distinguish between back pain due to PD and that caused by arthritis or scoliosis. Occasionally, further testing — including x-rays, bone scans, ultrasound and rheumatologic or orthopedic consultation — will be needed. The proper treatment of musculoskeletal pain in PD depends upon the cause of the pain. If the pain is the result of excessive immobility or rigidity, a physician may prescribe dopaminergic therapy, physical therapy and an exercise program. If the treatment is successful, patients should continue with an exercise program that strongly emphasizes range of motion, to prevent the development of further musculoskeletal problems.

### Radicular and neuritic pain

Pain that occurs close to a nerve or nerve root is described as neuritic or radicular pain. The classic root-pain syndrome is sciatica, caused by compression or inflammation of the L5 lumbar root. Patients usually describe root pain as a sharp, lightning-like sensation that radiates towards the end of a limb. Of course, any nerve or root may be subject to injury or compression, and a careful neurological assessment is needed for the diagnosis. Electrodiagnostic studies and neuroimaging are occasionally required to confirm the location of the involved nerve or root, and to determine the cause of the problem. Radicular pain can usually be successfully treated with a mobility program and pain medication and rarely requires surgery.

### Pain associated with dystonia

Dystonic spasms are among the most painful symptoms that a person with PD may experience. The pain arises from the severe, forceful, sustained twisting movements and postures that are called dystonia. This type of muscle spasm is quite different from the flowing, writhing movements described as dyskinesias, which are not painful. Dystonia in PD may affect the limbs, trunk, neck, face, tongue, jaw, swallowing muscles and vocal cords. A common form of dystonia in PD involves the feet and toes, which may curl painfully. Dystonia may also cause an arm to pull behind the back, or force the head forward towards the chest.

The most important step in evaluating painful dystonia is to establish its relationship to dopaminergic medication. Does the dystonia occur when the medication is at peak effect? Or does it occur as a “wearing-off” phenomenon, when the benefits of medication are waning? The answers to these questions will usually clarify the nature and timing of the dystonia, and determine its treatment. Most painful dystonia represents an “off” parkinsonian phenomenon, and occurs early in the morning or during wearing-off spells. In uncertain cases, the neurologist should observe the patient in the office over a period of several hours in order to appreciate the relationship of the dystonia to the medication-dose cycle.

In terms of treatment, early-morning dystonia is typically relieved by physical activity, or by the first dose of dopaminergic medication, whether it be levodopa (Sinemet®) or a dopamine agonist. When dystonia occurs as the medications wear off, the problem can be corrected by shortening the “off” period. In some patients, the dystonia is so severe that subcutaneous injections of apomorphine, with its onset of action in minutes, may be necessary. Individuals with intractable dystonia may benefit from deep brain stimulation, a neurosurgical procedure that involves implanting and activating electrodes in the brain.

A few patients experience dystonic spasms as a complication of their medications. When they take their levodopa, these patients experience dystonic facial grimacing or uncomfortable limb posturing. The standard treatment approach for these individuals is to reduce the amount of dopamine medication, sometimes by substituting a less potent agent, or adding a medication for dystonia, such as amantadine.

#### **Akathisia**

No discussion of physical discomfort in PD is complete without a mention of akathisia, or restlessness, a frequent and potentially disabling complaint. Some patients with parkinsonian akathisia are unable to sit still, lie in bed, drive a car, eat at a table or attend social gatherings. As a result of akathisia, patients may lose sleep or become socially isolated. In about half of the cases of parkinsonian akathisia, the symptom fluctuates with medications

and may often be relieved by additional dopaminergic treatment.

#### **Central pain syndromes**

The most alarming pain syndrome in patients with PD is also one of the rarest: “central pain.” This affliction — which is presumed to be a direct consequence of the disease itself, not the result of dystonia or a musculoskeletal problem — is described by patients as bizarre unexplained sensations of stabbing, burning and scalding, often in unusual body distributions: the abdomen, chest, mouth, rectum or genitalia. The treatment of central pain in PD is challenging, and usually begins with dopaminergic agents. Conventional painkillers, opiates, antidepressants and powerful drugs for psychosis, such as clozapine, may also be helpful treatments for central pain.

#### **Depression and pain**

It has long been known that chronic pain can induce depression, and depressed patients often experience pain. People who have PD are themselves at a higher-

than-average risk for developing depression, which occurs in some 40 percent of patients at some point during the illness. It is therefore important that any assessment of pain in an individual with PD take into account the potential contributing role of depression, which may also require treatment.

Many patients with PD experience pain at some point during the illness. The complaint is often overlooked because PD is primarily a motor disorder. Yet, for a minority of patients, pain and discomfort can be so debilitating that they dominate the clinical picture. It is therefore important that individuals who experience pain discuss the problem with their neurologist. A careful history and examination — including, in some cases, additional diagnostic testing — can usually determine the cause of the pain. Depending on the category of painful complaint — musculoskeletal, root or nerve pain, dystonic muscle spasm, akathisia or central pain — it is usually possible for the physician to design an effective treatment plan.

# 10

## Questions your doctor will ask you about pain

1. **Where is your pain located?**
2. **What does your pain feel like?**
3. **Does the pain radiate anywhere?**
4. **When does the pain occur?**
5. **Do you have pain continuously, or only at certain times?**
6. **Does the pain occur in relation to any particular activity?**
7. **What relieves the pain?**
8. **What makes the pain worse?**
9. **Do your anti-Parkinson’s medications relieve your pain?**
10. **Do you have arthritis?**

## The Parkinson's Mailbag



Ivan Suzman

## Using Your Pharmacy Wisely

Any person with Parkinson's (PWP) who goes out to fill a prescription will agree with me that "the times they are a changin'." The traditional corner drugstore, with its bespectacled pharmacist, for so long a main street fixture in every town or village in America, has become a rarity. In its place, more likely, is the large, impersonal branch store of a national chain, with a pharmacy section buried behind aisles laden with groceries, auto parts, clothing and more.

Then there is the huge and growing Internet marketplace, wherein the computer-savvy PWP can shop and order medications directly from home. And of course, there are the mail-order programs, featuring toll-free numbers, discounts and, again, the advantage of cutting out trips to the pharmacy.

### Finding a knowledgeable pharmacist

A good pharmacist will have an up-to-date knowledge not only of the pharmaceutical market, but also of medications for specific conditions, including Parkinson's. To determine whether a particular pharmacist is the one for you, ask about his or her familiarity with anti-Parkinson's medicines. A good pharmacist should have information not only about Sinemet®, but also about some of the less common drugs, the generic alternatives and the various strengths of medications that are available.

In addition to being well-versed in the above topics, your pharmacist should be

able to describe any possible side-effects of your medications and potential interactions with other medications that you may be taking. Some of these interactions could actually be dangerous. They can occur not only when several prescription medications are mixed, but also when a prescription medication is mixed with some over-the-counter medicines, certain foods, throat lozenges, cough syrups and tablets and even chewing gum! Again, a good pharmacist should know about these things and be able to advise you accordingly.

While knowledge is of course a key factor in choosing a pharmacist, it is also important to make sure that he or she is available to you. This can be essential when you need your prescription at a busy



time, such as mid-morning on a Saturday.

### Convenience is key

When you find yourself weighing the pros and cons of the various options in the pharmacy world, consider what you can do to make the experience as trouble-free as possible. For example, to avoid waiting in long lines at the drugstore, make it a habit to call in an order for a refill three days in advance. This can also give you plenty of time to make alternative arrangements with a different pharmacy if your medications happen to be out of stock. If you do not mind automation, many drugstores these days feature a "rapid refill" option, which allows you to reorder by computer or by voicemail. Just read the prescription number from your bottle and follow the recorded voicemail directions or the directions listed on the pharmacy's website.

If you work during regular business hours, look for a 24-hour drugstore near you. Sometimes you can even find pharmacies with drive-through windows, providing you with the ultimate convenience of not having to leave the car. Also, if trips out of the house are becoming difficult, you may see if your health insurance policy allows you to order up to a three-month supply of pills at once, and to have them shipped to your address. Some pharmacies will even deliver your prescription to your residence at no cost if you are unable to leave the home.

For readers who are retired from or currently in the armed forces, your regional Veterans Administration Hospital may offer to mail your prescriptions at no extra cost to you.

### Making sure the price is right

As you are well aware, prices of medications can vary, even between pharmacies that are across the street from one another. Because of this, it is important to shop around. You can do this by simply checking with pharmacies, Internet and web outlets, and asking for price quotes on your medications. (Remember, you cannot inspect your Internet order before you pay for it.) Make sure to ask whether there are any promotions when you call; some companies offer a reduction to customers who are transferring a prescription from another pharmacy.

Lastly, if you have a limited income, you may be eligible to receive prescriptions at no cost — either through the drug companies (all of which have patient assistance programs for low-income folks) or through your state's department of human services. For more information on the various patient assistance programs offered by drug companies, contact PDF at (800) 457-6676.

In an upcoming issue of *The Mailbag*, I will be writing about home safety tips. Please send any suggestions you have on this to me, care of PDF, at 1359 Broadway, Suite 1509, New York, NY 10018, or email [info@pdf.org](mailto:info@pdf.org).

*Ivan Suzman has lived with young-onset Parkinson's disease for 20 years. He resides in Portland, ME, and works with PDF on various projects, including writing his regular newsletter column, The Parkinson's Mailbag.*

## Levodopa

*Continued from page 1*

progression. The results are encouraging, but we still have much more work to do before we can definitively explain the relationship between levodopa and Parkinson's progression," said Dr. Stanley Fahn, principal researcher of the study.

Researchers also performed brain scans on 142 patients at the beginning and end of the study to assess the presence of the dopamine transporter (an enzyme in the dopamine nerve terminals that serves as a biological marker of the progression of Parkinson's). These tests seemed to show that the levodopa patients had a greater loss of the dopamine transporter than placebo-treated patients, suggesting that levodopa may in fact speed up the loss of these brain cells. One explanation could be that levodopa, itself, inhibits the activity of the transporter.

The discrepancy between the results of the clinical examinations and the brain scans has led to debate among researchers. The central issue regarding the effect of levodopa on the long-term progression of Parkinson's remains unresolved by this study. No change in the way patients use levodopa is recommended at present. Investigators plan to continue their research into levodopa's role in the treatment of PD.

## Alzheimer's Drug May Help People with Parkinson's

A report in the December 7 issue of *The New England Journal of Medicine* shows that Exelon® (rivastigmine tartrate), an Alzheimer's medication, may be moderately effective in the treatment of dementia in Parkinson's. This comes from the first large-scale, placebo-controlled clinical trial of a potential treatment for dementia in some PD patients.

Exelon, a dual cholinesterase inhibitor, is approved for treating Alzheimer's disease. The new report suggests that the product may also be useful in improving cognition and some aspects of behavior among people with Parkinson's disease.

The study enrolled 541 participants, who were randomly assigned to a placebo group or a treatment group taking increasing dosages of Exelon from 3 to 12 mg per day for 24 weeks. Using two Alzheimer's rating scales, investigators concluded that people in the Exelon treatment group experienced moderate improvements in cognitive symp-

toms (for example, memory impairments and attention problems) and behavioral problems such as agitation and mood swings, compared to participants taking placebo.

The most frequent side-effects reported with Exelon use were nausea, vomiting and a worsening of tremor.

The main limitation of the study is its short duration of only six months. Clinical experience with drugs for dementia often show declining benefits over time.

## Gene Mutation Identified as Cause of Some Familial PD

In three separate studies, scientists have identified a new gene mutation in approximately five percent of cases of inherited Parkinson's disease, and in one-to-two percent of people who do not report a family history of the disease. This research, published in the January 18 online edition of *The Lancet*, is an important step forward in our understanding of the genetic component of Parkinson's.

Investigators from the National Institute on Aging (NIA) and scientists funded by the National Institute of Neurological Disorders and Stroke (NINDS) played important roles in this discovery, along with two international research teams. In two of the studies, Dr. Vincenzo Bonifati of Erasmus Medical Centre, the Netherlands, and Dr. William Nichols of Cincinnati Children's Hospital Medical Center independently analyzed people who reported a high incidence of Parkinson's in their families. The two groups used the data to confirm that a single mutation on the recently discovered LRRK2 gene causes Parkinson's in five percent of people with a family history of PD.

A third study, led by Dr. Nicholas Wood of the National Hospital for Neurology and Neurosurgery in London, analyzed Parkinson's patients who do not have a family history of the disease. His team determined that the mutation also causes one-to-two percent of Parkinson's disease in people without inherited PD.

Dr. Juliette Harris, Genetic Counselor at Columbia University Medical Center, emphasizes that while this is an important and exciting discovery, it still does not account for the cause of PD in the majority of people.

"It is now becoming increasingly clear that Parkinson's is caused by numerous genetic factors and environmental factors," she told *PDF News & Review*. "It is therefore even more crucial that research focus on identifying these risk factors and use this knowledge to fight Parkinson's disease."

## Research Points to Link Between Exercise and Parkinson's

Data from a study published in the February 22 edition of *Neurology* indicate that men who exercise regularly and strenuously in early adult life may have a lower risk of developing Parkinson's disease in later years, as compared to men who did not exercise. The study, conducted by Dr. Alberto Ascherio and colleagues at the Harvard School of Public Health, suggests that for men, exercise is neuroprotective. The study did not establish a possible link for women between exercise and the risk of Parkinson's.

Researchers examined information collected from two large studies, the Health Professionals Follow-Up Study and the Nurses' Health Study. Participants completed questionnaires on lifestyle, disease history and physical activity beginning in 1986 and then updated the information every two years through 2000. The respondents (48,574 men and 77,254 women) were all middle-aged or older at the start of the survey. A total of 387 of them (252 men and 135 women) had been diagnosed with Parkinson's during the course of the study.

The scientists found that as male physical activity increased, the risk of Parkinson's disease seemed to decrease. Men who were the most physically active at the start of the study cut their risk of developing Parkinson's disease by 50 percent compared to men who were the least physically active. Although the data did not reveal the same relationship between Parkinson's and exercise for women, researchers point out that much or all of the difference might be explained by the fact that the women surveyed grew up during a time when there was less emphasis on exercise for females.

These results seem to coincide with the findings of some animal studies, such as the work of Dr. Michael Zigmond and his colleagues at the University of Pittsburgh. In Dr. Zigmond's work, rats were forced to exercise for seven days before being treated with chemicals to induce Parkinson's disease. The rats that had exercised showed significantly less cell death of dopamine-containing neurons than sedentary rats. Based on this information, Dr. Zigmond's group has begun a small pilot study in Parkinson's patients to learn more about the possible relationship between exercise and PD in humans.

## NETRP Targeted as First Priority for PD Funding Requests

**Mary Richards**

*Director of Government Relations, PAN*

One of the top legislative priorities for the Parkinson's community this year is also one of its best-kept secrets: the Neuro-



**Mary Richards**

toxin Exposure Treatment Program (NETRP) of the U.S. Department of Defense (DoD). NETRP is important to the Parkinson's community because it specifically targets innovative research into neurodegenerative diseases such as Parkinson's. For this reason, the Parkinson's Action Network (PAN) targeted the program as a priority issue for the participants at its recent Research and Education Forum & Public Policy Forum in Washington, DC, with \$40 million as the "ask" (read more about the Forum in *Around & About the Community* on page 11).

"NETRP has supplied us with vital knowledge about Parkinson's disease and how we can protect ourselves from dangers that may cause it," said Amy Comstock, PAN Executive Director. "As members of the Parkinson's community, it will absolutely benefit us to push for continued funding for this important and innovative research that may some day lead us to a still-better understanding of PD, and eventually, a cure."

Initiated in 1997, NETRP focuses on biomedical research designed not only to improve the treatment of neurological diseases but to identify the causes of such diseases and ways to prevent them. Currently, this program has 79 biomedical research projects underway in 22 states. While the explicit and legitimate purpose of the program is to generate information on how best to protect military personnel and minimize or eliminate future exposures to harmful substances and situations

## The Voice From Washington

(this is the Department of Defense, after all!), its ramifications are expected to be much wider. Soldiers and sailors face daily exposure to toxic chemicals such as pesticides and jet fuel and low-level radiation from sonar and radar. Scientific studies have found that these everyday exposures, along with head injuries, put our troops at an increased risk for developing neurodegenerative diseases such as Parkinson's, ALS and Alzheimer's — all of which cause permanent loss of brain and nerve cells.

"The power of the NETRP is in its dual-use nature," said Col. Brian Lukey, Director of the Military Operational Medicine Research Program, U.S. Army Medical Research Materiel Command. "The military can leverage scientific advancements in Parkinson's disease research to advance cognitive performance and mental health among our American warfighters, both when they are on the front line and when they return home to loved ones. The civilian community will better understand the causes of the disease to prevent its occurrence, will more quickly diagnose the disease to initiate treatment earlier and will — we hope — develop treatments to someday cure Parkinson's disease itself. Both the Parkinson's community and the military benefit."

Projects conducted with NETRP partnership or funding include the Michael J. Fox Foundation for Parkinson's Research Fast Track Program to establish early detection of Parkinson's disease through biomarkers (to which PDF, also, has contributed), investigations into oxidative damage in the brain and identification of possible neuroprotective agents. NETRP is also currently working to establish hereditary links to Parkinson's disease, which is opening the door to developing new treatments for both hereditary and environmentally-induced Parkinson's. This important research is expediting the discovery process,

significantly advancing the science of neurology and enhancing military readiness. The \$40 million in funding that advocates requested at PAN's 11th Annual Forum is crucial to maintain critical NETRP-funded projects.

For those who were unable to attend the Forum and learn about NETRP, we are pleased to announce that for the first time, through a generous donation from the Charles and Vivian Sukenik Philanthropic Foundation, the Forum has been cybercast and is still available via the



*Brathwaite Photography*

**Col. Brian Lukey addresses more than 300 advocates at the PAN forum with a review of NETRP's current research projects.**

Internet. You may find a link to the cybercast on PAN's website, [www.parkinsonsaction.org](http://www.parkinsonsaction.org). The cybercast allows online participants to watch all of the presentations from the PAN Forum. Online participants can also contact their Members of Congress through a special locating tool, the CapWiz system, available on the PAN website. We encourage all members of the Parkinson's community to familiarize themselves with the CapWiz system, and to contact their representatives. And, of course, don't forget to ask your representatives to support the \$40 million in NETRP funding.

*Founded in 1991 and based in Washington, DC, PAN is the unified education and advocacy voice of the Parkinson's community. PDF uses an important portion of your contributions to support PAN — \$150,000 in the current year. For more information on how you can join PAN and be an advocate for the Parkinson's community, please visit the PAN website or call (800) 850-4726.*

## PDF Research Proposals Due April 1: Last Call

Since 1957, PDF has supported hundreds of research projects and/or collaborative efforts throughout the world. Each component of the research program has its own procedure and reporting structure. To help researchers submit their requests for funding, we have provided here the information on the various grants that are quickly approaching the submission deadline. Our selection process is guided by the PDF Scientific Advisory Board, a committee of leading Parkinson's basic, clinical and translational scientists.

For the first time, PDF now offers online submission of applications. To access this feature, please visit the PDF website at [www.pdf.org/Research/](http://www.pdf.org/Research/) and click on the type of research program you wish to investigate. Another first for the application process should be noted: the International Research Grants Program and both postdoctoral fellowships now use the same application form. For further information on PDF's scientific grants programs or the application process, please contact Sharon Stone, Director of Research and External Programs, at (800) 457-6676, by email at [sstone@pdf.org](mailto:sstone@pdf.org) or by mail at 1359 Broadway, Suite 1509, New York, NY 10018.

### Summer Student Fellows

*Application Deadline: Friday, April 1, 2005*

*Funding of successful applications will begin July 1, 2005.*

Summer student fellowships are used to support high school seniors, undergraduates and medical students in the pursuit of Parkinson's-related summer research projects. Typically such fellowships are offered for 10 weeks of laboratory work under a sponsor who oversees the project.

### Postdoctoral Fellowship for Neurologists

*Application Deadline: Friday, April 1, 2005*

*Funding of successful applications will begin July 1, 2005.*

The purpose of this fellowship is to support neurologists who wish to train in movement disorders or to undergo advanced research training once they have finished their movement disorder training. Applicants who have completed a Movement Disorder Fellowship and wish to pursue research training in movement disorders will be given preference.

These awards are available for up to \$35,000 per year, for one or two years. Applicants must already have earned an M.D. and be completing or have completed a neurology residency.

### Postdoctoral Research Fellowship

*Application Deadline: Friday, April 1, 2005*

*Funding of successful applications will begin July 1, 2005.*

Postdoctoral Research Fellowships enable young scientists, fresh from their residencies, to study at a major research institution for one or two years. Most of the graduates of this program return to their home states and countries to lead, and in some cases to establish, movement disorder programs.

### International Research Grants Program

*Application Deadline: Friday, April 1, 2005*

*Funding will be effective July 1, 2005, concluding June 30, 2006.*

The International Research Grants Program (IRGP) is designed to support projects of the highest scientific caliber from around the world that are directly relevant to the study of a treatment for, or causes of, Parkinson's disease; that are complementary to, not duplicative of, other research in the field and that have the potential to lead to research proposals to the National Institutes of Health and other sources of government support. Basic, clinical and translational research proposals are eligible for support. Preference will be given to scientists who are at an early stage in their professional careers.

PDF has an annual budget of \$700,000 for this program. No single International Research Grant Award will exceed \$40,000. Applications must be submitted electronically at [www.pdf.org/Research/](http://www.pdf.org/Research/). Final decisions are expected by mid-May 2005.

## New Home for PDF



On March 11, 2005, the PDF office officially moved from upper Manhattan to our new location in midtown. While we will continue to maintain offices in Chicago and at Columbia University Medical Center, you can now contact PDF at our new address:

1359 Broadway, Suite 1509  
New York, NY 10018

Our phone and fax numbers will remain as follows:

Ph: (800) 457-6676 or (212) 923-4700

Fax: (212) 923-4778

You can also still reach us by email at [info@pdf.org](mailto:info@pdf.org).

## FDA Advisors to Include People with Parkinson's

On February 8, Dr. Lester Crawford, the Acting Commissioner of the U.S. Food and Drug Administration (FDA), announced that the agency's Patient Consultant Program will be expanded to include Parkinson's disease. The FDA Patient Consultant Program was designed to incorporate the perspective of patient advocates into drug development, and began in 2001 with the cancer community. Advocates from the HIV/AIDS patient community were the next group to be added, and Parkinson's advocates will be the third.

FDA will recruit, select and train Parkinson's disease patient advocates for the program. Those selected will serve as patient consultants primarily on the research

phase of such development that precedes approval and general release of a treatment. The patient consultants will provide advice to FDA and to the drug sponsor on such topics as clinical trial design, endpoint determination, expanded-access protocol development and clinical trial patient recruitment strategies. FDA will arrange for patient consultants to participate via telephone in FDA in-house meetings and meetings with sponsors.

The advocate selection process will be managed by the Office of Special Health Issues (OSHI) in collaboration with the Division of Neuropharmacological Drug Products (DNNDP) and the Center for Drug Evaluation and Research. Once selected, the consultants will be hired as Special Government Employees and will be subject to the same conflict of interest and confidentiality regulations that govern all other employees, consultants and advisors to the FDA. Each new consult-

ant will receive training at FDA's Rockville, MD facilities, at the agency's expense.

Perry Cohen, Ph.D., founder of the Parkinson Pipeline Project — a grassroots patient-centered group that is dedicated to involving patients in the treatment development process, and that is affiliated with PDF — described the move as a “decisive and thrilling step towards recognizing the necessary role of patients in drug and treatment development.” Dr. Cohen, who has lived with PD for almost a decade, was instrumental in conceiving and bringing the Parkinson's component of the program to fruition.

Information regarding how to apply, FDA's selection criteria and processes, training and consulting is available from the FDA Office of Special Health Issues at [www.fda.gov/oashi/cancer/pconback.html](http://www.fda.gov/oashi/cancer/pconback.html). For further information, please contact FDA employees JoAnn Minor or David Banks at (301) 827-4460.

## News to Note

### Excitement Builds for PDF's Annual Fundraiser

Friends and supporters will once again gather at the Pierre Hotel in New York City for the Parkinson's Disease Foundation's (PDF) annual black tie gala event, “Bal du



Printemps,” on Thursday, May 19, 2005. Guests will join together in the grand tradition of raising funds to support PDF programs and research grants, as well as to honor outstanding members of the community for

their work in the fight against Parkinson's. The evening will include cocktails, dinner, dancing and a silent auction.

The PDF Board of Directors and Gala Chairs Margo Catsimatidis, Karen Burke Goulandris, M.D., Ph.D. and Isobel Robins Konecky are proud to announce that the chair of this year's event will be Dr. Judith Sulzberger, a physician, author and long-time friend of PDF. Dr. Sulzberger will join the PDF Board of Directors and Gala Chairs in presenting The Lifetime Achievement Award to Page Morton Black, Chair-

man of the PDF Board, and The Page and William Black Humanitarian Award to Lucien J. Côté, M.D., Department of Neurology, Columbia University Medical Center.

For additional information on the “Bal du Printemps,” or to make a reservation to attend, please call event organizer Carla Capone at (212) 213-1166 or email [cccevents@aol.com](mailto:cccevents@aol.com).

### Lace Up for the 2005 Parkinson's Unity Walk

The Parkinson's community is eagerly awaiting the 11th Annual Unity Walk on Saturday, April 16, 2005 (rain or shine). People with Parkinson's, friends, family and others from across the U.S. will gather in Manhattan's Central Park and walk together with the common goals of raising awareness and finding a cure for Parkinson's disease.

The funds raised by the walk support Parkinson's research and are distributed amongst seven major U.S. Parkinson's organizations (including PDF). Help make this year's Unity Walk a success by registering today at [www.unitywalk.org](http://www.unitywalk.org)!

For questions about the Parkinson's Unity Walk, email [info@unitywalk.org](mailto:info@unitywalk.org) or call (866) PUW-WALK or (866) 789-9255.



### WPC Update — Important Dates to Remember

With less than a year to go until the opening ceremony at the World Parkinson Congress, the WPC steering committee is pleased to announce that the preliminary program is now available at [www.worldPDcongress.org](http://www.worldPDcongress.org). The WPC program offers sessions for physicians, scientists, allied health professionals, people with Parkinson's and caregivers on topics such as diagnosis, trends in treatment and the future research for Parkinson's.

A segment of the program, entitled “Creativity and Parkinson's,” will highlight works of art by people with Parkinson's disease, including visual, literary and performing arts. Artistic submission guidelines will be posted on the WPC website on April 1, 2005. Scientific abstract guidelines and criteria will also be posted on that date.

For more information on the WPC and details on its program, please visit [www.worldPDcongress.org](http://www.worldPDcongress.org), call (800) 457-6676 or email [info@worldPDcongress.org](mailto:info@worldPDcongress.org).

## AROUND &amp; ABOUT THE COMMUNITY

**Benjamin Shows Us the Light of Day**

Music promoter and friend of the Parkinson's Disease Foundation (PDF) Bob Benjamin has done it again! Over a three-

John Cavanaugh



Event organizer Bob Benjamin jams with the legendary Bruce Springsteen.

day weekend in early November, fans and friends packed The Stone Pony club in Asbury Park, NJ for the fifth annual "Light of Day" concert, a music fest that benefited PDF and one other charity. This year, the event raised over \$60,000 for PDF.

The concert has grown over the years, from a private 40th birthday celebration for Bob in 1998 to the spectacular weekend 2004 party that drew hundreds of music lovers. Bob was diagnosed with Parkinson's in 1996.

Bruce Springsteen once again made an unannounced appearance at the event with headliners Joe Grushecky & the Houserockers (a group that Bob manages).

Bruce rocked The Pony for more than an hour and a half with Grushecky, his musical and songwriting colleague from Pittsburgh. Among other highlights of the weekend were performances by

John Cavanaugh



Joe Grushecky gets The Stone Pony rocking at the "Light of Day" concert.

Pat DiNizio from the Smithereens, La Bamba And The Hubcaps, Shane Fontayne, Willie Nile, Boccigalupe and The Bad Boys and Joe D'Urso & Stone Caravan.

Especially touching were the moments when musicians related their personal experiences with Parkinson's disease, and spoke of how important it is to work for the cure. Bob urged the crowd to push their elected officials on such issues as stem-cell research and healthcare, both of which are hugely important to the Parkinson's community. He also thanked the crowd and told them that "working together, we can find a cure for Parkinson's and related diseases."

PDF extends its heartfelt thanks to Bob Benjamin for his hard work, dedication and generosity, as well as resounding "congratulations" on another great show. May the "Light of Day" continue to shine hope and promise on Parkinson's research to find a cure!

**Advocates Rally on Capitol Hill**

On Tuesday, February 8, 300 members of the Parkinson's community — the largest group of Parkinson's advocates ever to gather in Washington, DC — fanned out among

Bathwaite Photography



PAN Advocates Peggy Roberge (left) and Marsha Anthony (right) meet with Representative Thelma Drake (R-VA).

Congressional offices to present a clear message to Congress on such issues as funding for scientific research and the exploration of essential scientific avenues including stem-cell research. The traditional "day on the hill" — it included a record 200 legislative visits! — was the culmination of the Parkinson's Action Network's (PAN) 11th Annual Forum, a three-day conference on scientific developments and advocacy training.

First-time attendees and experienced forum-goers alike worked together to familiarize themselves with PAN's Action Agenda and to strategize on the best way to present it to Congress. This year's agenda focused on increasing appropriations for the National Institutes of Health (NIH),

and for the Parkinson's-related research currently being done through the Department of Defense's Neurotoxin Exposure

Bathwaite Photography



Dr. Elias Zerhouni, NIH Director, explains current NIH initiatives in Parkinson's research.

Treatment Program (NETRP) (for more information, see *The Voice from Washington* on page 8). A highlight of the training was a talk by NIH Director Dr. Elias Zerhouni. Dr. Zerhouni's presentation, entitled "Parkinson's Disease: New

Strategies at the National Institutes of Health," provided an overview of the current status of NIH funding and federal research priorities in Parkinson's disease at the NIH.

The Forum concluded with the Louis Fishman Advocacy Awards dinner, a special opportunity for PAN to recognize exemplary leaders in the community. This year, the Louis Fishman Advocacy Award was presented to Linda Herman, PAN's State Co-Coordinator for New York and a long-time champion for the Parkinson's disease community at both national and grassroots levels.

Another award, this one named for Murray Charters, the legendary Parkinson's advocate from British Columbia, was presented to Len Casavant. Len is PAN's State Co-Coordinator for South Carolina and also hosts the radio program, *Travels With Parkinson's*, which features live talk, oldies, easy listening and analysis on Parkinson's disease. Listeners can tune in to Len's radio show by pointing their Internet browsers to [www.live365.com/stations/travelswparkinsons](http://www.live365.com/stations/travelswparkinsons).

For more information on the Forum and PAN's Action Agenda, please visit [www.parkinsonsaction.org](http://www.parkinsonsaction.org). If you were unable to attend this year, you can view a webcast of the Forum on the PAN website. This medium was made available this year for the first time through a generous donation from the Charles and Vivian Sukenik Philanthropic Foundation.

# Calendar of Events



## The 12th Annual Morris K. Udall Awards Dinner

**Date:** Wednesday,  
April 13, 2005

**Place:** Washington, DC

The Parkinson's Action Network (PAN) will honor leading figures in the Parkinson's community at this annual dinner. Spend an evening in Washington, DC, to celebrate individuals who have made significant contributions to the cause and science of Parkinson's.

For details and ticket information, contact PAN at (800) 850-4726 or email [info@parkinsonsaction.org](mailto:info@parkinsonsaction.org).



## 11th Parkinson's Unity Walk

**Date:** Saturday, April 16, 2005  
**Place:** Central Park, New York, NY

Come and join thousands at the Parkinson's Unity Walk in New York City's Central Park. Learn from medical experts, talk to friends and walk to help cure Parkinson's disease.

For more information, call (866) PUW-WALK (789-9255) or visit [www.unitywalk.org](http://www.unitywalk.org).



## Support for Today Cure For Tomorrow

**Date:** Thursday,  
April 21, 2005

**Time:** 12:00 Noon – 1:00 PM

**Place:** Duke Mansion,  
400 Hermitage Road, Charlotte, NC

The Parkinson Association of the Carolinas will be hosting its fourth annual luncheon to educate the community about the work of the Association and Parkinson's disease. Guest speaker will be Marsha Anthony from the Melvin Weinstein Parkinson's Foundation, Virginia Beach, VA.

For more information, contact Debbie Huffman, Executive Director, at (704) 248-3722.

## Third Annual Wheels & Heels 5K/1K Race

**Date:** Saturday,  
May 14, 2005

**Time:** 10:00 AM start time

**Place:** City Park  
Denver, CO



Lace up your shoes and head out for this Third Annual Wheels & Heels run/walk in Denver's City Park to raise awareness and funds for Parkinson's disease services in the Rocky Mountain region.

For more information or to register for the Wheels & Heels 5K/1K race, call (303) 830-1839 or email [info@parkinsonrockies.org](mailto:info@parkinsonrockies.org).

## Bal du Printemps

**Date:** Thursday,  
May 19, 2005

**Place:** The Pierre Hotel  
New York, NY



"Bal du Printemps" is an elegant celebration of philanthropy and science to raise funds for and awareness of Parkinson's disease. This year, honorees are Page Morton Black, Chairman of the PDF Board, and Lucien Côté, M.D., a well-respected PD physician. Proceeds will be used to support PDF research programs.

For more information, contact event organizer Carla Capone at (212) 213-1166 or [cccevents@aol.com](mailto:cccevents@aol.com).



Parkinson's  
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WINTER 2005

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