MARK SELIGER

ACCELERATING THE CURE

The newsletter for friends and supporters of
The Michael J.Fox Foundation for Parkinson's Research

WINTER 2011-12

Pioneering Partnership with MJFF Drives New Parkinson's Treatment Toward Pharmacy Shelves

THE FOX APPROACH: A recurring series highlighting MJFF's out-of-the-box approach to speed the cure

In December 2007, the *Wall Street Journal* reported on a troubling trend in drug development.

"Over the next few years the pharmaceutical business will hit a wall," the paper wrote. In the modern era of complex disease, blue-chip drugmakers' in-house research operations were bringing fewer and fewer therapies to market. Struggling to recoup their research investments in the development of new treatments that can cost over a billion dollars, more and more companies were downsizing these programs as part of major cost-cutting initiatives. For many, patents on the most profitable products in their portfolios were soon to expire.

"In five years," the *Journal* predicted, "many [of these companies] may look very different. They will be in new businesses."

Yet disease — and the need for new and better treatments to benefit countless human lives — marched on without regard to business objectives or shareholder return. To The Michael J. Fox Foundation (MJFF), with its relentless focus on speeding scientific breakthroughs for Parkinson's disease (PD) and its habitual problem-solving approach, the need for out-of-the-box thinking had never been clearer. Promising alternative models were needed to supplement Big Pharma's resources and decades of expertise in developing drugs — and to get off the ground, they would need significant support from funders willing to champion new approaches.

Meanwhile, a scientist at Vanderbilt University in Nashville, Tennessee, was quietly undertaking his own mission to drive the pharmaceutical pipeline forward. Jeff Conn, PhD, was a member of the Foundation's Scientific Advisory Board and director of Vanderbilt University's Program in Drug Discovery. Since 2003, Conn, a former senior director of neuroscience at Merck & Co., had worked to assemble a team of more than 60 scientists devoted to conducting the long and specific series of studies — traditionally the purview of industry, not academia — that could usher a drug into clinical testing. Conn also had a particular research interest in developing drugs to treat complicated neurological diseases, including PD.

"Without the committed support of MJFF, it would have been impossible to develop this nascent and high-risk idea. Traditional sources of funding for academic research do not provide support for the type of team-based drug discovery efforts that are essential for translating novel ideas into medicines that can help Parkinson's patients."

—Dr. Jeff Conn

"Jeff had come to the Foundation with a proposal to develop an entirely new class of treatment for Parkinson's disease," recalls Todd Sherer, PhD, the Foundation's CEO. "He wanted to diverge from the classical pursuit of treatments targeting the dopamine system. His idea was to work within the glutamate system and bypass dopamine replacement altogether. The goal was to match the symptomatic benefit of levodopa while avoiding debilitating side effects like dyskinesias."

With funding from the Foundation starting in 2005, Conn's team at Vanderbilt had been screening drug compounds with potential to activate specific glutamate receptors implicated in Parkinson's disease. The compounds worked in a fundamentally different way from dopamine replacement therapy, instead modulating another of the brain's neurotransmitters, glutamate. Conn and his colleagues had been working to activate a specific glutamate receptor called mGluR4.

"Without the committed support of MJFF, it would have been impossible to develop this nascent and high-risk idea," said Dr. Conn. "Traditional sources of funding for academic research do not provide support for the type of team-based drug discovery efforts that are essential for translating novel ideas into medicines that can help Parkinson's patients."

By 2007, Dr. Conn's team had already produced significant results. That year, MJFF extended and

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A Note from the CEO

As a scientist and CEO of The Michael J. Fox Foundation (MJFF), I keep a close eye on all the latest news in Parkinson's disease (PD) research. At the year's end, I wanted to share my insights with you on the current state of the field — where we've made critical strides in PD research and where challenges remain. Please see page 3 for the first edition of "The Sherer Report," my take on the most important recent research developments affecting Parkinson's drug development. I hope you'll let us know if you enjoy it or what you'd like to see us cover in future editions.

Friends of the Foundation like you are valued members of a knowledgeable community. You are invested in our work, and, through your generous support, you help make it possible. As always, thank you for being part of our team. On behalf of everyone at the Foundation, our best wishes for a bright holiday season.

–Todd Sherer, PhD

New In This Issue:

Codes for a Cure!

We're bringing MJFF straight to you — and to your phone — in this issue, so you'll find QR codes throughout. Scan with a QR Reader on your smartphone to access exclusive Web-only content: podcasts, slideshows, videos, and more.

sample

NOTE: If you have an iPhone, you may need to use iTunes to listen to podcasts.

New Technique Brings Stem Cell Therapy Closer to Reality

Historically, embryonic stem (ES) cells have shown promise for treating Parkinson's disease in a Petri dish. But they have not yet been effective once transplanted into a living organism. A new technique, however, has revealed fresh promise in models of PD, reflecting the potential for dopamine cells' survival and function in the brain. The research was led by Lorenz Studer, MD, director of the Sloan Kettering Institute (SKI) for Stem Cell Biology.

Dr. Studer was funded by The Michael J. Fox Foundation in 2001 to investigate the potential of ES cells to treat PD, and was part of the team that first successfully induced human ES cells to turn into dopamine neurons in research experiments. Along the way, Dr. Studer received additional funding from MJFF in 2002 and 2006 to further his research on ES cells. MJFF spoke with Dr. Studer to gauge the impact of this recent discovery, and to discuss why the process of developing stem cell therapies is such a long and arduous one. While Dr. Studer's results are promising, there is still much work to be done before stem cells can be considered a viable therapeutic option for PD.

MJFF: Tell us more about your study's findings.

Lorenz Studer: After many years of trying, we have finally created a method to use human stem cells to generate dopamine nerve cells that maintain their function in pre-clinical models of PD. In the past, we were able to make cells in a Petri dish that took on many of the features of dopamine nerve cells. But when these cells were transplanted into pre-clinical models, they either died very quickly, or the cells that did survive tended to overgrow. It was such a mystery: Why did these cells look so good in a Petri dish, but not in a whole organism?

Another point of contention has surrounded why the cells didn't take the way we wanted them to: Was it because of the environment in which we were placing the cells, or was it the cells themselves? We have figured this out — it was the cells themselves, and we have created a new recipe for making them.

Historically, two specific cell pathways were used to make these cells. By delving back into the developmental biology, we figured out that a third pathway was missing from the equation. So we used a small molecule compound, which is a little bit like a pharmaceutical drug, to trigger this third pathway. By doing this, dopamine growth was activated, and at a much higher level of efficiency than we had previously seen. But more important than that, when we injected these cells into pre-clinical models of PD, they survived very well and were functionally active, meaning that the movement deficits in these models were largely corrected. In fact, after four or five months, several movement deficits were completely restored.

MJFF: How are you following up on this discovery in your current work?

LS: Another exciting aspect of this study was that we were able to show that our new technique can quite easily be scaled up in size. While it's not yet ready for study in humans, we were able to transplant these cells into a larger size pre-clinical model, and we found that they took to the brain very well, while showing the exact same characteristics as in the smaller models. We haven't yet done long-term functional studies in these larger models, so that is next, as we aim to determine if we can restore more complex movements.

We are also working with a specialized Good Manufacturing Practices facility to produce a very large number of cells. Over the next few years, we will test these cells in pre-clinical models to determine their efficacy and safety at a greater scale. This will help us to optimize procedures surrounding the production and purification of our cells ahead of a potential clinical study.

MJFF: What might this new study mean for cell replacement therapy moving forward?

LS: There are still many hurdles to overcome. In addition to showing that these cells work really well in large pre-clinical models over the long-term, we need to address the potential side effects of cell replacement therapy in human beings. This is a major concern — in past studies on PD, grafted cells did survive in human brains. However, in one such study using fetal cell transplants, the graft made the subjects' dyskinesia significantly worse than before the trial. Eventually, we will test our cells in a specific dyskinesia-prone model of PD, and hopefully this will prove to reduce dyskinesias, and not worsen them.

Again, we have a long way to go — stringent clinical studies would have to follow our studies in pre-clinical models. But we are optimistic.

MJFF: Realistically, what kind of timeline are we looking at before your technique makes its way to the clinic?

LS: People always ask how long it will take before cell replacement therapy is a viable option, and we've never had a good answer. But we've also never had a really good way to make the correct cell. Now we believe we do. The question now is more one of engineering than biology, so I think a timeline is more predictable. The big question is, can we better influence the behavior of the cells once we transplant them. Right now, we kind of place them in a black box and hope for the best. We're still perfecting how to better control the cells once they're transplanted into the brain.

Certainly, a lot can still go wrong. But if everything goes right, we believe we could establish these large-scale banks within three to four years. After that, we could begin to start thinking about clinical trials. We have set up a multidisciplinary team here at SKI and several neighboring institutions in New York comprising neurologists, neurosurgeons, and cell engineers to begin to think about the steps we will need to take to move into the clinic. We are confident that this group can go a long way to help us to make the right decisions moving forward.

NOTE: The medical information contained in this article is for general information purposes only. The Michael J. Fox Foundation has a policy of refraining from advocating, endorsing or promoting any drug therapy, course of treatment, or specific company or institution. It is crucial that care and treatment decisions related to Parkinson's disease and any other medical condition be made in consultation with a physician or other qualified medical professional.

PPMI Still Enrolling
First Results Coming In

PARKINSON'S PROGRESSION MARKERS INITIATIVE
Play a Part in Parkinson's Research

The Parkinson's Progression Markers Initiative (PPMI), the Foundation's landmark clinical study to find biomarkers of Parkinson's disease (PD), is now reporting its first results. The study has been amassing a large database of clinical and neuroimaging data, which has been online since March 2011. As part of PPMI's open-source research model, the repository is made available to anyone around the globe to conduct biomarkers research. While PPMI is a five-year study, its results are published in real time — accelerating the pace of biomarker validation, clinical testing and discovery. Data have been downloaded more than 4,000 times by scientists in the research community at large to conduct independent studies toward new treatments for PD. Initial analyses of biological samples collected through PPMI have demonstrated changes that occur in early-stage PD, which will open new avenues for follow-on studies.

More than a year into the study, 19 clinical sites are active across the United States and Europe, with sites in London, United Kingdom, and Naples, Italy, about to come online. New sites in Cincinnati, Ohio, Boca Raton, Florida, and Sydney, Australia, are expected to launch in 2012. Against the study's goal of enrolling 600 participants (400 newly diagnosed Parkinson's patients and 200 control participants who do not have the disease), over 250 people have volunteered so far (as of November 30, 2011).

With the aim of completing enrollment by the end of 2012, PPMI continues actively enrolling volunteers. In particular, the study needs newly diagnosed patients of at least 30 years of age and male control participants aged 55 and up. To learn more, visit www.michaeljfox.org/PPMI.

– Nate Herpich

Short but not Simple: Frequently Used Abbreviations in this Issue

We recognize the world of Parkinson's research can resemble alphabet soup at times. To help clarify, we've provided a list of the most popular abbreviations you'll find in this issue.

DBS: Deep Brain Stimulation
MJFF: The Michael J. Fox Foundation for Parkinson's Research
PD: Parkinson's disease
PPMI: The Parkinson's Progression Markers Initiative

THE SHERER REPORT


ELENA OLIVO

In this first edition of "The Sherer Report," which will become an ongoing series, I want to highlight recent developments in three of the Foundation's high-priority research areas, which hold clear implications for those living with PD today.

Todd Sherer

Todd Sherer, PhD, CEO

Read "The Sherer Report" on the MJFF Blog at blog.michaeljfox.org.

New Approaches to Treat Symptoms

Many of the motor symptoms of Parkinson's result from a decrease in dopamine, a brain chemical that helps control movement, balance and walking. For the last 40 years, nearly every treatment for PD, including the currently available medications Sinemet, Mirapex, Azilect and Stalevo, have focused on attempting to replace this lost dopamine.

However, new lines of research are developing PD treatments based on different mechanisms that target brain chemicals other than dopamine. These approaches could replace or supplement existing therapies, limiting side effects such as dyskinesias, the uncontrollable movements that are a common side effect of existing PD drugs, while targeting some of the currently untreated symptoms of PD.

MJFF's research staff believes that several non-dopamine-based approaches have the potential to tangibly impact patient's lives. Our support for several such approaches began at the ground floor with pre-clinical studies — and has now advanced to clinical trials. These projects include:

- Swiss biotech Addex Pharmaceuticals launched an MJFF-funded clinical trial last spring, targeting the neurotransmitter glutamate. Similar to dopamine, glutamate is responsible for transporting brain messages and controlling body functions. The hope is that, by bypassing the dopamine system altogether, it might be possible to provide the same symptomatic benefit of levodopa without triggering adverse effects such as dyskinesias. Addex is studying how limiting the activity of a particular glutamate receptor called mGluR5 could reduce these dyskinesias. The study is based on MJFF-funded work that dates back to 2005 by Angela Cenci-Nilsson, MD, PhD, of Lund University in Sweden and Erwan Bezard, PhD, of the University of Bordeaux, which validated this new therapeutic target in pre-clinical models. Other major pharmaceutical companies including Novartis have also moved mGluR5 therapies into the clinic.

- Significant evidence also exists to support the development of therapies targeting another glutamate receptor, mGluR4. As you read in our cover story, last summer, MJFF awardee Jeff Conn, PhD, of Vanderbilt University announced that his team was ready to declare drug candidate status on three compounds that act on mGluR4 as an alternative treatment for PD. Dr. Conn's team was funded by MJFF to demonstrate through pre-clinical evidence that this approach could improve PD symptoms while limiting dyskinesias. Now that the team has identified three drug candidates, clinical trials could begin as soon as 2013.

While there is no guarantee that any of these therapeutic strategies will ultimately be successful, for the first time in years, several approaches focused on novel biology are now in late-stage drug development for Parkinson's. New hypotheses provide the opportunity for dramatic progress toward new treatments for PD.

Role of Genetic Factors in PD

Thanks to improving technology and significant research investments over the past decade, we are homing in on genetic contributors to PD. Identifying genetic factors that cause or increase the risk for Parkinson's is the first step toward converting this information into new treatment strategies. MJFF support has been instrumental to build upon recent genetic findings that could open new avenues toward disease-modifying treatments — the most significant unmet need of Parkinson's patients:

Hear from Achim Schneeberger, MD, at AFFiRiS about the opportunities and challenges in developing a vaccine to treat PD.

- The alpha-synuclein gene plays a critical role in PD. Scientists at Austrian biotech AFFiRiS are working on new ways to target this gene and its protein product, whose clumps — known as Lewy bodies — are the pathological hallmark of Parkinson's. With up to $1.5 million in funding from MJFF announced in October, AFFiRiS is launching the first-ever PD vaccine clinical trial. The study draws on evidence from pre-clinical studies that suggest their vaccine helps clear clumps of alpha-synuclein from the brain, potentially slowing disease progression. Subsequent to the MJFF grant, AFFiRiS has received an additional of up to $30 million from private investors to accelerate their PD program. If successful, this could lead to a breakthrough in how we treat PD. Similar approaches to Alzheimer's disease are also progressing through the therapeutic development pipeline.

- As you will read on page 4 of this newsletter, mutations in the gene LRRK2 are the most common genetic cause of PD discovered to date, and MJFF is tackling it from multiple angles simultaneously to accelerate progress. Members of our LRRK2 Biology Consortium at Harvard University discovered a compound that blocks the action of LRRK2 — a prototype for a potential future treatment. This compound is now being shared with LRRK2 researchers around the world. A University of Ottawa lab in the consortium is studying how LRRK2 may influence immune system response to external triggers of PD, which could establish a link between environmental and genetic causes of Parkinson's disease.

Need for Parkinson's Biomarkers Remains Pressing

In other current events, a recent recommendation from an advisory committee to the Food and Drug Administration (FDA) underlined the urgent need for a biomarker for PD. In October, Teva Pharmaceuticals sought a new label for rasagiline (brand name Azilect) as a drug that slows clinical progression of Parkinson's disease — proposing that individuals who took Azilect had a slower change in their symptoms as measured in a clinical setting, compared to people who were not treated with the drug. Based on data available to date, the FDA advisory committee unanimously recommended against this status. Azilect remains available as a symptomatic treatment for PD.

Hear from Brian Fiske, PhD, MJFF director of research programs, on Azilect and the need for a biomarker.

As this story highlighted, the absence of a biomarker continues to slow the search for a PD treatment that can do more than alleviate symptoms. Because we were limited to only measuring symptoms, the effects of Azilect as a disease-modifying treatment remained unclear. But a biomarker would enable more definitive conclusions about PD progression, which could in turn help us to find drugs that modify the underlying cause of the disease itself. To find out more about how MJFF is leading the search for a biomarker, read our PPMI update on page 2, or visit www.michaeljfox.org/PPMI.

MJFF Expands LRRK2 Cohort Consortium

Since first being linked to Parkinson's disease in 2004, the LRRK2 gene has become an increasingly important target for PD researchers across the globe — and for MJFF. LRRK2 is now believed to be the most common genetic contributor to the disease in the general population.

With leadership funding from the Brin Wojcicki Foundation, The Michael J. Fox Foundation has invested more than $38 million in research projects devoted to LRRK2 to date, and has made the translation of this finding into meaningful therapeutics one of its key priority areas.

This fall, MJFF announced the expansion of the LRRK2 Cohort Consortium, a group of eight separate research teams funded by MJFF to bring together and learn from people with and without PD who carry mutations in the gene. The cohorts are made up of more than 3,000 people across 20 clinical sites worldwide. By building a large network of patients and their families, and compiling significant clinical data on LRRK2 parkinsonism over time, the Foundation hopes to lay the groundwork for effective LRRK2 clinical trials once appropriate drug candidates have been identified.

A global LRRK2 consortium takes shape

LRRK2 may play a particularly frequent role in cases of PD among certain populations, including Ashkenazi Jews, North African Berbers and Asians of Chinese descent. Yet a recent study by MJFF awardee Dr. Owen Ross suggests that we may have only begun to determine the significance of LRRK2 and its role in PD in other populations across the globe. Piloted in 2009 to assemble cohorts of Ashkenazi Jews in New York and Tel Aviv and North African Berbers in Tunisia, the LRRK2 Cohort Consortium today includes additional sites across the United States, Canada, China, Germany, France, Norway and Spain.

"One of our top priorities at MJFF is to find ways to alter the progression of PD. By studying individuals with the LRRK2 mutation, we hope to learn more about why certain populations are susceptible to the disease," said Brian Fiske, PhD, director of research programs at MJFF. "By investigating how this mutation works in people with PD, we also can find out more about Parkinson's on the whole, accelerating development of therapies that will benefit everyone with the disease, not just those with mutations in LRRK2."

Scientists in the Consortium will share clinical data, housed at a central repository at the University of Rochester in Rochester, New York. MJFF will coordinate the standardized collection of various biosamples from individuals with LRRK2 mutations, and make them available to the research community at large.

Initial findings from Consortium studies to date already have prompted MJFF to establish working groups to validate results related to issues including posture and gait disturbances, a LRRK2-cancer link, and impaired sense of smell as a pre-diagnostic biomarker for LRRK2-related PD.

A multi-pronged approach to speed progress

The Consortium is one element of the Foundation's multi-pronged approach to speeding development of LRRK2-based treatments for PD. MJFF is also funding and coordinating the LRRK2 Biology Consortium, a collaborative network of more than 30 investigator teams studying LRRK2's structure and function to advance development of practical treatment strategies. And MJFF's staff scientists are spearheading the creation and distribution of high-quality LRRK2 pre-clinical models, essential and traditionally elusive tools for high-impact research, for distribution at low cost to industry and academic labs starting in 2012.

"By investigating how the LRRK2 mutation works in people with PD, we also can find out more about Parkinson's on the whole, accelerating development of therapies that will benefit everyone with the disease, not just those with mutations in LRRK2." — *Brian Fiske, PhD*

LRRK2 and Industry

Pharmaceutical companies are interested in developing drugs to target LRRK2. It is a type of protein called a kinase, which, in PD, is believed to result in overactivity. Drugmakers have amassed extensive experience, primarily from cancer research, developing so-called kinase inhibitors, which can counter this molecular overactivity. There are not yet specific drugs in clinical testing to treat LRRK2 parkinsonism, but drug companies are actively pursuing research that could lead to potential therapies.

To this end, MJFF has also established a LRRK2 Industry Advisory Group, including representatives from Pfizer, Elan, Sanofi-aventis, Eli Lilly, MerckSerono, GlaxoSmithKline, and others. The group's goal is to ensure that LRRK2 therapeutic development is executed in a way that ultimately yields the most efficient results for patients. Members of the group come together in a precompetitive space to discuss how to best create and share resources that will most effectively push LRRK2-based drugs closer to the clinic.

Says Advisory Group member Alastair Reith, PhD, of GlaxoSmithKline: "MJFF's LRRK2 strategy allows for a unique approach where academia provides breakthrough science, industry provides capabilities for drug discovery and testing, and MJFF provides necessary disease focus to drive both forward." *–NH*

PIONEERING PARTNERSHIP

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expanded its partnership with Conn, awarding $4.4 million through its LEAPS (Linked Efforts to Accelerate Parkinson's Solutions) program to investigate mGluR4. Designed with projects like Conn's in mind, the LEAPS initiative funds "all-star" research teams to tackle important research questions for PD, engaging a collaborative, milestone-driven approach.

By 2009 it appeared that this approach was working: Dr. Conn reported the attainment of a major milestone. His team had discovered systemically active compounds targeting mGluR4. Working in pre-clinical disease models, Dr. Conn had verified that these compounds made it into the brain and went to all the intended places. Crucially, he had also confirmed that the compounds were beneficial in a pre-clinical model of PD. As *Chemical & Engineering* wrote that year, Conn's vision was coming to fruition; he had built an operation that resembled "a biotech company operating within the walls of a university."

In late summer 2011, Conn attained one of the final stages of pre-clinical testing prior to human trials. The team announced that it was ready to declare drug candidate status on three drug-like molecules acting on mGluR4, with the hope of moving forward to the clinic by 2013. The compounds are known as "positive allosteric modulators," or PAMs. To increase mGluR4 activity while minimizing the likelihood of adverse effects, Conn's team has taken a subtle approach to manipulating the mGluR4 receptor.

"You can liken it to a dimmer switch on a light in your home, where you can turn up the gain of the receptor and its activity, or turn it down, without completely activating it or shutting it off," Conn explains.

Typically, the timeline for translating a discovery like Dr. Conn's into a new treatment for a central nervous system disorder like PD can take as many as 20 years. With MJFF support, Dr. Conn's group had radically accelerated this process.

"Following the MJFF philosophy," said Dr. Conn, "we have now de-risked the idea of using mGluR4 for treatment of PD to a point where multiple pharmaceutical companies are now interested in working with us to evaluate this promising new approach." *–NH*

Stay tuned for more stories like this on "The Fox Approach" in future newsletter issues!

Deep Brain Stimulation Surgery Benefits Last a Decade or Longer

Researchers from Toronto, Canada recently published a paper in *Archives of Neurology* following up with Parkinson's disease patients who had undergone Deep Brain Stimulation (DBS) surgery 10 years earlier. The study found that motor improvement, on the whole, was sustained 10 years following the procedure, although overall benefit was less than patients had experienced in the immediate aftermath of the procedure.

MJFF spoke with Scientific Advisory Board member, DBS pioneer and study author Andres Lozano, MD, PhD, professor of neurosurgery and head of applied and interventional research at Toronto Western Hospital, on the meaning of these results to people with PD, especially those who are considering DBS as a treatment option.

MJFF: Let's begin with the basics. Why might an individual with PD opt to have DBS?

Andres Lozano: For those who are disabled by the motor aspects of PD, DBS can be a highly effective and reasonably safe therapy, and based on our recent findings, the benefits can be expected to last over the long term. For the right candidates, DBS is one of our best options to help people with PD feel better and experience greater quality of life.

Still, it is important to remember that while DBS provides an important symptomatic benefit, the patient's Parkinson's will continue to progress over time. DBS is not a cure.

MJFF: Who are the right candidates for DBS?

AL: Patients who are experiencing difficulties with the drugs they are taking, and, in particular, with unpredictability of response as related to motor fluctuations throughout the day, are good candidates for DBS. They tend to continue to have a good response to levodopa, but with motor fluctuations.

The minimum goal of the surgery is to ensure that each individual's best response to therapy is maintained, and we've seen that the procedure is particularly good at smoothing out these peaks and valleys experienced by patients taking levodopa.

The procedure is performed at almost all major centers in the world, and 8,000 to 10,000 patients now undergo DBS each year.

Scan this code with a QR Reader on your smartphone to hear from a patient who had DBS 10 years ago, and one about to undergo the procedure, in this podcast.

MJFF: Tell us more about your new findings.

AL: We found that the motor symptoms associated with PD — tremor, rigidity and bradykinesia, or slowness of movement — were improved after the procedure. Moreover, the benefit to these symptoms was sustained up to 10 years.

However, we found that in some aspects, in particular posture and gait, the patients were worse. Non-motor symptoms, such as cognitive impairment, fatigue and digestion issues, unfortunately also continued along their natural course without much influence from the surgery.

MJFF: How do you expect DBS to be used moving forward?

AL: We are now moving forward with research into DBS treatments that might begin to treat these non-motor symptoms of the disease. Traditionally, these symptoms are unresponsive to surgery. But there are different circuits in the brain, and each has its own unique job to do. Some are for tremor, some deal with rigidity, for example. Others regulate cognition and depression. We now believe that if we focus on specific circuits, we can isolate treatment for more specific symptoms. It's like if you took your car in to get repaired — just because you need a new muffler doesn't mean you also need to fix the engine. And even if you did, you wouldn't expect the same procedure to fix both parts of the car.

We are now analyzing areas of the brain that are involved in generating non-motor symptoms. Traditionally, DBS targets the subthalamic nucleus. One of these new targets is the pedunculopontine nucleus (PPN), which could specifically address posture and balance, symptoms that traditionally do not respond to DBS. As of this conversation, 100 patients in the world have undergone this procedure, and many centers are investigating the safety and efficacy of stimulating these areas of the brain.

Additionally, there's reasonable evidence that the earlier you intervene with DBS with Parkinson's the more effective it can be. There is now interest in not paying the opportunity costs of being ill for so long and introducing DBS earlier in the course of the illness with the view of keeping people functioning at a higher level. We suspect that these benefits will be long lasting. We have data for five years and 10 years, but we suspect these benefits will continue over the long term.

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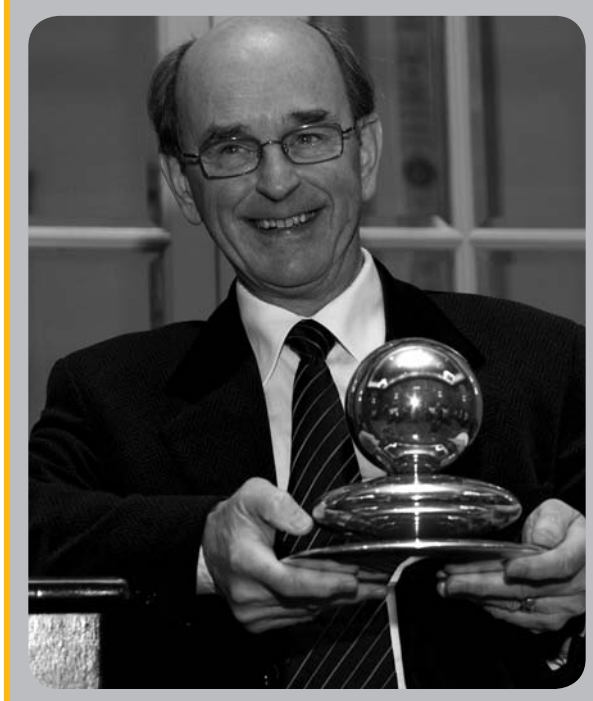
Björklund Awarded Inaugural Robert A. Pritzker Prize



On November 11, at a ceremony in New York City, MJFF awarded Anders Björklund, MD, PhD, of Lund University, Sweden, the first Robert A. Pritzker Prize for Leadership in Parkinson's Research. The prize is named in honor of Robert A. Pritzker, a renowned industrialist, entrepreneur and philanthropist, who founded The Marmon Group and was president of Colson Associates, Inc. Björklund was selected for his profound contributions to Parkinson's therapeutic development and his exceptional commitment to mentoring the next generation of PD researchers.

GET INVOLVED

Christopher Chadbourne and Felicia O'Keefe:
"The Right Decision at the Right Time"

"Had it not been for Parkinson's disease," said Christopher Chadbourne, "I would not have picked up the camera again. So in a bizarre way, I'm really grateful for my PD."

Over two decades as founder and creative director, Chris had built Christopher Chadbourne & Associates into an internationally renowned firm specializing in exhibit design and museum planning; his wife, Felicia O'Keefe, had worked alongside him as director of marketing. But as the news of his 2008 diagnosis sank in, his priorities changed. "While I loved what I did, I wanted to do what I loved," he explained — which meant returning to his first career as a photographer.

For the past three summers, Chris and occasionally Felicia have traveled around the country to state fairs, which Chris calls "America's most democratic institution." His photos from the fairs have been exhibited in galleries and museums around the country. Chris' next project, "My Country 'Tis of Thee," will continue to document his fascination with America's many stories.

In seeking all the information he could find about Parkinson's, Chris discovered The Michael J. Fox Foundation. He has come to rely on the Foundation, and its Web site in particular, for the updates he needs about PD. "While it's not always good news, it's always important," he said.

Chris also admired the Foundation's research funding strategy and its collaborative relationship with the private sector. "Scientists can make wonderful discoveries in potential PD treatments," he said. "But MJFF recognizes you need the drug companies on board to get these treatments out of the lab and onto pharmacy shelves."

Because of the success of their design firm, Chris and Felicia found themselves in a position to make a significant gift to a worthy cause. They decided their dollars would be most wisely spent by MJFF. Originally planning to contribute $25,000, they were inspired to double that to $50,000 last May. Chris explained: "We're not wealthy people. This is a one-time gift, and I want it to affect the rest of our life. We wanted to give enough so that I know I've given enough."

Photograph by Christopher Chadbourne, from his series, 'State Fair'

Their engagement with MJFF also brought to their attention the need for increased participation in clinical trials — especially among PD patients. Chris recently volunteered to take part in an exercise study at Boston University.

Not long after their gift, the Brin Wojcicki Challenge was announced — meaning Chris and Felicia's gift would be doubled again, to $100,000. "When we heard that news," said Chris, "we felt terrific. We clearly made the right decision at the right time." *– Lauren Anderson*

To see more of Chris' photos, scan this code.

Cliff and Sharron Tune:
Stepping Onstage — and Stepping Up to Cure Parkinson's

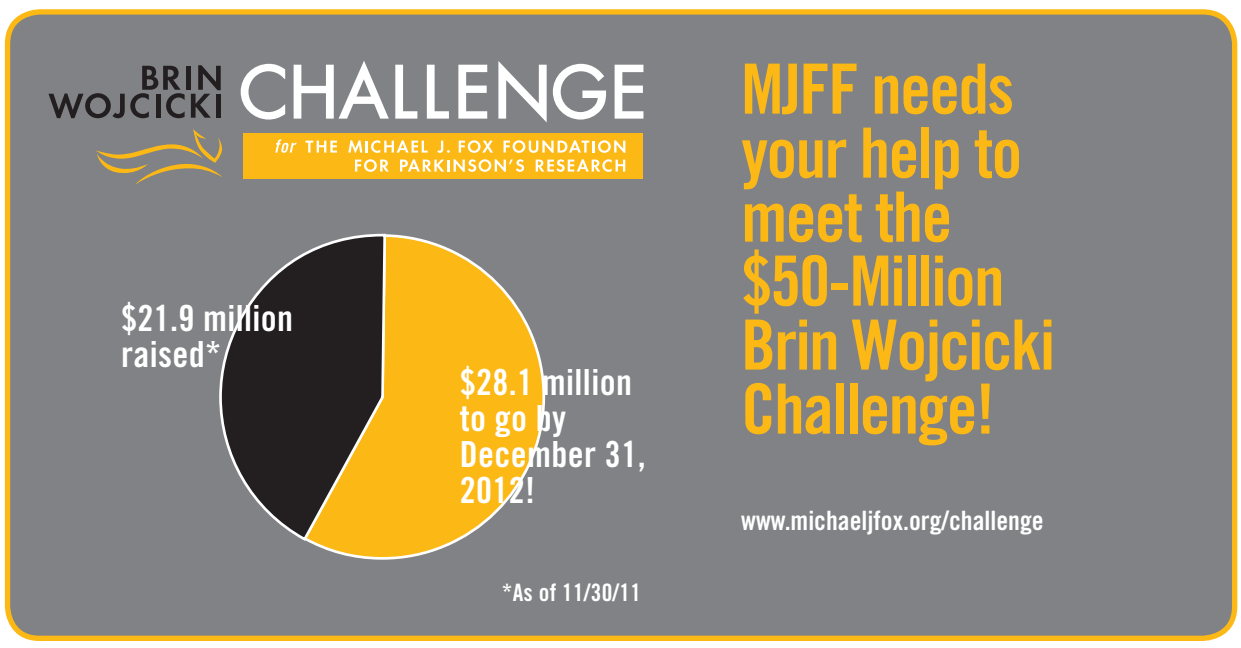
After his Parkinson's diagnosis nearly 15 years ago, Cliff Tune, of San Francisco, California, began to pursue a hobby that he and his wife, Sharron, had always shared: travel. What he didn't anticipate is that he would develop a new passion — for singing. Nor did he expect that these two interests would marry so well.

Cliff had always thought of himself as a shy person. But within a few years of his diagnosis, he started taking voice lessons, using a karaoke machine. Soon he was performing at a local venue during karaoke night, singing his favorite songs — from Neil Diamond to Kenny Rogers. During the cruises that he and Sharron took, he often competed in pop star contests aboard the ship. Known as "Karaoke Kliff," he said, "There's absolutely nothing like being onstage."

Along with their travel and Cliff's performing, the Tunes have dedicated their energy and resources to The Michael J. Fox Foundation. They look to MJFF as a source of inspiration and hope — knowing that someone is waking up every day to do whatever it takes to develop improved treatments and a cure for Parkinson's. Throughout the years, the couple has done whatever they could, by financially supporting the Foundation's mission.

When they learned of the Brin Wojcicki Challenge in June, they quickly wrote a check to fully leverage the opportunity to earn doubled dollars for the Foundation's research programs. That meant stretching their previous $100 contribution in 2010 to $500 in 2011, which, with the match, made their gift worth $900 to the Foundation's efforts to speed a cure. Cliff said, "For the millions of patients out there, we can't afford to sit on the sidelines and wait for a cure to come to us. That's why it's so important to meet the Challenge now — and we can all do something to contribute."

Cliff has had to take a break from performing, as he's experiencing freezing of gait. But he's staying active by walking a mile each day, and continues to sing at home — with the goal of returning to the stage soon. *– LA*



THE MICHAEL J. FOX FOUNDATION BLOG

The Michael J. Fox Foundation has launched a blog! Access the stories that matter now from MJFF and guest bloggers; gain an insider's perspective on the Foundation; and hear from patients about their experiences living with PD. Check out the MJFF Blog at blog.michaeljfox.org.

From Debi Brooks' Blog:

Why I Raised My Hand to Participate in PPMI

MJFF Co-Founder and Executive Vice Chairman Debi Brooks has not only been instrumental in conceiving, structuring and fundraising for the Parkinson's Progression Markers Initiative (PPMI); she also is participating in the study as a control.

MARK SELLINGER

This is the first time Debi has volunteered for clinical research, and she is blogging about what she learns along the way. In her first post (excerpted below), she reflects on her decision to enroll in the study. To follow her progress, visit blog.michaeljfox.org.

Early in our planning for PPMI, our goal was to recruit 30 people per site — 20 newly diagnosed Parkinson's patients, and 10 controls — by the end of 2012. That meant each site needed to recruit roughly one PD patient per month and one control every two months, which seemed doable to me. But the immediate reaction from the scientists in the room was that this was an incredibly lofty goal, maybe even impossible, due to the routine challenges they face in finding volunteers for studies. It was a striking exchange, and it inspired me to enroll.

I'm fortunate in that I don't face some of the everyday hurdles that can stand in the way of participation — like work obligations, distance, financial hardship... In fact, my being a part of PPMI furthers the mission of the organization I work for. The opportunity to walk in the shoes of a research participant is invaluable. So much of my work is about making it easier for people to act on an intention to get involved. Already, I am finding out more about how we can help facilitate this through increased clinical trial participation.

One of the things I've learned at the Foundation is that to get the most out of our investments in research, we as a society need to ask a lot, of many people, along the way. Scientists innovate — they get us started. But scientists alone cannot translate ideas into tangible treatments that make a difference to human health. This requires the involvement of the patient community.

PPMI is devoted to finding PD biomarkers, which could help us understand the cause of the disease and how it progresses over time. Clinical data and biological samples are being collected from people with and without PD. Scientists will compare patients' information with that of control subjects. And I am participating as one of these controls. I look forward to sharing my journey with you.

To learn more about PPMI, visit www.michaeljfox.org/PPMI.

To connect with clinical trials near you that are looking for PD or control volunteers, create a profile at Fox Trial Finder (www.foxtrialfinder.org).

Scan this code to explore the blog now!

Nike and MJFF Join Forces to Eradicate Parkinson's from the Space-Time Continuum

In September, The Michael J. Fox Foundation for Parkinson's Research was the recipient of an act of generosity unprecedented in the space-time continuum when footwear giant Nike announced the limited-edition release of the 2011 Nike MAG to benefit MJFF.

An exact replica of the *Back to the Future II* shoes worn by Michael J. Fox as Marty McFly in the year 2015, 1,500 pairs of the shoes were auctioned on eBay's Fashion Vault over a 10-day period, with net proceeds totaling over $4.7 million. Thanks to the $50-million Brin Wojcicki Challenge, that gift was doubled to result in a jaw-dropping $9.4 million generated for the Foundation's aggressive research programs to speed a cure for Parkinson's disease.

The project was the vision of Mark Parker, Nike CEO, who was on the *Back to the Future II* set in 1988 when Fox donned the original Nike MAG shoes. Development of the shoe was overseen by Tinker Hatfield, the original Nike MAG designer and vice president of design at Nike, and Pam McConnell, Nike's global director of entertainment marketing.

"We wanted to translate the excitement people have for the 'greatest shoe never made' and for *Back to the Future* into positive action," said Parker. "But the long-term objective was to raise awareness to help the Foundation achieve their goal of eradicating Parkinson's disease."

When the original *Back to the Future* creative team learned of Nike's desire to support MJFF with the release of the 2011 Nike MAG shoes, Executive Producer Frank Marshall joined the effort. A concept was hatched to develop a 'Lost Scene' to honor the original *Back to the Future* films and characters. Original cast members

2011 Nike MAG

Christopher Lloyd (Doc Brown) and Donald Fullilove (Goldie Wilson) reprised their beloved roles, and actor Bill Hader and basketball star Kevin Durant joined the *Back to the Future* legacy as store clerk and customer, respectively. (Tinker Hatfield had a cameo as a sales manager.) The Lost Scene quickly racked up over 3 million views on YouTube, becoming the number-one viral video on the Web.

Michael J. Fox kicked off a whirlwind of excitement around the project, appearing on "The Late Show with David Letterman" on September 8 to reveal the MAG to the world and officially launch the eBay auctions that closed on September 18.

The timing couldn't have been better, as the Challenge, effective through 2012, was announced earlier this year and is made possible by the leadership of longtime Foundation friends Sergey Brin, co-founder of Google, and his wife, Anne Wojcicki, co-founder of personal genetics company 23andMe."The enthusiasm this project ignited, and the funds and awareness the shoes generated for Parkinson's research, are both humbling and inspiring," concluded Fox. "Our Foundation is truly grateful to Nike for this unique partnership that brought *Back to the Future* fans, sneakerheads and the PD community together in the quest to make Parkinson's a thing of the past." *—Lauren Anderson and Holly Barkhymer*

Did you miss it? Catch the 'Lost Scene' from *Back to the Future II.*

GET INVOLVED

Robin Katsaros:
"You Can Be Part of the Solution"

Robin Katsaros of Los Alto Hills, California, is swift to take action. Soon after her husband, John, was diagnosed with Parkinson's disease in 2008, she formed a caregivers' support group. "Caregivers' needs are different from patients'," she said. "The group has been a terrific resource for all of us."

John and Robin Katsaros, with sons Christopher and Matthew

She also was quick to understand the importance of participating in clinical research — whether you have PD or not. Living in close proximity to The Parkinson's Institute & Clinical Center in Sunnyvale, she is currently volunteering in her third clinical trial related to PD.

"When a PD diagnosis first comes into your life, you're in shock. It's hard to even think about being in a trial," Robin said. "But it's so important to educate yourself about the disease and the critical importance of research. There's a bottleneck around clinical trial recruitment, and that holds up progress for all of us. The faster we get people into trials, the better the chances for the millions of people living with the disease today."

When she heard about the launch of Fox Trial Finder (www.foxtrialfinder.org), Robin was instantly enthusiastic about its potential to help increase the number of people volunteering for trials.

"You hope your neurologist is on top of trials in your area," she said. "But what's terrific about Fox Trial Finder is that it gives you the power to take action yourself to help speed breakthroughs."

Now Robin is tapping into her grassroots network to spread the word about clinical trial participation — and Fox Trial Finder — among her support group, local neurologists and family and friends.

"When someone you love has PD, time is of the essence," she concluded. "For John and for everyone living with this disease, I want to do all I can to help get us closer to a cure. While everyone may think that 'someone else' will participate in trials, that 'someone else' is us. So I want others to understand that — whether you have PD or not — you can be part of the solution, too."
–LA

Rocking Out for a Cure

Michael J. Fox jams with legendary guitarist Joan Jett at "A Funny Thing Happened on the Way to Cure Parkinson's." Held on November 12 at the Waldorf=Astoria in New York City, the benefit raised over $4.3 million for the Foundation, with performances by headliner Ricky Gervais, hip-hop artist Kid Cudi, actor/comedian Mike Birbiglia and host comedian John Oliver.

Check out Michael J. Fox playing "Johnny B. Goode" at Funny Thing — which instantly went viral on YouTube, with more than 1.7 million views to date.

MJFF Comes to Town:
Sharing the Latest in Parkinson's Research with Support Groups

The Michael J. Fox Foundation has stepped up efforts to connect locally with the Parkinson's community, and with support groups in particular. "It's an opportunity for patients to hear about the latest news in Parkinson's research and for us to learn from patients," said Seanna Bruno, associate director of advancement, who frequently updates support groups on Parkinson's drug development and the Foundation's strategy to speed a cure.

Groups have the opportunity to learn about recent research breakthroughs toward better treatments for Parkinson's and the Foundation's research programs — as well as how individuals and communities can help speed a cure by signing up for Fox Trial Finder and participating in clinical trials, or by supporting local Team Fox events.

Many patients travel miles to attend. "It gives them a sense of hope knowing that someone is really doing something on their behalf — to help us get to a cure, and sooner," said Eden Feldman, director of outreach at the University of South Florida Parkinson's Disease and Movement Disorders Clinic in Tampa, who recently invited Seanna to address six local groups. "It's a big deal to hear directly from MJFF."

If your patient or caregiver support group is interested in hosting a presentation by a Foundation representative, please contact Kara Lohse at (212) 509-0995 ext. 283 or klohse@michaeljfox.org.
– LA

HOW YOU CAN HELP SPEED A CURE

At year-end or any time of year, we hope that you will consider making a gift to The Michael J. Fox Foundation. With your support, together we can help speed a cure for Parkinson's disease. Outlined below are some of the most popular ways to give.

www.michaeljfox.org/holidays

Honor and Memory Gifts
Honor your friends and family and impact millions of lives with a gift to MJFF. Let them know immediately about your tribute gift with an MJFF E-card.

Monthly Giving
Recurring gifts save you time and enable you to express your support more fully — while providing MJFF with a reliable source of funds for our research investments. The frequency and the amount of your gift are up to you, and you can cancel at any time.

Matching Gifts
You can increase your contribution to MJFF by asking your employer about corporate matching gifts. Many corporations have programs in place to double your donation to an accredited charitable organization.

Planned Giving: The Legacy Circle
The Legacy Circle is MJFF's society honoring friends who provide for the Foundation in their wills or other planned gifts. A thoughtful planned gift enables charitable donations at a level you might not have thought possible, while maximizing tax benefits for you and your family.

Don't wait! Use your phone to make a gift now, and help speed breakthrough treatments into the hands of patients.

IRA Contributions
If you have an Individual Retirement Account (IRA), you may be eligible to make a gift directly through your IRA to MJFF without incurring tax consequences. To qualify, you must be: age 70½ or older; give $100,000 or less from your IRA in 2011 or 2012; transfer funds directly from an IRA or Roth IRA; and transfer the gift outright to MJFF.

Fox Shop
Visit Fox Shop for gifts that help raise awareness — and funds — for Parkinson's research. Find apparel and accessories for everyone on your list at shop.michaeljfox.org.

Year-End Giving
For your donation to be receipted (for tax credit) in 2011, please be aware of the following deadlines. Mailed checks (regardless of check date) must be received in envelopes postmarked no later than December 31, 2011. The deadline for making a gift over the phone is December 30 at 6:00 p.m. (US ET); for online gifts, the deadline is December 31 at 11:59 p.m. (US ET). For more details, please visit www.michaeljfox.org/holidays.

For more information on how to make a gift, please email donations@michaeljfox.org or call (800) 708-7644 (Monday–Friday, 9 a.m.–6 p.m. US ET). To make a gift online, visit www.michaeljfox.org/holidays.

AN ART COMMUNITY PRESERVED BY PARKINSON'S RESEARCH

February 2009 marked a life-changing event for Pat Hagan and his wife, Carol. The symptoms he had been experiencing for the previous six months were finally given a name: Parkinson's disease. At 57 years old, Pat had many unanswered questions: "What does this mean? What will my future look like? What can I do now?" he recalls wondering.

Pat and Carol were eager to learn more about the disease and how to cope. They found The Michael J. Fox Foundation's Web site, (www.michaljfox.org), which soon became their "home base for research and updates on PD." That's also where they first learned about Team Fox and were inspired to help raise funds for Parkinson's research.

Carol Hagan at the Inaugural Quick Finish Auction

Fast forward to September 2010, when Pat and Carol — who also are business partners running Carol's well-known painting studio in Montana — were expecting their invitation to the annual Western Masters Art Show & Sale. At this four-day fine art exhibition, over 140 artists gather at the Heritage Inn in Great Falls, Montana, to display their pieces, give live demonstrations and participate in auctions. Instead of an invitation, though, the Hagans learned that the March 2011 show had been canceled. "We were devastated, both for ourselves and for all the artists. For some of them, that event contributes half their income. We felt we had to do something; we couldn't see it falling off the face of the art world here," Pat explained.

That's when the Hagans figured out how they would raise funds and awareness for Team Fox.

Together with their friends Steve and Nancy Cawdrey, the Hagans formed the new "Western Masters Art Show & Sale" and created a charity component in which half of the Quick Finish Auction proceeds would be donated to Team Fox. During the Quick Finish on March 19, 2011, artists set up mini-studios for public viewing and put final touches on pieces that were then auctioned. Thirteen artists participated this past year, and the auction garnered $45,500 for Team Fox, far surpassing the fundraising goal of $15,000. Twelve are lined up for next March, and it is safe to say that the Hagans and the Cawdreys have brought the Western Masters back to life.

Yet Pat and Carol wanted to do more. To reach $50,000 by the year's end, which would be doubled to $100,000, thanks to the Brin Wojcicki Challenge, Pat and Carol launched a raffle on November 1, for a chance to win one of four pieces of Carol's artwork. All 500 tickets sold out in 36 hours, so they have launched another raffle to reach the $60,000 mark. The winning tickets will be drawn December 9.

"I am definitely hanging out with the right people," Pat concluded. "Some of the artists even gave 100 percent of their proceeds to Team Fox. We feel very blessed to have been able to do this and to have so many artists and friends take part. Together, we helped save the event and supported a cause we all believe in."

– Miranda Lanzillotti

TEAM FOX YOUNG PROFESSIONALS

The Team Fox Young Professionals (YPs) were established in New York, San Francisco and Chicago in response to the growing number of 20- and 30-somethings who wanted to support the Foundation's mission. While a personal connection to Parkinson's disease inspired many of the founding members, the groups have expanded to include those who haven't been directly impacted by PD but want to help speed a cure. Said founding member of the New York YPs Loren Berger: "Both within the YPs and beyond our group, our greatest success has been raising awareness among a demographic that may not know much about Parkinson's. The terrific thing about the YPs is the diverse array of viewpoints that all come together in support of a common cause."

Loren Berger and Ian Campbell, New York YP founding members

With more than 100 members in New York, San Francisco and Chicago, the YPs plan a variety of fun and creative fundraising events throughout the year. Collectively, they have raised over $32,000 for Parkinson's research. Team Fox hopes to expand to other cities and launch a YP group in Boston. Anyone can join or start their own group, so contact teamfox@michaeljfox.org to learn more.

– ML

"FOX FRIDAYS" AT SWEETANGEL.COM: GREAT GIFTS FOR A GREAT CAUSE

In September, James V. Mangini III of Hanahan, South Carolina, launched Sweet Angel™ (www.sweetangelgifts.com), an online gift shop with a twist: Up to half of every purchase benefits a charity of the buyer's choice. James, whose father was diagnosed with Parkinson's several years ago, especially wanted his company to give back to The Michael J. Fox Foundation. Every Friday, use the code "Fox Fridays" for a 10 percent discount — and 100 percent of the profits will be donated to the Foundation!

The site has raised more than $600 for Team Fox so far, and James hopes to keep generating more funds and awareness. "The mission of your Foundation is to go out of business," he says, "and I'm in business to help you get there."

– ML

THE MICHAEL J. FOX FOUNDATION FOR PARKINSON'S RESEARCH

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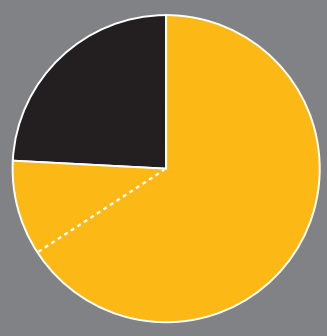
All Clinical Trials Need Participants. Fox Trial Finder Knows Which Ones Need You — Whether You Have PD or Not.

People with Parkinson's disease, and those without it, have a crucial role to play in PD research. Register now for Fox Trial Finder. You can help speed new treatments — and a cure — toward pharmacy shelves.

Complete your profile today at: www.foxtrialfinder.org



1,566 REGISTERED VOLUNTEERS*

66% with PD

10% caregivers (on behalf of PD volunteers)

24% controls

*As of 11/30/11

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