

Parkinson's Patients Support Groups, Inc.

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GENE THERAPY WITH A GROWTH FACTOR FOR PARKINSON'S DISEASE

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INTRODUCTION

Gene therapy is a technique with promising applications for the treatment of Parkinson's disease. Initial clinical trials (research studies) using various types of gene therapy in patients with Parkinson's disease (PD) are now underway or completed, and additional clinical trials are forthcoming. The aim of this article is to explain what gene therapy is and to provide information about a new clinical trial evaluating gene therapy that patients with Parkinson's disease may wish to consider.

DEFINITIONS

Genes are chemical entities that direct the development and day-to-day function of living organisms. Humans are estimated to have about 25,000 genes, which are located on the chromosomes that are part of their cells. In humans, genes are composed of DNA (deoxyribonucleic acid), chemical building blocks that are necessary for the production of proteins. Proteins, in turn, are molecules that cause the chemical reactions that take place in the body. Thus, genes play a central part in our development, growth, and daily existence. Abnormalities in genes can directly cause some diseases or can make people more susceptible to certain diseases.

Gene therapy refers to techniques that make use of the body's own cells and genes to produce an effect that improves health or treats a disease. Gene therapy typically involves the engineering of genes in the test tube that can then be delivered to the body to produce the desired biological effect. In some cases, the aim is to deliver the genes to cells in a specific part of the body

affected by the disease, with the goal of directly replacing defective or missing genes that are responsible for the disease. This would encourage the affected cells to function in a more normal way. In another application of this direct delivery approach, the genes might be delivered to tumor cells and cause them to be destroyed or their growth to be inhibited. Another gene therapy strategy delivers the engineered genes to a site and stimulates that part of the brain to make a protein that will have a beneficial effect on neighboring cells through local effects or distant cells through the blood stream.

Because genes cannot get into cells on their own, in order for the engineered genes to get inside the cells of the targeted body tissue, they are usually inserted into a carrier. Most often, the carrier is part of a virus that has been stripped of disease-causing properties (deactivated) and used to transfer the engineered genes into the target cells. These carriers are called viral vectors. Types of viruses that have been used as vectors include retroviruses, adenoviruses, and adeno-associated viruses (AAV). Current human studies using gene therapy for Parkinson's disease make use of the deactivated adeno-associated virus. This viral vector is preferred because it appears to have long-term safety, it can easily penetrate neurons (brain cells), and it does not appear to cause inflammation or an immune reaction when injected into the brain.

In PD, to get the viral vector and the gene that it carries into the part of the brain where it is needed, a neurosurgical procedure is used. This type of surgery, called stereotactic surgery, uses a metal frame that is temporarily attached to the patient's head on the day of surgery. This technique is also used to perform deep brain stimulation surgery. Once the frame is attached to the patient's head, a brain scan (MRI, CT scan, or both) is performed that allows the surgeon to combine the coordinates from the frame with images from the scans using mathematical software to calculate the exact starting points on the brain surface and trajectories

needed to direct their instruments to the brain target of interest. In the case of gene therapy, the instrument is a very fine needle that is inserted into the brain and used to deliver a tiny amount of the gene therapy material. In most cases, multiple injections are made to ensure complete coverage of the intended area. This procedure is done with the patient asleep under anesthesia.

Performing this type of surgery for the purpose of gene therapy is considered experimental, but the surgical techniques are very similar to those routinely used for other types of brain surgery. This type of surgery is generally safe, but not without risks. Anyone considering participation in a gene therapy clinical trial should speak with the medical/surgical team to understand what to expect on the day of surgery and to discuss potential risks and complications of the surgery.

DELIVERING A GROWTH FACTOR TO THE BRAIN

Parkinson's disease is a progressive, degenerative condition. Currently, no therapies are available that definitively slow disease progression. Growth factors are naturally occurring proteins made by the body to support the growth and health of cells, particularly during early development. The theory behind using growth factors to treat PD is that a growth factor might be able to slow, halt, or reverse disease progression. Growth factors have been delivered to the brain in past experiments using infusions into the ventricular system (the fluid-filled cavities of the brain) or via a small catheter implanted into the brain target of interest that is used to deliver tiny amounts of growth factor over long periods of time. Gene transfer techniques are now being used to deliver the growth factor neurturin to the brain using the AAV vector, a compound that together is called CERE-120. This approach is being developed by Ceregene, a biotechnology company specializing in growth factors. After numerous safety studies demonstrated safety and suggested effectiveness of CERE-120 in animals, a 12-patient phase I study was conducted at the University of California, San Francisco by Dr. William Marks, Dr. Jill Ostrem, Dr. Philip Starr, and Dr. Paul Larson and at Rush University Medical Center. Encouraging results in the initial study led to the design of a larger, multi-center study that enrolled 58 patients at 8 locations in the US; UCSF was the lead team for the study. Two-thirds of patients received CERE-120 and one third of patients had sham surgery in which no treatment was delivered. Results showed no significant difference between the active treatment and sham groups in the 12-month follow-up period defined as the main endpoint for the study but some improvement in those receiving the active treatment who were followed for 15-18 months under double-blind conditions. Later brain autopsies on two CERE-120-treated patients who died of unrelated causes indicated

that CERE-120 had not traveled from the putamen to the substantia nigra—one of the main areas affected by PD—like it had in animal studies. A small study of 6 patients was then conducted to evaluate the safety of delivery of CERE-120 to the putamen and substantia nigra.

NEW GENE THERAPY STUDY OPEN

A new study that will deliver CERE-120 to the putamen and the substantia nigra will be open for enrollment in Summer 2010. Fifty-two patients will be enrolled at 12 US study sites, including UCSF. The study is also being conducted at Stanford University.

To be eligible, patients must

- be 35-70 years old
- have idiopathic PD, the most common type of parkinsonism
- have motor fluctuations despite appropriate medication therapy
- be on stable doses of PD medications
- have good posture and balance when PD medications are working
- meet specific criteria on a number of PD and associated symptom scales
- have no significant memory, mood or thinking problems
- have no history of prior brain surgery for PD
- be willing to delay deep brain stimulation (DBS) surgery until the blinded portion of the study is complete (1-2 years)
- be in good general health.

What is involved?

- Nine study visits during the first 12 months of study; then 6 visits during the 2nd and 3rd years of study
- Surgery to inject the gene into the brain during 1-2 day hospital stay
- Random assignment to gene transfer or sham surgery (1:1)
- On-off testing during most study visits, after 12-hour PD medication hold
- Neurological and physical evaluations
- Brain MRIs, laboratory tests, electrocardiograms, chest x-rays
- Thinking, mood and memory testing
- All out-patient visits at UCSF Mt. Zion campus, 1635 Divisadero St., San Francisco, CA
- Reimbursement available for travel and parking expenses.

For further information, contact:

Robin Taylor at UCSF: robin.taylor@ucsf.edu, or 415-353-1555
Maria Coburn at Stanford: mcoburn@stanford.edu, or 650-723-5575.

Information about **Agent Orange**, Possible Health Problems, and Related VA benefits

VA Recognizes Additional “Presumptive” Diseases for Vietnam Veterans: On March 25, 2010, VA published a proposed regulation that will establish B-cell leukemias, such as hairy cell leukemia; Parkinson's disease; and ischemic heart disease as associated with Agent Orange exposure. Eligible Vietnam Veterans may receive [disability compensation](#) for these diseases when the regulation becomes final. You may [apply online now](#), so VA can begin development of your claim. Read the [press release](#) to learn more.

What Agent Orange Is

Agent Orange is the name given to a blend of herbicides the U.S. military sprayed from 1961 to 1971 to remove plants and leaves from foliage in Vietnam that provided enemy cover. The name “Agent Orange” came from the orange identifying stripe around the 55-gallon drums in which it was stored.

The U.S. military sprayed other herbicide combinations in the so-called Rainbow herbicides program, identified by the color of their storage drums, including Agent White and Agent Blue. Agent Orange was the blend used most widely.

When and Where Agent Orange Was Used in Vietnam

The U.S. military herbicide program in South Vietnam took place between 1961 and 1971. Herbicides were sprayed in all 4 military zones of Vietnam. More than 19 million gallons of various herbicide combinations were used. Agent Orange was the combination of herbicides the U.S. military used most often.

Agent Orange and Other Herbicide Exposure Outside of Vietnam

Korean War

During the Korean war, Republic of Korea forces used small amounts of Agent Orange in 1968-69 in the area from the Civilian Control line to the southern boundary of the Demilitarized Zone.

According to the Department of Defense, only Republic of Korea troops were involved in the actual spraying of Agent Orange in Korea. However, it is possible that some U.S. military personnel may have been exposed to herbicides in Korea.

Herbicide Tests and Storage

Agent Orange and other herbicides used in Vietnam were tested or stored elsewhere, including many military bases in the United States. Learn more about [herbicide tests and storage in the U.S.](#) and [outside the U.S.](#)

Download information from [Department of Defense on herbicide tests and storage outside of Vietnam.](#)

Source:

www.publichealth.va.gov/exposures/agentorange

The information was forwarded by Wesley Waltner.

UCSF is currently conducting a treatment trial for Parkinson’s Disease when associated with mild to moderate memory and/or thinking problems, or Parkinson’s Disease with Dementia. This is an open label (meaning there is no placebo – everyone receives the drug) 12-week study using the Exelon Patch. This study involves 4 visits in 12 weeks where the patient will receive neurological exams, cognitive testing, and MRI scans. A caregiver must be available to answer questions at every visit. This study is looking to enroll subjects ages 55-85 with mild to moderate memory and/or thinking complaints.

- **UCSF** is also currently running research studies that are attempting to gain a better understanding of how Parkinson’s Disease effects one’s cognition, including one’s memory, goal-oriented behavior, and orientation. These research studies are looking to study individuals with Parkinson’s Disease and Parkinson’s Disease when associated with mild memory problems (known as Parkinson’s Disease with Mild Cognitive Impairment (MCI)). These studies are open to all ages and usually only involve one 4 hour visit.

For information, please contact: **Reva Wilhelm**

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website: <http://memory.ucsf.edu>

Youtube lin www.youtube.com/ucsfmemor

To rent a scooter, go to www.staymobilescooter.com

Forwarded by Curt Chadwick

This newsletter was assembled by the Morgan Center. Thank you!

Davis Phinney Foundation Announces New Integrative Program for Living Well With PD

The Davis Phinney Foundation has a mission and a passion for improving the quality of life of people living with Parkinson's disease. A brand new initiative, the *Every Victory Counts*[™] program, is designed to help those living with PD do just that. The centerpiece of the program is an interactive patient care manual of the same name, co-authored by Monique Giroux, MD and Sierra Farris, PA-C, both movement disorder specialists. Other movement disorder experts from respected Parkinson's centers nationwide add their contributions on a variety of special topics.

The manual stresses the importance of self-care and proactive symptom management through lifestyle changes. It is filled with personal stories and messages of hope and inspiration shared by people who are living with Parkinson's. Many people with Parkinson's are often unsure or unaware of the kinds of questions they need to ask. The perspectives shared in the manual shed light on important topics – the benefits of exercise, dealing with depression, care for the caregiver, medication and more – and offer valuable support, from the day of diagnosis through long-term disease management. These first person insights urge people to take control of their disease and find the motivation so important to living well with a progressive disease.

The manual contains self-care worksheets on many topics that can be used to record motor and non-motor problems between clinic visits. By employing these tools to help with data collection and organization, as well as to facilitate productive discussion, it is possible to enhance care during doctor visits. Patients will be better able to report changes and challenges they are experiencing, and neurologists will be in a better position to focus care on the individual's most pressing concerns. The worksheets also can help engage family in the care plan, and enhance the individual's sense of control and commitment to the self-care that is important for quality of life with a chronic disease.

The *Every Victory Counts* program is more than a book; it is a wellness companion designed to provide support and inspiration throughout the year. Because Parkinson's changes over time, the *Every Victory Counts* program is designed to change with it. Participants will receive fresh materials, including DVDs, on a quarterly basis to keep the information relevant and motivation high.

Call **877-279-5277** or visit **www.everyvictorycounts.org** for more information on the program. There, you can preview an excerpt from the manual, download worksheets and register for the program. There is also an excellent blog where you can find useful information and connect with other people living with Parkinson's.

From American Academy of Neurology

Once again, Congress has failed to stop the scheduled 21.3 percent Medicare physician pay cut that will now take effect on April 1, 2010.

Physician reimbursement under Medicare is governed by a broken formula called the Sustainable Growth Rate (SGR). For too long, physicians have been forced to fight for annual and now monthly reprieves from mandatory pay cuts called for by the SGR formula. Though many in Congress say they agree on the need for reform, attempts to enact reform continue to fail.

That means that too many in Congress are not hearing from physicians and their patients on the urgent need to fix this broken payment system once and for all. We need your help!

Tell Congress that holding physicians and patients hostage over the threat of extreme pay cuts is not acceptable!

[Send a message now!](#)

Sincerely,
Elaine Jones, MD, FAAN
Laurence Kinsella, MD, FAAN
Co-Chairs, Government Relations Committee

Want to learn more about this issue? See the Academy's website for the **[latest information about the upcoming SGR cuts.](#)**

Dopamine levels in Brain Influences Decision making

BBC News - Dopamine, a chemical with a key role in setting people's moods, could have a much wider-ranging impact on their everyday lives, research suggests.

Experiments show that altering levels of the chemical in the brain influences the decisions people make. One expert said the results showed the relative importance of "gut feeling" over analytical decision making. The Current Biology study could help understand how expectation of pleasure can go awry, for example in addiction.

It follows previous research by the University College London team, which, using imaging techniques, detected a signal in the brain linked to how much someone enjoyed an experience. They found that signal could in turn predict the choices a person made.

With the suspicion that the signal was dopamine, the researchers set up a study to test how people make complex decisions when their dopamine system has been tampered with. The 61 participants were given a list of 80 holiday destinations, from Greece to Thailand, and asked to rate them on a scale of one to six. They were then given a sugar pill and asked to imagine themselves in each of 40 of the destinations.

Researchers then administered L-Dopa, a drug used in Parkinson's disease to increase dopamine concentrations in the brain, before asking them to imagine the other holidays. They rated all the destinations again, and a day later they were asked where they would prefer to go, out of paired lists of holidays. The extra dopamine gave people higher expectations when rating holiday options.

And that translated into the choice of trip they made a day later.

Study leader Dr Tali Sharot, from the Wellcome Trust Centre for Neuro-imaging at UCL, said humans made far more complex decisions than other animals, such as what job to take and whether to start a family, and it seemed dopamine played an important part in that. She said they had been surprised at the strength of the effect they had seen. "Our results indicate that when we consider alternative options when making real-life decisions, dopamine has a role in signaling the expected pleasure from those possible future events." "We then use that signal to make our choices."

Dr Sharot added that addicts overestimated the pleasure they would gain from something, be it heroin or gambling, because their dopamine system was

dysfunctional, and the latest research underpinned that the choices they made would be influenced by that.

Gut instinct

She added: "For many conditions we have medication which changes dopamine function, so knowing we may be changing people's expectations and their decision making might change how we think about giving these types of medications."

Professor John Maule, an expert in decision making, at Leeds University Business School, said that in recent years people had begun to realize emotional or "gut instinct" decision making was just as important in human choices as analytical decision making. "At any one time you will have both these processes going on, so it's not surprising to see these results, especially when it comes to emotionally based decisions, such as holidays. It is a sort of shortcut in our thinking."

This article was forwarded by Steven Russell

OLDER ADULT TRANSITIONS THE "OATs" PROGRAM

**FROM EL CAMINO HOSPITAL
BEHAVIORAL HEALTH SERVICES,
PROVIDING A GEROPSYCHIATRIC
INTENSIVE OUTPATIENT PROGRAM FOR
OLDER ADULTS WITH:**

**DEPRESSION, SEVERE ANXIETY, BIPOLAR
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"Psychiatric Diagnostic Evaluation and Psychopharmacologic Management
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"Goal-Oriented group and individual therapies with a Cognitive Behavior Therapy Approach
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Patients seen by appointment only.

Appointments can usually be scheduled within 2 weeks.

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New Ways to Diagnose and Treat Alzheimer's, Findings Suggest

ScienceDaily (Mar. 1, 2010) — A team of researchers at UMass Lowell has found a new mechanism by which a key protein associated with Alzheimer's disease can spread within the human brain.

The research, led by UMass Lowell biological sciences professor Garth Hall, gives new hope that the disease may someday be cured. It provides a new explanation of how the protein tau, a normal human protein that becomes toxic in Alzheimer's patients, can appear in their cerebrospinal fluid (CSF). The findings of the team from the UMass Lowell Center for Cellular Neuroscience and Neurodegeneration Research appear in the February issue of the *Journal of Alzheimer's Disease*.

"My team has discovered two different ways in which tau is secreted by neurons, or brain cells," said Hall, who has spent more than 20 years studying Alzheimer's on the cellular level using larval sea lampreys as a model system. "This might explain how tau-containing lesions seem to propagate between adjacent, interconnected parts of the brain during the development of the disease." Until very recently, it was universally assumed by scientists that tau is never secreted from or transferred between neurons, and that CSF-tau only appears after many neurons have died and irreversible harm has been done to the brain.

"That tau secretion can occur via two distinct mechanisms strongly indicates that it is biologically 'real' and is not just tau protein leaking out of dead neurons," said Hall. "The fact that it occurs in a pattern that reproduces what is seen in the CSF of Alzheimer's patients holds out hope that patients in early stages of the disease might someday be cured. If we can distinguish secreted tau from tau that is released from dying neurons in CSF samples, then maybe we can diagnose Alzheimer's in time to stop the disease before the neurons die."

Hall, together with graduate student WonHee Kim and UMass Lowell, has filed a provisional patent application in connection with a novel approach to the early diagnosis of Alzheimer's that is based on their studies of tau secretion.

As many as 5.3 million people in the United States are living with the disease, according to the Alzheimer's Association.

Gail Lampert was invited to speak and present some relaxation techniques at a recent Saratoga Support Group meeting. The following is her description of what her practice, Unique Yoga Therapy, helps people who attend her sessions:

Unique Yoga therapy benefits:

- **reduces pain**
- **eases and improves joint and muscle movement**
- **improves vocalization**
- **uplifts energy and mood**
- **strengthens and tones the body's support systems**
- **improves circulation**
- **reduces stress**
- **enhances sleep**

These individual sessions or classes are geared toward people without any yoga background and of any physical ability. They are a great way to introduce the rejuvenating benefits of yoga into daily life. Yoga postures promote balance, deep breathing invigorates or calms the mind and body, and the physical movement provides release from tensions and increases mobility.

To find out about having your own private class, group, or retreat,

go to www.uniqueyogaretreats.com
or call 408.377.3746.

Some testimonies:

"I was diagnosed with Parkinson's disease about 2½ years ago. My symptoms include rigidity, difficulty speaking, and slight balance problems. Gail suggested that I try a program of exercises she designed to improve my muscle tone and speech, increase joint flexibility, promote relaxation, and raise my energy level. I have been participating in this program for about six months and am extremely happy with the results. I had no previous experience with yoga and did not know what to expect. Now I really look forward to these sessions and highly recommend them to others with PD." **Larry Pavlak, San Jose, CA**

"As an orthopedic surgeon, I thought I had a good idea what Yoga was about. But my recent experience under the instruction of Gail Lampert, CMP, RYT, quickly showed me that I had a lot to learn. Many of us think of Yoga as a spiritual experience, with mainly psychological benefit. But after a single session with Ms. Lampert, I quickly learned how much more valuable Yoga could be.

For doctor or patient alike, a properly designed Yoga session can improve muscle tone, flexibility, strength, and coordination. This on top of the more commonly known benefits of restoring a peaceful, restive, calm feeling even if overwhelmed by a tense, frantic, out of control day. Is there anyone who wouldn't appreciate that? I can heartily recommend Yoga as taught by Ms. Lampert to anyone who wants to feel better about themselves, both physically and psychologically." **B.J. Miller MD**

Grass Roots, Team Approach to Integrated Parkinson's Care

President Obama recently highlighted Cleveland Clinic as a shining example of the effectiveness of the integrated, team oriented approach to medical care in the hospital setting. The Clinic has demonstrated that their approach is effective and works. The problem is, most of the United States healthcare delivery systems are the antithesis of the Cleveland Clinic model - highly fragmented specialists that structurally can't take into account the holistic nature of treating chronic, progressive diseases like Parkinson's despite their best intentions.

So given the current structure of care that likely won't change for decades, a Los Altos home care company, Homecare California, is addressing integrated care specifically for Parkinson's clients at the grass roots level.

Homecare California was founded by Greg & Lisa Hartwell in 2008 to provide certified nurse assistants and home health aides to those in need with assistance for activities like respite care for family caregivers, personal care (showering, bathing, grooming, dressing), meal preparation and feeding, transportation, light housekeeping, medication reminders and other needed activities. Mr. Hartwell had volunteered as a fundraiser for the Davis Phinney Foundation for Parkinson's.

The Hartwells quickly found that a large percentage of their clients were patients with Parkinson's. After working with these clients, they felt they needed more than just the services they provided in the home to truly provide great care for their clients. Holistically speaking, patients often had little support structure in place and as a result, crucial components of care such as medication management, physical and occupational therapy and other services were necessary additional services to maintain and improve their client's quality of life.

So the Hartwells formed The Home Care Alliance with several industry veterans in the medical home care field that provide physical therapists, occupational therapists, speech therapists and private duty registered nurses which provide medical nurse case management services including key Parkinson's care components such as medication management.

Together The Home Care Alliance members took a comprehensive 4 1/2 day Allied Team Training offered by the National Parkinson's Foundation at the

Parkinson's Institute in Sunnyvale, CA. The training focused on deep clinical knowledge of Parkinson's disease, its symptoms at various stages and successful integrated team-based approaches of physicians, doctors, nurses, medical assistants, social workers, physical therapists and working together for more effective, holistic care. The Home Care Alliance was unique in that while most of the attendees delivered care in the hospital or skilled nursing setting, the Alliance delivered their services to clients at home - where of course patients spend most of their time.

Since their November 2009 training, the Alliance members have been able to implement integrated care for their Parkinson's clients with positive effect. In one case, a 90 year old Parkinson's patient was hospitalized for symptoms caused by medication mismanagement and over dosage. Upon her release from the hospital, the patient was in fragile condition with her long time family doctor asking the family to prepare for hospice care. The transition home however was a success and hospice care was avoided. The Alliance members provided 24x7 care for the patient and made sure her medications were managed properly and monitored. On a periodic basis the team discussed the patient's progress with her primary physician, modified medications and slowly improved the patient's strength and mobility. Today, the patient, a former college professor, is thriving once again - trading stocks online, sitting down to nice dinners with her husband of 30 years who himself suffers from dementia, and preparing to write a book.

Having seen the success of the integrated care approach, Homecare California will continue to promote integrated care. As part of their care programs going forward, Homecare California intends to utilize the Every Victory Counts program for Parkinson's wellness created by the Davis Phinney Foundation in Boulder, CO. Please see the article in this newsletter about the Every Victory Counts program.

For more information on Parkinson's specialized home care, contact **Greg Hartwell**, founder of **Homecare California and The Home Care Alliance at 866-949-2329, email greg@homecarecal.com or visit www.homecare-california.com.**

PPSG Board Meetings

You are welcome to drop by our board meetings and share ideas with us! We meet on the **3rd Monday** of the month between **1:00 and 3:00 PM** at the Parkinson's Institute, at 675 Almanor Avenue, Sunnyvale, CA 94085. To confirm meeting dates and time, please call us at **408.542.5610**. If you are planning to attend, please call Charmaine Eng at 408.723.8116 (dial *82 before the number).

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The Parkinson's Institute is currently looking
for individuals with Parkinson's taking

Requip Or Mirapex

whose current dose is no longer sufficient
or who are not able to increase their dose to
a sufficient amount because of intolerable
side effects

Must not be taking Levodopa

You may qualify for an
18-week research study
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For more information, please contact Liza Infeld at 408-542-5626 or Linfeld@theipi.org

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