

## NORRIS ALS CENTER STAFF “Names in the News”

**Robert Miller, M.D., Director, Forbes Norris MDA/ALS Research Center**, received the highly esteemed Forbes Norris Award at the 2004 International ALS/MND Symposium in Philadelphia at the end of last year. This annual award is given to the international physician/scientist regarded by his or her peers as representing “exceptional compassion and humanity in the study, care, and management of ALS/MND.” It is the only award given in the field of ALS that honors a physician for not only their contributions to the science of ALS, but also for their concern in its clinical care. It is a well-deserved distinguished honor for Dr. Miller.



Patricia O'Connor, R.N., with a patient. (Photo by Erin Lubin, courtesy of MDA/ALS News Magazine.)

**Patricia O'Connor, R.N., the Norris ALS Center's Nurse Case Manager**, was featured on the cover of the *MDA/ALS News Magazine*, March issue. Inside was the powerful story of how Patty touches the lives of the Norris ALS Center's patients and their families. Expressive photos accompanied the in-depth feature article detailing the many roles Patty fulfills in managing each patient throughout the entire course of the disease. Patty facilitates the care of each patient by walking each ALS team member through medical management disciplines during clinic visits, from coordinating community referrals for recommended therapeutic interventions, to assisting families' caregiver problems and difficulties. Additionally, Patty teaches other nurses at professional meetings and in other facilities about problems specific to ALS and ALS

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management. Because of her vast experience and wealth of knowledge, she was recently invited to join Drs. Miller and Gelinas to co-author a book for the American Academy Neurology (AAN) titled “**Amyotrophic Lateral Sclerosis**,” published by Demos Press. A copy of this book may be obtained at the Norris ALS Center. We are honored to have Patty coordinating our seasoned talented clinical team.

**Susan Woolley Levine, Ph.D., the Norris ALS Center's Neuropsychologist**,

was also featured in the *MDA/ALS News Magazine*, March issue. This well written article focused on the increasingly important significance of cognitive changes sometime seen in ALS, called Frontal Temporal Lobe Dementia

(FTD), and its role in the overall ALS management care plan. Dr. Woolley Levine drew distinctions between the cognitive changes in ALS and Alzheimer's dementia from other more typical changes related to anxiety and depression associated with an ALS diagnosis. The Q & A format answers many common questions asked by ALS patients and their families. Dr. Woolley Levine is a major asset to the ALS comprehensive care team for the Norris ALS Center; we are honored to have her insight and expertise.

### Generosity in the Spirit of Giving

**Dr. Deborah Gelinas Receives Memorable Gift**

In April 2005, Dr. Gelinas received a memorable gift from Mary Jo Mishork, the wife of ALS patient Jim Mishork. Dr. Gelinas had cared for Mr. Mishork over the course of his disease until his death. To show her appreciation, Mary Jo sent a generous donation of funds from a fundraiser conducted by her fifth grade students, accompanied by letters and paste-up butterflies produced by each student. Dr. Gelinas and the entire Norris ALS Center staff were touched by this thoughtfully inspired special gift. Thank you, Mary Jo and your wonderful students from St. Jerome's School in El Cerrito.



Susan Woolley Levine, Ph.D. (Photo by Erin Lubin, courtesy of MDA/ALS News Magazine.)

  
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## The Gift of Giving

The Forbes Norris MDA/ALS Research Center is totally dependent upon private donations to support its patient services programs. It is supported, in part by the generous donors for ALS to the California Pacific Medical Center Foundation.

For more information on the Foundation or on ways you may give to the Forbes Norris MDA/ALS Research Center to support their services, please call Dee Norris at (415) 600-3608.

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# The Forbes Norris MDA/ALS Research Center Forbes Norris ALS Center News

SPRING | SUMMER 2005

## Norris ALS Center's Longtime Clinical Director Moves on and New Neurologist Steps in to Fill Her Shoes

Faced with the reality of the old axiom, “the only constant in life is change,” the Forbes Norris MDA/ALS Research Center has reluctantly accepted the resignation of its longtime, exceptionally talented, and well-loved clinical director, Deborah Gelinas, M.D., who has decided to return to her home state of Massachusetts to be nearer to her family. The loss of Dr. Gelinas will be felt worldwide throughout the ALS community, since she will no longer be focusing on ALS. In her new position as head of neurology in a private Massachusetts hospital, her practice will be focused on general neurology.



Deborah Gelinas, M.D.

She originally joined the Norris ALS Center team to fill the shoes of the late Forbes Norris, M.D., and in that role, she has done a superb job. She has made major contributions to our ALS team development and training, honing them into first-rate experienced ALS health care professionals whose top concern is the quality of care for our ALS patients and their families. Over the last 12 years, Dr. Gelinas has become one of the most knowledgeable experts on the clinical management of ALS. She has been a sought-after speaker nationwide

covering all aspects of ALS clinical care. Additionally she has contributed extensively to updating ALS literature in neurology texts, journal articles, and at international presentations. She was also a major contributor to the American Academy of Neurology's (AAN) ALS Practice Parameters Guidelines committee. Her colorful personality and good humor, her intense empathy for the ALS patients and their families, and her extraordinary intellect has made her a memorable presence, beloved by her patients. We will miss her and wish her well in her continued professional career.

Replacing her will be a big job; however, the Norris ALS Center staff has great confidence in and warmly welcomes Jonathan S. Katz, M.D. to join our team. Dr. Katz is a neuromuscular disorders specialist recently on the staff at Stanford Medical Center and the Palo Alto Veteran's Hospital, where he directed the electromyography unit. Dr. Katz has written extensively on various conditions involving nerve roots, the peripheral nerve and muscle, and the neuromuscular junction. He currently directs a popular course at

the AAN on Phenotypes of Neuromuscular Disease and is a Medical Advisor to both the Myasthenia Gravis Foundation and the Landry-Guillain-Barre and CIDP Foundations. He is married with two young daughters and lives in Menlo Park.

Dr. Katz is eager to expand his neurological focus to include ALS and its clinical management. He is currently learning the nuances of specific ALS techniques under the tutelage of Dr. Gelinas and Robert Miller, M.D. He is meeting ALS patients and working with the experienced multidisciplinary Forbes Norris MDA/ALS Research Center staff. With his varied experience and receptivity to this extensive new field, Dr. Katz will soon carry forth the banner of high standards for ALS care set by forth by his predecessors. We are delighted to have Dr. Katz join the Norris ALS Center team.

Jonathan S. Katz, M.D.



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## From the Desk of...

Robert Miller, M.D., Medical Director



It is with heavy heart that we announce the departure of **Deborah Gelinas, M.D.** from the Forbes Norris MDA/ALS Research Center. She will be greatly missed by patients and staff alike. Filling her shoes will be difficult but our new colleague from Stanford, Jonathan Katz, M.D., is an experienced neuromuscular and ALS specialist. Catherine Madison, M.D., who joined us last year, has become extremely knowledgeable in all aspects of ALS care. I will be evaluating new patients and provide care in the clinic as well as

continue my involvement with research studies. Our commitment to raise the standard of ALS care to the highest possible level remains undiminished.

**One year ago**, the National ALS scientific community agreed to band together, forming The ALS Research Group, committed to advancing research in ALS. Hiroshi Mitsumoto, M.D. from Columbia University, heads the ALS Research Group. It was my honor, as the Group's research committee co-chair, to recently chair a meeting at Harvard reviewing ALS study database integration. During this three-day meeting, new database guidelines were developed for gathering ALS patient clinical information. The database, sponsored by the NIH, would be a comprehensive information source widely available to ALS specialists. It would include clinical

information to better understand the disease, as well as maintain and store an ALS patient DNA databank.

I was also honored to be selected as the new Chair of the **World Federation of Neurology Committee on ALS Research**. As Chair, I will help guide this important group that brings together leading ALS investigators from around the world each fall. This fall the World Federation (WFN) meets in Dublin, Ireland to focus on the international collaboration using databases, and brainstorm investigations that will move us forward, helping us to understand and find the cause and a cure for ALS.

**Research continues** to be a large focus at the Norris ALS Center. Currently we are one of only five institutions in North America testing an exciting new antioxidant, manganese porphyrin, developed by AEOLUS. This antioxidant was injected for the first time in humans with ALS at the Norris ALS Center. This study has incredible promise. In the mouse model of ALS, the greatest impact upon survival in the past has been a 30% extension of life by gene therapy with IGF-1, and this new antioxidant extended survival by 250% in the mouse model. Further development of this drug is planned very soon. We also continue the NIH sponsored minocycline trial. I am excited about this trial as it is one of the only medications that clearly attacks two of the major aspects of ALS, neuroinflammation and pre-programmed cell death or apoptosis. In my view, Rilutek, the approved anti-glutamate drug, combined with minocycline, is likely to be effective as the first elements of a cocktail that might bring successful treatment for this disease.

## Norris ALS Clinic Notes

### “Reminder to Remember”

If you use a BiPap respirator, even occasionally, please remember to bring your BiPap machine with you to your clinic visit. Our respiratory therapist needs to check the function, fit, and settings to help assure effectiveness.

### Support Group Corner

The San Francisco Peninsula ALS Support Group meets the **4th Saturday of every month** at Mills Peninsula Medical Center, 1783 El Camino Real, Sierra Room, one floor down from the lobby level, Burlingame, CA 94010; **11:00 a.m. to 1:00 p.m.**

Each month will address a different topic as well as discuss subjects and answer questions that are important to you. **Next Meeting June 25, 2005: Special Speaker, Deborah Gelinas, M.D.**, Norris ALS Center Clinical Director, will give her farewell talk “Hope in ALS,” on the latest in ALS care and coming treatment interventions.

## 15th Annual International ALS/MND Symposium, the Best Yet

The most recent International ALS/MND Symposium, held December 2004 in Philadelphia, was easily the most informative and best attended in the 15-year history of the only international scientific meeting dedicated solely to ALS. The full gamut of international ALS scientists and clinicians attended the three-day event to hear presentations and read posters from all over the world covering every aspect of ALS research and management data. Full details from this meeting can be found on the International ALS/MND Alliance Web site at [www.alsmndalliance.org](http://www.alsmndalliance.org), sponsors of the symposium. You can also visit them on the Web to find out more about next year's International Symposium to be held December 2005 in Dublin, Ireland. If you do not have Internet access, write the ALS/MND Alliance at P.O. Box 246; Northampton NN1 2PR, United Kingdom.

## ALS Patient Experience

### My Day as a Mouse: AEOL 10150 Clinical Trials Underway

by Linda Lettieri, ALS research patient

When I first heard about the Phase I clinical trials for AEOL 10150, I must admit I was tempted. I had just been diagnosed with ALS and the idea of three days “rest” in a hospital while being “waited on” by doctors and nurses seemed oddly appealing. Then I read the fine print. This trial involved a lot more than catching up on my reading. It meant two extra visits to Forbes Norris, multiple blood draws, daily ECGs, constant monitoring by doctors nurses and research staff, and no shower for three days. Not to mention that it had only been tested on mice. But from everything I'd read, the drug showed promise and had been granted fast track and orphan status by the FDA. It sounded exciting and I wanted to help.

### AEOL 10150

In the last issue of the Forbes Norris ALS Center News, Dr. Miller spoke of evidence showing that oxidative stress plays an important role in ALS. Up until the development of AEOL 10150, a catalytic antioxidant, available antioxidants had demonstrated little or no impact when tested on ALS mice.

Aeolus Pharmaceuticals sponsored the Phase I trials. Six

clinical sites throughout the United States participated in this trial, each with five participants. Four out of the five participants received AEOL 10150, while one received a placebo. In addition to the Norris ALS Center, trials were conducted at Massachusetts General Hospital, Columbia-Presbyterian Medical Center, John Hopkins University Center for ALS Research, Upstate Medical Center at Syracuse University, and Drexel-Hahnemann University.

### Injection Day

I checked into my hospital room the night before the trial began. The excitement among the research staff was contagious as we prepared ourselves for a busy day of timed tests. Following a 12-hour fast, injection day began with a 5 a.m. wake up call. At that time my vital signs were tested and an IV line inserted to make the blood draws easier. Promptly at 8 a.m. a nurse not related to the study came with my injection. While she prepped the injection site near my naval, a researcher put a blindfold on my eyes so I could not see the syringe. AEOL 10150 apparently can be distinguished by its bright red color. The time passed quickly and before I knew it was time to go home.

There are many other trials being conducted at the Norris ALS Center. I felt excited and honored to be able to do something that may not help me but perhaps future persons with ALS. Did I get the real thing? Would I do it again? In a heartbeat!

## ALS Association Opens Satellite Clinic in Monterey

The ALS Association (ALSA), Bay Area Chapter, received a grant from the Monterey Peninsula Foundation to offer a quarterly ALS satellite clinic. On a one-year trial basis, California Pacific Medical Center's Norris ALS Center and University of California, San Francisco's ALS Clinic will staff the satellite clinic alternately. By bringing services closer to patients, ALSA hopes to make it easier for ALS families to receive care, reduce waiting times, and “decompress” the volume of the San Francisco clinics.

# RESEARCH AGENDA



## ALS Clinical Research

### CURRENT CLINICAL RESEARCH TRIALS

These trials are being conducted in collaboration with other ALS Centers nationwide.

### Myotrophin – Insulin-like Growth Factor-1

#### Phase 3 study

- Requires a breathing capacity of 60% or greater to participate.
- The study is 2 years long and requires seven visits over 24 months.
- Requires self-injection twice daily, seven days per week.
- Cannot be a diabetic or have had any history of cancer.
- Cannot use other prescription medications being tested in other clinical trials such as minocycline.
- Can use creatine/Co-Q-10.

**Enrollment Status:** Almost full nationwide

### Minocycline

#### Phase 3 study

- Requires a breathing capacity of 75% or greater to participate.
- The study is 13 months long: requires monthly visits.
- Oral medication twice daily.
- Cannot take minocycline or other meds (creatine or Coenzyme Q-10) being tested in other clinical trials while on study.

**Enrollment Status:** New enrollees needed

### Co-enzyme Q-10

#### Phase 2 study

- Breathing Capacity of 60% or greater.
- Study is 9 months long requiring 7 visits over 9 months.
- Medication is a wafer to be taken 3-times-a-day.
- Cannot take vitamin E or Co-enzyme Q-10 while on this study.
- Cannot take medications being tested in other clinical trials.

**Enrollment Status:** New enrollees needed

### CLINICAL TRIALS UPDATE

#### Aeolus

##### Phase 1A study

10 patients participated at our site. The study involved single dose testing of a “super anti-oxidant” (manganese porphyrin) shown to have great promise by prolonging life in the animal model with its action against “free radicals.” Our site hopes to be involved in the upcoming Phase 1B trial involving multi-dose testing.

**Current status:** Under analysis

#### Ceftriaxone

##### Phase 1 study

Early testing of Ceftriaxone, an antibiotic (cephalosporin) that is able to penetrate the central nervous system, is planned for early 2006. This medication has antioxidant properties and has shown benefit in blocking glutamate toxicity in nerve cells in tissue culture.

**Current status:** Under study

#### Novartis TCH346

##### Phase 2 study

15 patients participated at our site. 575 were enrolled throughout North America and Europe to test the effectiveness of a new study medication in delaying pre-programmed cell death (apoptosis).

**Current status:** Trial completed in January 2005. Results negative, no further testing planned

For further information concerning these trials, please call: Norris Center Research Nurse, Jason Mass, R.N. at 415-600-3967.